UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BENJAMIN COKER, *et al.*	)	
***Plaintiffs*,**	)	
vs.	)	**CIVIL ACTION NO.**
	)	**3:21-cv-01211-AW-HTC**
LLOYD AUSTIN, III, *et al.*,	)	
***Defendants*.**	)	

PLAINTIFFS' MOTION FOR LEAVE TO FILE THIRD AMENDED AND SUPPLEMENTAL COMPLAINT AND MEMORANDUM IN SUPPORT

Pursuant to Federal Rules of Civil Procedure 15(a) and 15(d), Local Rule 15.1, and this Court's November 8, 2022 order ("November 8 Order"), ECF 126, Plaintiffs move for leave of the Court to amend and supplement the December 8, 2021 Second Amended Complaint ("SAC"), ECF 56, and to file the attached Third Amended and Supplemental Complaint ("TAC"), and submit this memorandum in support thereof.

The TAC amends the SAC to address facts that were not known at the time of filing, to cure jurisdictional defects and mootness by amending claims to address the Food and Drug Administration's ("FDA") approval of SPIKEVAX®, and to amend or remove claims in accordance with the Court's November 8 Order. The TAC supplements the SAC by setting forth transactions, occurrences, and events that happened after the SAC filing date; to address the fact that ModernaTX, Inc. ("Moderna") products could not have been mandated until after the March 31, 2022 deadline, such that there would been no jurisdiction at that time; and to modify

existing claims based on those new facts. The TAC also supplements the SAC by adding new claims against the COVID-19 treatment manufacturers: BioNTech Manufacturing GmbH ("BioNTech"), Moderna, and Pfizer, Inc. ("Pfizer") (collectively, "Manufacturer Defendants").

Plaintiffs submit that good cause exists to amend and supplement the SAC because the amended and supplemental facts were not known, could not have been discovered with reasonable diligence, or had not occurred at the time the SAC was filed or by the March 11, 2022 deadline for adding parties or the March 31, 2022 deadline for amendments ("March 31 Deadline") set by the Court's February 23, 2022 scheduling order ("Scheduling Order"). ECF 70. Moreover, all of the operative facts giving rise to the new claim against the Military Defendants occurred after the March 31 Deadline. All or nearly all of the operative facts giving rise to the claims against the Manufacturer Defendants occurred after the September 2, 2022 hearing ("September 2 Hearing" or "Hearing"), where this Court stopped the clock, stating that it would "disregard the time from now until whenever [Plaintiffs] make that motion [to amend] and basically consider the timeliness as if" Plaintiffs filed on September 2, 2022. ECF 116, Sept. 2, 2022 Hearing Tr., at 47:3-5.[1]

[1] At the August 29, 2022 ("August 29 Hearing") and September 2 Hearings, Plaintiffs' counsel stated that Plaintiffs would seek to amend to address post-SAC facts, which would have been more properly characterized as a supplement. A leading treatise on the Federal Rules of Civil Procedure explains that:

MEMORANDUM IN SUPPORT

LEGAL STANDARD

Rule 15(a) Amendments. Rule 15(a)(2) permits a party to amend its pleading with the Court's leave, which should be "freely give[n] … when justice so requires." Leave should be granted unless there is "a justifying reason … for denial," *Moore v. Baker,* 989 F.2d 1129, 1131 (11th Cir.1993), such as "undue delay, bad faith, or dilatory motive on the part of the movant...." *Datastrip Int'l. Ltd. v. Intacta Techs., Inc*., 253 F.Supp.2d 1308, 1318 (N.D. Ga. 2003) ("*Datastsrip*"). "[L]eave to amend should only be denied on the ground of futility when the proposed amendment is clearly insufficient or frivolous on its face." *Taylor v. Fla. State Fair Auth.,* 875 F.Supp. 812, 815 (M.D.Fla.1995).

Rule 15(d) Supplements. Under FRCP Rule 15(d) "the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction,

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> Parties and courts occasionally confuse supplemental pleadings with amended pleadings and mislabeling is common. These misnomers are not of any significance, however, and they do not prevent the court from considering a motion to amend or supplement under the proper portion of Rule 15. ... [T]he formal distinction between amendment and supplementation is of no consequence.

6A Charles Alan Wright et al., § 1504 Supplemental Pleadings—In General, 6A FED. PRAC. & PROC. CIV. § 1504 (3d ed.) ("Wright & Miller"). Plaintiffs respectfully request that this Court interpret their statements in light of this clarification, and Plaintiffs' counsel have understood the Court's statements regarding amendments to encompass supplements as well.

occurrence, or event that happened after the date of the pleading to be supplemented." "[C]courts customarily have treated requests to supplement under Rule 15(d) liberally" because they enable:

> a court to award complete relief, or more nearly complete relief, in one action, and to avoid the cost, delay, and waste of separate actions which must be separately tried and prosecuted. … [Amendments] ought to be allowed as of course, unless some particular reason for disallowing them appears....

W. Ala. Women's Ctr. V. Miller, 318 F.R.D. 143, 148 (M.D. Ala. 2016) (citations omitted). *See also Harris v. Garner*, 216 F.3d 970, 984 (11th Cir.2000) (noting "the liberal allowance of amendments or supplements to ... pleading under Rule 15").

The Rule "is intended to give the court broad discretion in allowing a supplemental pleading," Fed. R. Civ. P. 15(d) Advisory Committee's Note to 1963 Amendment, provided that the supplemental facts occurred after the filing date and there is "some relation" with pleading being supplemented. *Miller*, 318 F.R.D. at 147 (citation omitted). Supplementation may include not only new facts, but new claims and new parties. *See, e.g., Griffin v. Cty. Sch. Bd. of Prince Edward Cty.*, 377 U.S. 218, 227 (1964) ("*Griffin*").

Where a Court has dismissed claims or parties based on jurisdictional defects, it should freely grant leave to amend or supplement to address those jurisdictional defects. "Only when the affidavits show that the pleader cannot truthfully amend to

allege subject matter jurisdiction should the court dismiss without leave to replead." Wright & Miller, § 1350 nn.55-58 (collecting cases).

