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February 9, 2023

VIA ELECTRONIC DELIVERY

Chair Charlotte A. Burrows
US Equal Employment Opportunity Commission
131 M Street NE Suite 4NW08R
Washington, DC 20507

RE: IGT EEOC Draft Strategic Enforcement Plan for FYs 2023-2027 [EEOC-2022-0006]

Dear Chair Burrows:

The Institute for Gene Therapies (IGT or "the Institute") is pleased to submit these comments to the US Equal Employment Opportunity Commission (EEOC) on the draft Strategic Enforcement Plan (SEP) for Fiscal years (FYs) 2023-2027 (the "draft SEP").[1] IGT was launched in February of 2020 to advocate for a modernized regulatory and reimbursement framework that encourages the development of transformative gene therapies and promotes patient access. Through a Corporate Advisory Council, Patient Advocacy Advisory Council, and Scientific, Academic & Medical Council, the Institute represents a wide array of patient advocacy groups, gene therapy manufacturers, and scientific, medical, and academic stakeholders seeking to advance the promise of gene therapies. IGT is devoted to promoting the value of transformative therapies and advocating for policies and practices to ensure patient access to these treatments. Our most vulnerable patients and their families anxiously wait for the life-altering treatments that gene therapies will offer to some of the most debilitating or rare diseases. A full list of our members is available at https://www.gene-therapies.org/advisory-councils.

IGT submitted comments in response to EEOC's draft Strategic Plan for 2022-2026 commending the EEOC for its efforts to enforce federal laws that protect against employment discrimination on the basis of race, color, religion, sex, national origin, age, disability, or genetic information. The Institute's comments to the draft SEP echo our focus on protecting employees from discrimination based on genetic conditions or disabilities that occurs through health insurance design or coverage restrictions. As the promise of gene therapy transitions from research to reality, the EEOC must ensure that employers are not designing employer-sponsored health insurance that restricts or blocks access to these transformative therapies.

I. About Gene Therapy

Scientists have been working for decades to deliver on the promise of gene therapy, with a goal of revolutionizing treatment paradigms and replacing life-long chronic therapies with potentially curative therapies for diseases for which limited or no treatment options exist – or where the only available treatment options are burdensome, expensive, painful, and lifelong. Gene therapies are potentially one-time treatments that aim to fix the underlying cause of genetic diseases at the DNA level. The effects are long-lasting – potentially lifelong – and

[1] 88 Fed. Reg. 1,379 (Jan. 10, 2023); available at: https://www.govinfo.gov/content/pkg/FR-2023-01-10/pdf/2023-00283.pdf.

will prompt changes in how we think about the value of treatment, payment models, and the like. Scientists in the United States have delivered on this vision, with several transformative gene therapies receiving Food and Drug Administration (FDA) approval since 2017, including three since August 2022,[2] and a robust pipeline of therapies for treating an array of life-threatening and devastating diseases.

The science underpinning gene therapies is highly complex. The development and manufacturing processes for gene therapies are built on a deep understanding of biologic medicines, e.g., vaccines, insulin, and monoclonal antibodies. While gene therapies and biologics share some characteristics, gene therapies are significantly more scientifically complex both in how they are designed for safety and efficacy and in how they are manufactured for scalability and capacity. Gene therapies deliver a functional gene to affected cells throughout the body, so that tissues can begin to produce the protein that is missing due to the patient's disease. For more information about the promise and science of gene therapies, we urge EEOC to visit https://www.gene-therapies.org/resources and also review several valuable resources.[3,4,5]

II. Draft SEP for FYs 2023-2027

IGT appreciates the work done by the EEOC to protect employees and agrees with the commission's mission to prevent and remedy discrimination and enforce civil rights in the workplace. We believe the draft SEP provides a valuable framework to help achieve the EEOC's vision and are particularly interested in ensuring that the EEOC views employer-sponsored health insurance as a particularly vulnerable area for employment-related discrimination. Our comments to the draft SEP focus on the very real threat that patients with genetic conditions and disabilities face as employers look to cut health benefits or carveout coverage for life-saving treatments such as gene therapies. **IGT reiterates its requests that EEOC identify as a strategic priority the elimination of disability discrimination in the application of employer-sponsored health insurance** and pursue enforcement against employers who violate employee rights.

