Rare Disease
Company Coalition

BY ELECTRONIC DELIVERY

December 5, 2022

The Honorable Charlotte A. Burrows
Chair
U.S. Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

RE: FY 2022-2026 Draft Strategic Plan for Public Comment (EEOC-2022-0004-0001)

Dear Chair Burrows:

The Rare Disease Company Coalition (RDCC) thanks you for the opportunity to provide comments on the Equal Employment Opportunity Commission's (EEOC) FY 2022-2026 Draft Strategic Plan. Employer-provided health insurance has increasingly come to engage in discriminatory practices that limit patient access to rare disease treatments or genetic-based therapies. We respectfully request that the EEOC consider the elimination of this discrimination against patients with rare disease associated disabilities in employer-provided health plans as a strategic priority in the finalized FY 2022-2026 Strategic Plan.

The RDCC is a coalition of 22 life science companies that are committed to changing the paradigm in rare disease treatment by discovering, developing, and delivering life-changing therapies to rare disease patients around the globe. Collectively, RDCC members invested over $12.4 billion in R&D in 2021, have brought 31 treatments to market to date – the majority of which are the first FDA approved treatments available for a given disease – and are working to advance more than 200 rare disease treatments, many of which would be the first ever FDA-approved therapies for patients with a given rare disorder.[1] We aim to inform policymakers of the unique challenges that face the biopharmaceutical companies who are diligently committed to bringing rare disease therapies from their discovery stage to the bedside of patients.

While rare disease is generally defined in the United States as a condition that affects fewer than 200,000 people, there are over 10,000 identified rare diseases that impact roughly 30 million Americans.[2] These diseases are devastating and often life-threatening: 80 percent of rare diseases are genetic in origin, and

[1] Rare Disease Company Coalition. https://www.rarecoalition.com/.

[2] National Center for Advancing Translational Science and Genetic and Rare Diseases Information Center. What is a rare disease? Updated January 26, 2021. Accessed April 2022 at https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases

50 percent impact children,[3] with many rare diseases resulting in premature deaths of infants and young children.[4]

Congress and federal agencies have incentivized the creation of rare disease treatments and therapies due to the severe unmet need of rare disease patients and demonstrated the imperative of providing access to such treatments or therapies for the patients who need them. In 1992, for example, Congress amended the Orphan Drug Act to implement tools to catalyze investment and development of rare disease treatments and therapies. The practices by employer-provided health plans described herein have turned the clock back on science, research, and development and undermine the progress made over the past three decades, ultimately resulting in obvious harm to rare disease patients.

Employer-provided health plans are intentionally or unwittingly discriminating against rare disease patients based on their disabilities.

Evidence has demonstrated a growing prevalence of discriminatory practices conducted by employer-provided health plans against rare disease patients.[5] An analysis conducted this year of employers and the levers they might use to control health benefits costs associated with a rare disease therapy showed that while 6% of studied employers said they would cover a high-cost rare disease therapy, 10% said they would categorically exclude coverage of that therapy, and 23% said they would laser out individual patients who were prescribed that therapy (for example, changing that individual patient's coverage policy terms by suddenly increasing individual premiums based upon whether a medically necessary rare disease therapy had been prescribed for them).[6] This sort of discrimination can have devastating impacts on employees and their dependents (including children and spouses) with rare diseases who are unable to access rare disease treatments as a result. These practices disadvantage patients with serious, often life-threatening conditions, preventing them from accessing urgently needed FDA-approved medicines when there are often no alternatives. These include:

- Alternative Funding Vendors (AFVs), which are an emerging business model that threatens to dismantle the promise of comprehensive drug coverage for many Americans, if left unabated. AFVs exploit a loophole in patient assistance programs designed to provide medication access to uninsured and underinsured individuals by advising health plans to exclude coverage for specialty drugs or rare disease treatments. This practice forces their rare disease patients, but not other plan beneficiaries, to navigate these charitable free-drug programs for specialty drugs, rather than receive coverage through their employer-provided health plan.
- The use of treatment valuation models, such as the quality-adjusted life year (QALY), which is a generic measure of disease burden that includes both the quality and quantity of life lived. Some health insurers design their drug coverage based on value assessments that utilize QALYs, which have known limitations, are based upon the public's subjective attitudes toward disabilities, and have a disparate, adverse impact on patients with rare diseases. Bioethicists,[7]

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[3] Batshaw ML, Groft SC, Krischer JP. Research into rare diseases of childhood. JAMA. 2014; 311(17): 1729-30.