Rule 16(b) Good Cause Showing. Where a motion to amend or supplement is filed after the deadline for amendments set forth in the Court's Rule 16 Scheduling Order, a party must demonstrate good cause under Rule 16(b). *See Smith v. Sch. Bd. of Orange County*, 487 F.3d 1361, 1366 (11th Cir. 2007) (Rule 15(a) amendment); *McGrotha v. Fed Ex Ground Package Sys., Inc.*, No. 5:05-CV-391(CAR), 2007 WL 640457, at *6 (M.D. Ga. Feb. 24, 2007) (Rule 15(d) supplement).

"Rule 16(b) does not define good cause, but the advisory committee note indicates that good cause exists if the schedule cannot reasonably be met despite the diligence of the party seeking the extension." *Green Island Holdings, LLC v. Brit. Am. Isle of Venice (BVI), Ltd.*, 521 F. App'x 798, 800 (11th Cir. 2013) (citation omitted). "[G]ood cause exists when evidence supporting the proposed amendment would not have been discovered in the exercise of reasonable diligence until after the amendment deadline had passed." *Donahay v. Palm Beach Tours & Transp., Inc.,* 243 F.R.D. 697, 699 (S.D. Fla. 2007) ("*Donahay*").

"[T]he Eleventh Circuit and other district courts have held that potential prejudice to an opposing party bears little weight in the good cause analysis …" *Walsh v. Chubb*, No. 4:20-CV-00510-HNJ, 2020 WL 8175594, at *6 (N.D. Ala. Oct. 21, 2020) (collecting cases). *See also Moyer v. Walt Disney World Co.*, 146 F. Supp.

2d 1249, 1252 (M.D. Fla. 2000) ("*Moyer*") ("prejudice ... is immaterial" in determining whether good cause has been established under Rule 16).

Supplement Adding New Parties and Claims. A motion to supplement under Rule 15(d) may also add new parties. *See, e.g., Griffin*, 377 U.S. at 227. "After a responsive pleading has been served, the standards for deciding a motion to amend a complaint to add a party are the same under Rule 15 or Rule 21." *Datastrip*, 253 F.Supp.2d at 1318 (*citing Loggerhead Turtle v. Cty. Council of Volusia Cty.*, 148 F.3d 1231, 1255 (11th Cir. 1998), *cert. denied*, 526 U.S. 1081 (1999)).

Rule 21 provides that "[o]n motion or on its own, the court may at any time, on just terms, add or drop a party." Fed. R. Civ. P. 21. The Eleventh Circuit interprets the rule liberally, granting district courts the authority to add a party "'at any time, even after judgment has been rendered.'" *Mid-Continent Cas. Co. v. JWN Constr., Inc.,* 823 F. App'x 923, 927 (11th Cir. Aug. 18, 2020) (*quoting Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 832 (1989)).

Courts may add a party pursuant to Rule 15 and Rule 21, even in the absence of "good cause" under Rule 16(b). *See, e.g., Walsh v. Chubb*, 2020 WL 8175594, at *7 (N.D. Ala. Oct. 21, 2020) (plaintiffs' "lack of diligence will not prove fatal to their attempt to add" new defendant). *See also Datastrip*, 253 F.Supp.2d at 1317-18 (declining to apply "good cause" analysis to add parties).

STATEMENT OF FACTS

Plaintiffs' Complaints. On October 6, 2021, Plaintiffs filed their Complaint for declaratory and injunctive relief against Defendants. ECF No. 1. The next day, October 7, 2021, Plaintiffs filed the First Amended Complaint, which had slight revisions as compared to the original Complaint. ECF No. 6. On December 8, 2021, Plaintiffs filed an unopposed motion for leave to file the SAC with the Court, ECF 52, which the Court granted on December 10, 2021. ECF 55.

Discovery and Administrative Records. The Military Defendants have provided what they have certified as the complete administrative records on March 16-17, 2022. The FDA has not provided the administrative record for the COMIRNATY® approval (which the FDA has represented is well in excess of one million pages) or for Plaintiffs' other claims, nor have they provided a certified index of that record. While Plaintiffs have sent discovery requests to Defendants, Defendants have uniformly rejected Plaintiffs' discovery requests and insisted that they need only provide the administrative record.[2] The time period for discovery expired on May 9, 2022. On June 3, 2022, Plaintiffs filed a motion to compel discovery or in the alternative to extend discovery, *see* ECF 89, which this Court

[2] *See* ECF 89-3, DF Mar. 11, 2022 Omnibus Response to PL First Set of Requests for Production (refusing to respond to Plaintiffs' discovery requests and objecting on the basis that these requests were "overbroad", "unduly burdensome", and/or "disproportionate" 83 times).

denied as moot in its November 8 Order. Accordingly, Plaintiffs have not been able to conduct discovery and have received only a tiny fraction of the administrative record.

Rule 15(a) Amendments: Pre-SAC Facts.

1. **COMIRNATY® Approval Without Evidence It Prevents Transmission.** Plaintiffs did not learn and could not have discovered through reasonable diligence that Pfizer/BioNTech did not perform any tests, and the FDA did not require any such tests, as to whether COMIRNATY® could prevent transmission to support the FDA's August 23, 2021 approval. The ability to prevent transmission is one of the defining features of the pre-COVID-19 definition of vaccines, and the public health benefits of preventing the spread of disease is why vaccines have a unique legal and may be mandated. The October 10, 2022 Pfizer admission that no such tests were performed or required conclusively demonstrates that Defendants never had any scientific or evidentiary basis for treating the mRNA Products as "vaccines" or for imposing the Military Mandates on the ground that they would stop the spread of COVID.

