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HEALTH LAW & POLICY BRIEF

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ARTICLES

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Acknowledgements:
We would like to thank our advisor, Maya Manian, for her support. We are also grateful to the American University Washington College of Law for providing a legal education that empowers us to champion what matters.

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LETTER FROM THE EDITORS

Dear Reader:

On behalf of the Editorial Board and Staff, we proudly present Volume 18, Issue 1 of the *Health Law & Policy Brief.* Since its formation in 2007, the Brief has published articles on an array of topics in health law, food and drug law, and emerging health technologies. In this issue, our authors discuss facets of substance use, treatment, and regulation in the United States. Volume 18.1 features two articles: one examining the perceived shortcomings of the Social Security Administration's approach to disability, and one discussing proposed revisions to the Food and Drug Administration's incentive structure around the production of orphan drugs.

Our first article, by Sierra Campbell, details the Social Security Administration's current approach to disability and how its subjectivity fails to adequately capture the nuances of harder-to-diagnose conditions, including Long COVID. Ms. Campbell concludes with recommendations to mitigate such subjectivity, address inequities, and ensure support for individuals with disabilities. Our second article, by David C. Edholm, examines the incentive structure of the Orphan Drug Act and proposes key revisions to the exclusivity provision. Mr. Edholm argues that adding a "proportional exclusivity" provision and implementing an additional user-fee credit incentive will enhance industry production of orphan drugs to treat America's most vulnerable populations.

We would like to thank the authors for their insight, creativity, and cooperation in producing these pieces. We would also like to thank the *Health Law & Policy Brief's* article editors and staff members who worked so diligently on this issue.

To all our readers, we hope you enjoy this issue, that the never-ending complexities of this area of law inspire your own scholarship, and that you continue to anticipate and scrutinize the inevitable challenges that our healthcare system continues to withstand.

Sincerely,

Devyn Malouf
Editor-in-Chief

Kimia Khatibi
Executive Editor

* * *

DETERMINING DISABILITY: LONG COVID HIGHLIGHTS THE SHORTCOMINGS OF SOCIAL SECURITY ADMINISTRATION'S APPROACH TO DISABILITY

Sierra Campbell

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I. INTRODUCTION

Long COVID impacts the health and economic security of millions. Yet, because it is a recent phenomenon and remains difficult to diagnose, people unable to work due to Long COVID are experiencing additional barriers to accessing Social Security Disability Insurance ("SSDI"). This paper explores the ways in which the Social Security Administration's ("SSA") approach to disability is influenced by individuals' discretion and subjective views of disability, impairment, and employment, especially when people are unable to work due to evasive or hard to diagnose conditions like Long COVID. The paper looks to other evasive conditions in order to offer recommendations to how SSA could better support people with Long COVID and people with disabilities generally.

Part I provides a brief overview of Long COVID; its impact on the health and financial security of millions of Americans; its developing interaction with federal civil rights law; and the uncertainties regarding its interaction with programs administered by the Social Security Act, including the Social Security Disability Insurance ("SSDI") program. Part II provides an overview of SSDI and the determination process for SSDI benefits. Part III introduces two hard-to-diagnose conditions that are analogous to Long COVID and can be used to inform the approach to SSDI benefits for Long COVID. In Part IV, this paper explores the influence of discretion and subjectivity throughout SSA's approach to disability—from the creation of the statutory definition of disability and the medical causation requirement to the Listing of Impairments and the SSDI determination process. Part IV further looks to hard-to-diagnose conditions to highlight the ways in which this subjectivity exacerbates inconsistencies and racial and economic inequities. Finally, Part V offers recommended solutions to mitigate this subjectivity, promote equity and consistency, and better ensure support for those with disabilities.

II. LONG COVID

A. Long COVID Overview

Recovery from SARS-CoV-2 (commonly referred to as "COVID-19") infection has varied, and although most previously-healthy individuals have recovered quickly and completely, many have experienced long-term, lingering symptoms.[1] Post-COVID-19 conditions—or Long COVID —can affect nearly every organ system and lead to serious health complications.[2]

A positive COVID-19 viral or antibody test result can help determine if an individual had a current or previous infection; however, there are currently no laboratory tests to definitively distinguish Long COVID from other conditions, and the symptoms can be non-specific and varied.[3] The most commonly described symptoms of Long COVID are tiredness or fatigue that interferes with daily life, general malaise and post-exertional malaise (symptoms that get worse after physical or mental effort), weakness, concentration impairment, and breathlessness.[4] Other common symptoms of Long COVID include: respiratory and cardiac symptoms like difficulty breathing, coughing, chest pain, and heart palpitations; neurological symptoms like headache, sleep problems, lightheadedness, changes in smell or taste, depression, and anxiety; digestive symptoms like diarrhea and stomach pain; and joint or muscle pain, rash, and changes in menstrual cycles.[5]

Long COVID can hinder an individual's ability to work, attend school, and participate in everyday activities. An estimated 37 percent of Long COVID patients

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[1] U.S. DEP'T HEALTH & HUM. SERVS., SERVICES AND SUPPORTS FOR LONGER-TERM IMPACTS OF COVID-19 5 (Aug. 2022), https://www.covid.gov/assets/files/Services-and-Supports-for-Longer-Term-Impacts-of-COVID-19-08012022.pdf [hereinafter LONGER-TERM IMPACTS].
[2] *Id.* at 16.
[3] *Id.* at 14–15.
[4] Melina Michelen et al., *Characterising Long COVID: A Living Systematic Review*, BMJ GLOBAL HEALTH 1, 7 (2021), https://gh.bmj.com/content/bmjgh/6/9/e005427.full.pdf; LONGER-TERM IMPACTS, *supra* note 1, at 15.
[5] LONGER-TERM IMPACTS, *supra* note 1, at 15.

("long-haulers") have reported reduced quality of life.[6] In an October 2021 survey of people with Long COVID, 44 percent of respondents reported they were not able to work at all and only 5 percent reported being able to work at 100 percent capacity.[7] In a December 2021 poll of people with Long COVID who have been out of work or reduced to working part-time due to their health, 48 percent of respondents reported experiencing financial ruin; 42 percent of respondents had medical bills over $5,000; and 41 percent had filed or were about to file for disability.[8] Based on the December 2021 poll, the COVID-19 Longhauler Advocacy Project—a patient-led non-profit advocacy organization—estimated that more than two million people with long COVID had filed or were about to file for disability, and that they were likely to experience long-lasting financial instability without assistance.[9]

The scope of the problem of Long COVID is still largely unknown given the current dearth of research and the difficulty in diagnosing it; however, estimates suggest Long COVID will have lasting health and economic implications for millions of Americans.[10] A 2022 CDC study found that at least 30 days after having COVID-19, one in five COVID-19 survivors aged 18-64 years and one in four survivors aged 65 years and older had a health condition that might be related to their previous COVID-19 illness.[11] Other estimates suggest nearly 10 million

[6] Michelen et al., *supra* note 4, at 7.
[7] *Mathematical Breakdown and Formulas for Long COVID Calculations,* COVID-19 LONGHAULER ADVOCACY PROJECT 2 (Jan. 10, 2022), https://www.longhauler-advocacy.org/calculations-formulas).
[8] *Id.* at 3.
[9] *Id.*
[10] LONGER-TERM IMPACTS, *supra* note 1, at 5, 16 (citing Lara Bull-Otterson et al., *Post-COVID Conditions Among Adult COVID-19 Survivors Aged 18-64 and >65 Years – United States, March 2020-November 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 713 (2022)); David M. Cutler, *The Costs of Long COVID,* 3 JAMA HEALTH F. 1 (2022).
[11] LONGER-TERM IMPACTS, *supra* note 1, at 5, 16 (citing Lara Bull-Otterson et al., *Post-COVID Conditions Among Adult COVID-19 Survivors Aged 18-64 and >65 Years – United States, March 2020-November 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 713 (2022)).

people in the US have developed long COVID and more than one million people may be out of the workforce at any given time because of Long COVID.[12] Research estimates that anywhere from 10 percent to 67 percent of individuals previously infected with COVID-19 will develop Long COVID.[13]

Given that COVID-19 infections and deaths have disproportionately harmed Black communities, other communities of color, and low-income communities, the same will likely be true of Long COVID.[14] Although research is limited, a 2021 review of studies on Long COVID found that people in a racial or ethnic minority, women, older adults, and those that had prior COVID-19 infections had increased risk of long COVID.[15]

B. Long COVID and Federal Civil Rights Law

The Department of Health and Human Services and the Department of Justice have published guidance on Long COVID, recognizing that Long COVID is a physical or mental impairment under federal laws protecting individuals with disabilities from discrimination, specifically, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Patient Protection and Affordable Care Act.[16] The guidance clarifies that long COVID can

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[12] David M. Cutler, *The Costs of Long COVID,* 3 JAMA HEALTH F. 1 (2022).
[13] Julia Puaschunder & Martin Gelter, *The Law, Economics, and Governance of Generation Covid-19 Long-Haul*, 19 IND. HEALTH L. REV. 47, 50 (2022); Destin Groff et al., *Short-term and Long-term Rates of Postacute Sequelae of SARS-CoV-2 Infection: A Systematic Review*, JAMA NETWORK OPEN, Oct. 2021, at 8.
[14] LONGER-TERM IMPACTS, *supra* note 1, at 12.
[15] *Id.*, at 16 (citing Lara Bull-Otterson et al., *Post-COVID Conditions Among Adult COVID-19 Survivors Aged 18-64 and >65 Years – United States, March 2020-November 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 713 (2022)); Melina Michelen et al., *supra* note **Error! Bookmark not defined.**, at 9.
[16] Puaschunder & Gelter, *supra* 13, at 94 (citing U.S. DEP'T HEALTH & HUM. SERVS. & U.S. DEP'T JUSTICE, GUIDANCE ON "LONG COVID" AS A DISABILITY UNDER THE ADA, SECTION 504, AND SECTION 1557 (July 26, 2021), https://archive.ada.gov/long_covid_joint_guidance.pdf; Lydia Wheeler, *Long Covid's Catch-22: Too Sick to Work, Yet Not Quite Disabled*, BLOOMBERG L.

constitute a disability under these statutes if an impairment following a COVID-19 infection "substantially limits' one or more major life activities."[17] The guidance also provides examples of substantial limitations: lung damage causing shortness of breath and fatigue that substantially limit respiratory function; symptoms of intestinal pain, vomiting, and nausea that substantially limit gastrointestinal function; and memory lapses and brain fog that substantially limit brain function, concentration, and thinking.[18] However, the guidance only addresses the definition of disability under federal civil rights laws and does not cover other definitions of disability or eligibility requirements, including those necessary to qualify for Social Security programs.

C. Long COVID and the Social Security Administration

Despite advocates' calls for federal guidance, the SSA and the Biden Administration have yet to update their policies or issue guidance to clarify whether Long COVID constitutes a disability for the purposes of federal benefits governed by the Social Security Act.[19] This has left outstanding questions and inconsistencies regarding the treatment of Long COVID in SSA disability determinations.[20]

(Nov. 18, 2021), https://news.bloomberglaw.com/health-law-and-business/long-covids-catch-22-too-sick-to-work-yet-not-quite-disabled).

[17] U.S. DEP'T HEALTH & HUM. SERVS. & U.S. DEP'T JUSTICE, GUIDANCE ON "LONG COVID" AS A DISABILITY UNDER THE ADA, SECTION 504, AND SECTION 1557 2–3 (July 26, 2021), https://archive.ada.gov/long_covid_joint_guidance.pdf; *see also* Puaschunder & Gelter, supra note 13, at 94–95.

[18] U.S. DEP'T HEALTH & HUM. SERVS. & U.S. DEP'T JUSTICE, GUIDANCE ON "LONG COVID" AS A DISABILITY UNDER THE ADA, SECTION 504, AND SECTION 1557, at 2–4.

[19] *See* Gabrielle Emanuel, *When Does COVID-19 Become a Disability? 'Long-Haulers' Push for Answers and Benefits*, NPR (Feb. 22, 2021), https://www.npr.org/sections/health-shots/2021/02/22/966291447/when-does-covid-19-become-a-disability-long-haulers-push-for-answers-and-benefit.

[20] *See* Puaschunder & Gelter, *supra* note 13, at 95–96; Betsy Ladyzhets, *People with Long Covid Face Barriers to Government Disability Benefits*, KAISER HEALTH NEWS (Nov. 9, 2022), https://khn.org/news/article/long-covid-barriers-government-disability-benefits/.

III. SOCIAL SECURITY DISABILITY INSURANCE (SSDI)

A. SSDI Overview

Social Security Disability Insurance ("SSDI") is a social insurance program for individuals with disabilities. SSDI is only available to individuals who have worked and paid Social Security taxes and are therefore "insured" for disability benefits.[21] If an individual is found eligible for SSDI, they can receive monthly payments based on their average earnings.[22]

For the purpose of establishing eligibility for SSDI, the Social Security Act defines "disability" as the "inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.[23]

B. SSDI Process

If an individual believes they are eligible for SSDI, they must file a claim by submitting an application to their state Disability Determination Services (DDS) office or through the SSA website.[24] DDS reviews this application and issues an initial determination of whether the individual is disabled. If DDS determines the individual is not disabled and denies the individual's claim, the individual can file a Request for Reconsideration for a new DDS examiner to review their claim. If

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[21] LONGER-TERM IMPACTS, *supra* note **Error! Bookmark not defined.**, at 48.
[22] *Social Security Benefit Amounts*, SOC. SEC. ADMIN., https://www.ssa.gov/oact/cola/Benefits.html.
[23] 42 U.S.C. § 423(d)(1)(A). This definition is used for the purpose of establishing eligibility for SSDI, as well as for Medicaid and Supplemental Security Income (SSI), a public assistance program that provides monthly payments to eligible individuals who cannot work full-time for medical reasons regardless of whether the individuals have previously worked.
[24] *See* Emily C. Russell & Hon. Glynn F. Voisin, *A Primer on Social Security Disability Law*, 62 LOY. L. REV. 829, 834 (2016).

the new examiner denies the individual's claim, the individual can then appeal the determination to the Office of Disability Adjudication and Review (ODAR).[25] An Administrative Law Judge (ALJ) then reviews the documents from DDS and the claimant's medical record; conducts a hearing to receive testimony of the claimant, medical experts, and vocational experts; and issues a determination of whether the individual is disabled based on a five-step sequential evaluation process:

> *Step 1) Substantial Gainful Activity*. The ALJ must consider the individual's work activity since filing their application and determine whether it constitutes substantial gainful activity. If the ALJ determines that the individual engaged in substantial gainful activity, then they are not considered disabled.[26]
>
> *Step 2) Severity of Impairment*. The ALJ must then consider the severity of the individual's medical impairment. The individual's impairment must be severe; medically determinable; and sufficient in duration—lasting or expected to last for at least 12 months or result in death. If the ALJ determines the impairment does not meet one of these requirements, the impairment does not meet the Social Security Act's definition of disabled.[27]
>
> *Step 3) Impairment that Meets a Listed Impairment*. Then, the ALJ must consider whether the individual's impairment meets one of the listings in the Commissioner's Listing of Impairments. The Listing designates specific impairments that are presumed to prevent an individual from doing gainful activity regardless of their age, education, or prior work experience. If the

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[25] SOC. SEC. ADMIN, YOUR RIGHT TO QUESTION THE DECISION MADE ON YOUR CLAIM 1–3 (May 2022), https://www.ssa.gov/pubs/EN-05-10058.pdf.

[26] *See* 20 C.F.R. § 416.920(4)(i); Russel & Voisin, *supra* note 24, at 845–46.

[27] *See* 20 C.F.R. § 416.920(4)(ii); Russel & Voisin, *supra* note 24, at 846–47.

medical evidence in an individual's record matches the symptoms or laboratory findings provided in a listing, the individual's impairment "meets" a listing, and the individual is found to be disabled without further consideration.[28]

Step 3.5) Residual Functional Capacity. If the impairment does not meet a listing criteria, the ALJ must instead conduct a "residual functional capacity" (RFC) assessment of the individual's maximum "ability to do sustained work activities in an ordinary work setting on a regular and continuing basis."[29] During the RFC assessment, the ALJ considers all medically determinable impairments, limitations from the impairments, objective medical evidence and opinions, and lay testimony to determine what the claimant can still do.[30] The individual's RFC is then used in Step 4 and Step 5 of the evaluation process.

