

Eugenics and the Development of U.S. Food and Drug Law

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I. INTRODUCTION

The Food and Drug Administration (FDA) and its core statutory authorities have a complex and storied history. Historians and lawyers recounting the agency’s early development—which roughly spanned from the debates culminating in the Pure Food and Drug Act of 1906 to the enactment of the Federal Food, Drug, and Cosmetic Act of 1938—typically cite a long list of influences, including coalitions and clashes among various business and consumer interests in an emerging national market for foods and medicines, product safety tragedies, “muckraking” journalists and the publication of Upton Sinclair’s *The Jungle*, and a shift from a *laissez-faire* era to federal regulatory power in a growing nation.² Yet, as in other fields, another

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² Pure Food Act, Pub. L. No. 59-384, 34 Stat. 768 (1906); Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); see generally JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 (Princeton Univ. Press, 1989); Richard M. Cooper, *The Struggle for the 1906 Act*, and Anthony A. Celeste & Arthur N. Levine, *The Mission and the Institution: Ever Changing Yet Eternally the Same*, in FDA: A CENTURY OF CONSUMER PROTECTION 25–98 (Wayne L. Pines, ed., Food and Drug Law Inst., 2006) [hereinafter FDLI, A CENTURY OF CONSUMER PROTECTION]; DANIEL P. CARPENTER, THE FORGING OF BUREAUCRATIC AUTONOMY: REPUTATIONS, NETWORKS, AND POLICY INNOVATION IN EXECUTIVE AGENCIES, 1862–1928 260–70 (Princeton Univ. Press, 2001); Marc T. Law & Gary D. Libecap, *The Determinants of Progressive Reform: The Pure Food and Drugs Act of 1906* 2 (Nat’l Bureau of Econ. Rsch., Working Paper No. 10984, 2004), https://www.nber.org/system/files/working_papers/w10984/w10984.pdf. (“We find that aspects of all three views of regulation explain the adoption of the Pure Food and Drugs Act, that producer, consumer, and bureaucratic interests maneuvered to mold the law to their benefit, and that the muckraking press influenced the timing of adoption.”); UPTON SINCLAIR, THE JUNGLE (See Sharp Press, 2003) (1906); DEBORAH BLUM, THE POISON SQUAD: ONE CHEMIST’S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE TWENTIETH CENTURY (Penguin Books, 2019); James Harvey Young, *Two Hoosiers and the Two Food Laws of 1906*, 88 IND. MAG. HIST. 303, 314 (1992) (“[I]n February, 1906, Upton Sinclair’s novel *The Jungle* was published. Aiming at people’s heads by presenting the grim lot of Packingtown workers so as to convert readers to socialism, Sinclair observed that he had hit their stomachs instead with his few pages describing the filthy conditions under which meat was processed. The book brought on a national trauma, and the sale of meat fell by half. [U.S. Senator Albert] Beveridge sent a copy of *The Jungle* to the president and began to draft an inspection bill to remedy the dire situation.”); PHILLIP J. HILTS, PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 19–34 (2003); CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY (Univ. of Mich. Press, 1999); LORINE S. GOODWIN, THE PURE FOOD, DRINK AND DRUG CRUSADERS, 1879–1914 (McFarland & Company, 2006) (1999); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Congressional Battle for the Enactment of the*

influential factor in that critical period typically goes unnamed or unexamined: eugenics.

Eugenics is the now-discredited notion that scientists and policy makers could rank human beings by race and eventually engineer what they believed was an optimal population by controlling heredity and eliminating what they called “degeneracy”—the proliferation of those considered “unfit.”³ While there were many areas of focus, the eugenicists’ beliefs and activities had two primary tracks: so-called “positive” eugenics—in which the focus was on increasing reproduction in favored races and improving hygiene—and “negative” eugenics—meaning, reducing the reproduction, such as through involuntary sterilization of the “unfit.”⁴ Ultimately, the goal of the eugenics movement was “a biologically superior race, which would gradually wipe away the existence of all inferior strains.”⁵

Today, issues relating to race and diversity are certainly an FDA focus in terms of clinical trial populations, regulatory science that may address disparities, vaccine hesitancy, and tobacco product use, among other areas.⁶ And other race-related issues and controversies have periodically emerged as an explicit issue in FDA regulation, such as in the initial scrutiny of the agency’s approval of the drug BiDil® (isosorbide dinitrate/hydralazine), a heart failure drug that was approved in 2005 for the treatment of “self-identified black patients.”⁷ However, as detailed herein, history suggests that we should dig deeper to better understand the potential role of eugenics as a formative and early ideological influence on FDA.

While the typically cited influences certainly played central and more immediate roles in the political development of our core U.S. food and drug laws in the early 1900s—as is reflected in the official legislative histories—eugenics or “race science” was in fact a powerful underlying driver of public policy in that era and beyond, and

First Federal Food and Drug Law in the United States, 37 *FOOD, DRUG, COSMETIC L.J.* 310–29 (1982); JONATHAN REES, *THE CHEMISTRY OF FEAR: HARVEY WILEY’S FIGHT FOR PURE FOOD* 88–89 (2021).

³ See DANIEL J. KEVLES, *IN THE NAME OF EUGENICS: GENETICS AND THE USES OF HUMAN HEREDITY* 90 (first paperback ed., Harv. Univ. Press, 1995) (1985). While the notion of “degeneracy” developed over centuries, in the late 1800s it gained increasing currency as a “biological” theory that the poor, with their supposedly “unrestrained reproductive capacities, hereditary diseases, and criminal propensities” would “swamp the intelligent middle classes and bring an end to civili[z]ation.” Those concerned about “degeneracy” believed that “[h]uman intervention through welfare was inhibiting nature’s weeding out of the unfit and the result was . . . a proliferation of the ‘pauper, hysteric, epileptic, prostitute, criminal, born-blind, deaf-mute, paranoiac, recurrent lunatic and idiot.’” Christopher Lawrence, *Historical Keyword: Degeneration*, 375 *THE LANCET* 975 (2010).

⁴ ALEXANDRA MINNA STERN, *EUGENIC NATION: FAULTS & FRONTIERS OF BETTER BREEDING IN MODERN AMERICA* 9 (2d ed., 2016); DOROTHY ROBERTS, *KILLING THE BLACK BODY: RACE, REPRODUCTION, AND THE MEANING OF LIBERTY* 65 (first Vintage Books ed., 1999) (1997).

⁵ EDWIN BLACK, *WAR AGAINST THE WEAK: EUGENICS AND AMERICA’S CAMPAIGN TO CREATE A MASTER RACE* 270 (Dialog Press, 2012).

⁶ See *Minority Health and Health Equity*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-information-audience/minority-health-and-health-equity> (last updated July 22, 2022).

⁷ Lannet Company, Inc., BiDil® (isosorbide dinitrate/hydralazine) [package insert], U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020727Orig1s0121bl.pdf (revised May 27, 2020, accessed Aug. 1, 2022); see generally JONATHAN KAHN, *RACE IN A BOTTLE: THE STORY OF BIDIL AND RACIALIZED MEDICINE IN A POST-GENOMIC AGE* (Columbia Univ. Press, 2013); Howard Brody & Linda M. Hunt, *BiDil: Assessing a Race-Based Pharmaceutical*, 4 *ANNALS OF FAM. MED.* 556–60 (2006) (arguing that “the popularity of this drug is almost certain to prompt the general impression that race works as a medical category”).

it particularly shaped matters relating to food and public health.⁸ In fact, as detailed in this Article, seminal figures in the early development of FDA and its key laws believed in and widely promoted eugenics. Moreover, the practice and impact of eugenics can be seen in the well-documented activities of various precursor organizations that ultimately became what we now know as FDA and the Public Health Service more generally.

The relative lack of attention or reference to eugenics in FDA histories is not particularly surprising. First, while key figures in FDA's early development openly advocated for eugenics, at the time, many major figures in the public health community were "sensitive to the need to avoid too often brandishing that term specifically, or officially embracing eugenic ideology" because "the very word 'eugenics' remained controversial in many circles, not only in the first quarter of the century but for many years thereafter."⁹ And, as one scholar of eugenics education wrote, eugenic history has also been obscured over the years:

Apologists dismissed eugenics as a short-lived, racist, reactionary, and pseudoscientific aberration that was gasping for breath in North America long before the collapse of the Third Reich. Many official histories of biology, and various social science disciplines . . . have been whitewashed to sanitize or at least trivialize the involvement of a host of important prophets, disciples, and converts in the eugenics movement.¹⁰

Yet, despite the frequent minimization of controversial eugenic history—and the late recognition by many that eugenics is a "Bad Idea"—eugenic notions have tended to persist in American life and law and reemerge in surprising ways.¹¹ Most recently,

⁸ See generally OXFORD UNIV. PRESS, *THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS* (Alison Bashford & Philippa Levine eds., first paperback ed. 2012) (2010); STERN, *supra* note 4; INDIANA UNIV. PRESS, *A CENTURY OF EUGENICS IN AMERICA: FROM THE INDIANA EXPERIMENT TO THE HUMAN GENOME ERA* (Paul A. Lombardo ed., 2011) [hereinafter *A CENTURY OF EUGENICS*]; BLACK, *supra* note 5; DIANE B. PAUL, *CONTROLLING HUMAN HEREDITY: 1865 TO THE PRESENT* (Margaret C. Jacob et al. series eds., 1995); KEVLES, *supra* note 3; WENDY KLINE, *BUILDING A BETTER RACE: GENDER, SEXUALITY, AND EUGENICS FROM THE TURN OF THE CENTURY TO THE BABY BOOM* (Univ. of Cal. Press, 2001); MIT PRESS, *THE NATURE OF DIFFERENCE: SCIENCES OF RACE IN THE UNITED STATES FROM JEFFERSON TO GENOMICS* (Evelynn M. Hammond & Rebecca M. Herzig eds., 2008).