2. **Military Administrative Records.** The vast majority of the materials in the Military Administrative Records are from the period prior to the issuance of the August 24, 2021 DOD Mandate and the Armed Services Mandates issued shortly thereafter.[3] The Military Administrative Records support a number of Plaintiffs' central contentions, namely: (1) the Military Defendants treated all EUA products as interchangeable with FDA-licensed products for the purposes of the mandates (*i.e.*, without any limitation to "BLA-compliant" doses); (2) there was no policy,

[3] Military Defendants provided the Military Administrative Records electronically March 16-17, 2022. Due to technical difficulties accessing the Department of Justice's file sharing site, Plaintiffs' counsel was not able to access these electronic materials until roughly one week later (*i.e.*, March 23-24, 2022). The Military Administrative Records were voluminous and it took roughly two weeks, using reasonable diligence to review thoroughly, after which time the March 31 Deadline had passed. In any case, Plaintiffs' review of the record merely confirmed Plaintiffs' allegations that there was no record evidence supporting these agency actions. It would have been pointless to amend or supplement the complaint pointing solely to the absence of supporting evidence, which would be more appropriately addressed in a summary judgment motion.

or even any mention, of "BLA-compliant" doses; (3) no alternatives to 100% vaccination were considered; and (4) no consideration of the relative risks and benefits to service members, or any allowance for individualized consideration or balancing of medical risks.

Rule 15(d) Supplement: Post-SAC Filing/Pre-Deadline Facts.

3. **Obsolescence & Ineffectiveness of mRNA Products Against Omicron.** On January 10, 2022, Pfizer's CEO acknowledged that the mandated two-dose regimen of COMIRNATY® provided little, if any, protection against the dominant Omicron variant and that Pfizer/BioNTech were developing a new Omicron-specific formulation. This fact is already in the record. *See* ECF 68, PL Opp'n to DF Mot. to Dismiss, at 41.

4. **FDA Waiver & "Enforcement Discretion."** Plaintiffs first learned that Defendant FDA purported to exercise its "enforcement discretion" to waive mandatory, statutory requirements or prohibitions regarding product labeling, including informed consent requirements in the EUA factsheet, in Defendants January 14, 2022 Motion to Dismiss, ECF 65, and the attached declaration of FDA official Peter Marks. *See* ECF 65-14, Marks Decl., ¶ 13.

5. **SPIKEVAX® Approval.** SPIKEVAX® was approved January 31, 2022, but was not available. The Military Defendants did not direct military healthcare providers to treat the Moderna EUA product and SPIKEVAX® as interchangeable until months later on May 3, 2022. *See* TAC, Ex. 4, Moderna Interchangeability Directive. Thus at the time of approval through the March 31 deadline, Plaintiffs were not being forced to take either the FDA-licensed SPIKEVAX®, which was not available, or the EUA Moderna product, which could not be mandated prior to the Moderna Interchangeability Directive.

Rule 15(d) Supplement: Post-Deadline Facts.

6. **Mandate of Moderna EUA Product & Interchangeability Directive.** The Military Defendants could not mandate the Moderna EUA product until at the earliest May 3, 2022, and they could not have done so for the FDA-licensed product until September 2022 at the earliest.

7. **Mandate of "Comirnaty-labeled" Pfizer/BioNTech Product.** It is undisputed that Military Defendants did not obtain any COMIRNATY®—or as Plaintiffs contend, misbranded, unlicensed "Comirnaty-labeled" product (the "FW Lots")—until June 2022 at the earliest. At this time, Military Defendants directed

all unvaccinated service members who, like Plaintiffs, objected to taking an unlicensed product, to take the new "Comirnaty-labeled" products.

8. **Evidence "Comirnaty-labeled" Pfizer/BioNTech Product Misbranded.** Because Military Defendants did not have any "Comirnaty-labeled" products until June 2022, Plaintiffs could not have obtained any evidence regarding the misbranding of such products until after that date. Plaintiffs and Plaintiffs' counsel expended significant time and effort, from June 2022 through September 2022, to determine whether these products were in fact FDA-licensed. They were able to obtain evidence that these products were not manufactured in an FDA-approved facility, which rendered them unlicensed and misbranded, based on research of publicly available records; review of the access-restricted CDC website; Freedom of Information Act ("FOIA") requests; information from and correspondence with military whistleblowers; and the previously non-public, official records filed by Defendants themselves, in particular, the declarations of FDA official Suzanne Burk.

9. **Manufacturer Abandonment of "Monovalent" mRNA Products.** Based on a review of the CDC website, Pfizer/BioNTech manufactured its last lot of COMIRNATY® in February 2022 and the Moderna manufactured its last lot of SPIKEVAX® in April 2022.[4] These facts combined with the decision by the U.S. Government to no longer purchase these products suggest that these products will never be produced or purchased again.

10. **CDC Admission That "Monovalent" mRNA Products Obsolete and Ineffective Against Omicron.** On August 11, 2022, the CDC finally caught up with Pfizer and acknowledged that the mRNA Products provided little, if any, protection from Omicron and that, because these products could not prevent infection or transmission, COVID-19 mitigation strategies should not differentiate based on vaccination status. *See* ECF 106-6.

[4] Lots are not posted to the CDC website until 2-3 months after manufacture. *See* TAC, Ex. 13, Kupper Decl., Ex. A (compare manufacture date and posting date). Due to the CDC posting delay, these facts could not have been discovered by Plaintiffs until well after the March 31 Deadline. Further, the manufacturers could have resumed production at any time and it is only after several months without production—and the August 2022 abandonment of monovalent mRNA Products by the U.S. Government—that Plaintiffs could reliably conclude that this was a permanent cessation of production.

11. **U.S. Government Abandonment of Monovalent mRNA Products.** On August 16, 2022, the U.S. Government, which is the sole customer and payor for COVID-19 vaccines, announced that it would no longer purchase or provide reimbursement for the "monovalent" mRNA Products, including COMIRNATY® and SPIKEVAX®, and going forward would purchase only "bivalent" mRNA Products. *See* ECF 117, Sept. 9, 2022 PL Response to DF Mot., at 4 & ECF 117-2.

12. **Supplemental Approvals of COMIRNATY® After Known Obsolescence.** Pfizer/BioNTech continued to apply, and the FDA continued to grant, supplemental approvals of Grey Cap COMIRNATY® (most recently August 25, 2022), long after the product was known to be obsolete and ineffective against Omicron, and even after Pfizer/BioNTech ceased production of these products and the U.S. Government ceased purchasing or paying for the product.