Step 4) Past Relevant Work. If the individual's impairment does not meet any listed impairment, the ALJ must determine if the individual can still do their "past relevant work" despite their impairment.[31] For work to constitute "past relevant work," it must be sufficient in (1) recency (within fifteen years of adjudication); (2) duration (long enough to learn how to do the work and achieve an average performance level); and (3) earnings (at "substantial gainful activity" levels).[32] If the ALJ determines the individual can still perform their past work despite their impairments, then the individual is not considered disabled.

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[28] 20 C.F.R. § 416.920(a)(4)(iii) (2023); Russel & Voisin, supra note 24, at 849–51
[29] Russel & Voisin, *supra* note 24, at 854 (citing 1996 WL 374184, at *2).
[30] 20 C.F.R. § 404.1545 (2023); 20 C.F.R. § 404.1513 (2023); *see also* Russel & Voisin, *supra* note 24, at 853–56.
20 C.F.R. § 404.1520(a)(iv) (2023); *see also* 20 C.F.R. § 416.920(a)(4)(iv) (2023); Russel & Voisin, *supra* note 24, at 856–58.
[32] 20 C.F.R. § 404.1560 (2023); *see also* Russel & Voisin, *supra* note 24, at 853–56.

Step 5) Adjustment to Other Work. The ALJ must finally determine if the individual can adjust to other work, considering their RFC, age, education, and prior work experience. Here, the ALJ must find that relevant jobs exist in "significant numbers in the national economy," but the ALJ is not required to find that these jobs are available near the individual's home or that the individual could actually procure a job if they applied.[33] If the ALJ determines the individual can adjust to some other work in the national economy, then they are not considered disabled; however, if the ALJ determines they cannot adjust to other work, then the person is found to be disabled under the Act.[34]

If the ALJ finds the claimant not disabled, the claimant can file a request for review by the Appeals Council. In response, the Appeals Council can accept review, reverse the denial of benefits, or remand the claim for a new hearing; however, the Appeals Council denies most requests for review.[35] Following the Appeals Council's final determination, the individual can request judicial review of the denial of benefits in federal district court. In reviewing a Social Security disability determination, a district court may "set aside the Commissioner's denial of benefits when the ALJ's findings are based on legal error or are not supported by substantial evidence in the record as a whole."[36]

IV. EVASIVE CONDITIONS ANALOGOUS TO LONG COVID

[33] Russel & Voisin, *supra* note 24, at 858–62.
[34] 20 C.F.R. § 416.920(a)(4)(v) (2023); Russel & Voisin, *supra* note 24, at 853–56.
[35] Nora Coon, *Honest or Histrionic? Credibility Evaluation in Judicial Review of Social Security Disability Decisions*, 23 GEO. J. ON POVERTY L. & POL'Y 161, 164 (2015) (citing SOC. SEC. ADVISORY BD., ASPECTS OF DISABILITY DECISION MAKING: DATA AND MATERIALS 62 (2012)).
[36] *See* Schneider v Comm'r of Soc. Sec. Admin., 223 F.3d 968, 973 (9th Cir. 2000); Morgan v Comm'r of Soc. Sec. Admin. 169 F.3d 595, 599 (9th Cir. 1999).

Long COVID poses unique challenges for SSA given that it can significantly impact individuals' ability to work, attend school, and conduct everyday activities but it cannot be diagnosed through specific laboratory testing. However, Long COVID is not the first condition to rely on self-reported symptoms rather than objective diagnostics. The following sections explore SSA's approach to Chronic Fatigue Syndrome ("CFS") and fibromyalgia, two similarly evasive conditions, to inform recommendations regarding SSA's approach to Long COVID.

A. Chronic Fatigue Syndrome (CFS)

Chronic Fatigue Syndrome is a disorder that causes extreme fatigue that worsens with mental or physical activity, does not improve with rest, and can last years.[37] Up to 2.5 million Americans live with CFS, according to Institute of Medicine reports.[38] Like those with Long COVID, those with CFS often have difficulties with memory, focus, and concentration, which can pose additional difficulties in tracking and reporting symptoms.[39]

Those with CFS face additional difficulties in the Social Security disability process because CFS cannot be substantiated by objective diagnostic tests. CFS diagnosis is "based on the existence of certain symptoms, and the exclusion by medical testing of all other illnesses and disabilities which could cause the same symptoms. There is no x-ray or laboratory test which an ALJ can rely on for proof the claimant is a CFS sufferer."[40] Because CFS and long COVID symptoms are

[37] Angélica Guevara, *To Be, or Not to Be, Will Long Covid Be Reasonably Accommodated Is the Question*, 23 MINN. J.L. SCI. & TECH. 253, 263 (2022).
[38] *Id.*
[39] *Id.* at 263–64.
[40] Fay E. Fishman, *Chronic Fatigue Syndrome and Social Security Disability*, 42 SOC. SEC. REPORTING SERV. 789, 793–94 (1993).

vague and they cannot be confirmed through objective testing, there is a greater risk of individual provider bias in diagnosis and treatment of both conditions. CFS and Long COVID can evoke skepticism or accusations of malingering.[41] Some people with CFS can manage their symptoms through deep breathing exercises, massage, and movement therapy like stretching or yoga; however, there is no known cure for CFS.[42] Many CFS advocates have allied themselves with Long COVID advocates given these shared hurdles to diagnosis and treatment.[43]

B. Fibromyalgia

Fibromyalgia involves chronic, widespread pain; decreased pain thresholds; sleep disturbances; fatigue; and cognitive difficulties.[44] Fibromyalgia is estimated to affect 4 million American adults—and although they have severe symptoms, most do not receive a clinical diagnosis.[45] People with fibromyalgia can manage their symptoms through physical activity, stress management techniques like massage and yoga, improved sleep hygiene, and pain relief medications; however, there is no known cure for fibromyalgia.[46]

Like those with Long COVID and CFS, those with fibromyalgia face additional difficulties in the Social Security disability process because fibromyalgia cannot be

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[41] Guevara, *supra* note 37, at 263–64.
[42] *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/me-cfs/treatment/index.html (last reviewed Jan. 28, 2021).
[43] Chelsea Cirruzzo, *Meet 3 Black Women Fighting for Long COVID Recognition*, U.S. NEWS (July 7, 2021, 6:45 AM), https://www.usnews.com/news/healthiest-communities/articles/2021-07-07/black-long-haulers-demand-recognition.
[44] Aimee E. Bierman, *The Medico-Legal Enigma of Fibromyalgia: Social Security Disability Determinations and Subjective Complaints of Pain*, 44 WAYNE L. REV. 259, 259 (1998); Winfried Hauser & Mary-Ann Fitzcharles, *Facts and Myths Pertaining to Fibromyalgia,* 20 DIALOGUES IN CLINICAL NEUROSCIENCE 53 (2018).
[45] Brian Walitt, Richard L. Nahin, Robert S. Katz, Martin J. Bergman, & Frederick Wolfe, *The Prevalence and Characteristics of Fibromyalgia in the 2012 National Health Interview Survey,* 10 PLOS ONE 9, Sept. 17, 2015, at 1.
[46] *Fibromyalgia*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/arthritis/types/fibromyalgia.html (last reviewed May 25, 2022).

substantiated by objective medical findings like laboratory tests and x-ray results.[47] Physicians often test for other conditions that can mimic fibromyalgia, ranging from Lyme disease to multiple sclerosis, but can only successfully make a fibromyalgia diagnosis through the application of subjective criteria.[48] The American College of Rheumatology (ACR) diagnostic criteria for fibromyalgia relies on a widespread pain index and a symptom severity score, both of which are self-reported.[49]

V. EVASIVE CONDITIONS ANALOGOUS TO LONG COVID

A. Discretion and Subjectivity in Establishing the Statutory Definition of Disability

Examining the establishment and evolution of the statutory definition of "disability" illustrates the influence of Congress members' discretion, moral judgments, and political considerations from the outset of the Social Security Act's approach to disability. Enacted in 1935, the Social Security Act intended to protect against the "hazards and vicissitudes of life" by establishing a federal social insurance program providing monthly benefits to workers when they retired at age 65.[50]

In the late 1940s, Congress considered adding disability categories as eligibility criteria for Social Security benefits.[51] In the debate regarding whether benefits programs should be extended and how these programs should define "disability," there were varying views of disability status. Some policymakers and advocates

[47] Bierman, *supra* note 44, at 260; Hauser & Fitzcharles, *supra* note 44, at 56.
[48] Bierman, *supra* note 44, at 262.
[49] Hauser & Fitzcharles, *supra* note 44, at 56–57.
[50] *Historical Background and Development of Social Security,* SOC. SEC. ADMIN., https://www.ssa.gov/history/briefhistory3.html (last visited Mar. 16, 2023).
[51] Frank S. Bloch, *Medical Proof, Social Policy, and Social Security's Medically Centered Definition of Disability*, 92 CORNELL L. REV. 189, 195 (2007).

viewed disability as among the "hazards and vicissitudes of life" from which workers should be protected.[52] Therefore, they saw disability-based benefits as an earned right or entitlement. On the other hand, some policymakers and advocates worried disability-based benefits could create a "respectable passport out of work."[53] It was not until the 1950s that Congress established disability coverage, by adding a new federal-state public assistance program and disability insurance benefits to the Social Security Act. At the time, many lawmakers were concerned about the uncertainty of future costs of the program given the open-ended nature of disability as an eligibility criterion and the effects disability insurance may have on workforce participation.[54]

To mitigate these concerns, Congress enacted a medically-centered definition of disability for social insurance benefits, limiting benefits to individuals who can show that they cannot work due to a *medically determinable* physical or mental impairment.[55] SSA's use of medical guidelines and the definition's emphasis on clinical determinations of physical or mental impairment were seen as a safeguard to keep "disability" narrowly defined and prevent fraud or abuse.[56] In the 1970s, Congress incorporated this medically-centered social insurance disability standard into the federal Supplemental Security Income ("SSI") public assistance program.[57]

Since the establishment of disability coverage, congressional changes to the statutory definition of "disability" have included changing the duration requirement to establish a permanent disability from "long-continued and of indefinite duration" to "lasted or can be expected to last for a continuous period of not less than 12 months"; specifying that SSA must consider the combined effects of a claimant's

[52] *Id.*
[53] *Id.* at 196-8 .
[54] *Id.* at 197.
[55] *Id.* at 197.
[56] *Id.* at 197–99.
[57] Bloch, *supra* note 51 at 199.

impairment; eliminating alcoholism and drug addiction as bases for eligibility; and clarifying that an individual is only disabled if they are unable to engage in any kind of substantial gainful work that exists in the national economy—in effect removing considerations of local labor market conditions.[58] To clarify requirements for establishing pain-based disability, Congress amended the Social Security Act to expressly require claimants to provide specific medical proof of a medical impairment that "could reasonably be expected to produce" the degree of pain or other subjective symptoms that the claimant alleges makes them unable to work.[59] These statutory changes do not reflect changes in medical understandings of disability but instead reflect line-drawing to clarify or change the boundaries between those included and excluded by disability coverage.

The Social Security Act's use of a medically centered definition of disability gave the disability programs legitimacy through the appearance of objectivity.[60] However, the debates during the establishment of disability coverage and the evolution of the statutory definition demonstrate how the definition of disability is informed by moral, political, and economic considerations regarding ability, social obligations to work, public assistance, and social insurance.[61]

B. Discretion and Subjectivity in Diagnoses and the Medical Causation Requirement

Subjective considerations are not limited to the creation of the definition of disability but also show up in the application of this definition. The Social Security Act requires that a qualifying impairment result "from anatomical, physiological, or psychological abnormalities, which are demonstrable by medically acceptable

[58] *Id.* at 201–05; Social Security Act Amendments of 1965, Pub. L. No. 89-97 § 303, 79 Stat. 286, 366 (codified as amended at 42 U.S.C. § 423 (2000)).
[59] Bloch, *supra* note **Error! Bookmark not defined.**, at 205–06.
[60] *Id.* at 225.
[61] *Id.*; Matthew Diller, *Entitlement and Exclusion: The Role of Disability in the Social Welfare System*, 44 UCLA L. REV. 361, 363 (1996).

clinical and laboratory diagnostic techniques."[62] SSA regulations require that claimants prove their qualifying impairments with "medical evidence consisting of signs, symptoms, and laboratory findings" beyond a claimant's own statement about their symptoms. [63]

These requirements do not make disability determinations objective. Instead, they set access to health care as a prerequisite for benefits and health care professionals as gatekeepers to benefits. Access to medical evidence is dictated by access to health insurance, access to high-quality health services, and clinician discretion—all of which are largely tied to income and race.[64] In 2021, more than eight in ten uninsured people were in families with incomes 400 percent below the Federal Poverty Line ("FPL"), and nearly half had incomes 200 percent below FPL.[65] Despite small increases in health insurance coverage across most racial and ethnic groups between 2019 and 2021, disparities in health insurance coverage persist.[66] For example, among nonelderly adults, 21.2 percent of American Indian and Alaska Native, 19.0 percent of Hispanic, 10.9 percent of Black, and 10.8 percent of Native Hawaiian or Other Pacific Islander people are uninsured compared to 7.2 percent of white people.[67]

Race and income also influence access to high-quality care. Between 2002 and 2015, Black and Latino adults were less likely to have a primary care provider than

[62] 42 U.S.C. § 423(d)(3) (2000).
[63] Bloch, *supra* note **Error! Bookmark not defined.**, at 220 (citing 20 C.F.R. §§ 404.1508, 416.908 (2006)).
[64] Jennifer Tolbert, et al., *Key Facts about the Uninsured Population*, KAISER FAM. FOUND. (Dec. 19, 2022), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/; Samantha Artiga, et al., *Health Coverage by Race and Ethnicity, 2010-2021*, KAISER FAM. FOUND. (Dec. 20, 2022), https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/.
[65] Tolbert, *supra* note 64.
[66] Artiga, *supra* note 64.
[67] *Id.*

white adults.[68] Adults with poor, low, or middle incomes were less likely to have a primary care provider than adults with high incomes.[69] A 2004 study found that, in the United States, 22 percent of physicians provided care for 80 percent of Black patients and that physicians treating Black patients were less likely to be board certified, more likely to report an inability to provide high-quality care to all of their patients, and more likely to report limited access to advanced health care resources, such as specialists and diagnostic imaging.[70] A 2009 study similarly found that primary care clinics, in which at least 30 percent of patients belong to underrepresented racial or ethnic minorities, had less access to medical supplies, had fewer examination rooms per physician, and referred fewer patients to specialists.[71] Health insurance coverage, access to high-quality primary care, and referrals to specialists likely impact individuals' ability to receive formal diagnoses of their impairments.[72]

Take the following hypotheticals as examples. First, Ava is a 40-year-old Black woman who works as a bus driver. Following her COVID-19 infection, Ava has experienced shortness of breath, chest pain, fatigue, and weakness. However, Ava does not have health insurance, so she has put off seeking costly care even though her symptoms have persisted for more than a year and have forced her to miss work

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[68] David M. Levine, et al., *Characteristics of Americans with Primary Care and Changes over Time, 2002-2015*, 180 JAMA INTERNAL MED. 463 (2020).
[69] *Id.*
[70] Randall W. Knoebelet al., *Treatment Disparities Among the Black Population and Their Influence on the Equitable Management of Chronic Pain*, 5 HEALTH EQUITY 596, 600 (2021) (citing Peter B. Bach et al., *Primary Care Physicians Who Treat Blacks and Whites*, 351 N. ENGLAND. J. MED. 575 (2004)).
[71] *Id.* at 600 (citing Anita B. Varkey et al., *Separate and Unequal: Clinics Where Minority and Nonminority Patients Receive Primary Care*, 169 INTERNAL MED. 243 (2009).
[72] *See e.g.*, Jennifer L. Berrian, et al., *Relationship Between Insurance Status and Outcomes for Patients with Breast Cancer in Missouri*, 127 CANCER 931 (2020) (finding that patients with public insurance or no insurance were more likely to experience a late-stage diagnosis and treatment delays than patients with private insurance); Sean Martin, et al., *Delays in Cancer Diagnosis in Underinsured Young Adults and Older Adolescents*, 12 ONCOLOGIST 816 (2007) (finding that the mean diagnosis lagtime in patients with public or no health insurance was 13.1 weeks longer than in patients with private health insurance).

sporadically for months. On the other hand, John is a 50-year-old white man employed at a large consulting firm. He has employer-sponsored health insurance and generous sick leave. John visits his long-time primary care provider a few weeks after having COVID-19 to discuss the similar symptoms he has been experiencing, and John's primary care provider refers him to a cardiologist and neurologist for continued monitoring.[73]

In addition to systemic barriers to care and diagnosis, people of color and people with low incomes may be less likely to receive formal diagnoses for their impairments due to clinician bias.[74] Bias in medical settings is hard to quantify; however:

> Non-clinical influences on decision making by clinicians—particularly the impact of race/ethnicity, social class, and culture—have been identified and discussed for many years in the medical and social science literature. More recent contributions have explicitly linked the perceptions of providers at every level—from medical students to residents to experienced practitioners—to processes and decisions as varied as judgments of patients' quality of life, physician-patient communication during the medical encounter, recommendations for cardiac catheterization, and the management of pain.[75]

For example, a 2016 study examined whether beliefs about biological differences are associated with racial bias in pain perception and treatment recommendations.[76] The study found that many white medical students and

[73] Ava and John are fictional long-haulers, based on compilations of real-life experiences. The paper will use Ava and John to illustrate the real-life impacts of subjectivity and inequity throughout the current process of obtaining SSDI benefits—from diagnosis to SSA determination.
[74] *See, e.g.*, Michael Sun, et al., *Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record*, 41 HEALTH AFFS. 203, 203 (2022); H. Jack Geiger, *Racial and Ethnic Disparities in Diagnosis and Treatment: A Review of the Evidence and a Consideration of Causes*, in UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE 440, 440 (Brian D. Smedley et al., eds., 2003); Kelly M. Hoffman, et al., *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs about Biological Differences Between Blacks and Whites*, 113 PNAS 4296, 4299–30 (2016).
[75] Geiger, *supra* note 74.
[76] Hoffman, *supra* note74, at 4299–30.

residents held false and fantastical beliefs about biological differences between Black and white individuals and that these false beliefs were related to racial bias in pain perception and treatment.[77] More specifically, white medical students or resident participants who endorsed more false beliefs about biological differences between Black and white individuals tended to rate the pain of a Black patient as lower than that of a white patient.[78] White participants were also less accurate in their treatment recommendations for Black patients 15 percent of the time.[79]

The role of subjective views and clinician bias is likely to significantly impact diagnoses that rely on interpreting patients' reports of pain and other symptoms and subsequently ruling out other illnesses. Demonstrating the influence of non-objective views on evasive conditions, Dr. Winfriend Hauser and Dr. Mary-Ann Fitzcharles reviewed myths pertaining to fibromyalgia and argued that some debates about the legitimacy of fibromyalgia diagnoses are fought "because of the belief systems of medical and psychological specialties, the interests of patient self-help organizations, financial advantages for the pharmaceutical industry, and personal academic advancement, rather than the objective of valid scientific and clinical progress."[80] With greater individual discretion and subjectivity, there is also a greater risk of clinician bias and medical racism in diagnosing and treating evasive conditions. In a 2020 pediatric myalgic encephalomyelitis (ME)/chronic fatigue syndrome prevalence study, researchers screened a random sample of more than 10,000 youth and found that Black and Latinx youth were twice as likely to be living with undiagnosed ME/CFS than their white peers.[81] Advocates are already

[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] Hauser & Fitzcharles, *supra* note **Error! Bookmark not defined.**, at 54.
[81] DePaul University, *Study Finds Many Youth Living with Undiagnosed Chronic Fatigue Syndrome*, NEWS WISE (Jan. 22, 2020), https://www.newswise.com/articles/study-finds-many-youth-living-with-undiagnosed-chronic-fatigue-syndrome (citing Leonard A. Jason et al., *The Prevalence of Pediatric Myalgic Encephalomyelitis/Chronic Fatigue Syndrome in a Community-Based Sample*, 49 CHILD & YOUTH CARE F. 563 (2020)).

seeing similarities with long COVID: During a congressional hearing in April 2021, three Black women shared their experiences of being ignored and disrespected when seeking medical care for long COVID.[82]

Returning to our fictional long-haulers, John has regularly visited his primary care provider, cardiologist, and neurologist who have run numerous tests, ruled out other possible conditions, and concluded that he has long COVID. Meanwhile, Ava goes to the emergency room once her symptoms have gotten unbearable and caused her to lose her job due to her slower pace and absences. The junior resident that examined Ava was skeptical of Ava's reported pain, was hesitant to run diagnostic tests, and suggested that her diet and limited exercise were causing her symptoms.[83] Ava's symptoms persist and weeks later, she visits a health clinic where another junior resident believes Ava's complaints, runs tests to rule out other possible conditions, and concludes that she has long COVID.

C. Discretion and Subjectivity in Commissioner's Listing of Impairments

The Commissioner's Listing of Impairments ("the Listings") is intended to serve as a screening tool at the initial decision stage to avoid time- and resource-intensive inquiry, expedite the disability determination process, and promote consistency in outcomes.[84] SSA publishes criteria for Listings as regulations, using

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[82] *The Long Haul: Forging a Path through the Lingering Effects of COVID-19*, Before the Subcomm. on Health of the H. Comm. on Energy & Commerce, 117th Cong. (Apr. 28, 2021)*; see also* Cirruzzo, *supra* note **Error! Bookmark not defined.**.

[83] For more information regarding the interactions between race and weight in patient experiences, *see, e.g*, Carly Stern, *Why BMI is a Flawed Health Standard, Especially for People of Color*, WASH. POST (May 5, 2021), https://www.washingtonpost.com/lifestyle/wellness/healthy-bmi-obesity-race-/2021/05/04/655390f0-ad0d-11eb-acd3-24b44a57093a_story.html; Michelle Wong, Kimberly A. Gudzune, & Sara N. Bleich, *Provider Communication Quality: Influence of Patients' Weight and Race*, 98 PATIENT EDUC. & COUNSELING 492, 492 (2015).

[84] INST. MEDICINE, IMPROVING THE SOCIAL SECURITY DISABILITY DECISION PROCESS 1, 79–82 (John D. Stobo et al. eds., 2007).

the Administrative Procedure Act ("APA") regulatory process.[85] As discussed in Part II, Step 3 of an ALJ's disability determination process is to determine whether the claimant's impairment meets one of the listings in the Commissioner's Listing of Impairments and whether the claimant is therefore presumed disabled without further inquiry into their ability to perform their past work or to adjust to different work.[86] The ALJ has discretion in interpreting medical evidence; however, even before the disability determination process, subjective moral, political, and economic considerations go into the decisions regarding which impairments are on the Listing and the specific criteria for each Listing. When deciding to revise the Listings, SSA considers advances in medicine, legislation, and court decisions and relies on information from "in-house medical experts, individual subject-matter experts from outside the agency, literature reviews, and contracted research," as well as input from agency personnel that use the Listings, the public, other government agencies, professional associations, and advocacy organizations.[87]

The Listings have the air of objectivity because the SSA uses the expertise of medical professionals to inform the creation of individual listings and their criteria; however, these decisions are not based on evolving medical understandings of impairments alone:

> [W]hat is a correct decision on presumptive disability? Certainly, it is not whether the claimant is, in fact, eligible for SSI disability benefits, let alone whether the claimant is 'disabled.' Presumptive disability is tied to a broader set of social policy considerations than simple eligibility for disability benefits, as reflected by the fact that presumptive-disability findings and the early payments that go with them are offered only in the public assistance program. As a result,

[85] *Id.* at 86.
[86] *See supra* Part III.
[87] INST. MEDICINE, *supra* note 84, at 87.

> medical expertise can play only a limited role in setting the criteria for determining who is presumptively disabled.[88]

Although the Listings were originally intended to be based on medical diagnostic criteria, they are now based more on functional criteria, meaning they focus on specific limitations caused by a medical condition. As the National Council of Disability Determinations Directors explained, this shift to functional criteria has made the Listings even more "complex and subjective" and, as a result, caused inconsistencies in outcomes and longer processing times.[89]

The discretion and subjectivity involved in deciding to revise the Listings are especially influential when it comes to emerging and evasive conditions. The Institute of Medicine has expressed concern regarding SSA's ability to revise the Listings to keep pace with advances in medicine.[90] Despite these weaknesses, the Listings can significantly impact a claimant's experience in the disability process. Since CFS and fibromyalgia are currently not listed impairments, an ALJ cannot find that a claimant with CFS or fibromyalgia alone has an impairment that meets a listing and is presumed disabled at Step 3. Instead, the ALJ has to determine the claimant's residual functional capacity ("RFC") based on all medical and non-medical evidence and use this RFC in Steps 4 and 5 of the evaluation process. Because emerging and evasive conditions like CFS, fibromyalgia, and long COVID are not in the Listings, the ALJ's discretion plays an even more significant role in the determination process.

D. Discretion and Subjectivity in SSA Determinations

[88] Bloch, *supra* note 53, at 231–32.
[89] INST. MEDICINE, *supra* note 84, at 82–83.
[90] *Id.* at 104.

When determining if an individual is disabled for the purposes of SSDI eligibility, a DDS examiner or ALJ must determine whether the claimant has a medically determinable impairment and whether the claimant's impairment precludes them from engaging in substantial gainful activity. This determination is informed by medical records, medical and vocational expertise, and the Listing of Impairments and SSA policies; however, it is also subject to the discretion and subjective views of the decisionmaker, who often does not have medical training or expertise.

1. Evaluations of Medical Opinions

Throughout the sequential evaluation process, ALJs must evaluate opinions from medical professionals and determine the weight of each opinion.[91] SSA regulations provide guidance regarding the criteria ALJs must consider when evaluating physician opinions: SSA regulations provide guidance regarding the criteria ALJs must consider when evaluating physician opinions:

> (1) whether the doctor is a treating, examining, or non-examining source [whether they have an ongoing treatment relationship with the claimant and have personally examined the claimant]; (2) the medical signs and laboratory findings that support the opinion; (3) the consistency of the opinion with all of the other evidence of record; (4) the doctor's specialization; and (5) any other factors that tend to support or contradict the opinion.[92]

Opinions from treating physicians are generally given more weight than those of medical personnel that only briefly examined the claimant, and opinions from

[91] Russel & Voisin, *supra* note 24, at 862.
[92] Ken Matheny, *The Social Security Disability Appeals Backlog Crisis and the Necessity of Radical Reform*, 45 CAP. U. L. REV. 361, 380 (2017) (citing 20 C.F.R. § 404.1527).

medical personnel that have examined the claimant are given more weight than those of medical personnel that have not examined the claimant.[93] Despite these guidelines, ALJs must still make highly-subjective determinations about whether physicians have provided sufficient medical evidence to support their opinions.[94] For instance, in *Mosteller v. Bowen*, a case involving a claimant whose numerous doctors made numerous diagnoses, including multiple sclerosis and Epstein Barr virus syndrome, the district court upheld a finding of not disabled, effectively endorsing the ALJ's decision to pick and choose which diagnoses and opinions to believe and which to disregard.[95] Other courts have been more critical of ALJs' evaluations of medical evidence. For instance, in *Reddick v. Chater*, the ALJ rejected the opinions of a treating physician and a consulting physician because they were based on the claimant's subjective complaints.[96] The circuit court concluded that this rejection was inappropriate given that "the symptom of persistent fatigue is necessarily self-reported in a diagnosis of chronic fatigue syndrome."[97] In *Vega v. Commissioner of Social Security*, the circuit court found that the ALJ failed to acknowledge the claimant's diagnosis of CFS or discuss why he disregarded it and that the ALJ failed to give any weight to the assessment and findings of the claimant's two treating physicians.[98] The opportunity for judicial review of final SSA decisions to deny benefits may mitigate some subjectivity in ALJs' evaluations of medical evidence; however, there are numerous barriers to a claimant's ability to appeal, and judicial review provides little protection against subjectivity in ALJs' difficult judgment calls regarding how much weight to give medical opinions and how to address inconsistencies in the medical evidence.

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[93] Russel & Voisin, *supra* note 24 at 862; Bloch, *supra* note 53, at 223–24.
[94] Matheny, *supra* note 92, at 380.
[95] Fishman, *supra* note 40, at 800; Mosteller v. Bowen, 702 F.Supp. 1534 (D.Kan.1988).
[96] Yesipovich v. Colvin, 166 F. Supp. 3d 1000, 1003 (N.D. Cal. 2015) (citing Reddick v. Chater, 157 F.3d 715, 725–26 (9th Cir.1998)).
[97] *Id.*
[98] Vega v. Comm'r of Soc. Sec., 265 F.3d 1214, 1219 (11th Cir. 2001).

During the ALJ hearing for our fictional long-hauler John, the ALJ receives medical records and medical opinions from John's primary care provider, cardiologist, and neurologist, all attending physicians with at least ten years of experience. The ALJ gives significant weight to their opinions given that they were all treating physicians, the cardiologist and neurologist have relevant specialties, the physicians have had long ongoing treatment relationships with John, and they base their opinions on multiple diagnostic tests and examinations across multiple visits. During Ava's hearing, the ALJ receives medical records from her two visits to the ER and the clinic as well as medical opinions from the clinic's junior resident and another physician who reviewed her records. The ALJ decides to give little weight to these medical opinions given that neither is a treating source and only one examined the claimant, neither have a relevant specialty, their opinions are based on only an examination and tests from only one clinic visit, and the medical records from Ava's ER visit raise concerns about consistency in medical opinions.

2. Determinations Regarding Credibility of Claimant's Testimony

In addition to ALJs making subjective evaluations of medical opinions and other medical evidence, ALJs must also make subjective credibility determinations. When evaluating the effects of subjective symptoms like pain, ALJs evaluate claimants' "statements about the intensity, persistence, and limiting effects" of their symptoms in relation to "objective medical evidence and other evidence."[99]

> Recognizing that an individual's symptoms can sometimes suggest an impairment is more severe than can be shown by the objective-medical evidence alone, the ALJ must consider certain factors in addition to the objective-medical evidence when assessing the credibility of an individual's subjective statements. Those factors include, *inter alia* the: (1) individual's

[99] 20 C.F.R. § 404.1529(c)(4); *see also* Matheny, *supra* note 91 at 378–79; Russell & Voisin, *supra* note 24, at 856.

> daily activities; (2) location, duration, frequency, and intensity of the individual's pain or other symptoms; (3) factors that precipitate and aggravate the symptoms; (4) type, dosage, effectiveness, and side effects of any medicine the individual takes, or has taken, to alleviate pain or other symptoms; and (5) measures, other than treatment, the individual uses to relieve pain or other symptoms (such as sleeping on the floor to alleviate back pain).[100]

ALJs can reject claimants' subjective testimony regarding their symptoms if the ALJs determine the testimony is not credible.[101] In their decision, ALJs must state whether the claimant's testimony is consistent with the other available evidence and the rationale for the decision.[102] There are also varying standards for evaluating the credibility of subjective testimony. This can lead to drastically different results for similar claims.[103] Requiring individuals without medical expertise to perform these complex analyses leaves room for the influence of individual biases and subjective views and promotes inconsistent and inequitable outcomes.[104]

The credibility determination is even more significant in claims involving conditions that cannot be substantiated by objective diagnostic tests, like CFS, fibromyalgia, and long COVID. For example, in *Reed v. Secretary of Health and Human Services*, the ALJ found that while the claimant's testimony regarding his symptoms and experiences suffering from CFS was generally credible, the medical evidence did not support the alleged severity of his symptoms. On review, the court stated that the importance of credibility determinations is enhanced in cases of CFS as methods of diagnosing CFS are limited and dependent on the claimant's subjective complaints. The court found there was insufficient evidence to reject the

[100] Russel & Voisin, *supra* note 24, at 856 (citing 20 C.F.R. § 404.1529).
[101] *See* Coon, *supra* note **Error! Bookmark not defined.**, at 177–78.
[102] *See* Matheny, *supra* note **Error! Bookmark not defined.**, at 379 (citing SSR 16-3p, 2016 WL 1119029 (Mar. 16, 2016)).
[103] *See* Coon, *supra* note **Error! Bookmark not defined.**, at 191.
[104] *See* Matheny, *supra* note **Error! Bookmark not defined.**, at 379.

claimant's testimony about her fatigue and other symptoms, given that there were no inconsistencies in the medical records and no evidentiary reasons to disbelieve the claimant's reports of fatigue.[105]

Similarly, in *Forehand v. Barnhart*, the ALJ rejected the claimant's testimony regarding her pain and limitations due to fibromyalgia as not credible.[106] As justification, the ALJ reasoned that she did not need assistive devices to walk; she chose a conservative course of treatment; and her activities, such as caring for her personal hygiene, doing laundry and other housework, and moving furniture once, contradicted her alleged limitations.[107] On review, the court held that the ALJ improperly discounted the treating physician's opinion and erred in rejecting the claimant's testimony, given that tests indicated the claimant had significant memory and concentration difficulties and medical reports supported her complaints of difficulty walking and standing.[108] These are only two examples of ALJs determining that claimants' testimony was not credible despite supporting medical evidence, and they were both rectified on review. However, *Reed* and *Forehand* make clear the influence that bias and subjective views can play in ALJ credibility determinations, especially when claims involve conditions that cannot be substantiated by objective diagnostic tests.

