November 18, 2024

Jessica Looman
Administrator
Department of Labor
Wage and House Division
200 Constitution Ave NW
Washington, DC 20210

Re: Use of Family Medical Leave Act for Clinical Trial Participation

Dear Administrator Looman:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to finding cures for Crohn's disease and ulcerative colitis, and improving the quality of life of children and adults affected by these diseases.

Jointly, we are reaching out to request your office publish additional guidance confirming that consumers can use leave under the Family Medical Leave Act (FMLA) to participate in a clinical trial.

I. Clinical Trials

Historically, participation in clinical trials has been considered as a last-resort when other approved treatments options are ineffective.[1] However, in recent years participation in clinical trials has been considered a treatment option rather than a last resort.[2] Unfortunately, participation in clinical trials can be challenging due to hardships associated with participation such as missed work, job loss, health insurance coverage, and other out-of-pocket expenses.[3] As a result, consumers who want to be able to participate in clinical trials are denied the opportunity.

These barriers to clinical trial participation also perpetuate health disparities among treatments and outcomes. For example, a 2022 analysis by the Food and Drug Administration found that between 2014 and 2021, fewer than 20 percent of drugs had data on the benefits or side effects for Black/African American patients.[4] This lack of inclusion perpetuates health

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[1] FDA, *Clinical Research Versus Medical Treatment,* https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment.
[2] John Hopkins Medicine, *About Cancer Clinical Trials,* https://www.hopkinsmedicine.org/kimmel-cancer-center/clinical-trials/about-clinical-trials.
[3] Ryan D. Nipp, et al., *Overcoming Barriers to Clinical Trial Enrollment,* https://ascopubs.org/doi/10.1200/EDBK_243729.
[4] USC Schaeffer, *Lack of Diversity in Clinical Trials Costs Billions of Dollars. Incentives Can Spur Innovation,* https://healthpolicy.usc.edu/article/lack-of-diversity-in-clinical-trials-costs-billions-of-dollars-incentives-can-spur-innovation/

disparities and treatment outcomes for consumers. For instance, less than 5% of participants in IBD clinical trials are Black/African American.[5]

Ultimately, to improve treatment outcomes and ensure diverse consumers can participate in clinical trials we must eliminate barriers that limit clinical trial participation, such as unprotected leave for clinical trial participation.

II. Family Medical Leave Act

Under the Family Medical Leave Act (FMLA), eligible employees may take up to 12 weeks of unpaid, job-protected leave for a specified medical or family reason.[6] A qualifying reason includes "a serious health condition that makes the employee unable to perform the essential function of his or her job."[7]

A serious health condition is defined as "an illness, injury, impairment or physical or mental condition that involves either inpatient care or continuing treatment by a health care provider."[8] As such, FMLA recognizes that intermittent care such as quarterly infusion treatments is a justifiable use of FMLA leave.[9] Importantly, guidance from the Department of Labor (DOL) already recognizes that chronic conditions, permanent, and long-term conditions are conditions that require multiple treatments, and as such would be eligible to use FMLA for intermittent leave.[10]

However, under current guidance, DOL does not address whether participation in a clinical trial constitutes continuing treatment. Under our interpretation of the intent of the FMLA and its requirements, we believe the use of FMLA to participate in a clinical trial is justifiable as the consumer is seeking continuous treatment for a serious health condition.[11]

First, if a patient is participating in a clinical trial, it is likely because they have a complex, chronic, rare, or other long-term condition (cancer, inflammatory bowel disease, arthritis, etc) that satisfies the requirements of a serious health condition under the statute. Second, when participating in a clinical trial consumers are under continued treatment by a health care provider monitoring the clinical trial process. Time off is necessary for clinical trial participation as short-term clinical trial participation typically requires 6 visits over 8 weeks, each lasting 1 hour; and longer clinical trials may include 8 visits over 6 months, each lasting 1 hour. The time

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[5] Nathaniel A. Cohen, *Inclusion of Under-Represented Racial and Ethnic Minorities in Randomized Clinical Trials for Inflammatory Bowel Disease,* https://pmc.ncbi.nlm.nih.gov/articles/PMC8678318/
[6] DOL, *Family and Medical Leave Act,* https://www.dol.gov/agencies/whd/fmla
[7] *Id.*
[8] DOL, *Fact Sheet #28P: Taking Leave from Work When You or Your Family Member Has a Serious Health Condition under the FMLA,* https://www.dol.gov/agencies/whd/fact-sheets/28p-taking-leave-when-you-or-family-has-health-condition
[9] *Id.*
[10] *Id.*
[11] For this analysis, we presume all FMLA requirements for covered and eligible employees are satisfied.

requirements are similar to what an individual with a chronic condition may require for monthly infusions or doctor's appointments. As such, participation in a clinical trial meets the statutory requirements for taking protected leave under the FMLA; and is consistent with DOL guidance on FMLA usage.

While some participants in a clinical trial will receive a placebo, they are administered this in addition to their existing treatment for the underlying condition. As such, potentially receiving a placebo should not impair their ability to use FMLA to participate in the clinical trial. Placebo participants are necessary for clinical trials to produce innovative and effective treatments while patients remain under the clinical monitoring of a healthcare provider to assess adverse events associated with the clinical trial. Thus, for the public benefit, the use of FMLA should not be limited based on the potential that some individuals may be in the placebo arm of a clinical trial, as this is a necessary safeguard in our drug development process.

Moreover, FMLA was not intended to solely benefit individuals when they are seeking to improve or care for their own health. Not only does the FMLA allow family members to take time off to care for ill relatives, DOL guidance also specifically recognizes that FMLA can be used when a healthy individual wants to donate an organ to an unknown recipient.[12] As such, it would be consistent with the intent of the FMLA and DOL guidance to clarify that FMLA may be used for clinical trial participation.

III. Conclusion

We appreciate the consideration of our letter and urge your office to swiftly publish guidance confirming that FMLA can be used for clinical trial participation. Please contact us at avantrees@aimedalliance.org or emckeon@crohnscolitisfoundation.org if you have any questions.

Sincerely,

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[12] Massachusetts General Hospital, *Placebo-Controlled Trials,* https://www.massgeneral.org/neurology/als/research/placebo-trials#:~:text=So%2C%20why%20use%20placebos%20in,an%20active%20treatment%20is%20effective.