13. **Defense Counsel Admissions at August 29, 2022 Hearing.** Defendants' counsel made several significant admissions in the hearings, in particular, confirming that: (1) Defendants' policy has from the outset been to mandate EUA-labeled vaccines, which contradicted their statements at the November 3, 2021 hearing on which this Court's November 12, 2021 Order, ECF 47, was based; (2) Defendants have in fact punished service members for refusing to take an EUA vaccine; and (3) abandoning their previous defense that the Military Mandates were limited to so-called "BLA-compliant" doses. *See* ECF 115, Aug. 29, 2022 Hearing Tr., at 27:20-21 & 31:11-12.

Rule 15(d) Supplement: Post-Hearing Facts.

14. **SPIKEVAX® Availability.** As of the date of the September 2 Hearing and related briefing, Military Defendants claimed only that SPIKEVAX® was "available to order", ECF 107-16, Rans Decl., ¶ 4, but not that they had any in their possession. It was not until the October 18, 2022 filing ("October 18 Response") that Military Defendants stated that they had SPIKEVAX® in their possession that could have been administered to service members. *See* ECF 124-1, Rans Decl., Ex. A.

15. **COMIRNATY® Approval Without Evidence It Prevents Transmission.** While the operative facts occurred pre-SAC and are relevant to Claim 4 (FDA Unlawful Approval of COMIRNATY®), they were not known until after the September 2 Hearing, and should be treated as a post-Hearing fact for claims against Pfizer and BioNTech.

16. **Misbranded "Bivalent" EUA Products.** Defendants' October 18 Response revealed for the first time, in official records and sworn testimony, that: (1) Military Defendants had obtained "bivalent" EUA products (the "G Lots"), which are unlicensed, use a different formulation, and cannot be licensed as COMIRNATY®; and (2) the Military Defendants described such unlicensed, EUA products as "Comirnaty-labeled, BLA-approved" products. ECF 124-1, Rans Decl., ¶ 4 & Ex. A. The labeling of an unlicensed, EUA product with a different formulation as COMIRNATY® was performed by the manufacturers (*i.e.*, Pfizer, BioNTech or their subcontractor) and was authorized or performed with the knowledge of the FDA.[5]

17. **Misbranding of All FW Lots.** After the September 2 Hearing, Plaintiffs obtained additional official records and other information confirming that all of the FW Lots of "Comirnaty-labeled" products were unlicensed and misbranded because they were manufactured at a facility that was not FDA-approved at the time of manufacture, lot release, or delivery to Military Defendants. Plaintiffs sought leave to file this information in reply to Defendant October 18 Response, *see* ECF 125, but the Court denied this request in the November 8 Order.

18. **Mandate of Expired or Adulterated FW Lots.** While Plaintiffs had some anecdotal evidence that Defendants were seeking to mandate expired doses from FW Lots, it was only after the hearing that Plaintiffs had evidence demonstrating that this was a widespread, generally applicable policy. First, Military Defendants adopted a generally applicable policy to violate the FDA-approved storage requirements, namely, that the policy to ship mRNA products at refrigerated temperatures (2-8 C), rather than the required deep freeze (-30 C to - 90 C) from Fort Detrick to other U.S. facilities, which triggered the 10-week clock for expiration (*i.e.*, August 2022), regardless of the date stated on the labeling.

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[5] On November 28, 2022, one day before the date of this motion, Defendants submitted a filing in a related proceeding, *Bazzrea v. Austin*, SDTX 3:22-cv-265, ECF 56, that included a declaration from Colonel Rans stating that the G Lots (which represent over 20,000 or 40% of the doses DOD claimed to be FDA-licensed) were "incorrectly listed … as Comirnaty," and are instead "lots of other COVID-19 vaccines." Defendants did not assert that they are not bivalent EUA products, as Plaintiffs claim. Defendants have not brought this material misstatement to this Court's attention, despite the fact that Plaintiffs raised this precise allegation over one month ago in their October 25, 2022 motion for leave to file a reply. *See* ECF 125 at 1. The TAC is based on the information contained in the record for this proceeding, which stands uncorrected after Defendant have had ample time to do so.

Second, all FW Lots expired no later than October 31, 2022, yet Defendants still seek to mandate these expired and likely adulterated products. Plaintiffs included some of this information in their September 26, 2022 motion for evidentiary hearing and sought to submit the evidence of systematic violations in the reply.

19. **Unequivocal Evidence of Manufacturer Culpability for Misbranding and Unfair and Deceptive Trade Practices.** While Plaintiffs had strong evidence of manufacturer culpability for misbranding and unfair and deceptive trade practices prior to the September 2 Hearing, they did not possess unequivocal evidence until after the Court stopped the clock at the Hearing. Labeling as COMIRNATY® unlicensed, "bivalent" EUA products with a different formulation than COMIRNATY® is a *per se* violation of federal and state laws prohibiting misbranding laws and unfair and deceptive trade practices, as is their failure to market and not to require the recall of expired and adulterated doses.

20. **Manufacturers' Actual or Constructive Knowledge That Military Defendants' Were Administering mRNA as Non-Prescription Drugs.** While Plaintiffs previously had anecdotal evidence of "vaccine" rodeos and changes to rules governing treating physician or medical director authority over treatments and medical exemptions, Plaintiffs have only recently obtained evidence that Military Defendants had adopted generally applicable procedures to administer mRNA Products as non-prescription drugs and that Manufacturer Defendants knew or should have known of these practices.

ARGUMENT

I. PLAINTIFFS' MOTION IS SUPPORTED BY GOOD CAUSE.

A. There Is Good Cause To Amend And Supplement For All Facts That Occurred or Were Discovered After the March 31 Deadline.