Returning to our fictional long-haulers: At his disability attorney's suggestion, John kept a log for months tracking his symptoms, their severity, and the ways they limited his ability to do daily activities. During John's hearing, the ALJ accepts John's testimony about his experiences of intense pain and fatigue given that his statements are supported by his medical records from numerous doctor visits and

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[105] *See* Fishman, *supra* note **Error! Bookmark not defined.**, at 799 (citing Reed v. Sec'y of Health & Hum. Services, 804 F.Supp. 914, 924 (E.D. Mich. 1992)).
[106] *See* Forehand v. Barnhart, 364 F.3d 984, 985 (8th Cir. 2004).
[107] *See id.*
[108] *See* Monique C.M. Leahy, 99 AM. JURIS. PROOF OF FACTS 3d, *Proof of Chronic Fatigue Syndrome and Fibromyalgia* (2023) (citing Forehand v. Barnhart, 364 F.3d 984, 988 (8th Cir. 2004)).

the symptom log he presented. During Ava's hearing, the ALJ decides Ava's testimony is not credible given that there is a record that the ER resident was skeptical of her symptoms, there are limited medical records to support her statements, and there is anecdotal evidence that she has continued to do occasional housework and child care work raising concerns about her alleged limitations.

3. Residual Functional Capacity (RFC) Assessment and Application of Vocational Factors

Finally, ALJs must make subjective decisions when determining whether the claimant can still do their past relevant work or adjust to other work despite their impairment. At Step 5 of the sequential evaluation process, ALJs must consider a claimant's age, education, and work experience, shifting the overarching considerations when deciding if someone is disabled even further from medical understandings of disability and toward employability.[109] This shift from a medical focus to an employability focus allows for even greater subjectivity and inconsistencies.

> For example, a claimant who is 49 years old and limited to sedentary work will usually be found to be not disabled, while a claimant with identical impairments and limitations, but who is age 50 will usually be found to be disabled. Or, to take another example, a person who is 54 years old, has no transferable skills and is limited to light exertion will ordinarily be found to be not disabled while a person with identical impairments and limitations but who is 55 years old will ordinarily be found to be disabled. Clearly, an age difference of 12 months or less is highly unlikely to render one person disabled

[109] *See* Matheny, *supra* note **Error! Bookmark not defined.**, at 375–76.

> and another person with the same medical impairments not disabled. But, these examples illustrate the indefensible inconsistency that results when ALJs are required to go beyond the medical determination of disability by considering claimants' employability.[110]

At Step 5, ALJs rely on the Medical-Vocational Guidelines—grid rules the SSA adopted in 1980 to simplify the Step 5 analysis and promote consistency—but the grid rules only address a claimant's vocational factors and exertional limitations. They do not consider non-exertional limitations like limitations in mental, postural, manipulative, visual, or auditory abilities (e.g. concentrating, bending, squatting, hearing).[111] Most claimants have a non-exertional limitation, and when they do, ALJs often must rely on vocational evidence, meaning the grid rules do not promote consistency or simplify the Step 5 analysis in most cases.[112] ALJs also rely on testimony of vocational experts (VEs) to determine whether a claimant can perform jobs that exist in significant numbers in the national economy. However, reliance on VE testimony similarly does not promote consistency or mitigate subjectivity. VE testimony is typically based on the obsolete Dictionary of Occupational Titles (DOT), a 1991 Department of Labor publication that is based primarily on data from the 1970s and is no longer used by the Department of Labor, raising further questions of reliability and fairness.[113]

Fictional long-hauler John's disability attorney has significant experience with SSA determinations, so he suggests John hires his own vocational expert. The VE evaluates John before the hearing and provides testimony countering the government's VE opinion that John can still do his past consulting work. The ALJ

[110] *Id.* at 377-78.
[111] *See id.* at 371.
[112] *See id.* at 371.
[113] *See id.* at 369-71.

is persuaded by the testimony of John's VE. The ALJ finds that John is disabled, and John begins to receive nearly $3,000 in monthly benefits based on his high average earnings prior to becoming disabled. Meanwhile, Fictional long-hauler Ava does not have legal representation, is unfamiliar with the SSA determination process, and would not have been able to afford to hire a VE even if she knew it would help her case. After the ALJ gives little weight to the medical opinions and Ava's testimony about her symptoms, he determines that Ava can continue her past work as a bus driver or adjust to other work based on her age, skill level, and work experience; the grid rules; and the testimony of the government's VE. The ALJ finds that Ava is not disabled. She must now decide if she wants to appeal this decision without representation, seek further costly medical treatment to better document the severity of her symptoms, or seek potentially costly legal representation to assist her with the appeals process—all while managing her severe health condition and being unable to work.

VI. Proposed Solutions: Mitigating Subjectivity, Addressing Inequities, and Ensuring Supports for Those with Disabilities

As outlined in Part IV, individual discretion and subjectivity play a significant role throughout the seemingly objective process of disability determinations—decisions about statutory language in the Social Security Act; diagnoses and documentation of conditions; decisions about which conditions are added to the SSA Commissioner's Listing of Impairments and are presumed disabilities; and individual SSA disability determinations. This discretion and subjectivity leaves room for inequities and inconsistencies, especially when claims involve evasive conditions like long COVID, CFS, and fibromyalgia. The following are recommendations to address these concerns and better support people who are

experience health and economic harms due to evasive conditions as well as people with disabilities more generally.

A. Investments to Promote Health Equity

To start, we must make investments to address underlying racial and economic disparities in health insurance coverage and access to high-quality health care as these disparities likely contribute to inequities in access to SSDI benefits. This includes closing the Medicaid coverage gap in the 10 states that have yet to adopt Medicaid expansion to ensure health insurance coverage for those with the lowest incomes.[114] Other critical policies include reducing administrative obstacles to health insurance enrollment;[115] investing in pathways for and institutional supports of medical providers of color to increase recruitment and retention;[116] and increasing education and mitigation of implicit provider biases.[117]

B. Research on Long COVID

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[114] *See e.g.*, Madeline Guth & Meghana Ammula, *Building on the Evidence Base: Studies on the Effects of Medicaid Expansion, February 2020 to March 2021*, KAISER FAM. FOUND. (May 6, 2021), https://www.kff.org/medicaid/report/building-on-the-evidence-base-studies-on-the-effects-of-medicaid-expansion-february-2020-to-march-2021/; Status of State Medicaid Expansion Decisions: Interactive Map, KAISER FAM. FOUND. (May 8, 2023), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/.

[115] Christen Link Younget al., *How to Boost Health Insurance Enrollment: Three Practical Steps that Merit Bipartisan Support*, HEALTH AFFS. (2020), https://healthpolicy.usc.edu/article/how-to-boost-health-insurance-enrollment-three-practical-steps-that-merit-bipartisan-support/.

[116] *See e.g.*, Boghuma K. Titanji & Talia H. Swartz, *A Diverse Physician-Scientist Pipeline to Fight Structural Racism*, 73 CLIN. INFECTIOUS DISEASES VIEWPOINTS (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8246787/.

[117] *See e.g.*, Khiara M. Briggs, *Implicit Bias and Racial Disparities in Health Care*, 43 HUM. RTS. 19 (2018).

Disability determinations for Long COVID have been especially challenging given the uncertainty regarding Long COVID, its symptoms and effects, and its prevalence. Significant investments must be made in research on Long COVID to develop a better understanding of the impairment and its impact. This must include more research on racial and socioeconomic disparities in COVID infection and Long COVID prevalence, diagnosis, and treatment. As of November 2023, information about race and ethnicity was only available for 67 percent of the COVID cases tracked by the CDC.[118] Even worse, a 2021 systematic review of studies on Long COVID found that only 15 percent of the studies reported data on ethnicity (6 of 39 studies reviewed).[119]

C. Social Security Ruling or Guidance on Long COVID

In June 2023, SSA published a guide for health professionals, describing the kinds of medical evidence needed for SSA to evaluate disability claims related to Long COVID.[120] This guidance is a critical step towards better ensuring people with Long COVID can access needed disability insurance.[121] SSA should also publish a Social Security Ruling (SSR) or additional guidance aimed at state Disability Determination Services (DDS) and ALJs to further support people with Long COVID by preventing inequities and inconsistencies in the disability determination process. The SSR or guidance should provide a definition of Long COVID, acknowledge the absence of objective medical testing for Long COVID,

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[118] *COVID Data Tracker*, CTRS. DISEASE CONTROL & PREV., https://covid.cdc.gov/covid-data-tracker/#demographics (last visited Nov. 17, 2023).
[119] Michelen et al., *supra* note 4.
[120] *Long COVID: A Guide for Health Professional on Providing Medical Evidence for Social Security Disability Claims*, SOC. SEC. ADMIN. (June 2023), https://www.ssa.gov/disability/professionals/documents/EN-64-128.pdf.
[121] *Id.*

and provide specific recommendations for decisionmakers at each step of the evaluation process.

In 1990, the Department of Labor, Health and Human Services directed SSA to update its guidelines on CFS. In response, SSA compiled a report on its activities relating to CFS in which it recognized an operational definition of CFS. The report also acknowledged the challenges presented by the lack of clinical signs or laboratory findings to confirm CFS given that symptoms alone were not sufficient to establish a disability under the Social Security Act and stated they were working diligently to educate all disability adjudicators on the current tends of CFS. SSA also promulgated POMS 24515.075 to provide guidance on dealing with CFS cases.[122] The guidance clarifies the definition of CFS and acknowledges the absence of scientifically validated clinical signs and laboratory findings to evaluate CFS objectively.[123] However, the 1991 report and guidance proved insufficient: A 1993 article highlighted that many local DDS offices did not even have a copy of the 1991 POMS and were continuing to rely on the outdated 1988 version on Chronic Epstein-Barr virus.[124] SSA should issue guidance directing adjudicators on how to treat disability claims involving Long COVID, but must learn from the shortcomings of the CFS guidance. SSA should ensure the Long COVID guidance provides clear recommendations and is coupled with comprehensive training and technical assistance to prevent inconsistencies and inequities.

Social Security Rulings (SSRs) related to Long COVID may also provide further clarity on evaluating long COVID. SSRs are agency rulings published in the Federal Register and are binding on all components of SSA.[125] In 1999, SSA

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[122]SSA's Program Operations Manual System (POMS) is a set of employee operating instructions comprising administration interpretations. U.S. Social Security Administration § DI 24515.075; *See* Frederick W. Watson*, Disability Claims, Guidance Documents, and the Problem of Nonlegislative Rules,* U. CHICAGO L. REV. 2037, 2048 (2013).
[123] U.S. Social Security Administration § DI 24515.075; *see also* Fishman, *supra* note 40, at 795.
[124] Fishman, *supra* note 40, at 795.
[125] *See* INST. MEDICINE, *supra* note 84, at 86; Watson*, supra* note 122, at 2043.

published SSR 99-2p to clarify the SSA policies "for developing and evaluating title II and title XVI claims for disability on the basis of Chronic Fatigue Syndrome."[126] The SSR defines CFS; outlines the requirements for evaluating the existence of a medically determinable impairment; and provides guidance for each step of the sequential evaluation process, resolution of conflicting evidence, and assessment of credibility in disability claims involving CFS.[127] In 2014, SSA provided updated clarification of SSA policies for CFS-related claims through SSR 14-1P.[128] SSA similarly published SSR 12-2p in 2012 to provide guidance on fibromyalgia-related claims.[129] SSR 12-2p defines fibromyalgia; outlines the general and specific criteria to establish that a person has a medically determinable impairment of fibromyalgia; outlines necessary documentation; and provides guidance for each step of the sequential evaluation process.[130] SSA can similarly publish an SSR providing guidance on how best to evaluate disability claims involving Long COVID, and update this policy as needed, to mitigate subjectivity and promote consistency in outcomes.

D. Legal and Non-Legal Representation throughout Disability Process

While SSDI claimants are permitted to appoint an attorney or other third-party representative to help them, legal representation is not guaranteed throughout the application, hearing, or appeals process. Therefore, claimants are left to find and pay for representation on their own. The informational and financial barriers to

[126] SSR 99-2p, 1999 WL 271569 (Apr. 30, 1999), https://www.ssa.gov/OP_Home/rulings/di/01/SSR99-02-di-01.html.
[127] *Id.*
[128] SSR 14-1p, 2014 WL 1371245 (Apr. 3, 2014), https://www.ssa.gov/OP_Home/rulings/di/01/SSR2014-01-di-01.html.
[129] SSR 12-2p, No. 4 Current Soc. Sec. News 1 (2012), https://www.ssa.gov/OP_Home/rulings/di/01/SSR2012-02-di-01.html.
[130] *Id.*

legal representation leave many claimants without assistance through the complex and high-stakes SSDI process, leading to worse health outcomes.[131] A recent study on the impact of legal representation in the SSDI process found that legal representation increased the probability of an initial award by 23 percentage points and reduced the need for appeal.[132] The study found that legal representation in the initial stage leads to earlier disability awards to individuals who otherwise would have been awarded benefits only on appeal and reduces total case processing times by nearly one year.[133] Increasing SSDI claimants' access to legal representation throughout the process would promote equity in SSDI access, better ensure claimants are able to access benefits as early as possible, and help to mitigate the role of subjective judgments throughout the process. Strategies to increase legal representation can include increasing public awareness of the benefits of legal representation in the SSDI process and increasing funding for no-cost and low-cost legal assistance for people with disabilities.

There are some concerns that the current "pay-for-delay" attorney's fee system creates inappropriate incentives as a claimant's counsel can receive higher fees the longer a case is delayed.[134] Expanding access to legal representation in the SSDI process must be coupled with the elimination or mitigation of this inappropriate incentives to encourage timely resolutions and prevent claimants from being harmed by unnecessary delays and legal fees.

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[131] *See e.g.*, *Equity Action Plan Summary: Social Security Administration*, WHITE HOUSE 3 (2022), https://www.whitehouse.gov/wp-content/uploads/2022/04/SSA-EO13985-equity-summary.pdf; Hilary W. Hoynes, Nicole Maesta, & Alexander Strand, *Legal Representation in Disability Claims* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. NB19-29, 2021), https://www.nber.org/sites/default/files/2021-10/NB19-29%20Hoynes%2C%20Maestas%2C%20Strand%20FINAL_0.pdf.

[132] Hoynes, Maesta, & Strand, *supra* note 128, at 1.

[133] *Id.*

[134] Jeffrey S. Wolfe, *The Times They Are a Changin': A New Jurisprudence for Social Security*, 29 J. NAT'L ASS'N ADMIN. L. JUDICIARY 515, 561–62 (2009).