Employer Health Insurance Coverage Increasingly Relies on Discriminatory Metrics in Determining Coverage

It is well documented in literature that value assessments derived from the quality-adjusted life year (QALY) may lead to unfair discrimination against individuals with less than perfect health, particularly for individuals with rare diseases. The QALY framework relies on a system of numeric utility to quantify the value of various health states wherein the highest possible utility for a health state is 1, representing "perfect health," and 0 which is an arbitrary value for death. The central criticism to the use of the QALY framework is that QALYs place greater value on years lived in full health, or on interventions that prevent loss of perfect health while discounting gains in health for individuals with chronic conditions or disabilities. Within the QALY framework, individuals with chronic conditions and disabilities experience a lower maximum baseline in health than their non-disabled counterparts. As a result, a treatment that improves their quality of life may result in fewer QALYs gained than a

[2] Food and Drug Administration (FDA), bluebird bio, Inc. Biologic License Approval (BL 1257/0); (Aug. 17, 2022); available at: https://www.fda.gov/media/160994/download. See also: FDA, bluebird bio, Inc. Accelerated BLA Approval; (Sept. 16, 2022); available at: https://www.fda.gov/media/161665/download, and FDA, CSL Behring LLC BLA Approval (BL 125772/0); (Nov. 22, 2022); available at: https://www.fda.gov/media/163466/download.

[3] Global Genes, "A Guide to Gene Therapy," (Aug. 2018); available at: https://globalgenes.org/wp-content/uploads/2018/11/Guide-to-Gene-Therapy_Toolkit_spread_DIGITAL-1.pdf.

[4] American Society of Gene and Cell Therapy, "Gene Therapy 101," (2022); available at: https://patienteducation.asgct.org/gene-therapy-101.

[5] FDA, "How Gene Therapy Can Cure or Treat Disease," (Jul. 28, 2022); available at: https://www.fda.gov/consumers/consumer-updates/how-gene-therapy-can-cure-or-treat-diseases.

similar treatment for individuals who are not disabled. These individuals are thus at a serious disadvantage as the framework favors those with greater potential for health.

The QALY was originally developed for use in academic population-level assessments. However, use of QALYs has expanded over time in the US to determine the economic value of health care interventions for the purposes of guiding coverage and reimbursement decisions, though not without objection. Notably, in 1992, the Department of Health and Human Services (HHS) found that Oregon's efforts to use a QALY-based cost-effectiveness standard in the state's Medicaid program violated the Americans with Disabilities Act (ADA) by systematically disadvantaging individuals with pre-existing disabilities.[6] The Affordable Care Act (ACA) also explicitly prohibits the Patient-Centered Outcomes Research Institute (PCORI) from using the cost-per-QALY as a threshold to establish what type of health care is cost effective or recommended.[7] The ACA further restricts the use of QALYs by precluding their use as a threshold to determine coverage, reimbursement, or incentive programs in Medicare.[8] Moreover, the National Council on Disability (NCD), an independent federal agency, has found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates.[9] Finally, the recently-enacted Inflation Reduction Act (IRA) of 2022 expressly prohibits HHS from considering "evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill" when negotiating drug prices under the new Drug Price Negotiation Program.[10]

Discriminatory Metrics in Determining Health Coverage Raise Legitimate ADA Discrimination Concerns

IGT has heard from stakeholders that employer-sponsored health insurance increasingly includes categorical treatment denials for rare disease and targeted genetic treatments, such as gene therapy. The ADA makes it unlawful for an employer to discriminate on the basis of disability in regard to, among other things, the "terms, conditions, and privileges of employment."[11] EEOC's regulations clarify that this extends to "[f]ringe benefits available by virtue of employment, whether or not administered by the [employer]," including health insurance plans provided by an employer to its employees.[12] As the EEOC further confirmed in its *Interim Enforcement Guidance on the Application of the American Disabilities Act of 1990 to Disability-based Distinctions in Employer Provided Health Insurance*, the ADA prohibits employers from discriminating on the basis of disability in the provision of health insurance to their employees.[13]

Therefore, under the ADA, an employer may not directly discriminate through the health insurance plan it provides as part of its benefits; nor may an employer enter into, or participate in, a contractual or other arrangement or relationship that has the effect of discriminating against their own qualified applicants or employees with disabilities.[14] Both the use of the QALY and categorical denials results in discrimination on the basis of disability. As noted above, the NCD has recognized the discriminatory use of the QALY as a violation of