"It cannot reasonably be disputed that newly discovered evidence can supply the necessary good cause under Rule 16(b)(4) to enlarge an expired deadline for amending pleadings." *Allstate Ins. Co. v. Regions Bank*, 2014 WL 4162264, at *3 (S.D. Ala. Aug. 19, 2014) (citation omitted); *see also Long v. Blair*, 2010 WL 1930220, at *4 (S.D.W. Va. May 12, 2010) (concluding there to be good cause under

Rule 16(b)(4) where counsel amended a complaint after the discovery of new evidence); *Wilson v. TelAgility Corp.*, 2019 WL 2410963, at *3 (D. Md. June 7, 2019) (finding good cause where a complaint was amended after the receipt of "information that provides the basis for his new claims"). As set forth above in the "Statement of Facts," all or nearly all of the material facts that Plaintiffs seek to introduce in the TAC were not known and could not have discovered through the exercise of reasonable diligence prior to the March 31 Deadline. As explained below in Sections II-III, any facts that were known, discovered, or could have been discovered through reasonable diligence prior to the March 31 Deadline simply update the TAC to the present and do not form the material basis for any new or modified claims.

All of the transactions, occurrences and events underlying Plaintiffs' new claim against Military Defendants happened after the March 31 Deadline. Further, all or nearly all of the material facts underlying Plaintiffs' new claims against the Manufacturer Defendants happened or were discovered after the March 31 Deadline, and the most probative evidence of the manufacturers' violations did not occur or was not discovered until after the September 2 Hearing.

B. All Operative Facts for New Claim Against Military Defendants Occurred After March 31 Deadline.

Plaintiffs raise a single new claim against the Military Defendants, namely TAC Claim 2, which addresses the Military Defendants' new or modified mandate

of "Comirnaty-licensed" products (the G Lots and FW Lots) that Plaintiffs allege are in fact unlicensed, misbranded, expired, and/or adulterated. As explained in Section III.A below, TAC Claim 2 is related to SAC Claims 1 and 2 (TAC Claims 1 and 3), but it is distinct because it alleges that shots from these lots are not only not licensed (and so cannot be mandated to service members), but they may not be sold, distributed or administered to anyone, and must be recalled and destroyed.

Plaintiffs could not have made any challenge to the FW Lots until June 2022 at the earliest, but more reasonably not until August or September 2022, after they had gathered the facts necessary to show these products are not in fact licensed and therefore are misbranded as licensed "Comirnaty-labeled" products. Further, Plaintiffs did not have a claim that they were expired until at the earliest August 2022 (when the ten-week shelf life expired) or September 30, 2022 or October 31, 2022 (when they expired based on the product label). Plaintiffs could not have had a claim regarding the G Lots until after October 18, 2022, when Military Defendants first claimed that these lots were "Comirnaty-labeled, BLA-approved" products, ECF 124-1, Rans Decl., ¶ 4 & Ex. A, and after the opportunity to use this information to determine that these lots were unlicensed bivalent EUA products.

The new claim against the Defendants demonstrates that Plaintiffs' claims against them are not moot, namely, that the same violations alleged by Plaintiffs in have been and will be repeated by Defendants against Plaintiffs. In the SAC, the

Plaintiffs challenge, among other things, the Military Defendants' mandate of unlicensed monovalent Pfizer/BioNTech EUA products, facilitated by both the DOD and FDA Interchangeability Determinations and related challenged actions. The new TAC Claim 2 and the modified SAC Claims (TAC Claim 3 for Military Defendants and TAC Claim 5 against the FDA) are based on three subsequent violations: the May 2022 Moderna Interchangeability Directive, the June 2022 mandate of unlicensed, monovalent Pfizer/BioNTech FW Lots, and the most recent mandate of unlicensed, bivalent Pfizer/BioNTech G Lots. Each of these represent distinct, and repeated, attempts by Military Defendants to impose generally applicable mandates of unlicensed EUA products for all unvaccinated service members, including Plaintiffs.

C. Moderna Products Were Not Mandated Until After Deadline.

The Court dismissed all claims against the FDA as moot based on the fact that the SAC did not challenge the SPIKEVAX® approval. *See* ECF 126, November 8 Order at 11. However, the DOD Moderna Interchangeability Directive was not issued until May 3, 2022, and it is undisputed that the Military Defendants did not have any FDA-licensed SPIKEVAX® at that time. Accordingly, any Plaintiff challenge to SPIKEVAX® or the Moderna EUA product filed by the March 31 Deadline would likely have been dismissed as unripe or for lack of standing because

no Plaintiff (or any other service member) was subject to forced administration of either product as of that date.

Even assuming that the Military Defendants supply of "Spikevax-labeled" products does not suffer from the same defects as the "Comirnaty-labeled" products that make up over 98% of its inventory, the Military Defendants did not have any FDA-licensed SPIKEVAX® in their possession until after the September 2 Hearing, when the Court stopped the clock. Thus, good cause should be presumed to permit the Plaintiffs to supplement the TAC with this post-Hearing fact.

D. Nearly All Operative Facts for New Claim Against Manufacturer Defendants Occurred After March 11 and March 31 Deadlines.

Plaintiffs submit that all of the material and most probative facts giving rise to the claim against Manufacturer Defendants are the following, all of which happened or were discovered after the March 31 Deadline and most after the September 2 Hearing:

- The October 10, 2022 admission by Pfizer that COMIRNATY® was approved and mandated without any evidence it prevented transmission (Fact 15);
- The June 2022 mandate of misbranded "Comirnaty-labeled" FW Lots (Fact 8);
- The decisions by Pfizer/BioNTech and Moderna, respectively, to cease altogether production of the monovalent COMIRNATY® and SPIKEVAX® respectively, yet to continue marketing these obsolete and ineffective products (Fact 9);
- The August 15-16, 2022 decisions by the CDC and U.S. Government to no longer purchase or pay for the manufacturers' monovalent mRNA Products (Fact 11);

- The August 2022 expiration of all "Comirnaty-labeled" FW Lots that were shipped from Fort Detrick at refrigerated temperatures (*i.e.*, all U.S. based doses listed in the Rans Declaration) (Fact 18);
- The September or October 2022 first availability of SPIKEVAX® (Fact 14);
- The October 18 Response stating that unlicensed, bivalent EUA Pfizer/BioNTech products were "Comirnaty-labeled" and being mandated (Fact 16);
- The October 31, 2022 expiration of all FW Lots, regardless of storage conditions (Fact 18);
- The post-October 31, 2022 mandate of expired and adulterated FW Lots, without any attempt to recall or destroy these inherently unsafe and unlicensed products.