Increasing access to nonattorney representation can also address inequities and mitigate subjectivity in the SSDI process. Intermediary organizations that provide nonattorney representation services support SSDI claimants by preparing vocational and medical evidence, helping claimants prepare for the hearing, and appearing with the claimant at the hearing.[135] Research on the impact of nonattorney representation is limited but suggests positive effects on claimants' likelihood of being awarded benefits.[136]

E. Procedural Reform to Disability Process

Some scholars have proposed procedural reforms to the disability determination process to address the subjectivity and inconsistencies of the current process. Ken Matheny—a retired Administrative Appeals Judge with the SSA—has proposed amending the Social Security Act to establish a three-step disability process with clearer, easier-to-apply criteria: (1) determine if the claimant is engaging in substantial gainful employment; (2) determine if the claimant has a severe impairment; and (3) determine if the claimant has an impairment that meets or equals in severity the criteria of an impairment listed in the Listings of Impairments.[137] Matheny further proposed that these determinations should be made by a team of medical doctors and psychologists, rather than an ALJ without medical qualifications or expertise, and the process should ensure the right to a fair hearing before a non-attorney hearing officer rather than an ALJ.[138]

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[135] Dara Lee Luca & Yonatan Ben-Shalom, *The Role of Nonattorney Representation in the SSDI Determination Process: A Case Study of One Prominent Intermediary*, 32 J. DISABILITY POL'Y STUD. 119 (2021).
[136] *Id.* at 127–29.
[137] Matheny, *supra* note 92, at 383–84.
[138] *Id.*

This process would be less costly; reduce the backlog of disability claims as the hearings would be more focused and quicker; shift decision-making to those with medical expertise; and shift to more objective criteria to reduce subjectivity and inconsistencies in determinations.[139] However, this reform is not a panacea. First, the determinations made by teams of medical experts would still be subject to discretion, individual biases, and influence by individuals' moral judgments about disability and work. In addition, to be successful, this reform must be part of a larger, comprehensive economic reform that includes more robust unemployment insurance or guaranteed work or income. Without broader economic reform, individuals who are partially disabled or who suffer from an impairment but are found to be able to do some sort of work may no longer qualify for disability benefits under this three-step process and be left without needed economic supports.[140]

F. Creation of Article I Social Security Disability Court

Other scholars have argued that a complete restructure of the disability determination process would better address ongoing concerns.[141] As described in Part II, claimants may request review of an ALJ's determination by the Appeals Council and then judicial review by federal district courts.[142] Although Social Security disability cases make up only a small percentage of total Social Security claims filed in a year, they represent a significant percentage of federal courts'

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[139] *Id.* at 384–85.
[140] Matheny, *supra* note 92, at 385-86.
[141] *See* Nate Ghubril, *Social Security Disability Reform: Steps Toward Economic Efficiency and Improved Claimant Care*, 74 U. PITT. L. REV. 549 (2013); Paul R. Verkuil & Jeffrey S. Lubbers, *Alternative Approaches to Judicial Review of Social Security Disability Cases*, 55 ADMIN, L. REV. 731 (2003).
[142] *See supra* Part II.

workload.[143] For instance, in 2011, over 15,000 Social Security disability cases were filed in federal courts, accounting for over 4 percent of the federal district court docket.[144] The current review process floods district courts; uses significant federal court resources; puts significant discretion in the hands of Article III judges who may be uninterested or less equipped for the unique, technical natural of disability cases; and risks inconsistent outcomes.[145] To increase efficiency and consistency, a few legal scholars and policymakers have proposed creating a specialized Article I Social Security Disability Court.[146]

Verkuil and Lubbers' 2003 review of proposed alternatives argued that the appeals process for veterans benefits could be instructive in developing reforms to the Social Security disability appeals process and highlighted six proposals for the creation of an Article I Social Security Court.[147] They outline the benefits of an Article I Social Security Court: increased uniformity of outcomes, better utilization of ALJs, timelier processes, and reduced burdens on the federal court system.[148] They also outline potential concerns with the creation of an Article I court: less independence, a loss of geographical convenience, and a risk of creating an even larger bureaucracy unless the new Article I court structure replaced the Appeals Court.[149]

Ghubril's 2013 proposal similarly suggested an Article I Social Security Court that would be a stand-alone judicial entity, similar to the Tax Court, and would consist of two tiers.[150] At the first tier, judges would review the record of the ALJ hearing and ensure that the law was properly applied and procedures properly

[143] Ghubril, *supra* note 141, at 556.
[144] *Id.* at 556–557, 557 n.47.
[145] *Id.* at 560–61.
[146] *See* Ghubril, *supra* note 141, at 556–557, 565–66; Verkuil & Lubbers, *supra* note 141, at 763–71.
[147] Verkuil & Lubbers, *supra* note 141, at 762–771, 774–76.
[148] *Id.* at 762–771, 777.
[149] *Id.* at 777–78.
[150] Ghubril, *supra* note 141, at 565–68.

followed.[151] At the second tier, the court could grant or deny review and, if granted, the court would review to a more substantial degree than the current Appeals Council.[152] Under this proposal, claimants would have an opportunity to file an appeal of the Social Security Court's final decision with the federal circuit courts regarding legal issues.[153] Critiques have raised concerns that replacing Article III judicial review with a specialized Article I court will result in a loss of Article III judges' expertise and independence throughout the process.[154] Ghubril argues that his proposed structure—which includes an opportunity for Article III judicial review—addresses these concerns while reducing the burden on Article III courts and promoting more consistent and timely outcomes.[155]

The small-scale procedural reform discussed in Section E and the restructure discussed in Section F both raise concerns about potential unintended consequences. Yet, the current SSA determination process is riddled with delays, inconsistencies, and subjectivity that exacerbate racial and economic inequities and keep people from accessing needed benefits. Either procedural reform or restructure would be a positive step towards addressing these concerns and promoting timely, consistent, equitable outcomes. Policymakers and the SSA should work with experienced disability advocates and impacted communities to better understand shortcomings of the system, protect against unintended harms, and advance broader economic reform.

VII. CONCLUSION

[151] Id. at 568.
[152] *Id.*
[153] *Id.*
[154] *Id.* at 558–60.
[155] *Id.* at 568.

Through SSDI, more than nine million individuals with disabilities an average monthly cash benefit of $1,289 as well as health insurance benefits.[156] SSDI is critical to the financial stability and well-being of those that are unable to work due to their disabilities. Despite these high stakes, the SSDI disability process is unnecessarily complex and influenced by the subjective views and moral judgments of several actors: policymakers creating the statutory definition of disability; medical professionals diagnosing individuals' conditions; agency staff revising the Listing of Impairments; and ALJs making subjective determinations regarding the evaluation of medical opinions, the credibility of claimants' testimony, and the application of vocational factors. This paper explored the role of discretion and subjectivity at each of these steps, using evasive conditions like CFS, fibromyalgia, and Long COVID to highlight these influences. This paper then offered recommendations to mitigate subjectivity, address inequities, and ensure support for individuals with disabilities. These recommendations include government investments in closing racial and economic gaps in health care; further research on Long COVID; further SSA guidance on Long COVID; increased funding for legal and non-legal support of people with disabilities; and SSA collaboration with disability advocates and impacted communities to consider procedural reform or restructure of the disability determination process.

[156] Soc. Sec. Admin., *Annual Statistical Report on the Social Security Disability Insurance Program, 2021*, at 12, 22 (2022), https://www.ssa.gov/policy/docs/statcomps/di_asr/2021/di_asr21.pdf.

NO ORPHAN LEFT BEHIND: A NOVEL APPROACH TO THE ORPHAN DRUG ACT INCENTIVE SCHEME

David C. Edholm

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Since its enactment in 1983, the Orphan Drug Act ("ODA") has incentivized the development of more than 600 drugs used to treat rare diseases, or "orphan drugs." But today, most of the 7,000 identified rare diseases lack an FDA-approved therapy. The ODA uses a combination of mechanisms to stimulate orphan drug development, including a seven-year exclusivity period, user fee waivers, and tax credits. However, the Eleventh Circuit decision in Catalyst Pharmaceuticals, Inc. v. Becerra *dampened the incentive by narrowing the FDA's authority to grant drug manufacturers seven years of marketing exclusivity. Rather than allowing multiple companies to earn exclusivity for an orphan drug approved to treat the same rare disease or condition, the* Catalyst *decision altered the FDA's authority so that the first company to gain approval for an orphan drug will have exclusivity for the entire class of rare disease. In effect, this decision eliminates the exclusivity incentive for companies to develop an orphan drug that could be approved to treat a different indication of the same rare disease. In the response, Congress considered the Retaining Access or Restoring Exclusivity ("RARE") Act to restore the previous incentive scheme. But is this the most ethical solution to effectuate the spirit of the ODA? This paper examines the pre-*Catalyst *incentive structure of the ODA and proposes key revisions to the exclusivity provision, introducing "proportional exclusivity," and suggesting an additional user-fee credit incentive to continue to enhance industry production of orphan drugs to treat our most vulnerable populations.*

I. INTRODUCTION AND BACKGROUND

In 1983, Congress enacted the Orphan Drug Act ("ODA") to amend the Federal Food, Drug and Cosmetic Act ("FD&C Act").[1] The ODA incentivizes

[1] Orphan Drug Act of 1983, 21 U.S.C. §§ 301–360.

pharmaceutical companies to develop "orphan drugs": drugs intended to treat a rare disease or condition.[2] The incentives provided by the ODA have encouraged the development of more than 600 orphan drugs between 1983 and 2020.[3] While more than 7,000 rare diseases have been identified, the majority lack treatment approved by the U.S. Food and Drug Administration ("FDA").[4]

In the Orphan Drug Designation Program, tax credits, user fee waivers, and marketing exclusivity periods provide economic opportunity for drug manufacturing companies.[5] Tax credits and user fee waivers allow pharmaceutical companies to offset pricey research and development ("R&D") expenses while exclusivity ensures an opportunity to recoup expenditures and potentially profit in a small market without competition.[6] The ODA also established a seven-year marketing exclusivity period, stating that the FDA may not approve the same

[2] A rare disease is defined as a "disease or condition [that] affects less than 200,000 persons in the United States, or [] affects more than 200,000 [persons] in the U.S. but there is no reasonable expectation that the cost of developing . . . a drug for such disease will be recovered from sales . . . ." 21 U.S.C. § 360bb(a)(2).

[3] *Progress in Fighting Rare Diseases*, PHRMA, https://phrma.org/Scientific-Innovation/Progress-in-Fighting-Rare-Diseases (last accessed Oct. 31, 2023).

[4] *New Study Investigates the Number of Available Orphan Products, Generics and Biosimilars*, NAT'L ORG. FOR RARE DISORDERS (Mar. 25, 2021), https://rarediseases.org/new-study-investigates-the-number-of-available-orphan-products-generics-and-biosimilars.

[5] *See Designating an Orphan Product: Drugs and Biological Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products (last updated July 8, 2022) (listing the incentives that orphan drug designations are qualified for); *see also* Tran T. Le, *Incentivizing Orphan Product Development: United States Food and Drug Administration Orphan Incentive Programs*, 1031 ADVANCES IN EXPERIMENTAL MEDICINE & BIOLOGY 183 (2017) (providing an overview of orphan drug incentive programs, the incentives provided, and the successes of each program).

[6] Tax credits, however, were cut in half in 2017 and nearly eliminated altogether in 2022. *See infra* Part III. (discussing user free credit). Exclusivity is commonly viewed as the largest of the three incentives. *See* Le, *supra* note 5, at 186 ("[E]xclusivity ensures predictable and often significant revenue from sales due to the lack of competition from other sponsors."); U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. INSPECTOR GEN., THE ORPHAN DRUG ACT:—IMPLEMENTATION AND IMPACT 8 (2001), https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf.

orphan drug used to treat the "same disease or condition" until that period has expired, absent certain circumstances or clinical superiority.[7]

For nearly thirty years, the FDA has withheld approval of a new orphan drug on exclusivity grounds only if an existing drug was already approved to treat the same *indication or use* of a rare disease.[8] This interpretation encouraged pharmaceutical companies to develop orphan drugs for previously unapproved indications or uses because the FDA would grant the applicant seven-years of marketing exclusivity upon approval.[9] For example, a pharmaceutical company could seek approval for a new indication or use in a specific population, such as children or the elderly, if the existing drug was only approved for use in adults aged eighteen through sixty-five and the FDA would approve the new drug for use in these subpopulations under its interpretation of the ODA, as long as the applicant met the benchmarks for approval.[10] There could also be smaller subsets of the population with a particular genetic marker, living with one or more comorbidities, or taking certain medications concomitantly that the FDA could approve a therapy for under the same interpretation, although it would be harder to prove safety and

[7] 21 U.S.C. § 360cc(a)(2)–(c) (listing exceptions, including if the manufacturer cannot ensure sufficient quantities of the drug to meet demand, if the sponsor waives exclusivity, or if the drug is clinically superior – chemically or structurally distinct with a "significant therapeutic advantage"– from the existing drug).
[8] *See* 21 C.F.R. § 316.3(b)(12) (2022) ("A designated drug will receive orphan-drug exclusive approval only if the same drug has not already been approved for the same use or indication.").
[9] Although ODA marketing exclusivity continues to play a key role for incentivizing orphan drug development, the relative value compared to patent exclusivity has arguably lessened in recent years. *See* Ameet Sarpatwari et al., *Evaluating the Impact of the Orphan Drug Act's Seven-Year Market Exclusivity Period*, 37 HEALTH AFFS. 732 (2018) (studying the relationship between patent and marketing exclusivity in small-molecule drugs over 29 years); *see also* discussion *infra* Section I.C.ii. (describing the interface of patent infringement with market exclusivity).
[10] U.S. FOOD & DRUG ADMIN., INDICATIONS AND USAGE SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS – CONTENT AND FORMAT: GUIDANCE FOR INDUSTRY 3–5 (July 2018), https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-—-Content-and-Format-Guidance-for-Industry.pdf (outlining scope of indications and usage in labeling in context of populations studied, including age groups).

efficacy in these subgroups due to low sample size in clinical trials.[11] In September 2021, however, the United States Court of Appeals for the Eleventh Circuit struck down the FDA's longstanding interpretation in *Catalyst Pharmaceuticals., Inc. v. Becerra*.[12]

The three judge panel[13] in *Catalyst* sided with Florida-based Catalyst Pharmaceuticals by interpreting the plain language of the ODA to authorize the FDA to grant marketing exclusivity for an orphan drug approved for any indication or use for an *entire disease or condition*.[14] In essence, this holding eliminated the exclusivity incentive that was previously available to pharmaceutical companies that would have sought orphan drug approval for a novel indication or use for a particular rare disease, and thus creates additional challenges for pharmaceutical companies to receive funding, profit, or recover costs in a scarce marketplace for orphan drugs. If upheld, this decision has the potential to prevent some of the thirty

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[11] *Id.* at 3–4. Instances where a New Drug Application ("NDA") fails to meet FDA criteria for approval due to limited availability of trial participants can be handled in a variety of ways. For example, the FDA could withhold approval outright, or base approval contingent on post market surveillance data. In any event, the FDA's ODA interpretation has no impact on the ability to draw bright lines where evidence presented in an applicant's NDA fails to satisfy high quality approval standards while incentivizing market availability. *See generally New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/new-drug-application-nda (presenting an overview of and access to regulations and guidance documents detailing NDA requirements).

[12] Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021), cert. dismissed sub nom. Jacobus Pharm. Co. v. Catalyst Pharms., Inc., 142 S. Ct. 2904, 213 L. Ed. 2d 1139 (2022); *see also* Sara W. Koblitz, *Catalyst Pharms., Inc. v. Becerra*, FOOD & DRUG L. INST., https://www.fdli.org/2022/06/catalyst-pharmaceuticals-inc-v-becerra/ (last accessed Dec. 15, 2022) (explaining why *Catalyst* is a top case to watch in 2022).

[13] The case was decided by the Hon. Barbara Lagoa, Hon. R. Lanier Anderson III, and Hon. Stanley Marcus. Lagoa previously served on the Florida Supreme Court after being appointed by Gov. Ron DeSantis, and was nominated to the Eleventh Circuit by former President Donald Trump; Anderson was originally appointed to the Fifth Circuit by President Carter; and Marcus, originally appointed to the Southern District of New York by President Reagan, was appointed to the Eleventh Circuit by President Clinton. *See Biographical Directory of Article III Federal Judges*, 1789–Present, FED. JUD. CTR., https://www.fjc.gov/history/judges (containing repository of biographical information on Lagoa, Anderson, and Marcus); *see also* Lawrence B. Solum, *The Positive Foundations of Formalism: False Necessity and American Legal Realism*, 127 HARV. L. REV. 2464 (2014) (addressing how judicial philosophies frame decision making).