⁹ Paul A. Lombardo & Gregory M. Dorr, *Eugenics, Medical Education, and the Public Health Service: Another Perspective on the Tuskegee Syphilis Experiment*, 80 *BULL. HIST. MED.* 291, 315 (2006) (as time went by, "the eugenic movement had . . . suffered public embarrassment because of the race and class biases of its most extreme advocates" making explicit references to eugenics by Public Health Service physicians, such as those who designed and ran the infamous Tuskegee syphilis study, "impolitic" despite being trained at the preeminent center for eugenic medical training in the country); THOMAS C. LEONARD, *ILLIBERAL REFORMERS: RACE, EUGENICS & AMERICAN ECONOMICS IN THE PROGRESSIVE ERA* 99 (Princeton Univ. Press, 2016) ("Hundreds, perhaps thousands of Progressive Era scholars and scientists proudly called themselves eugenicists.") [hereinafter LEONARD, *ILLIBERAL REFORMERS*].

¹⁰ Michael J. Kohlman, *Evangelizing Eugenics: A Brief Historiography of Popular and Formal American Eugenics Education (1908–1948)*, 58 *ALTA. J. EDUC. RSCH.* 657, 658 (2013).

¹¹ As an economic historian of the era wrote:

Eugenics and race science are historically important, and during the Gilded Age and Progressive Era many people—most conspicuously the progressives—thought they were good ideas. The events of the intervening century, some of them horrific, have changed our view. Eugenics and race science are now bad ideas, indeed Bad Ideas, which is why twenty-first century geneticists, economists, sociologists, demographers, physicians, and public

various commentators have cited a reemergence of eugenic thinking in the governmental and public response to the COVID-19 pandemic, both in the handling of the “captive and vulnerable” and in public xenophobia resulting from its origins.¹²

But is examining the long history of eugenics in relation to the early development of FDA merely an academic exercise? What possible impact could such history have on FDA regulation and policy today? Surely the repeated amendments to the statutory schemes and many decades of regulatory developments and achievements have thoroughly cleansed FDA regulation of any trace of eugenic influences from that period?

First, it is a myth that eugenic programs and policies just precipitously declined after the Progressive Era until wholly abandoned after World War II. While over time eugenics ultimately lost much of its former funding and legitimacy in mainstream science, the pursuit of deeply racist eugenic studies, goals, and practices continued for decades and had a long and enduring impact on society, public health, and medical practice.¹³ Moreover, the eugenicists’ reification of notions of racial purity, ranking, and superiority as “science” directly coincided with the birth and development of the

health officials remain reluctant to look too closely at their respective disciplines’ formative-years enthusiasm for now discredited notions. The very word “eugenics” remain radioactive, and the temptation to dismiss eugenics and race science as inconsequential pseudosciences is ever present.

LEONARD, ILLIBERAL REFORMERS, *supra* note 9, at 189–90.

¹² Laura Appleman, *Hiding in Plain Sight: Public Health, Eugenics, and COVID-19*, 30 HPHR J., 2021, at 2; *see also id.* at 1 (citing the “long tail” of eugenics in the way “we institutionalize, detain, and sequester in long-term care and group homes”); Christina McCarroll, *Plague of Ages: How Xenophobia Links Two Epidemics, a Century Apart*, JUST HUMAN (Apr. 15, 2021, 4:49 PM), <https://www.justhumanproductions.org/articles/plague-of-ages-how-xenophobia-links-two-epidemics-a-century-apart/>. There has also been considerable controversy over efforts to distribute COVID-19 treatments in a manner that attempts to address disparities in treatment of Black Americans and other populations resulting from eugenics and other historical racist beliefs and practices. *See* J. Corey Williams, Nientara Anderson, Myra Mathis, Ezelle Sanford 3rd, Jeffrey Eugene & Jessica Isom, *Colorblind Algorithms: Racism in the Era of COVID-19*, 112 J. NAT’L MED. ASS’N 550, 550–52 (2020) (critiquing “color-blind” algorithms as resulting in a racially inequitable resource distribution in the current COVID-19 crisis); *see also* Walter Olson, *Race-Based Allocation of COVID Therapies Is a Problem*, THE DISPATCH (Jan. 25, 2022), <https://thedispatch.com/p/race-based-allocation-of-covid-therapies?s=r> (discussing governments around the country “directing medical providers to allocate potentially lifesaving COVID therapies among patients on the basis of race, a policy that is almost certainly unconstitutional as well as morally questionable”).

¹³ *See* Susan Currell, *Introduction*, in POPULAR EUGENICS: NATIONAL EFFICIENCY AND AMERICAN MASS CULTURE IN THE 1930S 2 (Susan Currell & Christina Cogdell eds., 2006) (“Sterilization rates climbed throughout the 1930s and reached record numbers, even though eugenic beliefs were supposedly on the wane.”) [hereinafter POPULAR EUGENICS]. The impact of eugenic ideas was enduring. As Professor Lewis Grossman recently wrote:

Fear of a eugenic turn is one of the chief reasons (along with religiosity) that African Americans are dramatically less likely than whites to support PAS [patient-assisted suicide] legalization. In light of the infamous “Tuskegee Study of Untreated Syphilis in the Negro Male” from the 1930s to the 1970s and of the systematic undertreatment of black patients today, many African Americans understandably fear that PAS will be employed in a discriminatory manner.

LEWIS A. GROSSMAN, CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICA 307–08 (Oxford Univ. Press, 2021). However, the Tuskegee Study is just one of many historical incidents that have fostered a distrust of medical practices among Black Americans. *See* Vanessa Northington Gamble, *Under the Shadow of Tuskegee: African Americans and Health Care*, 87 AM. J. PUB. HEALTH 1773 (1997) (advocating an examination of the study “within a broader historical and social context”).

powers and autonomy of our science-based food, drug, and public health regulatory institutions and laws.¹⁴

Second, as addressed herein, the echoes of “race science”—including eugenicists’ spurious concepts of the meaning and scientific measurement of race—are increasingly being found embedded in medical practices, specifications, and data. If remnants of eugenics and its deeply flawed anthropometric pursuits have been incorporated into clinical measures utilizing FDA-regulated products, perhaps a more systematic approach would find other continued traces of eugenic influence on FDA regulation today.

Finally, and perhaps of greatest consequence, various factors could magnify such concerns in the future. Some now seek to revive certain “useful” eugenic concepts, and even advocate for a “new” public health eugenics that would be sanitized of racism and ableism.¹⁵ Rapid advances in technology now permit unprecedented control over the human genome and heredity.¹⁶ We are also witnessing the increasing deployment of artificial intelligence-based tools incorporating clinical guidelines, assumptions, and real-world data that reflect current medical practice, including, in certain cases, embedded historical assumptions and biases.¹⁷ While genetic therapies and digital health clearly offer huge promise in improving health outcomes and reducing disparities—and they are subject to governmental oversight in critical respects—the adoption of new technologies obviously takes place in the context of our societal biases and ideologies. Thus, by examining the potential historical influence of eugenics on our current laws, regulatory science, and policies, perhaps we can reduce the risk of replicating the mistakes of the past.

This Article is intended to be a contribution to that effort. I begin by describing the development of eugenics, its adoption as a core belief and driver of public policy in the Progressive Era, and its influence over many decades. I then examine the specific eugenic statements and actions of Theodore Roosevelt, Harvey Wiley, Royal Copeland, and other important figures in early FDA history, as well as the deep entanglement of early U.S. public health leaders and institutions in eugenics and its practices.¹⁸ Finally, I examine the ways in which that seemingly remote history could

¹⁴ See CARPENTER, *supra* note 2, at 212; LEONARD, ILLIBERAL REFORMERS, *supra* note 9, at 46 (describing the rise of federal regulatory power in the Progressive Era).

¹⁵ See *infra* notes 269–73.

¹⁶ See generally NAT’L ACAD. OF MED., NAT’L ACAD. OF SCIS. & THE ROYAL SOCIETY, HERITABLE HUMAN GENOME EDITING (Nat’l Acads. Press, 2020).

¹⁷ See *infra* note 268; see generally Amit Kaushal, Russ Altman & Curt Langlotz, *Health Care AI Systems Are Biased*, SCI. AM., Nov. 17, 2020; LaPrincess C. Brewer, Karen L. Fortuna, Clarence Jones, Robert Walker, Sharonne N. Hayes, Christi A. Patten & Lisa A. Cooper, *Back to the Future: Achieving Health Equity Through Health Informatics and Digital Health*, 8 JMIR MHEALTH & UHEALTH 5 (2020); Cynthia J. Sieck, Amy Sheon, Jessica S. Ancker, Jill Castek, Bill Callahan & Angela Siefer, *Digital Inclusion as a Social Determinant of Health*, NPJ DIGIT. MED., Mar. 17, 2021.

¹⁸ Many fields are grappling with the notion of the “cancellation” of historical or formative figures, many of whom made fundamental and enduring contributions. See, e.g., Adam Rutherford, *Race, Eugenics, and the Canceling of Great Scientists*, 175 AM. J. PHYSICAL ANTHROPOLOGY 448 (2020) (noting that “[s]cience and scientists are not exempt from” the “so called ‘canceling’ of historical figures”). Readers can make their own judgments about historical figures based on their own words and actions in this Article and other sources. My objective is merely a candid and factual examination of eugenic thinking by founding figures in FDA and public health history, and an exploration of how their beliefs and practices at the time could continue to impact regulation today and in the future, while suggesting areas for further legal and historical study.

continue to impact FDA-regulated products and regulation today, and subtly shape policy in the future.

II. EUGENICS, RACE, AND PURITY

Although often portrayed as a bygone “pseudoscience” that has little relevance today, the actual history and impact of eugenics is much more complex, primarily because it evolved and persisted over time, became a deeply embedded ideology via pervasive dissemination in educational institutions and the media, and had various strands that influenced society in numerous ways.¹⁹ Thus, I begin by providing an overview of the vast and convoluted history of eugenics, with a particular emphasis on aspects of that history that are pertinent to the early development of FDA.