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[6] Pear R. White House Expected to Back Oregon's Health-Care Rationing, New York Times (Mar. 1993).
[7] 42 U.S.C. §1320e-1(e).
[8] *Id.*
[9] National Council on Disability (NCD), "Quality-Adjusted Life Years and the Devaluation of Life with Disability," (Nov. 6, 2019); available at: https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[10] Inflation Reduction Act (IRA) of 2022, Pub. L. No. 117-169, adding new Social Security Act § 1194(e)(2)(D).
[11] 42 U.S.C. § 12112(a).
[12] 29 C.F.R. § 1630.4(a)(vi).
[13] EEOC, "Interim Enforcement Guidance on the Application of the American Disabilities Act of 1990 to Disability-based Distinctions in Employer Provided Health Insurance," (Jun. 8, 1993); available at: https://www.eeoc.gov/laws/guidance/interim-enforcement-guidance-application-ada-disability-based-distinctions-employer.
[14] 42 U.S.C. § 12112(b)(2); 29 C.F.R. § 1630.6(a), (b).

the ADA.[15] These discriminatory practices can have a devastating impact on employees and their dependents (including children and spouses with rare diseases) who are unable to access innovative genetic-modifying treatments with limited to no other treatment alternatives.

IGT Offers Four Concrete Steps for EEOC's Consideration to Help Eliminate Disability Discrimination in Employer-Sponsored Health Insurance

(1) EEOC should **explicitly identify in the SEP the elimination of disability discrimination in the application of employer-provided health benefits.** EEOC outlines the criteria used to identify six subject matter priorities for the draft SEP, including "issues involving policies or practices that impede or impair full enforcement of federal employment laws."[16] EEOC should explicitly clarify and emphasize in the SEP as part of its second and third subject matter priorities – "Protecting Vulnerable Workers and Persons From Underserved Communities From Employment Discrimination" and "Addressing Selected Emerging and Developing Issues," respectively—that the commission will make efforts to identify and eliminate disability discrimination in employer-provided health benefits.

(2) **EEOC should update its 1993 ADA Guidance.** Under the section titled, "Integrating Education and Outreach Activities," EEOC addresses plans to update existing guidance and training materials and create new, user-friendly resources and tools to address and prevent workplace discrimination.[17] As part of this vital endeavor, EEOC should update and modernize its 1993 ADA Guidance to: (1) reflect the realities of modern medicine and treatments, including substantial strides in the treatment of rare diseases and the development of gene therapies; and (2) help ensure that employers do not overtly or unwittingly discriminate on the basis of disability with respect to how they design and apply their health benefits.

(3) **EEOC should investigate this growing and systemic form of discrimination.** Consistent with EEOC's Systemic Program, EEOC should dedicate resources to investigate systemic discrimination in the provision of health benefits. EEOC should support commission investigators and trial attorneys in pursuing enforcement action where needed. Disabled employees and family members, including spouses and children with rare pediatric diseases, who face discriminatory treatment in the workplace by virtue of their employer's health insurance design deserve EEOC protection.

(4) **EEOC should utilize its existing authority to educate members of the public, employers, and employees regarding their** disability protections as it relates to genetic conditions and rare diseases. As the field of gene therapy remains nascent, many employers and employees may be unaware of the potential transformative nature of these therapies. Employers and employees may also be unaware of the potential discriminatory impact of employer-sponsored health insurance coverage decisions. We urge EEOC to include these topics in the commission's guidance and educational programs.

[15] NCD, "Quality-Adjusted Life Years and the Devaluation of Life with Disability," (Nov. 6, 2019); available at: https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[16] 88 Fed. Reg. at 1,381.
[17] 88 Fed. Reg. at 1,384.

III. Conclusion

IGT is leading the effort to educate policymakers and stakeholders about what constitutes value. Given the transformative promise of gene therapies, value cannot be limited to one or two elements, such as a QALY. For patients, families, and society, value must include patient preferences with respect to a treatment, the impact of a treatment on the patient's family and caregivers, a treatment's ability to advance health equity and address unmet needs, and the societal impact. Restrictive health insurance coverage decisions for gene therapies or patients with rare diseases not only fail to take into account the proper metrics of value, but also violate federal law and employers' responsibilities to their employees. We hope that EEOC will help to ensure that employees receive protection from discrimination in employment as it relates to health insurance. The most vulnerable in our society deserve this security.

The Institute welcomes the opportunity to engage with the EEOC over the coming years regarding employers' responsibility to provide meaningful health insurance coverage and access to gene therapies and to ensure that employees with genetic conditions or disabilities do not face discrimination in violation of federal law. IGT is pleased to serve as a resource to EEOC on gene therapy issues and answer any questions regarding our comments.

Sincerely,

John R. Feore, III
Director, Health Policy and Advocacy
Institute for Gene Therapies