[14] *Catalyst*, 14 F.4th 1299, 1307 (11th Circ. 2021).

million Americans living with rare diseases from having life-saving or life-altering medications available.[15]

In response, the FDA complied with the Eleventh Circuit's Order to revoke approval of Jacobus Pharmaceutical Company's drug used to treat Lambert-Eaton Myasthenic Syndrome ("LEMS"), Ruzurgi (amifampridine).[16] However, the FDA declared non-acquiescence to the Eleventh Circuit's plain language interpretation of the ODA in a January 2023 *Federal Register* notice, stating it would apply its longstanding interpretation to future orphan drug approvals.[17] The FDA explained that its interpretation is more attuned to the purposes of the ODA, balancing incentives with patient access and encouraging further orphan drug innovation and availability.[18] Complying with the Eleventh Circuit's ruling would prevent the FDA from approving new orphan drugs that treat different indications of a rare disease, which could lead to pharmaceutical companies scrapping existing projects or failing to initiate project plans because these projects would be less likely to recover

[15] *About GARD*, NAT'L INSTS. OF HEALTH, https://rarediseases.info.nih.gov/about (last accessed Dec. 15, 2022).
[16] Notice Clarifying Orphan-Drug Exclusivity Following Catalyst Pharms., Inc. v. Becerra; Notification, 88 Fed. Reg. 4086 (Jan. 24, 2023) (to be codified at 21 C.F.R. pt. 316), https://www.govinfo.gov/content/pkg/FR-2023-01-24/pdf/2023-01179.pdf; *see also* discussion *infra* Part II. (applying "proportional exclusivity" to the facts of *Catalyst*).
[17] Notice Clarifying Orphan-Drug Exclusivity Following Catalyst Pharms., Inc. v. Becerra; Notification, 88 Fed. Reg. 4086 (Jan. 24, 2023) (to be codified at 21 C.F.R. pt. 316), https://www.govinfo.gov/content/pkg/FR-2023-01-24/pdf/2023-01179.pdf. ("This notification announces that, at this time, in matters beyond the scope of [the Eleventh Circuit] order, FDA intends to continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.").
[18] *Id.* at 4087 *("*"FDA believes that its statutory interpretation embodied in its regulations best advances the Orphan Drug Act's purposes, appropriately balancing the need to incentivize the development of drugs for rare diseases and conditions with the need to provide patient access to orphan drugs.").

pricey R&D costs and earn profit in a small patient marketplace.[19] To avoid stymying innovation, FDA has been lobbying Congress for a legislative solution.[20]

At first look, the issue invites a quick legislative fix, such as that provided by the Retaining Access and Restoring Exclusivity ("RARE") Act introduced by Senators Baldwin (D-WI) and Cassidy (R-LA) in May of 2022.[21] The RARE Act intends to restore the status quo by amending the ODA to strike "same disease or condition," under which the Eleventh Circuit upheld the plain meaning, and replace it with "same approved use or indication within such rare disease or condition."[22] Although this would codify the FDA's ODA interpretation and nullify the potential

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[19] *See* Mikel Berdud et al., *Establishing a Reasonable Price for an Orphan Drug*, 18 COST EFFECTIVE RES. ALLOCATION 31 (2020), https://doi.org/10.1186/s12962-020-00223-x (estimating average R&D costs for developing a new orphan drug to exceed $500 million).

[20] Jacobus' petition for certiorari was withdrawn pursuant to a settlement agreement. Brief for Petitioner, *Jacobus Pharm. Co. v. Catalyst Pharms.*, 142 S.Ct. 2904 (2022). The issue of non-acquiescence writ large has not been addressed by the Supreme Court, although circuit courts tend to recognize an agency right to do so. *See generally* KRISTIN E. HICKMAN & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 2.9 (6th Ed., 2023-2 Cum. Supp. 2018) (summarizing circuit court cases that emphasize the limited reach of circuit court decisions where the issue at hand remains unresolved at the highest level). The FDA's non-acquiescence to *Depomed, Inc. v. U.S. Department of Health & Human Services*, 66 F. Supp. 3d 217 (D.D.C. 2014), triggered Congressional response. *See* Policy Clarification on Orphan-Drug Exclusivity, 79 Fed. Reg. 76,888 (Dec. 23, 2014) (establishing that new orphan drug sponsors must demonstrate clinical superiority to existing orphan drugs for marketing exclusivity against the D.C. Circuit's interpretation). The issue was relitigated four years later. Eagle Pharmaceuticals, Inc. v. Azar, No. 16-790, 2018 WL 3838265 (D.D.C. June 8, 2018). In response to *Eagle*, Congress codified the FDA's interpretation. FDA Reauthorization Act of 2017, Pub. L. No. 115-52, § 607, 131 Stat. 1051, § 607 (amending the Orphan Drug Act, Section 360(cc)).

[21] Retaining Access and Restoring Exclusivity Act, S. 4185, 117th Cong. (2022), https://www.govinfo.gov/bulkdata/BILLS/117/2/s/BILLS-117s4185is.xml; *see also* Kurt R. Karst, *FDA, in a RARE Act, Takes to Lobbying for a Change to the Orphan Drug Act*, FDA L. Blog (May 17, 2022), https://www.thefdalawblog.com/2022/05/fda-in-a-rare-act-takes-to-lobbying-for-a-change-to-the-orphan-drug-act/ (describing the background and key impacts of the *Catalyst* holding that led to the RARE Act); Rohan Marayanan, *NORD Applauds Congressional Efforts to Restore Intent of the Orphan Drug Act*, NORD (May 11, 2022), https://rarediseases.org/nord-applauds-congressional-efforts-to-restore-intent-of-the-orphan-drug-act/ (same).

[22] Retaining Access and Restoring Exclusivity Act, S. 4185, 117th Cong. (2022), https://www.govinfo.gov/bulkdata/BILLS/117/2/s/BILLS-117s4185is.xml; SENS. TAMMY BALDWIN & BILL CASSIDY, RARE ACT SUMMARY, https://www.baldwin.senate.gov/imo/media/doc/RARE%20Act%20Summary.pdf (last accessed Dec. 15, 2022).

impact of the *Catalyst* decision, a broader review of the incentive structures underlying the ODA in wake of *Catalyst* is necessary to achieve an equitable solution. On close examination, the Eleventh Circuit's interpretation substantially increases the value of first approval by the FDA, which may provide even more incentive to develop orphan drugs for rare diseases where none are approved than the previous structure.[23] The challenge then becomes how to create a more effective solution that provides well-balanced incentives for pharmaceutical companies to both develop orphan drugs where none currently exist and to seek approval for new uses and indications of existing drugs. Done properly, a solution would ensure that the FDA maximizes incentives to increase availability of orphan drugs. This paper proposes novel amendments to the FD&C Act, specifically the incentive structure under the Orphan Drug Act, and Section 736 of the FD&C Act, governing user fees.

II. PROPOSAL

The proposal in this paper aims to increase the holistic incentive for pharmaceutical companies to develop new orphan drugs and to seek FDA approval for new indications or uses for existing orphan drugs with three adjustments. First, it suggests that Congress expand the timeframe for market exclusivity from seven years to ten years.[24] Second, that the FDA should only grant a proportion of the ten-

[23] By the FDA's interpretation, other orphan drug companies could seek and obtain approval for a new use or indication of an existing orphan drug, a use or indication that the drug sponsor of the approved orphan drug is also aiming to obtain approval for. However, the Eleventh Circuit's interpretation would prevent other companies from seeking approval for a new use or indication because the exclusivity incentive would be exhausted, leaving no room for profit, decreasing competition, and therefore increasing the economic value of being the first company to obtain approval. *See* Koblitz, *supra* note 12 (predicting the impact of *Catalyst*).

[24] *See* Viviana Giannuzzi et al., *Orphan Medical Products in Europe and U.S. to Cover Needs of Patients with Rare Diseases: An Increased Common Effort Is to Be Foreseen*, 12 ORPHANET J.

year exclusivity period correlating with the percentage of the total population with a rare disease rather than granting the full-scope of exclusivity to the first pharmaceutical company that earns approval by default. Third, offering a universal and transferable FDA user fee credit in addition to the existing user fee waiver. In sum, these three proposed adjustments collectively strive to enhance the overall incentive structure for pharmaceutical companies in the orphan drug development landscape.[25]

III. EXTENDING THE EXCLUSIVITY TIMEFRAME TO TEN YEARS

Marketing exclusivity is considered one of the biggest incentives that encourages orphan drug development.[26] Once a drug is designated orphan status pursuant to Section 360bb(a)(1) of the FD&C Act, the sponsor is eligible for various financial incentives that encourage drug development.[27] But with respect to the other incentives, such as tax credits and user fee waivers, the exclusivity period is likely the most important because it allows the sponsor to operate without market competition and profit at a higher margin.[28] Extending the exclusivity period from

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RARE DISEASES 1, 8 (2017), https://ojrd.biomedcentral.com/articles/10.1186/s13023-017-0617-1 (arguing that the U.S. and EU should merge existing orphan drug approvals to expand availability and access).

[25] *See generally* U.S. DEP'T HEALTH & HUM. SERVS. OFF. INSPECTOR GEN., *supra* note 6 (reporting on the implementation and impact of the ODA and concluding that no legislative or regulatory changes were needed at that time); Hannah-Alise Rogers, *The Orphan Drug Act and* Catalyst Pharmaceuticals, Inc., v. Becerra, CONG. RSCH. SERV., https://crsreports.congress.gov/product/pdf/R/R47653/1 (providing background on the ODA and *Catalyst*; then suggesting considerations for Congress in wake of modern legal developments). The content of the CRS report sets the stage for the proposal here.

[26] *See* Le, *supra* note 5, at 186 ("[E]xclusivity ensures predictable and often significant revenue from sales due to the lack of competition from other sponsors.").

[27] 21 U.S.C. §360bb(a)(1).

[28] *See* Annemieke Aartsma-Rus et al., *Orphan Medicine Incentives: How to Address the Unmet Needs of Rare Disease Patients by Optimizing the European Orphan Medicinal Product Landscape Guiding Principles and Policy Proposals by the European Expert Group for Orphan Drug Incentives (OD Expert Group)*, 12 FRONTIERS IN PHARMACOLOGY 1, 11 (2021) (explaining

seven to ten years is essential to the ODA incentive scheme and to the collective reform outlined in this proposal, which aims to balance the potential impact of the *Catalyst* decision and a proposed decrease in tax credit incentives.

A. Orphan Drug Exclusivity Post Catalyst

The FDA offers a variety of exclusivity periods pursuant to innovation initiatives, but the seven-year term for orphan drug exclusivity is the highest incentive by a margin of two years compared to other programs.[29] This is likely because orphan drugs sales have a lower potential to recoup development and marketing costs compared to nonorphan drug sales due to lesser demand.[30]

The FD&C Act states that the FDA may not approve an orphan drug application "for the same drug for the same disease or condition" as a previously approved drug until the expiration of a seven-year exclusivity period.[31] However, the FDA has used its regulatory authority to approve orphan drugs treating the same disease or condition as long as the new drug is approved to treat a new use or indication of that rare disease.[32] This interpretation incentivizes drug companies to seek approval for new uses or indications of a particular rare disease where there is no approved therapy.[33] In upholding the plain language of the statute, *Catalyst* diminished this

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that the 10-year marketing exclusivity period in the EU "protects [Orphan Medical Product] developers from competition from similar medicines thus ensuring a sufficiently high level of revenues to recoup investments and remunerate the risk taken.").

[29] *FAQ on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#howlongexclusivity (last updated Feb. 5, 2020) (listing each of the FDA's exclusivity programs and respective terms).

[30] Hana Althobaiti et al., *Disentangling the Cost of Orphan Drugs Marketed in the United States*, NAT'L INSTS. HEALTH, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9957503/ (last accessed Nov. 2, 2023).

[31] 21 U.S.C. §360cc(a)(2).

[32] 21 C.F.R. § 316.20(a) (2023).

[33] *See* U.S. DEP'T HEALTH & HUM. SERVS. OFF. INSPECTOR GEN., *supra* note 6, at 8 (noting that market exclusivity is the most important incentive in the ODA).

incentive to apply for approvals for new indications or uses of existing orphan drugs. However, *Catalyst* does not eliminate the exclusivity incentive where an approved therapy does not exist because it ensures exclusivity for the treatment of an entire rare disease or condition even if an approval does not cover every use or indication for a particular rare disease.[34] The incentive value of ab initio marketing exclusivity remains after *Catalyst* and thus remains an essential part of the ODA incentive scheme. On balance with the mechanisms introduced in Part II ("proportional exclusivity"), extending the exclusivity period to ten years ensures that the exclusivity incentive is not de minimis.[35] The extension also provides a compensatory incentive boost with a recent decrease in tax credit incentives.

B. Tax Credit Incentive in Jeopardy

Another reason to extend the exclusivity time period is to balance the predicted diminution of the tax credit incentive, which has been under threat since the *Tax Cuts and Jobs Act of 2017* reduced the percentage of clinical trial costs recovered in the form of a tax credit from fifty percent to twenty-fice percent.[36] Under Section 45C of the Internal Revenue Code, orphan drug sponsors are now eligible to receive a tax credit for only twenty-five percent of the cost of eligible clinical trials.[37] Given that clinical trials expenditures can amount to tens-of-millions of dollars, especially for rare diseases where there are limited participants available and

[34] Koblitz, *supra* note 12.
[35] *See* discussion *infra* Part II (illustrating the value of a 10 year exclusivity period in the context of the facts from *Catalyst* with proportional exclusivity).
[36] Tax Cuts and Jobs Act, H.R. 1, 115th Cong. § 282 (2017); *see also* Rohan Narayanan, *NORD Statement on Proposed Changes to the Orphan Drug Tax Credit*, NAT'L ORG. RARE DISORDERS, (Sept. 13, 2021), https://rarediseases.org/nord-statement-on-proposed-changes-to-the-orphan-drug-tax-credit/ ("The ODTC can help to offset the cost of developing and testing orphan therapies as they move through the clinical trial process.").
[37] 26 U.S.C. § 45C(a).

orphan designation is made later in the development process, typically in Phase III, this tax credit can result in substantial savings.[38] But the threat to tax credits goes beyond the twenty-five percent decrease from 2017. The *Build Back Better Act of 2021* proposed to eliminate the tax credit altogether.[39] Although negotiations that resulted in the *Inflation Reduction Act of 2022* extended the twenty-five percent tax credit for three more years, the continued existence of the tax credit may likely be at risk after the three-year extension period expires as Congress will be considering several financial, organizational, and operational changes at the FDA.[40] With the tax credit in possible jeopardy, Congress should aim to compensate for decreased incentive with an extended exclusivity period to ensure a strong incentive for drug manufacturers.

C. Legal and Political Challenges

1. Antitrust and Cost Control

In concept, the exclusivity period is vulnerable to criticism from an antitrust and cost control perspective.[41] Being granted a period of exclusivity up to ten years

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[38] Kiran N. Meekings et al., *Orphan Drug Development: An Economically Viable Strategy for Biopharma R&D*, 17 DRUG DISCOVERY TODAY 660, 664 https://www.sciencedirect.com/science/article/pii/S1359644612000529#bib0080 (noting that locating participants and organizing studies contribute to the increased the cost of orphan drug clinical trials).

[39] Narayanan, *supra* note 36.

[40] Inflation Reduction Act, H.R. 5376, 117th Cong. (2022); Rohan Narayanan, *NORD Statement on the Passage of the Inflation Reduction Act*, NORD (Aug. 12, 2022), https://rarediseases.org/nord-statement-on-passage-of-the-inflation-reduction-act/ ("We are grateful the current 25 percent tax credit for clinical trial testing services remains unchanged and believe it is a critical tool to help foster robust rare disease drug development."). On current legislative regarding changes in FDA Law and Policy, see discussion *infra*, Part III.

[41] *See* Kao-Ping Chua et al., *Spending for Orphan Indications Among Top-Selling Orphan Drugs Approved to Treat Common Diseases*, 40 HEALTH AFFS. 453 (2021), https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2020.01442 (examining the budgetary impact of spending on orphan drugs).

results in a monopoly-based pricing scheme, forcing higher costs on payers as patients with rare diseases are unlikely to bypass available therapies.[42] This monopolization can impact patient access by a lack of affordability.[43] A 2016 study published in the *Journal of the American Medical Association* found that marketing exclusivity induces the high price of prescription drugs.[44] This argument has even more validity when there is potential competition, despite advocacy reports showing that high pricing does not prevent patients from obtaining orphan drugs.[45]

However, other research has shown that FDA approval of an orphan drug can lead to further R&D for other orphan drugs for the same rare disease, and thus promotes innovation.[46] The incentive provided by the exclusivity period should promote R&D efforts into new orphan drugs to treat rare diseases where therapy options are lacking. The antitrust concern is valid in theory, but is less of a concern in the orphan drug market where competition is scarce.[47]

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[42] Todd Gammie et al., *Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries*, 10 PLoS ONE 1, 16, 21 (2015), https://pubmed.ncbi.nlm.nih.gov/26451948/ ("The presence of marketing exclusivity remains critical to monopolization research and development of orphan drugs but poses risks, most notably monopolization and high prices for orphan drugs, which may limit patient access to these needed medicines.").

[43] *See generally* Gianna Melillo, *More than One-Third of Americans Haven't Filled a Prescription Due to Cost: Survey*, The Hill (Mar. 10, 2023), https://thehill.com/changing-america/respect/poverty/3893811-more-than-one-third-of-americans-havent-filled-a-prescription-due-to-cost-survey/ (citing survey based on 1,500 adults in the U.S. resulting in 37 percent admitting they have forgone filling a prescription due to high cost); Zachary Tracer, *Millions of Americans are Skipping Doses Because They Can't Afford Their Prescription Drugs*, Bus. Insider (June 2, 2023), https://www.businessinsider.com/americans-cant-afford-their-prescription-medications-cdc-2023-6 (citing survey results that 8.3% of adults aged 18–64 did not take prescription medications as prescribed due to high cost).

[44] Aaron S. Kesselheim et al., *The High Cost of Prescription Drug Prices in the United States*, J. Am. Med. Ass'n (2016), https://jamanetwork.com/journals/jama/article-abstract/2545691 ("The most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon Food and Drug Administration approval and by patents.").