From a legal perspective, eugenics is typically associated with involuntary sterilization and the notorious 1927 Supreme Court decision in *Buck v. Bell*.²⁰ In that opinion, Justice Oliver Wendell Holmes—joined by Justices Louis Brandeis and William Howard Taft—ruled that a Virginia statute met due process standards in allowing involuntary sterilization of the so-called “unfit” (specifically, Carrie Buck, an eighteen-year-old patient at the “Virginia State Colony for Epileptics and Feeble-minded”) to ensure the “welfare of society.”²¹ Holmes declared that “[i]t is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind” and infamously concluded that “[t]hree generations of imbeciles are enough.”²² The *Buck* decision was a landmark in the eugenics movement, and eugenicists “rejoiced.”²³ Virginia soon sterilized Carrie Buck, and by the mid-1930s “some twenty thousand sterilizations had been legally performed in the United States.”²⁴

However, eugenics went well beyond involuntary sterilization laws and campaigns and was a potent and wide-ranging cultural and ideological force, driving concepts of

¹⁹ There is extensive evidence that the Nazis in fact learned from U.S. eugenics in framing their racial policies and planning the death of Jews and others in the Holocaust. PAUL, *supra* note 8, at 86 (“The Nazis regularly quoted American geneticists who expressed support for their sterilization policies” and “invoked the large-scale California experience with sterilization.”); see generally BLACK, *supra* note 5; Dirk Moses & Dan Stone, *Eugenics and Genocide*, in THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 192. The learning flowed both ways: in the late 1930s, a Nazi exhibition on “Eugenics in New Germany” sponsored by the American Public Health Association toured the United States. Robert Rydell, Christina Cogdell & Mark Largent, *The Nazi Eugenics Exhibit in the United States, 1934–43*, in POPULAR EUGENICS, *supra* note 13 at 359.

²⁰ *Buck v. Bell*, 274 U.S. 200 (1927). While seen as pejorative and offensive today, at the time the notion of “unfitness” “did not necessarily indicate intentional conscious hostility” because it was based on various factors, including intelligence testing and a “technical, medical diagnos[is].” Martin S. Pernick, *Eugenics and Public Health in American History*, 87 AM. J. PUB. HEALTH 1767 n.1 (1997) [hereinafter Pernick, *Eugenics and Public Health*].

²¹ *Buck*, 274 U.S. at 205–08.

²² *Id.* at 207. Although now obsolete as a medical term, at the time—and for many decades after *Buck v. Bell*—the term “imbecile” indicated moderate to severe intellectual disability, including people with an IQ of 35–49, falling between “idiot” (IQ of 0–20) and “moron” (IQ of 50–70). WORLD HEALTH ORG., MANUAL OF THE INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES, INJURIES, AND CAUSES OF DEATH 212–13 (1977).

²³ KEVLES, *supra* note 3, at 111.

²⁴ *Id.* at 112.

racial and societal “purity” and “hygiene” throughout the Progressive Era and well beyond.²⁵ Many aspects of eugenics incorporated older racist constructs and practices, reframed as scientific thinking based on Mendelian principles that they believed demonstrated that genetics, rather than the environment, controls all.²⁶ But eugenicists’ uses of the term “race” were often cryptic—at times meaning the human race, and at other times referring to a “superior” Anglo-Saxon race or to what they believed were “dysgenic” races that could be characterized as an “internal or external threat.”²⁷ However the term was used, the eugenicists’ conceptions of race—like most historical “scientific” theories about race—were largely based on pigmentation, erroneous measurements of various types, or self-reporting of a racial category with little genetic meaning.²⁸ Yet, despite this fatally flawed foundation, eugenic beliefs about race and purity shaped numerous aspects of our nation, while over many decades doing profound and sustained damage to those that the eugenicists tended to deem less desirable or “unfit,” such as Black Americans, the disabled, and immigrants.

The name and concept of eugenics originated with Francis Galton (1822–1911), a British statistician who focused on human heredity. Galton, a cousin of Charles Darwin, “proposed that humans take charge of their own evolution” and defined the term “eugenics” (Greek for “good in birth”) variously as “‘the study of agencies under social control which may improve or impair the racial qualities of future generations’ and ‘the science which deals with all influences that improve the inborn qualities of a race; also with those that develop them to the utmost advantage.’”²⁹ Galton believed that different races had genetically distinctive features and characters that could be ranked (with those of Anglo-Saxon ancestry at the apex), and that the randomness of natural selection could be replaced with efforts to influence heredity on a population basis.³⁰

Eugenicists like Galton were not merely theoreticians: they proselytized and aimed to put their theories into practice.³¹ And eugenics found particularly fertile ground in the United States. For whites in the early 1900s United States concerned about the

²⁵ See REES, *supra* note 2, at 59 (“the racism inherent in any quest for ‘purity’ in this era is worth noting”).

²⁶ C. Kurbegovic, *Gregor Mendel publishes his paper, “Versuche über Pflanzenhybriden,”* Eugenics Archive (Sept. 14, 2013), <https://eugenicsarchive.ca/discover/tree/5233a7b05c2ec5000000005c>. In the mid-1800s, Gregor Mendel’s research in hybridization of peas demonstrated that traits may be dominant or recessive and will produce various characteristics in plants, indicating that “genes” determined heredity. Eugenicists interpreted Mendel’s work as dictating that environment had no impact on heredity, and human fate was solely determined by genetics. For eugenicists rediscovering Mendel’s research, this suggested policies of sterilization and euthanasia rather than attempting to improve the lot of those they deemed “degenerates.”

²⁷ PAUL, *supra* note 8, at 106.

²⁸ Rutherford, *supra* note 18, at 448 (“[T]he legacy of the invention of race (primarily based upon pigmentation . . .) from the 18th Century onwards is present with us today, in the language that we use to describe populations, and in the stereotypes associated with the folk taxonomies of race. This is despite the fact that genetics has clearly and repeatedly demonstrated that racialized groups do not make biologically meaningful categories, and that racial purity is a myth.”) (citations omitted).

²⁹ PAUL, *supra* note 8, at 3 (citations omitted).

³⁰ See ROBERTS, *supra* note 4, at 61.

³¹ Galton’s ideas rapidly gained ground, and “in less than two decades, the word he invented to describe this new field of study had spread, with his ideas, around the globe.” Paul A. Lombardo, *The Power of Heredity and the Relevance of Eugenic History*, 20 GENETICS MED. 1305 (2018) [hereinafter Lombardo, *The Power of Heredity*].

“degeneration” of their own race and historical power relative to immigrants and Black Americans, eugenics allayed such anxieties by creating a framework for “race improvement” or “betterment.”³² Americans at the time—including prominent elected leaders—often spoke with alarm at the possibility of “old stock” Anglo-Saxon ancestry Americans’ lower birth rates presenting a risk of being eclipsed by Black Americans and immigrants.³³ As Professor Dorothy Roberts wrote:

White Americans had for over two centuries developed an understanding of the races as biologically distinct groups, marked by inherited attributes of inferiority and superiority. Scientific racism predisposed Americans to accept the theory that social characteristics were heritable and deviant behavior was biologically determined.³⁴

Thus, eugenics provided a “scientific” basis for racism, and existing racism fertilized its expansion: the two beliefs were often intertwined and mutually supporting.

A particularly important proselytizer of eugenics in the United States was the then-respected geneticist Charles Davenport [1866–1924], who historians have referred to as “America’s leading eugenicist” and its “scientific pope.”³⁵ Secretary of the Eugenics Research Association, Davenport “was obsessed with the biological threat of blacks and immigrants.”³⁶ With funding from Harrimans, Carnegies, and Rockefellers, he established the Eugenic Records Office, a private research institute which operated from 1918 to 1939 in Cold Spring Harbor in New York, conducting eugenic research including anthropometric assessments of World War I recruits and “race crossing” in Jamaica.³⁷ The Eugenic Records Office “supplied the burgeoning American eugenics movement with adherents and research” by conducting training on eugenic methods, sending trainees out to do so-called “field studies,” and assembling

³² See PAUL, *supra* note 8, at 6 (the new “science” of eugenics was buoyed by a “specter of evolutionary degeneration” that “haunted middle-class Victorians”); see also KLINE, *supra* note 8, at 159; THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 63 (“The idea of race played a seminal and decisive role in the ideological growth of eugenics during the late nineteenth and first half of the twentieth centuries . . . [E]ugenics was in many ways a form of ‘biological determinism’ presupposing that ‘shared behavioral norms and the social and economic differences between human groups—primarily races, classes, and sexes—arise from inherited, inborn distinctions and that society, in this sense, is an accurate reflection of biology.’”).

³³ See ROBERTS, *supra* note 4, at 61.

³⁴ ROBERTS, *supra* note 4, at 61.

³⁵ KEVLES, *supra* note 3, at 44; WILLIAM H. TUCKER, THE FUNDING OF SCIENTIFIC RACISM: WICKLIFFE DRAPER AND THE PIONEER FUND 24 (Univ. of Ill. Press, 2002).

³⁶ TUCKER, *supra* note 35, at 24.

³⁷ Paul A. Lombardo, *Anthropometry, Race, and Eugenic Research: “Measurements of Growing Negro Children” at the Tuskegee Institute, 1932–1944*, in THE USES OF HUMANS IN EXPERIMENT: PERSPECTIVES FROM THE 17TH TO 20TH CENTURY 225 (Brian Dolan et al. eds., 2016) [hereinafter Lombardo, *Anthropometry, Race, and Eugenic Research*]; KEVLES, *supra*, note 3, at 75. Such work built on earlier eugenic studies, such as those of Frederic Hoffman, an insurance industry statistician whose influential 1896 compendium of data published by the American Economic Association, *Race Traits and Tendencies of the American Negro*, concluded that Black Americans had “inferior” constitutions. THE NATURE OF DIFFERENCE, *supra* note 8, at 107. He concluded that “the time will come, if it has not already come, when the negro, like the Indian, will be a vanishing race.” *Id.* at 107.

them for a conference every year to update them on the latest research findings and techniques.³⁸

Davenport's studies were also funded by Wyckliffe Draper's Pioneer Fund, which was founded to promote "the genetic stock of those 'deemed to be descended predominantly from white persons who settled in the original thirteen states prior to the adoption of the Constitution'" and which supported various eugenic and white supremacist causes, including the preservation of Jim Crow laws in the South.³⁹ At the time of his death in 1972, "Draper's money had become the most important and perhaps the world's only funding source for scientists who still believed that white racial purity was essential for social progress."⁴⁰

Davenport's primary research focused on what he considered the "main problem"—"the relative capacity of negroes, mulattoes, and whites to carry on a white man's civilization."⁴¹ From 1932 until 1944, Davenport and his colleague Morris Steggerda conducted annual anthropometric measurements of students at the Tuskegee Institute as part of a "long-term experimental program of comparative racial research designed to provide data to support the conclusion that the 'races' are separated by hereditary differences."⁴² However, even when the numerous measurements produced data that did not support his eugenic theories of Black inferiority and the dangers of miscegenation, Davenport nonetheless rationalized the findings to support eugenic objectives.⁴³

Such efforts were highly effective. In the initial decades of the 20th Century, eugenics gained rapid acceptance in the United States and "was simply considered applied genetics."⁴⁴ Articles on eugenics "appeared regularly in medical journals like *JAMA* or the *New England Journal of Medicine*, and were also constant fare in state

³⁸ ROBERTS, *supra* note 4, at 62; KEVLES, *supra* note 3, at 55.