Prior to the March 31 Deadline, Plaintiffs and Plaintiffs' counsel had limited and anecdotal evidence that could have supported claims against the Manufacturer Defendants. But it was only beginning in August 2022 that Plaintiffs obtained unequivocal evidence of manufacturers' misbranding and unfair and deceptive trade practices and that manufacturers knew or should have known of Military Defendants' systematic violations of manufacturers' duties to service members.

Good cause has been found in similar circumstances. *See Island Creek Coal Co. v. Lake Shore, Inc.*, 832 F.2d 274, 279 (4th Cir. 1987) (allowing for an amended complaint months after the discovery of new facts, reasoning "plaintiffs were entitled to a reasonable time to investigate through other sources the information they had secured from the deposition of defendant's witnesses"); *see also Macias v. Cleaver*, 2016 WL 8730687, at *2, *4 (E.D. Cal. Apr. 8, 2016) (finding good cause

where a plaintiff sought leave, based on new evidence, to modify a scheduling order approximately one year after the amendment deadline had passed).

Plaintiffs sought to introduce the evidence of the post-Deadline and post-Hearing transactions, occurrences, and events regarding the unlicensed, misbranded, and expired Pfizer/BioNtech in their reply to the Defendant's response to Plaintiffs' Hearing Motion. ECF 125. But this Court denied the motion for leave in its November 8 Order. Plaintiffs' attempt to submit these facts into the record as soon as they were discovered further demonstrates good cause and that Plaintiffs satisfied their duty to exercise reasonable diligence. *See, e.g., Sheet Metal Workers Loc. No. 20 Welfare & Benefit Fund v. CVS Pharmacy, Inc.*, 305 F. Supp. 3d 337, 344 (D.R.I. 2018) (finding good cause where plaintiffs were "diligent enough in their review").

E. There Is Good Cause for Amendments or Supplements Required to Comply with November 8 Order.

Plaintiffs also propose a number of amendments in compliance with the November 8 Order. *See infra* Section II.A. Plaintiffs submit that all of these amendments are supported by good cause, to the extent such a showing is required.

F. Prejudice Immaterial If Motion Supported by Good Cause.

The proposed amendments will not unduly prejudice existing Defendants or Manufacturing Defendants. But even if it did, such "prejudice ... is immaterial" in determining whether good cause has been established under Rule 16. *Moyer*, 146 F. Supp. 2d at 1252.

II. LEAVE TO AMEND UNDER RULE 15(a) SHOULD BE GRANTED.

A. Amendments Required by November 8 Order.

Certain amendments have been made in compliance with this Court's directives and findings in the November 8 Order. For example, for SAC Claim 1 (APA Challenge to Military Mandates), Plaintiffs have removed "as applied" challenges and procedure-based challenges. For SAC Claim 2 (Informed Consent), which is TAC Claim 3, Plaintiffs have limited the challenge to the Armed Services Mandate. Plaintiffs have eliminated altogether SAC Claims 5 and 7 against the FDA,

B. Justice Requires Plaintiffs' Proposed Amendments.

In Section I above, Plaintiffs have demonstrated that there is good cause to permit Plaintiffs' proposed amendments to address pre-SAC facts that were discovered after the March 31 Deadline. The Eleventh Circuit "expresses a strong preference that cases be heard on the merits, and strives to afford a litigant his or her day in court, if possible." *Perez v. Wells Fargo NA*, 774 F.3d 1329, 1342 (11th Cir. 2014) (citations omitted) (cleaned up). Granting Plaintiffs' motion to file the TAC would achieve that purpose.

C. Amendment is Required to Cure Jurisdictional Defects.

In the November 8 Order, this Court dismissed as moot all claims against the FDA, *i.e.*, based on facts that arose after the filing of the SAC. These facts all concerned the FDA's approval of Moderna's SPIKEVAX®. *See* November 8 Order at 11. Where there are jurisdictional defects, "leave to amend should be freely given"

unless it would be "futile", *i.e.*, where even amended complaint would not survive motion to dismiss. *U.S. ex rel. Schubert v. All Children's Health System, Inc.*, 941 F.Supp.2d 1332, 1334 (M.D. Fla. 2013). *See also Mimbs v. Commercial Life Ins. Co.*, 818 F.Supp. 1556, 1559 (N.D. Ga. 1993) (the court "may grant leave to amend a complaint to cure jurisdictional defects"); Wright & Miller § 1350 nn.55-58 (collecting cases).

In the TAC Plaintiffs have alleged post-SAC facts that were not known or could not have been discovered with reasonable diligence prior to the March 31 Deadline in support of their challenge to the SPIKEVAX® approval, as well as related claims regarding misbranding and unfair and deceptive trade practices against Moderna, the manufacturer of SPIKEVAX®. Plaintiffs' amendments and supplements regarding SPIKEVAX® are supported both by good cause, and they meet the lower standards required under Rule 15(a) and Rule 15(d).

D. Amendment Would Not Result in Undue Prejudice or Delay.

Defendants would not face undue prejudice or delay by virtue of granting leave to file the TAC. *Equity Lifestyle Props., Inc. v. Fla. Mowing & Landscape Serv., Inc.*, 556 F.3d 1232, 1241 (11th Cir. 2009) (discussing undue prejudice being a factor in whether to grant a motion to amend). They have not filed an answer; the deadline for dispositive motions has not passed; nor have they even begun to produce the FDA administrative record. Discovery is similarly not a factor because

Defendants have not provided any, and the Court has not required them to do so. Moreover, the proposed TAC allows for the incorporation of pre-SAC facts that were not known or could not have been discovered through reasonable diligence at that time. Finally, the granting the motion to file the TAC will not result in undue delay as discussed below in Section III.