[45] U.S. Dep't of Health & Hum. Servs. Off. Inspector Gen., *supra* note 6, at 9.

[46] Gammie et al., *supra* note 42, at 16.

[47] In a small marketplace, high prices are more likely to be the result of normal market forces rather than anticompetitive practices, such as an anticompetitive merger or a "pay-for-delay"

2. *Patent Infringement*

Patent infringement is another consideration that is slightly tangential to the scope of this proposal. Marketing exclusivity and patent property rights are distinct concepts and how they interact on a case-by-case basis varies.[48] In theory, a patent that would interfere with a pharmaceutical company's incentive to develop new orphan drugs may or may not be in existence at the time a company seeks orphan drug approval by the FDA. Patent protection is typically available for twenty years and exclusivity would be granted for up to only ten years, leading the degree that these two concepts interfere with the motivation to develop a new orphan drug to widely vary.[49] A patent term may expire without the property owner ever applying for orphan designation or marketing approval, eliminating an infringement concern.[50] In any event, a pharmaceutical company should evaluate the issue of patent infringement before developing its own intellectual property to avoid potential risk.

The patent application process, like seeking FDA approval, is similarly expensive, time-consuming, and resource-intensive.[51] Further, it is unpredictable how much time it will take for the United States Patent and Trademark Office to

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agreement. *See* Amanda J. Hamilton, *What Can the FTC Do About Orphan Drug Prices?*, ANTITRUST HEALTH CARE CHRON. 19–24 (Aug. 2017), https://haugpartners.com/wp-content/uploads/2021/12/Hamilton_Article-1.pdf (outlining FTC orphan drug pricing investigations and enforcement actions).

[48] *See generally* U.S. FOOD & DRUG ADMIN. ET AL., PATENTS & EXCLUSIVITY (May 19, 2015), https://www.fda.gov/media/92548/download (distinguishing patents as a property right issued by the United States Patent and Trademark Office from various forms of FDA exclusivity) .

[49] *Id.* at 1.

[50] *Id*. at 3.

[51] *See Patent Prosecution Overview*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/patent-process-overview#step5 (detailing a five-step process for preparation, application, prosecution, grant, and maintenance of a patent) (last accessed Nov. 18, 2023).

issue a new patent.[52] Patents provide an additional level of protection to promote innovation and prevent competition because they give the patent owner a right to recover from a competitor's infringement, making for a prudent investment.[53] However, patent protection in itself is not necessarily enough of an incentive to develop orphan drugs because the threat of infringement by competition is lower, especially if exclusivity is granted. If an orphan drug sponsor is uncertain about the marketability of a new orphan drug, they may not invest the time, resources, or effort into applying for a patent, so exclusivity would provide the larger incentive. To that end, small orphan drug companies may have less resources to apply for fast-track patent review. On the other hand, exclusivity status can help smaller companies secure more funding from venture capital groups to assist in the costly drug development process, including seeking patent protection or carrying out clinical trials, not necessarily in a particular order.[54]

IV. PROPORTIONAL EXCLUSIVITY

A predominant concern arising out of the *Catalyst* decision is that subgroups of patients with a particular rare disease may be without an available therapy.[55] This concern is heightened in light of research showing that approval of one orphan drug triggers further R&D that could result in expanded approval of an existing drug or

[52] *See generally* U.S. PAT. & TRADEMARK OFF., FY 2020 PERFORMANCE & ACCOUNTABILITY REPORT 60–61 (2020), https://www.uspto.gov/sites/default/files/documents/USPTOFY20PAR.pdf (providing meta data on patent approval timeliness).
[53] 35 U.S.C. § 154(a)(1).
[54] DEP'T HEALTH & HUM. SERVS. OFF. OF THE INSPECTOR GEN., *supra* note 25, at 8.
[55] *See FDA's Overview of Catalyst Pharms., Inc. v. Becerra*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/fdas-overview-catalyst-pharms-inc-v-becerra ("If, for example, the FDA grants orphan-drug designation to a drug for 'treatment of cystic fibrosis,' and then approves that drug for 'treatment of adult patients with a particular gene mutation with cystic fibrosis,' the approval of the application will block FDA from approving – for seven years – another company's application for the same drug for **any** indication within cystic fibrosis, including for children and for patients without the particular mutation.").

an entirely new orphan drug, either of which could be used to treat new uses or indications.[56] The danger of following *Catalyst* is that pharmaceutical companies would lose the marketing exclusivity incentive to develop orphan drugs that could have provided a therapy to vulnerable patient subgroups. Although *Catalyst* increased the value of exclusivity for developing new orphan drugs (i.e., exclusivity for an entire rare disease or condition), it eliminated the financial incentive for companies to conduct studies and apply for new uses or indications of existing drugs.[57] Proportional exclusivity acts as an incentive for the same orphan company, or a competitor, to continue R&D in a particular line of orphan drugs so that subpopulations without an approved therapy will potentially have a remedy approved. It accomplishes this incentive by offering a proportion of the proposed ten-year exclusivity period to an orphan drug company based on the percentage of the total population with a rare disease that its medication is approved for use in.

Proportional exclusivity aims to reconcile the extended ten-year exclusivity period that promotes new orphan drug innovation with the continued need to incentivize companies to apply for new uses or indications of existing orphan drugs.[58] It would not eliminate the incentive for companies to develop new orphan drugs based on a minute risk that a competitor could be granted marketing exclusivity for any uses or indications that have not been FDA-approved. Nor would it discourage investing in the R&D of the initial drug or investing in the idea of competitors riding the coattails of the original research. This scenario provides a large public health benefit to those with rare diseases, particularly patients with

[56] Gammie et al., *supra* note 42, at 16 ("Turnover of the first orphan drug authorized for a rare disease indication is linked to increased likelihood of 'follow up' orphan drug research and development").
[57] Koblitz, *supra* note 12.
[58] *See* discussion *supra* Part I. (proposing an extended exclusivity period).

atypical indications of a certain rare disease or those in subgroups without an approved therapy.[59]

To effectuate the mechanisms of proportional exclusivity, this paper proposes that the ODA be amended to authorize the FDA to grant a proportion of the total ten-year exclusivity period to an orphan drug equal to the number of patients who would have an approved therapy with the drug relative to the entire patient population with the rare disease. This would leave room for additional incentive to innovate for the purpose of developing a drug to be approved for a new indication or use despite ultimately treating the same rare disease. In scenarios where multiple drug companies have exclusivity periods during the same time, the periods would run concurrently and operate without interference because the periods would be based on indications or uses rather than the entire disease or condition. For example, "Company A" could have three-years of exclusivity on the drug market for pediatric patients, whereas "Company B" could have six years for use in adults, and "Company C" could have one year for use in elderly populations, all treating "Disease X." These periods could run concurrently or years apart, depending on when the drug is FDA-approved for a particular indication or use.

The RARE Act proposes to codify the FDA's interpretion of the ODA for nearly 30 years pre-*Catalyst*.[60] However, proportional exclusivity is a novel concept that is arguably more equitable than the pre-*Catalyst* incentive scheme because it

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[59] *See, e.g.*, *FDA's Overview of Catalyst Pharms., Inc. v. Becerra*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/fdas-overview-catalyst-pharms-inc-v-becerra ("If, for example, the FDA grants orphan-drug designation to a drug for 'treatment of cystic fibrosis,' and then approves that drug for 'treatment of adult patients with a particular gene mutation with cystic fibrosis,' the approval of the application will block FDA from approving – for seven years – another company's application for the same drug for **any** indication within cystic fibrosis, including for children and for patients without the particular mutation.").

[60] Retaining Access and Restoring Exclusivity Act, S. 4185, 117th Cong. (2022), https://www.govinfo.gov/bulkdata/BILLS/117/2/s/BILLS-117s4185is.xml; SENS. TAMMY BALDWIN & BILL CASSIDY, RARE ACT SUMMARY, https://www.baldwin.senate.gov/imo/media/doc/RARE%20Act%20Summary.pdf (last accessed Dec. 15, 2022).

distributes exclusivity based on precise epidemiological data rather than less precise negotiation and politically-driven interest balancing.[61] In tandem with the extended ten-year exclusivity period, it can provide more incentives than the previous scheme.[62]

In *Catalyst*, the rare disease LEMS affected somewhere between 950 and 1,300 individuals in the U.S.[63] Catalyst Pharmaceuticals' drug Firdapse (amifampridine phosphate) was FDA-approved for LEMS treatment "in adults only," leaving room for an FDA-approved drug that could treat pediatric patients who suffered from LEMS.[64] Jacobus Pharmaceutical Company's drug, Ruzurgi (amifampridine), had ongoing development and testing for more than twenty years and gained FDA approval for use in children aged six through seventeen during Catalyst's exclusivity period.[65] At the time, LEMS was only known to affect "a couple dozen" children in the U.S.[66] Applying proportional exclusivity to these facts, the FDA would rely on credible epidemiological data and allocate up to ten years of exclusivity to both Firdapse and Ruzurgi. Assuming that the prevalence of LEMS was roughly 1,125 individuals (the average based on the range provided above), including 900 adults and fifty children, for example, the FDA would grant eight years of exclusivity to Catalyst's Firdapse and 163 days of exclusivity to Jacobus' Ruzurgi in their respective populations.[67]

Under this new framework, notwithstanding the Eleventh Circuit's Order to revoke the approval of Ruzurgi, Firdapse would have one additional year of

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[61] *See* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmacuetical and Health Product Industry in the United States, 1999-2018*, 180 J. AM. MED. ASS'N INTERN. MED. 1 (2018) (finding that the pharmaceutical and health products industries spent $4.7 billion on lobbying and campaign contributions from 1999-2018).
[62] *See* discussion *supra* Part I. (proposing an extended exclusivity period).
[63] Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299, 1304 (11th Cir. 2021), cert. dismissed sub nom. Jacobus Pharm. Co. v. Catalyst Pharms., Inc., 142 S. Ct. 2904, 213 L. Ed. 2d 1139 (2022).
[64] *Id.* at 1304–05.
[65] *Id.*
[66] *Id.* at 1304.
[67] These numbers are not official and are provided only for the sake of example.

exclusivity in adults, and Ruzurgi would be entitled to nearly six months of exclusivity in children aged six through seventeen, resulting in a fairly balanced reward. Prior to initial approval, the proposed framework would have increased the incentive for Catalyst to gain approval in adults, and, as importantly, would not have completely eliminated the incentive for Jacobus to seek approval for use in children. It also provides an exclusivity incentive for either Catalyst, Jacobus, or a third-party company to continue their R&D efforts to seek approval for the benefit of remaining subpopulations without an approved therapy. As such, the FDA could provide equitable periods of exclusivity to both Catalyst and Jacobus based on their proportional contributions to overall patient care. Although 163 days of exclusivity is arguably a small incentive, the exclusivity proportion is variable in each case and could fall at, above, or below the 163 days in this example, depending on the data.

In *Catalyst*, the proportion of exclusivity would have been cleanly divided based on adults and children aged six through seventeen.[68] However, the flexibility of the proposed framework is adaptable to any approved indication, notwithstanding multiple variables. For example, if Firdapse had been approved in all adults except those taking certain autoimmune medications, the exclusivity period would be slightly shorter because the fractional numerator would not include adults taking the autoimmune medications. Any other variables that fall under the scope of an approved indication would alter this calculus, but as long as the FDA has access to the most relevant epidemiological data through the National Center for Health Statistics ("NCHS") at the Centers for Disease Control ("CDC") or another government agency, such as the National Institutes of Health ("NIH"), proportional exclusivity would remain equitable and flexible.[69]

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[68] *Id*.

[69] Using government data would provide a shield against potential bias or manipulation compared to data provided by interested third-parties. For example, the CDC has direct access to data from healthcare systems under authorities such as HIPAA. Katrina Hedberg & Julie Maher, *Collecting*

Under the Eleventh Circuit's interpretation of the of the ODA, however, once Catalyst was granted seven years of exclusivity for the use of Firdapse in adults, it is reasonable to predict that Jacobus would have withdrawn its continued development and testing efforts. In following the Eleventh Circuit, the FDA could not legally approve the Rizurgi application for use in children, effectively leaving that subpopulation without FDA-approved therapy despite the potential for one.[70] These scenarios demonstrate the communitarian benefits of proportional exclusivity weighed against the potential harms of following the *Catalyst* opinion.

A. Legal Challenges

1. Arbitrary and Capricious

In the future, pharmaceutical companies could claim that the FDA violated the Administrative Procedure Act ("APA") by making an arbitrary and capricious determination based on the data that was relied upon to calculate proportional

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Data, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/eis/field-epi-manual/chapters/collecting-data.html (last reviewed Dec. 13, 2018). Compared to studies that are funded by interested parties, the raw data accessed by government entities may be less susceptible to outside influence. *See* Wendy E. Wagner, *When a Corporation's Deliberate Ignorance Causes Harm: Charting a New Role for Tort Law*, 72 DEPAUL L. REV. 413, 417–23 (2022) (illustrating the mechanisms that corporations use to control the information environment, including funding results-oriented studies, attacking conflicting studies, and manipulating scientific concensus) This proposal suggests using data sources that have at least been screened for potential conflicts of interest. In some cases, the broader scientific literature may provide the most robust data available. In these cases, the FDA should make a case-by-case determination on how to measure proportionality equitably and fairly.

[70] Certain patients with serious or immediately life-threatening diseases could be eligible to receive non-FDA approved therapies through the FDA's Compassionate Use program, however, the benefits of clinical trials to establish safety and effectiveness cannot be overstated. *See generally Expanded Access*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/expanded-access (describing the circumstances when a patient may potentially access an investigational new product outside of clinical trials) (last updated Dec. 21, 2022).

exclusivity.[71] An agency action is arbitrary and capricious and will be set aside if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[72] Proportional exclusivity would be authorized by the ODA pursuant to the proposed amendment. However, the FDA would have discretion to rely on the most relevant data available at the time, which would, in most cases, be provided by the NCHS.[73] In a battle for market share, companies would have incentive to challenge the data that the FDA relied upon, if winning meant a longer period of exclusivity.[74]

In recent years, courts have set aside FDA rulings on arbitrary and capricious grounds for inadequately relying on available data,[75] or claiming to rely on reported data when the FDA stopped requiring that data from other companies seeking similar approvals,[76] unable to provide a rational connection between the data and its ruling, and thus failing to overcome an arbitrary and capricious challenge.[77] The amendment here should limit the epidemiological data that the FDA could rely on

[71] 5 U.S.C. § 706(2)(A).
[72] Cigar Ass'n Am. v. U.S. Food & Drug Admin., No. 1:16-cv-01460, 11 (D.D.C. 2020) (citing Motor Vehicle Mfrs. Ass'n. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).
[73] U.S. FOOD & DRUG ADMIN., FRAMEWORK FOR FDA'S REAL WORLD EVIDENCE PROGRAM 25 (Dec. 2018), https://www.fda.gov/media/120060/download.
[74] *See generally id.* at 4, 14–15 (The FDA emphasizes "relevance and reliability" of the Real World Data it relies on in extracting Real World Evidence of safety and efficacy in the drug screening process. In this context, the FDA could rely on the same principles – examining methods of data accrual, data quality control, and "whether the data are fit for purpose" – in making a proportional exclusivity determination.).
[75] *Cigar Ass'n. of Am.*, No. 1:16- cv-01460 (D.D.C. 2020).
[76] All. Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z 49–50 (N.D. Tx. 2023) (striking down FDA's approval of "chemical abortion" in the year 2000).
[77] Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.").

to the most robust datasets available, such as raw data accumulated by government sources.[78] In some cases, the most robust data will be available in the broader scientific literature rather than at a government agency. In these cases, it is important to screen the data for potential conflicts of interest, such as funding by outside sources, to establish whether a conflict exists.[79] Once the dataset is selected, the FDA should offer a rational connection between the data relied upon and the proportional exclusivity determination, including that the data is the most accurate and robust available at the time. In these circumstances, an arbitrary and capricious challenge would likely be dismissed.[80]

V. UNIVERSAL, TRANSFERABLE, AND CONDITIONAL FDA USER FEE CREDIT

[78] This determination may hinge on the credibility and legitimacy of the data. *See* U.S. FOOD & DRUG ADMIN., FRAMEWORK FOR FDA'S REAL WORLD EVIDENCE PROGRAM (Dec. 2018), https://www.fda.gov/media/120060/download (emphasizing "reliability and relevancy" of the data used to prove safety and efficacy in new drug applications).