³⁹ *Pioneer Fund*, S. POVERTY L. CTR., <https://www.splcenter.org/fighting-hate/extremist-files/group/pioneer-fund> (last visited Aug. 3, 2022); TUCKER, *supra* note 35; see generally Michael G. Kenny, *Toward a Racial Abyss: Eugenics, Wickliffe Draper, and the Origins of the Pioneer Fund*, 38 J. HIST. BEHAV. SCIS. 259 (2002).

⁴⁰ TUCKER, *supra* note 35, at 23.

⁴¹ KEVLES, *supra* note 3, at 75.

⁴² Lombardo, *Anthropometry, Race, and Eugenic Research*, *supra* note 37, at 215. Beginning in the same year as the Tuskegee Syphilis Study, Steggerda, who "shared many of the attitudes of Davenport about the need for racial separation" would conduct hundreds of anthropometric measures, grouping subjects in "an attempt to create a standard that would . . . typify 'the Negro.'" Paul A. Lombardo, *Excerpt: The Banality of Eugenics*, UNDAK (Apr. 4, 2016), <http://undark.org/article/the-banality-of-eugenics-tuskegee/>.

⁴³ TUCKER, *supra*, note 35, at 31–32. While from the distance of 2022 it may seem strange that Davenport had the cooperation of prominent figures such as Booker T. Washington and other Black academics in his anthropometric pursuits, that is far from a refutation that the core eugenic agenda was fundamentally racist. Rather, it further indicates the extensive reach and power of eugenic thought in that era: Davenport was then a "respected scientist" and leading researcher supported by major philanthropies and academic bodies, and "there was nothing inherently suspect about anthropometry" at the time—it was accepted for many decades as a legitimate area of scientific inquiry. Lombardo, *Anthropometry, Race, and Eugenic Research*, *supra* note 37, at 232–33. In fact, prominent Black Americans such as W.E.B. Dubois also conducted anthropometric studies to "counter claims of Black inferiority." See Gregory Michael Dorr & Angela Logan, "Quality, Not Mere Quantity, Counts": *Black Eugenics and the NAACP Baby Contests*, in *A CENTURY OF EUGENICS*, *supra* note 8, at 68; see also SHANTELLA Y. SHERMAN, *IN SEARCH OF PURITY: POPULAR EUGENICS & RACIAL UPLIFT AMONG NEW NEGROES 1915–1935* 2 (2012).

⁴⁴ PAUL, *supra* note 8, at 4.

and regional medical journals.”⁴⁵ Various mainstream foundations continued to subsidize the development of eugenic institutions and scientific projects well into late 1930s.⁴⁶ The Race Betterment Foundation, and many other organizations, formed to permit the exchange of eugenic ideas and results.⁴⁷

An important eugenics popularizer in the United States was Paul Popenoe, the editor of the *Journal of Heredity*. Popenoe believed Black Americans were racially inferior and “germinally lacking in the higher developments of intelligence” and advocated for the “sterilization and segregation of ‘waste humanity.’”⁴⁸ In the 1930s, Popenoe went on to praise Nazi Germany’s sterilization laws, attributing them to the “best specialists in Germany,” and he eventually “began writing advice columns for Ladies’ Home Journal.”⁴⁹

Not all eugenicists focused on the most extreme measures. Eugenics was marked by “ideological diversity and fluidity” and many supporters chose aspects of the ideology to emphasize.⁵⁰ It was also “common to reject one aspect of eugenics while endorsing others.”⁵¹ As reflected in *Buck v. Bell*, however, a central feature of “negative” eugenics was the pursuit of sterilization of the so-called “unfit.” Indiana was the pioneer in this area, and numerous states began enacting eugenic sterilization laws, in some cases incorporating sweeping powers to sterilize criminals and those with various medical conditions or disabilities.⁵² By 1935, a majority of states had enacted such sterilization laws.⁵³

This sterilization focus of eugenicists—which persisted many years after the supposed end of eugenic thinking in the United States—was in no way separate from many eugenic racial beliefs. Indeed, there is significant evidence that state eugenic sterilization programs “specifically targeted black Americans.”⁵⁴ In the south, numerous Black women, including civil rights leader Fannie Lou Hamer, were victims

⁴⁵ Lombardo, *The Power of Heredity*, *supra* note 31, at 1308.

⁴⁶ KEVLES, *supra* note 3, at 55.

⁴⁷ PAUL, *supra* note 8, at 10; *see generally* BRIAN C. WILSON, DR. JOHN HARVEY KELLOGG AND THE RELIGION OF BIOLOGIC LIVING (Indiana Univ. Press, 2014).

⁴⁸ Jonathan Burdick, *A Horrifying Experiment*, ERIE READER (Oct. 13, 2021), <https://www.erie reader.com/article/a-horrifying-experiment>.

⁴⁹ *Id.*

⁵⁰ MARTIN S. PERNICK, THE BLACK STORK: EUGENICS AND THE DEATH OF “DEFECTIVE” BABIES IN AMERICAN MEDICINE AND MOTION PICTURES SINCE 1915 15 (Oxford Univ. Press, 1995) [hereinafter PERNICK, THE BLACK STORK].

⁵¹ *Id.* at 14.

⁵² KEVLES, *supra* note 3, at 100.

⁵³ Lisa Ko, *Unwanted Sterilizations and Eugenics Programs in the United States*, PBS (Jan. 29, 2016), <https://www.pbs.org/independentlens/blog/unwanted-sterilization-and-eugenics-programs-in-the-united-states/>.

⁵⁴ Gregory N. Price, William Darity Jr. & Rhonda V. Sharpe, *Did North Carolina Economically Breed-Out Blacks During its Historical Eugenic Sterilization Campaign?* AM. REV. POL. ECON., June 6, 2020 at 1 (finding in a study of sterilizations in the state of North Carolina during the period 1958–1968 that, “eugenic sterilization was apparently tailored to asymptotically breeding-out the offspring of a presumably genetically and undesirable surplus black population. This suggests that the presumption of genetic inferiority was unique to, and a burden born by blacks, as only their sterilizations in North Carolina were a function of their surplus population shares.”).

of “Mississippi appendectomies”—forced sterilization without consent, legal process, or at times even foreknowledge of the procedure.⁵⁵

And sterilization was just one aspect of eugenics. In this period, “it came to be a hallmark of good reform government to shape public policy with the aid of scientific experts,” and eugenics was considered quite “scientific.”⁵⁶ Thus, eugenics “sanctioned racist domestic policies including segregation and anti-miscegenation laws and efforts to restrict immigration.”⁵⁷ The legal impact was profound:

Laws prohibiting interracial marriage, a vestige of the colonial era, were revised to include a new, scientific gloss with biological definitions of “race” during the eugenics era. The entire US system of legally mandated racial segregation was bolstered by eugenic thinking. The 1924 federal law restricting immigration to the United States by means of an ethnic/national quota system was also designed by leaders in eugenics to prevent the “pollution” of American bloodlines.⁵⁸

In essence, eugenics “provided a vocabulary for casting ancient prejudices in a scientific voice, thereby sanitizing bigotry.”⁵⁹ And in medicine, it “bolstered a medical tradition in which the maladies of Black patients were linked to racial differences.”⁶⁰

Obviously, racism and white supremacy were far from the unique beliefs of eugenicists—scientific justifications for slavery and racism existed well before Galton, and “[t]reating other races as ‘germs’ was at least as common as labeling them genetic defectives.”⁶¹ Moreover, there was dissent against eugenic thinking: the Catholic Church objected to eugenic sterilization, and some philosophers and anthropologists refuted aspects of eugenics.⁶² Upton Sinclair, whose *The Jungle* is credited with galvanizing public and political support for the enactment of the Pure Food and Drug Act of 1906, mocked eugenics in his book *Arrowsmith* (but he

⁵⁵ Jessica Pearce, *Mississippi Appendectomies: Reliving Our Pro-Eugenic Past*, Ms. (Oct. 28, 2020), <https://msmagazine.com/2020/10/28/ice-immigration-mississippi-appendectomies-usa-eugenics-forced-coerced-sterilization/>; SHERMAN, *supra* note 43, at 112–13; Rosalind Early, *The Sweat and Blood of Fannie Lou Hamer*, 42 HUMANITIES, No. 1, 2021 at 2. Southern states were mixed on eugenics. Some, such as Virginia, embraced eugenics—the “philosophy’s racist and sexist underpinnings complemented a social hierarchy that they felt should be preserved, but the fact that eugenics would allow their efforts to be viewed as modern and scientific, in line with the march of time and progress, was a tremendous asset.” ELIZABETH CATTE, *PURE AMERICA: EUGENICS AND THE MAKING OF MODERN VIRGINIA* 35 (Belt Publishing, 2021). However, other states in the Deep South were slower or less systematic in implementing eugenic policies for religious or other reasons, while promoting segregation and supremacy. *See generally* EDWARD J. LARSON, *SEX, RACE, AND SCIENCE: EUGENICS IN THE DEEP SOUTH* (Johns Hopkins Univ. Press, 1995); POPULAR EUGENICS, *supra* note 13, at 124–27 (noting that the potential challenge to white supremacy played a role in the “traditional Southerner’s fear of eugenics: could Southern poor whites be inferior to African Americans?”).

⁵⁶ KEVLES, *supra* note 3, at 100–01.

⁵⁷ PAUL, *supra* note 8, at 107, 112; Paul A. Lombardo, *Miscegenation, Eugenics, and Racism: Historical Footnotes to Loving v. Virginia*, 21 U.C. DAVIS L. REV. 421, 423 (1988).

⁵⁸ Lombardo & Dorr, *supra* note 9, at 316.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ PERNICK, *THE BLACK STORK*, *supra* note 50, at 58–59.