[4] Institute of Medicine (US) Committee on Accelerating Rare Diseases Research and Orphan Product Development; Field MJ, Boat TF, editors. Rare diseases and orphan products: Accelerating research and development. Washington (DC): National Academies Press (US); 2010. Available from: https://www.ncbi.nlm.nih.gov/books/NBK56189/ doi: 10.17226/12953

[5] *See generally* National Council on Disability. (2019). *Quality-Adjusted Life Years and the Devaluation of Life with Disability*. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

[6] Estimates based on Emerging Therapy Solutions propriety calculations, 2021 – 2022. https://emergingtherapies.com/

[7] *See National Council on Disability*

patient advocacy groups,[8] and members of Congress[9] all have raised serious concerns about its use.

- "Fail first" or step therapy plan designs or utilization management. Health plan designs or utilization management techniques can discriminate by requiring patients to fail on several medications before their plan will pay for the medication first prescribed by their doctor. This practice delays patient care, creates unnecessary stress, and can result in hospitalizations, worse health outcomes, and higher healthcare costs.

The disparate treatment of rare disease patients by some employer-sponsored health plans raises legal questions about discrimination based on disability in the workplace.

- The EEOC has recognized in its *Interim Enforcement Guidance on the Application of the ADA to disability-based distinctions in employer-provided health insurance* (issued June 8, 1993) ("ADA Guidance") that the ADA prohibits employers from discriminating based on a disability in the provision of health insurance to their employees.

- Under the ADA, an employer cannot discriminate through the health benefits it provides to an employee or enter into a contractual relationship that effectively discriminates against an employee with a disability.[10] The ADA makes it unlawful for an employer to discriminate based on disability regarding the "terms, conditions, and privileges of employment."[11] According to EEOC this includes "[f]ringe benefits available by virtue of employment, whether or not administered by the [employer]," including health benefits provided by an employer to its employees.[12]

Recommendations and Conclusion

Because of the above concerns regarding the discriminatory practices of employer-sponsored health plans against rare disease employees and dependents, the RDCC believes the EEOC should consider the following three steps as it finalizes its strategic plan:

1. EEOC should clarify as part of its Strategic Plan that "health benefits" discrimination falls within its jurisdiction and that it will take action to eliminate discrimination based on disability in health benefits provided by employers. It is imperative not only that EEOC include this clarification in its Strategic Plan, but also that it takes steps to assign resources to the investigative and enforcement personnel who will be assigned to this matter.

2. EEOC should update its 1993 ADA Guidance as a part of its plans to update other existing guidance addressed in Strategic Plan Objectives II.A and II.B. to make clear that discrimination against rare disease patients in the provision of health benefits by employers is itself improper and potentially illegal discrimination based on a disability. Such an update is critical in light of advances in medicine and health care technology, particularly as related to rare disease. Tremendous progress has been achieved to battle rare disease thanks to federal legislative efforts, such as the Orphan Drug Act, as well as regulatory strategies by federal agencies,

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[8] Patients Rising Now. Barriers to Rare Disease Treatments [podcast]. 1 Mar 2020. https://patientsrisingnow.org/season-2-episode-8-barriers-to-rare-disease-treatments/

[9] *See, e.g.,* House Energy & Commerce Committee Republicans. (2022 April 4). *Rodgers, Banks, & Wenstrup Lead QALY Ban to Affirm Every Person's Life has Value* [Press release]. https://republicans-energycommerce.house.gov/news/74988/

[10] 42 U.S.C. § 12112(b)(2).

[11] 42 U.S.C. § 12112(a).

[12] 29 C.F.R. § 1630.4(a)(vi).

tireless work by the rare disease community and untold billions of dollars of investments made by rare disease companies and our partners in the private sector. For these reasons, it is vital that EEOC exert its proper authority within its jurisdiction to prevent employers from intentionally or unintentionally discriminating against rare disease patients based on their disabilities and, in so doing, preventing those patients from accessing the transformative treatments that have become available through decades of healthcare innovation.

We appreciate the opportunity to provide comments on EEOC's FY 2022-2026 Draft Strategic Plan and look forward to working together to end the discriminatory practices of employer-sponsored health plans, ensuring that rare disease patients have access to the treatments and therapies they desperately need.

Should you have any questions, please feel free to contact me at amanda@rarecoalition.com.

Sincerely,

Amanda Malakoff
Executive Director
Rare Disease Company Coalition