III. RULE 15(d) LEAVE TO SUPPLEMENT SHOULD BE GRANTED.

The purpose of Rule 15(d) "is to promote as complete an adjudication of the dispute between the parties as is possible." Wright & Miller § 1504. Permitting Plaintiffs to supplement the SAC would permit the Court "to award complete relief, or more nearly complete relief, in one action, and to avoid the cost, delay, and waste of separate actions which must be separately tried and prosecuted." *Miller,* 318 F.R.D. at 148 (citation omitted). Granting Plaintiffs' motion to file the TAC furthers these goals by supplementing the SAC with the transactions, occurrences, and events that happened after the filing of the SAC and modifying or adding claims against Defendants in light of these subsequent facts and avoid filing a new complaint.

A. The New or Modified Claims Against Defendants Are Substantially Related to Existing Claims in SAC.

All of the supplemental facts that Plaintiffs propose to add to the TAC: (1) provide additional evidence in support of existing claims; or (2) support new or modified claims that grow out of the existing claims. All of the evidence in the SAC

bears on these claims in the TAC and all of these arguments have already been considered by the Court in connection with the SAC.

Claim 1: APA Challenge to Military Mandates. This is the same claim as Claim 1 in the SAC (amended as directed by the November 8 Order). Plaintiffs propose to supplement this with additional evidence showing that the Armed Services Mandates violate 5 U.S.C. § 706 that has arisen or been discovered after the SAC was filed, in particular, evidence that: (1) the mRNA products are not "vaccines" based on revelations that COMIRNATY® was approved without any tests that it prevented transmission (Facts 1 & 15); (2) the Military Administrative Records demonstrating the lack of any record evidence supporting key Plaintiff contentions and Defendants' defense that mandates were limited to "BLA-compliant" doses (Fact 2); (3) the consensus among manufacturers, public health agencies and the U.S. government that mandated vaccines are obsolete and ineffective (Facts 3 & 9-11).

Claim 2: Mandate of Misbranded, Expired or Adulterated Products. This additional claim is a modified version of Claim 1—that the Military Defendants are mandating misbranded, expired, or adulterated products—which is a related, but distinct mandate from the initial Military Mandates and Interchangeability Directives. This relies on the same evidence as Claim 1 insofar as the renewed directive violates 5 U.S.C. § 706(2)(A). But it alleges distinct violations of federal

laws and regulations prohibiting the sale, distribution and administration of misbranded, expired, or adulterated products. These violations are based on the evidence that has emerged starting in June 2022 and most recently in Defendants' October 18 Response regarding the FW Lots and G Lots (Facts 7-8 & 16-18).

Military Defendants had previously sought to mandate only EUA-labeled products because, as is now undisputed, no FDA-licensed products were available. As far as Plaintiffs are aware, Military Defendants have not previously attempted to mandate unlicensed products that were misbranded as COMIRNATY®, expired or adulterated. The "Comirnaty-labeled" products had not expired until at least August 2022 or October 31, 2022 at the latest. Claim 2 thus addresses distinct, modified Military Mandates issued after the initial mandates, that are generally applicable to all unvaccinated service members, including Plaintiffs. This claim should be evaluated in light of the evidence before the relevant decisionmakers at the time these modified mandates were adopted.

Claim 3: Informed Consent & Interchangeability Directives. This is the same as Claim 2 in the SAC, which was not dismissed by the November 8 Order, supplemented by additional post-SAC facts. This claim is supplemented by: (1) discussion of the Military Administrative Records, and how these records do not support the challenged agency action and provide no basis for Defendants' affirmative defense that the mandates were limited to "BLA-compliant" doses (Fact

2); (2) the May 3, 2022 Moderna Interchangeability Directive, prior to which no Plaintiff or service member could have been required to take an EUA-labeled Moderna product (much less SPIKEVAX®, which was not available until at least September 2022) (Facts 6 &14); and (3) Defendants' counsel admissions at the August 29 Hearing confirming Plaintiffs' contention that the Military Defendants have always mandated EUA-labeled products and abandoning their defense that they were mandating only so-called "BLA-complaint" doses (Fact 13).

Claim 4: Unlawful FDA Approvals of COMIRNATY® & SPIKEVAX®. This is the same as SAC Claim 4, supplemented by the following post-SAC or post-Deadline facts: (1) challenge to January 31, 2022 approval of SPIKEVAX® on largely the same grounds as COMIRNATY® (Fact 5); (2) the October 10, 2022 admission in sworn testimony that COMIRNATY® was approved without any attempt to test whether it could prevent transmission and that that it could not have been a vaccine (Fact 15); and (3) the supplemental approvals of Grey Cap COMIRNATY® (as recently as August 25, 2022), long after Pfizer, the CDC, and the U.S. Government had determined that the "monovalent" vaccines were obsolete and ineffective against Omicron (Fact 12). As discussed above, no service member or Plaintiff could have been required to take any Moderna EUA product until at least May 3, 2022, when the Moderna Interchangeability Directive was issued, or

SPIKEVAX® prior to September 2022 when Military Defendants first had SPIKEVAX® (Facts 6-14), so a challenge to SPIKEVAX® approval was not ripe.

Claim 5: Misbranding Violations. The misbranding violations addressed in TAC Claim 5 are a modified version of SAC Claim 6 regarding interchangeability. Plaintiffs have SAC Claim 6 supplemented this claim by: (1) clarifying Plaintiffs' allegations regarding the FDA's violation of mandatory statutory requirements regarding product labeling, including the mandatory EUA factsheet informing service members of their informed consent rights; (2) refuting the FDA's defense that it was authorized to take these actions through the exercise of "enforcement discretion," ECF 65-14, Marks Decl. (Fact 4); and (3) alleging that the FDA Waiver and related actions also render the product labeling to false and misleading in violation of federal laws prohibiting misbranding.