⁶² PAUL, *supra* note 8, at 17.

nonetheless at times voiced support for eugenics).⁶³ Even some religious white supremacists rejected eugenics as “unscriptural.”⁶⁴

Eugenics was by no means confined to legal proceedings or scientific and medical institutions—it became a regular topic in popular culture and education. “By 1910, eugenics was one of the most frequently referenced topics in the Reader’s Guide to Periodical Literature,” and it “was endorsed in over 90 percent of high school biology textbooks.”⁶⁵ Prominent authors such as H.G. Wells, George Bernard Shaw, Virginia Woolf, T. S. Eliot, and W. B. Yeats were supporters of eugenics.⁶⁶ As one scholar wrote, Progressive Era eugenics was “the broadest of churches” and “appealed to an extraordinary range of political ideologies, not just progressives”⁶⁷

Despite its focus on race and genes over environment, eugenics was seen as having a particularly important connection to hygiene, diet, and public health. In the eugenic mindset, “[c]leanliness often referred to as much having a pure hereditary lineage and unblemished moral record as it did keeping one’s body and home free from dirt.”⁶⁸ Hygiene indicated “high evolutionary status, for by avoiding disease the health-conscious individual increased personal and national productivity, fitness, and superiority.”⁶⁹ Eugenicians also had a preoccupation with efficiency and “flow” through the digestive system as well as optimizing the human body.⁷⁰ A regular feature of eugenic displays at state fairs and national expositions were displays on hygiene and the ideal (and invariably white) human body.⁷¹ This was part of a broader “exhibitionary culture” at the time that utilized such events to reach “the multitudes with their messages of better healthcare for mothers and infants, immigration reform, and sterilization of the socially and racially unfit.”⁷² Advertisements presented the streamlined “eugenic ideal,” showing products in which eugenics ideas had a direct relationship to product design, from cars to kitchens to buildings to dinnerware.⁷³ The

⁶³ STERN, *supra* note 4, at 210.

⁶⁴ PERNICK, THE BLACK STORK, *supra* note 50, at 58.

⁶⁵ PAUL, *supra* note 8, at 10–11.

⁶⁶ See DONALD J. CHILDS, MODERNISM AND EUGENICS: WOOLF, ELIOT, YEATS, AND THE CULTURE OF DEGENERATION (Cambridge Univ. Press, 2001); Thomas C. Leonard, *Mistaking Eugenics for Social Darwinism: Why Eugenics is Missing from the History of American Economics*, 37 HIST. POL. ECON. 200, 203–05 (2005) [hereinafter Leonard, *Mistaking Eugenics for Social Darwinism*].

⁶⁷ Thomas C. Leonard, *Retrospectives: Eugenics and Economics in the Progressive Era*, 19 J. ECON. PERSP. 207, 216 (2005) [hereinafter Leonard, *Retrospectives*].

⁶⁸ CHRISTINA COGDELL, EUGENIC DESIGN: STREAMLINING AMERICA IN THE 1930S 157 (Univ. of Penn. Press, 2004) [hereinafter COGDELL, EUGENIC DESIGN].

⁶⁹ *Id.* at 158.

⁷⁰ *Id.* at 134–35, 82–83.

⁷¹ *Id.* at 122; see generally Mary K. Coffey, *The American Adonis: A Natural History of the “Average American” (Man), 1921–32*, in POPULAR EUGENICS, *supra* note 13, at 185–216.

⁷² POPULAR EUGENICS, *supra* note 13, at 361, 363.

⁷³ *Id.* at 178. “Hygiene concerns shaped fashion, raising women’s hemlines and shaving away men’s beards, while profoundly transforming architecture and interior design with the sleek, cleanable forms of art deco replacing drape-heavy nooks and crannies of Victorian design.” Aaron Bobrow-Strain, *White Bread Bio-Politics: Purity, Health, and the Triumph of Industrial Baking*, 15 CULTURAL GEOGRAPHIES 19, 24 (2008).

objective was achieving an “earthly utopia”—“a seamless society made of perfected people and products.”⁷⁴

III. THE PROGRESSIVE ERA AND THE ORIGINS OF FDA

The initial statutory frameworks providing FDA’s authorities and roles were created in the Progressive Era, generally regarded as spanning the period from the mid-1890s until about 1920.⁷⁵ Thus, in the same period in which eugenics was gaining scientific and popular acceptance in the United States, FDA—an agency focused on purity and hygiene that has had perhaps the most intimate impact on American lives and bodies—was created and became a model for the national exercise of science-based regulatory powers.⁷⁶ Eugenics was a “perfect fit” for the Progressive Era reformers, who “were first and foremost confident problem solvers, people who identified social problems and set about systematically trying to solve them”—and they brought an intense focus on efficiency, purity, and hygiene in that effort.⁷⁷

Indeed, one of the most important areas of the Progressives’ success was in the regulatory sphere, where they focused on dismantling the long history of *laissez-faire* economic and social policy and “remaking American economic life with a newly created instrument of reform, the administrative state.”⁷⁸ Although it can be difficult to appreciate the radical nature of these changes today, Progressives fundamentally transformed the government, expanding and assigning regulatory power to agencies supported by science.⁷⁹

But many Progressive Era reformers sought “social control” that went beyond regulation of markets and extended to race.⁸⁰ They were advised to “discard the sentimental, religious equalitarianism of the old abolitionists and base their ideas of reform on hard science.”⁸¹ This thinking also permeated medical education, with physicians being taught that “equality must not be allowed to cloud racial thinking.”⁸²

⁷⁴ COGDELL, *EUGENIC DESIGN*, *supra* note 68, at 188–89.

⁷⁵ For background on the Progressive Era, see generally JOHN WHITECLAY CHAMBERS, *THE TYRANNY OF CHANGE, AMERICA IN THE PROGRESSIVE ERA* (Rutgers Univ. Press 3d ed., 2006) (2000); MICHAEL MCGERR, *A FIERCE DISCONTENT: THE RISE AND FALL OF THE PROGRESSIVE MOVEMENT IN AMERICA 1870–1920* (Oxford Univ. Press, 2005). Readers should clearly distinguish the Progressive Era and reformers of the early 1900s United States from other “progressive” movements that currently exist.

⁷⁶ The need to address public health concerns “led to a new conception of government, of which the [USDA’s] Bureau of Chemistry was a model: a group of professionally qualified civil servants continuously monitoring and intervening in an economic sector to protect people dependent on that sector.” FDLI, *A CENTURY OF CONSUMER PROTECTION*, *supra* note 2, at 68; *see also* HILTS, *supra* note 2, at xii.

⁷⁷ HELEN ZOE VEIT, *MODERN FOOD, MORAL FOOD: SELF-CONTROL, SCIENCE, AND THE RISE OF MODERN AMERICAN EATING IN THE EARLY TWENTIETH CENTURY* 3 (Univ. of N.C. Press, 2013); DAVID W. SOUTHERN, *THE PROGRESSIVE ERA AND RACE: REACTION AND REFORM 1900–1917* 45 (Harlan Davidson, Inc., 2005); *see also* KLINE, *supra* note 8, at 13.

⁷⁸ LEONARD, *ILLIBERAL REFORMERS*, *supra* note 9, at ix. Progressives focused on regulation “in a broader, sociological sense . . . which, in the context of eugenics, meant a ‘program for survival’ of the Anglo-Saxon race.” Leonard, *Retrospectives*, *supra* note 67, at 218.

⁷⁹ *See* SOUTHERN, *supra* note 74, at 44; LEONARD, *ILLIBERAL REFORMERS*, *supra* note 9, at 46.

⁸⁰ Leonard, *Mistaking Eugenics for Social Darwinism*, *supra*, note 66, at 46.

⁸¹ SOUTHERN, *supra* note 77, at 48.

⁸² *Id.* at 50. While “obsessed with race,” Progressives also used the term race with “colossal imprecision.” SOUTHERN, *supra* note 77, at 2, 37. Often, the notion was extended well beyond Black Americans to include Southern and Eastern Europeans, and others who did not fit “a theory of Anglo-Saxon

Thus, despite their many achievements, many believe that Progressives were “illiberal reformers.”⁸³ In particular, while the reform-minded Progressives initially presented a “glimmer of hope” for Black Americans, ultimately, their reforms “almost always stopped short of the color line,” and Progressives generally “acquiesced in the consolidation of Jim Crow.”⁸⁴ Progressives viewed race as a “biological fact that had ultimate importance” and it was a “powerful, controlling element[] in progressive social and political thinking,” but their primary concern was the potential for “race suicide”—the notion that the Anglo-Saxon “nature” of the United States was in danger due to the “degeneration” of the American population and immigration.⁸⁵ This resulted in various initiatives aimed at “race betterment.”⁸⁶

The pursuit of pure food and drugs and eugenic “race betterment” went particularly well together because both Progressives and eugenicists believed that society is like a body requiring regulation: “an organic, evolved, singular entity—a social organism” that “subordinated its constituent individuals, and its health, welfare, and morals trumped the individual’s rights and liberties.”⁸⁷ Eugenicists frequently focused on dietary habits, and their objectives “often dovetailed with broad public health and hygiene practices.”⁸⁸ Thus, eugenics provided a background ideology that complemented and supported Progressive Era pure food and drug law goals, whether or not all such reformers declared their views and actions as driven or influenced by eugenic theories.⁸⁹ And eugenic beliefs also “drove adherence to those common goals,

superiority” that was widely held by Progressive reformers. *Id.* at 36. However, Progressives were also “highly diverse on the question of race, ranging from the explicit racism . . . to the more egalitarian views held by the mainly white founders of the NAACP in 1909, including Jane Addams, John Dewey, Oswald Garrison Villard, and also Afro-Americans W.E.B. DuBois, Booker T. Washington, and Ida B. Wells.” Herbert J. Hovenkamp, *The Progressives: Racism and Public Law*, 59 ARIZ. L. REV. 947, 950 (2017).

⁸³ See generally LEONARD, ILLIBERAL REFORMERS, *supra* note 9.

⁸⁴ SOUTHERN, *supra* note 77, at 1.

⁸⁵ *Id.* at 2–3.

⁸⁶ This is not to say that Progressives were the only group holding racist beliefs in this era, but it was their focus on creating the science-based “administrative state” that is of interest here, and the eugenic thinking of Progressives of the era who were highly successfully in framing that state, including FDA. “Conservatives and socialists also drank deeply from the seemingly bottomless American wells of racism, sexism and nativism, and they, too, borrowed evolutionary and eugenic ideas in support of their politics.” LEONARD, ILLIBERAL REFORMERS, *supra* note 9, at xiii.