[79] For example, a conflict would arise if a company that has a history of "deliberately ignoring" data unfavorable to their end-goal funds a scientific journal when the journal publishes the data relied on for a proportional exclusivity determination. In this case, there would be a conflict of interest and another data source should be used. *See* Wagner, *supra* note 70 (introducing "deliberate ignorance" and discussing deceptive corporate practices that are used to manipulate the integrity of the information environment).

[80] This analysis relied on the Hard Look review regime used in *Federal Communications Commission v. Prometheus Radio Project* and associated Administrative Law cases. *See* Fed. Commc'ns Comm'n v. Prometheus Radio Project, 141 S.Ct. 1150 (2021) (upholding a Federal Communications Commission ("FCC") decision for landing in a "zone of reasonableness" even though the FCC did not have "perfect statistical or empirical data" because the APA "imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies."); Motor Vehicle Mfrs. Ass'n. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) (holding that a National Highway Traffic Safety Administration order was arbitrary and capricious for failure to provide an adequate basis and explanation for rescinding a motor vehicle safety standard).

The FDA's current user fee waiver is an important incentive for short-term drug development and should be sustained. However, to further incentivize companies to promote R&D of orphan drugs that could be approved to treat minority indications of a rare disease, the proposed amendment would authorize the FDA to grant a single-use, universal, and transferable user fee credit. Although the FDA has long issued user fee waivers, this would be the first time the FDA would issue a user fee credit per se.[81] This asset could be used by a pharmaceutical company applying for approval, or sold or transferred to another company for future use, an incentive that the waiver in itself does not provide.[82] Additionally, the credit could be conditioned on receiving FDA approval for a new use or indication for an orphan drug that increases the pool of available therapies to encompass "virtually all" patients living with a particular rare disease, absent specific patient-outliers.

Pursuant to Section 736(a)(1)(F) of the FD&C Act, which governs user fees, an orphan drug sponsor is exempt from a user fee when they submit a marketing application for an orphan designated drug.[83] The traditional user fee waiver results in substantial cost savings as the fiscal year ("FY") 2023 user fee rates for New Drug Applications ("NDAs") were $3.2 million for an application requiring clinical data and $1.6 million for an application not requiring clinical data.[84] User fee waivers also provide direct and easily-measurable cost savings, as well as an incentive to develop a particular orphan drug. However, the data shows that only ten percent of orphan products are approved to treat three or more indications of a

[81] *See* U.S. FOOD & DRUG ADMIN., PRESCRIPTION DRUG USER FEE ACT WAIVERS, REDUCTIONS, AND REFUNDS FOR DRUG AND BIOLOGICAL PRODS. 4–11, https://www.fda.gov/media/131797/download (delineating user fee waivers in Section 736(d) of the FD&C Act).
[82] *See id.* (explaining available waivers and fee reductions).
[83] 21 U.S.C. § 379h(a)(1)(F); *id.* at 11.
[84] FY 2023 PDUFA Rates, 87 Fed. Reg. 61,063 (Oct. 7, 2022), https://www.federalregister.gov/documents/2022/10/07/2022-21968/prescription-drug-user-fee-rates-for-fiscal-year-2023; Ferdous Al-Faruque, *FDA Posts FY2023 User Fee Tables*, REGUL. FOCUS (Oct. 6, 2022), https://www.raps.org/news-and-articles/news-articles/2022/10/fda-posts-fy2023-user-fee-tables.

rare disease, shedding light on the need for future orphan drug R&D that could lead to a new orphan drug approved for a new use or indication, which would cover additional subgroups that lack an available therapy.[85]

In addition to the incentive value provided by the user fee waiver, the user fee credit value could be proportional to the contribution that met the threshold, with a maximum of $1 million.[86] For example, if orphan drug "A" was approved for some indications that covered eighty percent of the patient population, then orphan drug "B" was approved for other indications that covered seventeen percent of the remainder of the population (enough to constitute "virtually all" of the rare disease population, absent anomalous cases), the sponsor of drug B could be granted a user fee credit for $117 thousand (seventeen percent of $1 million). Patient subgroups that are the small minority in rare disease populations are the most vulnerable patients because the incentive to invest millions of dollars in R&D only to have access to seventeen percent of a small patient population, for example, is comparatively low. It is likely that a pharmaceutical company would rather invest in R&D for a new orphan drug where a higher demand would make it easier to recover costs and profit.[87] The proposed user fee credit provides a little more of an incentive for companies to promote R&D in attempts to prevent these minority patient subgroups from falling through the cracks.

A. Legal and Political Challenges

[85] *See* NAT'L ORG. FOR RARE DISORDERS, *supra* note 4 ("[J]ust 10% of all orphan products have three or more orphan indications, demonstrating that the majority of orphan products treat very few rare diseases and, in turn, small numbers of rare disease patients").
[86] Given that the number of orphan drugs continues to increase and the FY 2023 user fee rate of $3.2 million, $1 million seemed like a modest amount. However, more accounting and economic analysis is necessary to pin down a precise maximum threshold.
[87] *See*, Robert D. Buzzell, *Marketshare–A Key to Profitability*, HARV. BUS. REV. (JAN. 1975), https://hbr.org/1975/01/market-share-a-key-to-profitability (finding a positive correlation with market share and return on investment).

1. Arbitrary and Capricious

Similar to the proportional exclusivity amendment above, a pharmaceutical company could bring a claim against the FDA for violating the APA for making an arbitrary and capricious determination of the "virtually all" threshold.[88] Like the arbitrary and capricious standard above, the FDA would only need to demonstrate a rational connection between the data relied on and the choice made. The same data used to establish proportional exclusivity would be used here because the FDA would have determined that the data was the most robust available and that it had been screened for integrity from conflicts of interest. Unlike proportional exclusivity, the user fee credit is only provided when "virtually all" of the population with a particular rare disease is covered by approved therapies. This means that only patient-outliers, who would not be covered under an indication because of an anomalous condition, would not be eligible for therapy for the approved uses. For example, there may be a very small number of patients who cannot metabolize a drug orally, and therefore would not be covered by the approved indication. A possible threshold for these anomalous subgroups is if they constitute less than one percent of the rare disease population. Thus, as long as the FDA relies on the appropriate data, which can be used to characterized certain subgroups as anomalous, and can make a rational connection between the threshold for "virtually all," the arbitrary and capricious challenge would likely be dismissed.[89] As the user fee credit incentive to develop new orphan drugs for new

[88] 5 U.S.C. §706(2)(A).
[89] This analysis relies on Hard Look review. *See* Fed. Commc'ns Comm'n v. Prometheus Radio Project, 141 S.Ct. 1150 (2021) (upholding a Federal Communications Commission ("FCC") decision for landing in a "zone of reasonableness" even though the FCC did not have "perfect statistical or empirical data" because the APA "imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies."); Motor Vehicle Mfrs. Ass'n. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) (holding that a National Highway Traffic Safety Administration order was arbitrary and capricious for failure to provide an adequate

uses or indications is a novel concept, there is no direct precedent on the matter. However, compared to other arbitrary and capricious challenges, courts could remand a dispute to the FDA for further fact finding if the basis for which it supports a ruling is lacking in evidence or if the evidence is vague.[90]

B. Equal Protection

Any anomalous patient subgroup could bring a Fourteenth Amendment claim for violating the Equal Protection Clause by treating certain patient subgroups differently under the law.[91] The proposed user fee credit would incentivize R&D only to the extent that "virtually all" of the patient population would be covered by approved uses. This effectively leaves out the user fee credit incentive to develop drugs for extraordinary patients in anomalous subgroups. However, a Fourteenth Amendment claim here would be subject to rational basis review because the patients are not considered a suspect class based on their anomalous medical conditions.[92] Therefore, the FDA would only need to show a legitimate government interest in the user fee credit (i.e., promoting drug innovation to benefit public health) and that the user fee credit is rationally related to that interest. Here, these

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basis and explanation for rescinding a motor vehicle safety standard). Administrative Law doctrine is in constant flux, but this phenomena remains outside the scope of this proposal. *See generally* Paul R. Verkuil, *Welcome to the Constantly Evolving Field of Administrative Law*, WM. & MARY L. SCH. SCHOLARSHIP REPOSITORY (1990), https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=2058 (presenting a brief history and predictions on where the field seems to be going).

[90] *See* Amgen, Inc. v. Hargen, No. 17-1006 (D.D.C. 2018), https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2017cv1006-76 (dismissing in part and remanding in part a summary judgment motion filed by Amgen asserting that FDA's decision denying additional pediatric exclusivity to drug Sensipar (cinacalcet hydrochloride) was arbitrary and capricious for being inconsistent with FDA's approval of two similar pediatric drugs).

[91] U.S. Const. art. XIV, § 1 (Equal Protection clause).

[92] Marcy Strauss, *Reevaluating Suspect Classifications*, 35 SEATTLE L. REV. 135, 146 (2011) (describing factors used to determine whether an individual is a discrete and insular minority and thus considered a suspect class).

demonstrations should be straightforward.[93] For example, the FDA could argue that the user fee incentive is to promote innovation that could result in approved treatment for these subgroups. Even though these anomalous subgroups may not be represented equally from a quantitative perspective, and thus would not necessarily be the intended beneficiary of a companies' R&D efforts for earning the user fee credit, the innovation may result in a drug that is approved for the subgroup indication. Or in the very least, it would advance the efforts to develop drugs for that rare disease population generally and that this innovation would trigger follow-up R&D that could lead to a therapy approved for that subgroup.

C. Disdain from Nonorphan Drug Companies

FDA user fees are reauthorized by Congress every five years.[94] The funds from user fees are pooled together to pay for FDA's workforce, application reviews, various programs, and certain FDA inspections.[95] User fee credits would require the resources that user fee payments typically fund, such as application review. However, the resources required for these operations would require either Congress increase general user fee rates for the FDA to increase its resources or the FDA adjust its allocation of existing resources. In either scenario, there would likely be industry disdain from nonorphan drug companies because the economic value provided by the user fees that are funded by nonorphan drug companies would, to

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[93] *See* Raphael Holoszyc-Pimentel*, Reconciling Rational Basis Review: When Does Rational Basis Bite?*, 90 N.Y.U. L. Rev. 2070, 2074–75 (2015) (analyzing rational basis review). For a broad description of the rational basis test, see generally *Rational Basis Test*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/rational_basis_test.

[94] U.S. FOOD & DRUG ADMIN., FDA USER FEES: EXAMINING CHANGES IN MEDICAL PRODUCT DEVELOPMENT AND ECONOMIC BENEFITS, https://aspe.hhs.gov/sites/default/files/documents/e4a7910607c0dd76c40aa61151d154f9/FDA-User-Fee-Issue-Brief.pdf (March 2023).

[95] *User Fees: Explained*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained (last visited Nov. 2, 2023).

a certain extent, be allocated to orphan drug companies that benefit from the user fee credit. This political conflict could create tension between the FDA and the nonorphan pharmaceutical industry as the number of orphan drug approvals tripled between 2010 and 2019.[96] However, nonorphan drug companies would likely not speak out against an increase in user fee amounts due to the political value of a mutual relationship with the FDA and the fear of negative publicity.

VI. CONCLUSION

The *Catalyst* decision sparked a dilemma regarding marketing exclusivity under the ODA. If followed, the decision would prevent the FDA from approving a drug application for a new use or indication of a particular rare disease for seven years even if an orphan drug is already approved to treat the rare disease..[97] In effect, this would prevent vulnerable patient populations from having some types of therapies available.

The FDA's non-acquiescence to the ruling serves as a platform for Congressional action. The proposed amendments to the FD&C Act and the ODA would maintain the incentive for pharmaceutical companies to develop new orphan drugs for new indications of a rare disease and would allow the FDA to continue to approve these drugs under its longstanding interpretation and provide a maximum communitarian benefit. Alternatively, the RARE Act proposes to amend the ODA back to its pre-*Catalyst* form, but there are reasons why the amendments proposed here are more desirable. In a real-world scenario, proportional exclusivity would

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[96] Kathleen L. Miller et al., *Using Four Decades of FDA Orphan Drug Designations to Describe Trends in Rare Disease Drug Development: Substantial Growth Seen in Development of Drugs for Rare Oncologic, Neurologic, and Pediatric-Onset Diseases*, 16 ORPHANET J. RARE DISEASE 1, 6, https://pubmed.ncbi.nlm.nih.gov/34107994/ ("In just ten years since the last quantitative analysis performed by OOPD, designations and approvals for rare disease drugs have hearly tripled.").
[97] Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021), cert. dismissed sub nom. Jacobus Pharm. Co. v. Catalyst Pharms., Inc., 142 S. Ct. 2904, 213 L. Ed. 2d 1139 (2022).

have allowed *Catalyst*'s exclusivity period to increase by one year in adult populations and would not have precluded Jacobus' Ruzurgi from being approved and marketed for the treatment of LEMS in children aged six through seventeen. Furthermore, extending the exclusivity period would create more flexibility for competing pharmaceutical companies to each earn a fair and equitable incentive for their respective contributions to patient care. Finally, the user fee credit provides more incentive to develop drugs for new indications when a drug for a particular rare disease is already approved. Patient subpopulations with these rare diseases are already the most vulnerable to being left without a treatment because the market share available is not large enough to induce innovation on its own.

These amendments are new in concept and would likely not be without legal and political pushback. However, the time to implement change to FDA Law and Policy is on the horizon. The FY 2023 User Fee Reauthorization nearly failed to pass because of politically divisive policy riders that would have been expensive but are arguably vital to the FDA's mission of protecting public health.[98] Even though a "clean" user fee reauthorization was signed into law in September 2022, Senator Murray (D-WA) and Former Senator Burr (R-NC), Chair and Former Ranking Member of the Health, Education, Labor, and Pensions Committee

[98] Policy riders omitted from the reauthorization include the following: (1) new regulatory framework for In Vitro Diagnostics and LDTs, (2) modernization of cosmetics regulation, (3) listing requirements for dietary supplements, (4) reforms to improve diversity in clinical studies, (5) reforms to accelerated approval, and (6) reforms in response to infant formula crisis. Gregory H. Levine et al., *Congress Enacts Clean Reauthorization of FDA User Fees, Leaving Uncertain Future for Important Policy Reforms*, ROPES & GRAY (Sept. 30, 2022), https://www.ropesgray.com/en/newsroom/alerts/2022/september/congress-enacts-clean-reauthorization-of-fda-user-fees-leaving-uncertain-future (explaining that Congress was unable to reach consensus on the policy rides to be included as part of reauthorization legislation and consequently incorporated a "clean" user fee package into the continuing resolution); *see* Rachel L. Sher, *Negotiations on Reauthorizing FDA's User Fee Programs Hit Snag*, MANATT HEALTH INSIGHTS (July 26, 2022), https://www.manatt.com/insights/newsletters/health-highlights/negotiations-on-reauthorizing-fdas-user-fee-progr (providing political background).

("HELP"), issued a joint statement that more bipartisan negotiation is necessary to implement some of the proposed policy changes.[99]

There has been talk on Capitol Hill about major structural changes to the FDA, particularly moving the Food Administration into its own agency as there would be benefits such as elevated visibility and separating budgets.[100] It is unclear when Congress and FDA Commissioner Rob Califf will declare major changes — perhaps as early as January 2024. However, changes to the ODA and the FD&C Act, such as those proposed here, are critical to providing equitable therapy to the nation's most vulnerable patients and thus must be on the agenda.

[99] Erik Wasson, *Gov't Shutdown Averted as Biden Signs Stopgap Funding Bill*, BLOOMBERG POLS. (Sept. 30, 2022), https://www.bloomberg.com/news/articles/2022-09-30/us-averts-government-shutdown-as-house-passes-short-term-funding-bill?leadSource=uverify%20wall; *Murray, Burr Statement on Agreement to Reauthorize FDA User Fee Programs, Continue Work on Additional Critical Priorities*, U.S. SEN. COMM. HEALTH, EDUC., LABOR & PENSIONS (Sept. 27, 2022), https://www.help.senate.gov/chair/newsroom/press/murray-burr-statement-on-agreement-to-reauthorize-fda-user-fee-programs-continue-work-on-additional-critical-priorities.

[100] Laura Reiley, *Scathing Report Urges Major Changes at FDA, Including Possibly Breaking Up Agency*, WASH. POST (Dec. 6, 2022, 2:21 PM), https://www.washingtonpost.com/business/2022/12/06/fda-food-safety-formula/ (listing other changes to the FDA: establishing a new structure with clear leaders and roles, developing a culture where decision-making is rooted in scientific evidence, and committing to better transparency, timeliness, and predictability in decision-making).