IV. JOINDER OF MANUFACTURER DEFENDANTS IS REQUIRED BY JUSTICE AND SUPPORTED BY GOOD CAUSE.

The Florida Plaintiffs seek to add a new claim to the TAC that Manufacturer Defendants violated the Florida Unfair and Deceptive Trade Practices Act ("FDUPTA"). Fla. Stat. §§ 501.201, *et seq.* All the material transactions, occurrences, and events giving rise to the Florida Plaintiffs' FDUPTA claim happened or were discovered post-Deadline, and nearly all of these were post-Hearing. *See supra* Section I.D.

A. The FDUPTA Claim Against Manufacturer Defendants Is Factually and Logically Related to Claims Against Defendants.

Plaintiffs' FDUPTA claim is largely based on the same evidence as the claims against the existing Defendants. Much of the relevant evidence required to prove Plaintiffs' claims against the Manufacturer Defendants would be part of the FDA administrative records for approval of COMIRNATY® and SPIKEVAX®. This evidence would resolve key issues whether these products are "vaccines" and when it was determined that they were obsolete and ineffective against Omicron.

Further, Plaintiffs allege *per se*, statutory FDUPTA violations based on violations of same federal laws allegedly violated by Defendants and which federal laws serve as the standard for FDUPTA violation. For misbranding, the evidence to resolve these claims would be largely identical to that necessary to resolve the existing Defendants' misbranding claims, *i.e.*, TAC Claim 2 for the Military Defendants and TAC Claim 5 for the FDA. The same applies to the FDUPTA violations involving false and misleading advertising, which rely on the Federal Trade Commission Act and regulations thereunder to provide the standard.

B. Joinder of Manufacturer Defendants Is Required For This Court to Grant Relief.

Plaintiffs do not have a private cause of action for violations of federal laws prohibiting sale, distribution or administration of misbranded, expired or adulterated products and prohibiting unfair and deceptive trade practices. Florida Plaintiffs may,

however, seek relief under FDUPTA. Granting the requested declaratory and injunctive relief under FDUPTA by enjoining the marketing, sale or administration of these products in Florida and requiring a recall of the misbranded, expired, and/or adulterated products would provide Florida Plaintiffs the relief that they seek and would protect the consuming public that FDUPTA seeks to protect.

Conversely, failure to join the Manufacturer Defendants could deprive Florida Plaintiffs of any injunctive relief for Manufacturer Defendants' violations of both federal and state laws prohibiting misbranding and unfair and deceptive trade practices. *See, e.g., Datastrip*, 253 F.Supp.2d at 1317 (adding additional defendants to ensure effective injunctive relief). Also as in *Datastrip*, Plaintiffs knew of the existence of the Manufacturer Defendants at the outset, but did not have sufficient evidence of their illegal conduct in concert with Defendant until after the amendment deadline had passed. *Id.*

Granting this relief would also resolve, in whole or in part, Florida Plaintiffs claims against the Military Defendants and FDA. Recalling or enjoining the administration of misbranded, expired and/or adulterated products would protect Florida Plaintiffs from imposition of the unlawful Military Mandates without the need to enjoin Military Defendants or to resolve issues regarding separation of powers, justiciability, and the scope of injunctive relief raised by Defendants.

C. Plaintiffs' Request for Joinder is not Due to Improper Motive and Would not Cause Undue Prejudice to Manufacturer Defendants.

In the absence of "undue delay, bad faith or dilatory motive on the part of the movant," "futility" or "undue prejudice to the opposing party, "the leave sought should, as the rules require, be freely given." *Datastrip,* 253 F.Supp.2d at 1318 (*quoting Foman v. Davis,* 371 U.S. 178, 182 (1962)).

As discussed above, Plaintiffs have only recently obtained evidence that appear to establish *per se* FDUPTA violations, most of which was post-Hearing. Joinder of the Manufacturer Defendants would not cause undue delay or undue prejudice to the existing Defendants.

Much of the relevant evidence for the claims against Manufacturer Defendants would be in the FDA administrative records, *e.g.,* communications between the manufacturers and the FDA, underlying the unlawful approvals of COMIRNATY® and SPIKEVAX® and the supplemental approvals of COMIRNATY®. The FDA has not even begun to produce the COMIRNATY® approval administrative record. Accordingly, no delay would result from the addition of claims based on this record evidence.

Moreover, any non-record evidence required to prove the FDUPTA claims would largely consist of publicly available materials that would not require discovery such as the Manufacturing Defendants' labeling, advertising and marketing materials; the Military Defendants' use of mass inoculations and "vaccine

rodeos" that were publicized in media, social media or written orders; Military Defendants' generally applicable policies governing individualized assessments for vaccine risks and exemptions; or Manufacturing Defendants' contracts with Military Defendants setting forth how Military Defendants would ensure service members received warnings and other information and disclosures required by law for prescription drugs.

Discovery of non-record materials or depositions from Manufacturer Defendants could be conducted in parallel while the FDA produces the voluminous administrative records for the COMIRNATY® and SPIKEVAX® approvals. Accordingly, no delay would result from the limited discovery that may be required for statutory, *per se* FDUPTA violations alleged by Plaintiffs.

In any case, the existing Defendants refused to provide any responses to Plaintiffs' discovery requests, and this Court denied Plaintiffs' motion to compel discovery. Plaintiffs have never obtained any discovery materials from existing Defendants or Manufacturer Defendants. Accordingly, Plaintiffs' illusory "opportunity" to conduct discovery cannot be grounds for denying joinder of Manufacturer Defendants or for the claim that Plaintiffs have failed to exercise reasonable diligence to discover Manufacturer Defendants' FDUPTA violations.

CONCLUSION

Plaintiffs respectfully move for the Court to accept for filing Plaintiffs' Third Amended and Supplemental Complaint, effective November 30, 2022.

Dated: November 29, 2022

Respectfully submitted,

s/ Brandon Johnson
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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing motion and memorandum is 7,820 words or less according to Microsoft Word's word count function.

/s/ Brandon Johnson

CERTIFICATE OF CONFERENCE

The undersigned conferred with Defendants' counsel on November 17 & 29, 2022, and Defendants have not stated whether they do or do not oppose the motion.

/s/ Brandon Johnson

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing via CM/ECF on November 29, 2022, which notifies counsel of record of the filing.

/s/ Brandon Johnson