⁸⁷ LEONARD, ILLIBERAL REFORMERS, *supra* note 9, at 191; see also VEIT, *supra* note 77, at 7. As a prominent historian of eugenics notes, for Progressives, eugenics:

provided a shorthand for talking about methods of social improvement, and suggested biologically based solutions to social problems—an efficient avenue for reform. In the United States, it was common to see people who called themselves *eugenicists* participating in campaigns to outlaw prostitution, eradicate sexually transmitted disease, prohibit alcohol, and give the vote to women. Others in the movement concentrated on cleaning up the milk supply or eradicating environmental toxins that poisoned mothers and their babies, elevating levels of infant morbidity and mortality.

Lombardo, *The Power of Heredity*, *supra* note 31, at 1307.

⁸⁸ VEIT, *supra* note 77, at 7.

⁸⁹ THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 8; see also E. MELANIE DUPUIS, DANGEROUS DIGESTION: THE POLITICS OF AMERICAN DIETARY ADVICE 79 (Univ. of Cal. Press, 2015) (“Germs, vitamins, and modern economics—all invisible to the naked eye—encouraged the view of a healthy society as one, interdependent body dependent on experts to ‘see’ good health. As a result, ‘reluctantly rather than enthusiastically, the average American tended more and more to rely on government regulation to seek in governmental action a counterpoise to the power of private business.’”).

including enactment of legislation” across coalitions that “were united in a belief that the biological expertise they commanded should determine the essential human issues of the new urban, industrial order.”⁹⁰

Some disagree with this assessment of the Progressives and cite what they perceive as an eventual waning of widespread support for eugenics during the Progressive Era.⁹¹ This perspective depicts eugenics as being in its “last gasp” at that time, and argues that “[t]he most notable thing about the Progressives is that they were responsible for bringing these views to an end, although that did not happen immediately.”⁹²

But even this argument ultimately falls back on the notion that the Progressives were merely as racist as many others at the time, and the perspective that eugenics waned is also hard to reconcile with the overall record.⁹³ Subsequent history undermines the notion that eugenics faded from relevance during the Progressive Era, and its precepts clearly persisted even across political lines.⁹⁴ For decades, broad support continued for sterilization laws.⁹⁵ Calvin Coolidge, noting that “there cannot be too many inhabitants of the right kind”—later signed historically restrictive immigration laws.⁹⁶ Harry Laughlin, the Superintendent of the Eugenic Records Office, was appointed the “Expert Eugenical Agent” of the Committee on Naturalization, testifying that “southern and eastern European immigrants were degenerate ‘stock’ that must be stopped at the gates”—his data supported national origins quotas that lasted from the 1920s into the 1960s.⁹⁷

IV. THE DECLINE OF EUGENICS

While throughout the 1930s eugenic experts “bombarded” the public with literature, eugenics eventually did begin to change and decline in various ways.⁹⁸ Some eugenicists—while remaining “committed to the primacy of heredity”—focused on “biotypology,” an approach which sought to classify humans scientifically as composite organisms as opposed to pure races.⁹⁹ Others pursued “reform” eugenics,

⁹⁰ See LEONARD, *ILLIBERAL REFORMERS*, *supra* note 9, at 190.

⁹¹ Hovenkamp, *supra* note 83, at 948 (noting that “while many Progressives advocated for more restrictive immigration laws, nothing that was passed during the Progressive Era matched the explicit restrictions on Chinese immigration that came earlier, or the racist immigration restrictions enacted during the terms of anti-Progressive Presidents Harding and Coolidge after the Progressive Era had ended”).

⁹² Hovenkamp, *supra* note 83, at 948.

⁹³ See *id.* at 949 (“The claim that many Progressives were racists is true. Some Progressives also held strongly exclusionary views about immigration and supported the sterilization of perceived mental defectives. However, Progressives inherited these views, and they were not appreciably different from those held by most of their non-Progressive predecessors and contemporaries.”).

⁹⁴ SOUTHERN, *supra* note 77, at 127; COGDELL, *EUGENIC DESIGN*, *supra*, note 68, at 229 (discussing the persistence of eugenics into the 1930s); KEVLES, *supra* note 3, at 97.

⁹⁵ Alexandra Stern, *Forced Sterilization Policies in the US Targeted Minorities and Those With Disabilities—and Lasted Into the 21st Century*, UNIV. OF MICH. INST. FOR HEALTHCARE POL’Y & INNOVATION (Sept. 23, 2020), <https://ihpi.umich.edu/news/forced-sterilization-policies-us-targeted-minorities-and-those-disabilities-and-lived-21st>.

⁹⁶ PAUL, *supra* note 8, at 97–98.

⁹⁷ STERN, *supra* note 4, at 208.

⁹⁸ POPULAR EUGENICS, *supra* note 13, at 92.

⁹⁹ See, e.g., Devon Stillwell, *Eugenics Visualized: The Exhibit of the Third International Congress of Eugenics, 1932*, 86 *BULL. HIST. MED.* 206–36 (2012).

which allowed for “greater latitude for psychological, hormonal and environmental factors”¹⁰⁰ The Eugenic Records Office closed, and the American Eugenics Society “began to chart a more moderate course,” backing away from ascribing “superiority to any social class or race as a whole” and denouncing the Nazis. Others attempted to transform eugenics into a notion of “genetic hygiene”: a “collection of policies designed to improve the genetic well-being of our species.”¹⁰¹ Eugenacists “increasingly turned their attention” away from sterilization and “toward the apparently neutral fields of birth control and human genetics.”¹⁰²

Ultimately, attempts to carve out a “good” version of eugenics failed, at least in name: “[p]ublic aversion to anything labeled eugenics (at least when called by that name) ultimately swamped the reform movement.”¹⁰³ The general consensus of eugenicists was that continued use of the term would “more hinder than help” in the adoption of measures previously rejected by eugenicists but now perceived as “eugenic advances,” such as birth control.¹⁰⁴ Philanthropic dollars were shifted to other pursuits, and the Carnegie Institution shuttered the Eugenics Record Office in 1939.¹⁰⁵ Eventually, scientists in the 1940s and 1950s left or steered clear of eugenic research programs, with even the President of the American Eugenics Society conceding that “differences between individuals far outweighed ‘any differences which might be discovered between the averages of the larger racial or social groups.’”¹⁰⁶ For others, however, a better understanding of genetics was seen as enabling “a firmer scientific foundation” for achieving “the social direction of human biological evolution.”¹⁰⁷ But, as one scholar of the era wrote, while “American eugenics declined under the weight of its political, demographic and scientific liabilities, the eugenic dream did not.”¹⁰⁸

In fact, despite this public decline of eugenics, negative eugenic measures persisted, including marriage restrictions, immigration quotas, and forced sterilizations.¹⁰⁹ It was only in the 1960s that eugenics came under “sustained popular assault.”¹¹⁰ Eugenic laws were increasingly repealed or held unconstitutional. The Indiana state-sponsored eugenic sterilization law was repealed in 1974, and a public apology was issued by the state in 2007.¹¹¹

¹⁰⁰ STERN, *supra* note 4, at 177; PAUL, *supra* note 8, at 119.

¹⁰¹ PAUL, *supra* note 8, at 124.

¹⁰² *Id.* at 124. While most leading eugenicists were opposed to the use of birth control among the so-called “fit” in the population, others supported its use if it “permitted the rational spacing of children” and promoted “healthy, long-lasting marriages with plenty of eugenically fit children.” POPULAR EUGENICS, *supra* note 13, at 106–07. For an examination of the context for the approval of the first oral contraceptive pill in the United States, see Suzanne White Junod & Lara Marks, *Women’s Trials: The Approval of the First Oral Contraceptive Pill in the United States and Great Britain*, 57 J. HIST. MED. 117 (2002).

¹⁰³ PAUL, *supra* note 8, at 120.

¹⁰⁴ *Id.* at 125.

¹⁰⁵ Garland E. Allen, *Is a New Eugenics Afoot?* 294 SCIENCE 59, 61 (2001).

¹⁰⁶ STERN, *supra* note 4, at 175.

¹⁰⁷ Leonard, *Retrospectives*, *supra* note 67, at 220.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ STERN, *supra* note 4, at 207.

¹¹¹ *Indiana Eugenics, History and Legacy: 1907-2007*, INDIANA UNIVERSITY-PURDUE UNIVERSITY, INDIANAPOLIS, <https://eugenics.iupui.edu>.

Nonetheless, eugenics continues to be the subject of eruptions in academic and legal discourse, and it is also periodically invoked—either explicitly or as a subtext—in cultural and political debates.¹¹² Indeed, as noted, some have cited a reemergence of eugenic practices during the COVID-19 pandemic.¹¹³

V. EUGENICS AND THE EARLY FOOD AND DRUG ADMINISTRATION

The complex legislative and organizational origins of FDA, including the enactment of the 1906 and 1938 Acts regulating foods and drugs (and ultimately other categories of products based on later interpretations and amendments), and the regulation of vaccines and other biological products under the 1902 Biologic Act and 1944 Public Health Service Act, have been well-documented.¹¹⁴ Structurally, until the late 1920s, what we now know as FDA was initially the Division and then Bureau of Chemistry within the U.S. Department of Agriculture (USDA), which had been created in 1862. In 1927, the regulatory aspect of the Bureau was renamed the Food, Drug and Insecticide Administration, and in 1930 it was renamed the Food and Drug Administration.¹¹⁵ The 1938 Act expanded FDA's central oversight and enforcement powers, and it gained critical review processes and other mechanisms and responsibilities over time. FDA was transferred from USDA to the Federal Security Agency in 1940, and then to the Department of Health, Education and Welfare (later to become the Department of Health and Human Services) in 1979.

The regulation of biologics, such as blood products and vaccines, had a very different path, beginning in the Department of Treasury's Marine Hospital Service,

¹¹² Perhaps the most notable such eruption was the intense controversy over the best-selling 1994 book by political scientist Charles Murray and psychologist Richard Herrnstein, entitled *The Bell Curve: Intelligence and Class Structure in American Life*. RICHARD J. HERRNSTEIN & CHARLES A. MURRAY, *THE BELL CURVE: INTELLIGENCE AND CLASS STRUCTURE IN AMERICAN LIFE* (Simon & Schuster, 1996) (1994). The authors proposed developing national social policies based on intelligence differences in the population, focusing on an alleged relationship between low test scores among Black Americans compared to whites and Asians, and genetic factors governing intelligence, as opposed to socioeconomic status. They proceeded to argue that a “cognitive elite” was developing in the country and that domestic policy should consider the cognitive capabilities of the target population of policies to avoid social division. For a rebuttal to *The Bell Curve*, see generally STEPHEN JAY GOULD, *THE MISMEASURE OF MAN* 367–90 (W.W. Norton & Co., 1996) (1981). See also Paul A. Lombardo, “*The American Breed*”: *Nazi Eugenics and the Origins of the Pioneer Fund*, 65 ALBANY L. REV. 743, 744 (“The argument advanced in *The Bell Curve* closely parallels assertions routinely made in the early years of the twentieth century by advocates of the eugenics movement. The book's conclusions, disparaging the government's role in ameliorative social programs and forecasting the demise of American civilization as the result of increasingly ‘dysgenic’ birthrates among the ‘underclass,’ are themes found firmly rooted in the eugenic tradition.”).

¹¹³ Appleman, *supra* note 12, at 30 (“Specifically, U.S. public health policy has continued to prioritize the healthy, free, and able-bodied over the medically fragile, incarcerated, and disabled. With COVID-19 still surging through the United States after a full year of pandemic response, we are neglecting these populations at our own cost and peril.”).

¹¹⁴ See generally *supra* note 2; Suzanne White Junod, *Biologics Centennial: 100 Years of Biologics Regulation*, UPDATE, FOOD & DRUG L. INST., Nov.–Dec. 2002; Biologics Control Act, Pub. L. No. 57-244, 32 Stat. 728 (1902); Public Health Service Act, Pub. L. 78-410, 58 Stat. 682 (1944); Daniel A. Kracov, *FDA's Role in Regulating Biologics*, in FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 195–208; Terry S. Coleman, *Early Developments in the Regulation of Biologics*, 71 FOOD & DRUG L.J. 544 (2016).

¹¹⁵ See generally Law & Libecap, *supra* note 2.

which ultimately took up the role of preventing epidemics by “examin[ing] passengers arriving on ships for signs of infectious disease.”¹¹⁶ In 1887, Marine Hospital Service physician Joseph J. Kinyoun set up a “Laboratory of Hygiene” in the Marine Hospital in Staten Island, New York (later moving it to Washington as the “Hygienic Laboratory”) and focused on “applying the emerging sciences of bacteriology and immunology to the activities of the service.”¹¹⁷ The laboratory’s work was hugely important to the development and oversight of early biologics, such as vaccines and antitoxins, including responding to safety crises that led to the enactment of the 1902 Act, which provided for critical powers not afforded under the 1906 Act, such as the issuance of establishment licenses and inspections.¹¹⁸ Although enacted only several years apart, these legislative developments had little commonality—the laws were considered by different committees and were driven to enactment by very different safety and policy concerns.

In 1912, what had then been renamed the Public Health and Marine Hospital Service was reorganized as the Public Health Service, remaining responsible for both its border medical inspection and biologics regulatory roles.¹¹⁹ The Hygienic Laboratory became part of the new National Institute of Health in 1930, and the laws relating to biologics were then revised and consolidated into the U.S. Public Health Service Act in 1944. Ultimately, in the 1970s and 1980s, various administrative changes resulted in a Bureau of Biologics, which became what is now FDA’s Center for Biologics Evaluation and Research (CBER).¹²⁰

As detailed below, in their formative years, these entities routinely became involved in eugenic controversies, research, and tasks. Yet past writing in the field of food and drug law rarely refers to eugenics or the eugenic activities and views of key figures in the development of the agency, or generally dismisses the impact of eugenic thinking on FDA’s early development.¹²¹ The modern FDA is also described as transformed from its origins, and largely impervious to its early historical influences:

¹¹⁶ FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 197.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 201–02.

¹¹⁹ *Id.* at 202–04.

¹²⁰ *Id.*

¹²¹ In the Food and Drug Law Institute’s commemoration of the 1906 Act, *FDA: A Century of Consumer Protection*, “The Struggle for the 1906 Act” is depicted as a shift from a *laissez faire*, social Darwinist era toward American constitutionalism, the growing rights of consumers, and federal regulation of business interests, and tangentially references birth control interests at the time. FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 36–37. As the Princeton economics scholar Thomas Leonard wrote, the “social Darwinism” narrative is quite distinct from eugenics, and that confusion tends to mislead with “respect to the influence of Darwinian and other biological thought upon the Progressive Era sciences of society, this by treating eugenics as social Darwinism and by treating social Darwinism as a synecdoche for all ideological aspects of Gilded Age American capitalism that progressives are seen to oppose: individualism, *laissez-faire* economics, imperialism, racism, and militarism. Of the several consequences of this historiographical construct, one is that the influence of eugenics has been obscured.” Leonard, *Mistaking Eugenics for Social Darwinism*, *supra* note 66, at 213. In fact, “the eugenicist’s case for state control of human breeding did not endorse natural selection; on the contrary, it ordinarily was predicated on a belief that natural selection did not or could not work. These important differences help explain why progressives were drawn to eugenics but not to social Darwinism.” *Id.* at 229. More recently, historian Jonathan Rees’s *Chemistry of Fear: Harvey Wiley’s Fight for Pure Food* references FDA founder Harvey Wiley’s eugenics but dismisses it as a “flirtation” and “fad” that had no significant impact on his central work as food reformer. See REES, *supra* note 2, at 208–11.

Food and Drug regulation as it existed 100 years ago bears little relation to what occurs today. The principles and objectives of regulation remain the same, but the statutes and their implementation and enforcement have changed dramatically. This transformation of U.S. food and drug law can be found in every element of regulatory programs.¹²²

These are quite reasonable characterizations in many respects: there were many factors at work in the early years of FDA, and the regulatory powers and methodologies of a modern FDA have evolved in numerous ways since 1906, as most institutions in our society have.

Nonetheless, it is compelling that the principles and objectives of FDA regulation were in fact originally framed by key individuals who espoused eugenic precepts and saw it as a blueprint for national “race betterment” initiatives of various types. These individuals determined the initial policies, priorities, and practices of FDA and the Public Health Service, and some had critical formative influence over central standard and specification-setting bodies and activities that remain highly integrated into many aspects of “modern” FDA regulation.¹²³

Given the evolution of food and drug laws over time, and the decline of eugenics as a driving force, significant remediation of the influence of eugenic programs and practices has certainly been achieved, such as via the adoption of good clinical practices in research.¹²⁴ But the remnants of the eugenic thinking and practices of the founders of food and drug law and regulation, examined below, may be much more subtle and deeply embedded, and recent events indicate that the continued relevance of American eugenic history and culture in FDA’s formative period has also been underestimated.

VI. THEODORE ROOSEVELT AND FDA

While a recounting of Theodore Roosevelt’s background and presidency is beyond the scope of this Article, Roosevelt is generally considered “a dynamic, reformist president” who promoted progressivism and regulation of big business to provide the “square deal” to citizens.¹²⁵ The crusade culminating in the enactment of the Pure Food and Drug Act of 1906 was central to that effort. Despite what we now recognize

¹²² FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 99.

¹²³ In examining such influences, it is important to bear in mind that eugenics was about much more than heredity and sterilization practices. Rather, the public health goals associated with FDA’s creation and development were considered consistent with eugenic thinking at the time:

Eugenics could even be expanded to include not just germ fighting but virtually all of public health. While eugenics aimed at improving heredity, the meaning of *heredity* could reach far beyond genetics. In both common usage and some scientific literature, calling a trait hereditary meant that “you got it from your parents,” regardless of whether “it” was transmitted by genes or germs, precepts or probate The goals of early 20th-century public health and eugenics also converged to promise the permanent eradication of disease rather than just the reduction of morbidity. Such a thorough and lasting elimination of illness now seemed attainable owing to new concepts in both bacteriology and genetics.

Pernick, *Eugenics and Public Health*, *supra* note 20, at 1770.

¹²⁴ See generally SUZANNE WHITE JUNOD, FDA AND CLINICAL DRUG TRIALS: A SHORT HISTORY, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/110437/download> (last accessed July 7, 2022).

¹²⁵ SOUTHERN, *supra* note 77, at 111.

as that law's inherent limitations, such as weak enforcement authorities, at the time, the "question of whether or not [the] law would be passed by Congress was the dominant challenge to the Progressive Movement and to Congress" and a key step in putting the federal government into a new relationship with Americans at the beginning of the 20th Century.¹²⁶

While President Roosevelt's relationship with the primary founder of FDA, Harvey Wiley, was notoriously difficult both during the development of the legislation and its implementation, it was not due to differences of opinion relating to eugenics. Rather, Roosevelt felt that Wiley was impractical and created political problems with major industry groups, such as in his efforts to rein in the sale of rectified whiskey and his absolute views on certain food additives as adulterants.¹²⁷ In Roosevelt's view "[t]he Pure Food and Drug bill became a law purely because of the active stand [he] took in trying to get it through Congress," and Wiley's approach had been too strident to succeed.¹²⁸ Indeed, at the signing ceremony, "[t]he president did not acknowledge Wiley . . . not in the ceremony and not by any other gesture." Thereafter, Wiley inquired as to whether he might also receive "some token of the victory"—but all of the pens used to sign the bills had been given to others.¹²⁹ In fact, "Roosevelt had not championed the legislation."¹³⁰

Much has been written about Theodore Roosevelt and race. As Frederick Douglass concluded, "Roosevelt was in many respects a White Man's President."¹³¹ He was steeped in racial theories, and his "emphasis on breeding and the power of northern 'blood' to strengthen the presumably weaker southern races foreshadowed a principal cornerstone of his racial theories, the idea that a race must maintain a very high fertility rate to avoid losing its identity to a people of superior breeding powers."¹³²

Roosevelt made eugenic concerns about race degeneration a "centerpiece of his national reform agenda" and he clearly aimed to take action to stop it.¹³³ Indeed, in the same year the Pure Food and Drug law was enacted, Roosevelt proposed a constitutional amendment that would place "the whole question of marriage and divorce under federal authority in order to safeguard the nation's home life" and promote fecundity.¹³⁴ He also routinely referenced "the old-stock American and . . . the 'desirable' classes who were guilty of shirking their procreative duties."¹³⁵ While Roosevelt took advice from eugenicists such as Davenport, he rejected certain

¹²⁶ Litman & Litman, *supra* note 2, at 329 ("The year 1906 thus saw the Progressive Movement, President Theodore Roosevelt, and the United States Congress in a momentous battle over achieving a national food and drug law. Because of the efforts of President Roosevelt, the public, and the Congress, the twentieth century looked brighter for American society.").

¹²⁷ Oscar E. Anderson, *The Pure-Food Issue: A Republican Dilemma, 1906–1912*, 61 AM. HIST. REV. 550, 557 (1956); *see generally* BLUM, *supra* note 2, at 185–88; REES, *supra* note 2, at 107–20, 121–47.

¹²⁸ THOMAS G. DYER, *THEODORE ROOSEVELT AND THE IDEA OF RACE* 56 (La. State Univ. Press, 1980).

¹²⁹ *Id.*

¹³⁰ *See* Cooper, *in* FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 58.

¹³¹ SOUTHERN, *supra* note 77, at 121.

¹³² DYER, *supra* note 128, at 56.

¹³³ ROBERTS, *supra* note 4, at 61.

¹³⁴ DYER, *supra* note 128, at 154.

¹³⁵ *Id.* at 155.

aspects of the eugenic focus on the quality of the gene pool, preferring the approach of increasing the quantity of those in the upper classes to hasten the production of children who could “maintain racial integrity and national preeminence.”¹³⁶

VII. USDA LEADERSHIP: JAMES WILSON AND WILLET HAYS

In this era, the U.S. Department of Agriculture, which included the FDA precursor Bureau of Chemistry, was “the strongest voice for scientific policymaking in the federal government, if not the entire nation . . . it occupied a unique space in turn-of-the-century national politics.”¹³⁷ That influence went well beyond agriculture and food, and the leaders of USDA sought to extend their influence and knowledge directly into matters of eugenics and human breeding.¹³⁸ James Wilson, who was the Secretary of Agriculture during three presidencies, from 1897 to 1913, served as President of the American Breeder’s Association, a national organization that focused on both animal and human breeding, and championed eugenic race betterment efforts while tempering Harvey Wiley’s attacks on business.¹³⁹ He lauded the human eugenics work of the Eugenics Record Office, and urged them to seek additional funding.¹⁴⁰

The Assistant Secretary at the time, Willet M. Hays, was a truly devoted eugenics promoter. Hays was the “earnest” and “energetic” founder of the American Breeder’s Association and believed that efforts at breeding animals could be used as a model to achieve the goal of improving “the human race by the careful selection of parents for future Americans” in order to “produce a race equal, if not superior, to the physical and intellectual attractiveness of the Greeks of old.”¹⁴¹ He also proposed assigning an eleven-digit “number name” indicating one’s genetic lineage, thus facilitating “mating with those of equal genetic excellence.”¹⁴²

In 1906—the year in which the Pure Food and Drug Act was enacted—Assistant Secretary Hays founded the Heredity Commission to advise the U.S. government on eugenic matters.¹⁴³ Hays specifically advocated for “discouraging the vicious elements in the cross-bred American civilization,” including those who had “no racial right to perpetuate their kind, a large percentage of whom cannot sustain themselves and must

¹³⁶ *Id.* at 160.

¹³⁷ CARPENTER, *supra* note 2, at 179.

¹³⁸ BLACK, *supra* note 5, at 97–98.

¹³⁹ See generally Vivian Wiser, *Public Policy and USDA Science, 1897–1913*, 64 AGRIC. HIST. 24 (Spring 1990), <http://www.jstor.org/stable/3743793>. As a result of efforts by Charles Davenport and USDA Assistant Secretary Willet Hays, “[b]y the time the American Breeders’ Magazine was launched in 1910, eugenics had become an integral part of the ABA programme.” Barbara A. Kimmelman, *The American Breeders’ Association: Genetics and Eugenics in an Agricultural Context, 1903–13*, 13 SOC. STUDS. SCI. 163, 183 (1983).

¹⁴⁰ BLACK, *supra* note 5, at 98.

¹⁴¹ Burdick, *supra* note 48.

¹⁴² DANIEL OKRENT, *THE GUARDED GATE: BIGOTRY, EUGENICS, AND THE LAW THAT KEPT TWO GENERATIONS OF JEWS, ITALIANS, AND OTHER EUROPEAN IMMIGRANTS OUT OF AMERICA* 129 (Scribner, May 19, 2020) [hereinafter *THE GUARDED GATE*].

¹⁴³ *The Heredity Commission*, N.Y. TIMES, May 20, 1906, at 8, https://timesmachine.nytimes.com/timesmachine/1906/05/20/101779033.pdf?pdf_redirect=true&ip=0.

be a burden on society.”¹⁴⁴ Such people, he believed, “must ‘be rendered unproductive, by segregation or otherwise.’”¹⁴⁵

VIII. HARVEY WASHINGTON WILEY

Although Roosevelt and others claimed much credit, history has rightly deemed Harvey Washington Wiley the “Father of FDA.”¹⁴⁶ Wiley performed a “unique and stunning feat” in achieving enactment of the 1906 Act, and his role was both critical and unprecedented.¹⁴⁷ And there can be no doubt that Wiley’s slow development of a coalition to support the successful pure food and drugs campaign—and his at times masterful public relations instincts—were primary factors in the adoption of the seminal 1906 Act.

In considering Wiley’s relationship to eugenics, it is interesting to note that his early background appears to separate him from the typical racism of the time. His father was an abolitionist and their family farm in Indiana was part of the Underground Railroad.¹⁴⁸ Wiley also briefly served in the Union Army during the Civil War.¹⁴⁹ But Wiley also developed as a medical professional and scientist at a time when race and heredity were a topic of intense inquiry and discussion. In his brief tenure in medical school at Harvard, Wiley took biology with Professor Louis Agassiz, who “promoted ‘polygenism’—a theory positing that human races were distinct species.”¹⁵⁰ Notably, Indiana, where Wiley was born and spent his formative professional years, later became a national leader in eugenic sterilization efforts and was the first to launch a major effort to “remedy race degeneration by sterilizing criminals” that became a model for other states.¹⁵¹

Wiley left Indiana in 1883, joining the U.S. Department of Agriculture as Chief of the Division of Chemistry (later the Bureau of Chemistry), remaining in that role until 1912. His work has been extensively chronicled, including hundreds of investigations into food adulterants, the famous Poison Squad “Hygienic Table” experiments beginning in 1902, and decades of careful cultivation of a coalition of food and drug reform supporters.¹⁵²

Wiley’s work in the founding years of FDA made fundamental contributions to the safety and integrity of the U.S. food and drug supply, establishing “long-lasting

¹⁴⁴ Burdick, *supra* note 48.

¹⁴⁵ *Id.*

¹⁴⁶ *Harvey W. Wiley: Pioneer Consumer Activist*, FDA CONSUMER MAGAZINE (Jan.–Feb. 2006), <https://www.fda.gov/about-fda/fda-leadership-1907-today/harvey-w-wiley-pioneer-consumer-activist> (adapted from *Good Housekeeping Magazine*).

¹⁴⁷ See CARPENTER, *supra* note 2 at 268, 274.

¹⁴⁸ BLUM, *supra* note 2, at 12.

¹⁴⁹ *Id.*

¹⁵⁰ See REES, *supra* note 2, at 23; *Confronting Anti-Black Racism Resource: Scientific Racism*, HARVARD LIBRARY, <https://library.harvard.edu/confronting-anti-black-racism/scientific-racism>.

¹⁵¹ ROBERTS, *supra* note 4, at 66; see generally Jason S. Lantzer, *The Indiana Way of Eugenics: Sterilization Laws: 1907–1974*, in A CENTURY OF EUGENICS, *supra* note 8; see also Elof Axel Carlson, *The Hoosier Connection*, in A CENTURY OF EUGENICS, *supra* note 8, at 11; COGDELL, EUGENIC DESIGN, *supra* note 68, at 100.

¹⁵² CARPENTER, *supra* note 2, at 263–64; see generally BLUM, *supra* note 2.

national esteem for his bureau.”¹⁵³ He “was perhaps the best known of all American food experts” and was also part of a dense network of elites.¹⁵⁴ While it can be difficult to parse Wiley’s beliefs and motives from a distance of a century, there can be no doubt that Wiley was the dominant force in the scientific and political development of the law, and his personality and views fundamentally shaped the debate.¹⁵⁵

Wiley and other Progressive Era reformers’ moral focus on food “shaped Americans’ understandings of their dietary choices and the food systems that support them ever since.”¹⁵⁶ While in office, Wiley was both a major media figure and national promoter of pure food and drugs while also advocating for the planting of certain crops. Among other changes, he helped bring on the development of corn as “the new American King.”¹⁵⁷ Wiley’s work also had a critical impact on the expansion of sugar beets as a sugar source in the American diet.¹⁵⁸ Notably, even such seemingly innocuous crop promotion efforts were closely tied to the racial thinking at the time— “[b]eet-sugar advocates would advertise the racial dimensions of their product” and “investors in this nascent industry wanted ‘to offer sugar untouched by dark hands,’ referring to the Caribbean processing of sugarcane by ex-slaves.”¹⁵⁹

Major expositions were a critical way for Wiley and other pure food and drug reformers to pursue their goals at the time, and such events had a massive cultural impact. At the Columbian Exposition of 1893, he delivered a series of public presentations focused on the U.S. food supply and his analytical work, and he hosted pure food exhibits at the St. Louis and Pan-American Expositions.¹⁶⁰ These expositions were also powerful vehicles for eugenic propaganda, routinely incorporating eugenic exhibits, “Fitter Family” and “Better Babies” contests, and “Race Betterment” booths, juxtaposed with racist exhibits of indigenous peoples.¹⁶¹

¹⁵³ CARPENTER, *supra* note 2, at 273.

¹⁵⁴ VEIT, *supra* note 77, at 53.

¹⁵⁵ CARPENTER, *supra* note 2, at 260. “The very multiplicity of Wiley’s ties defies modern historians attempts to pigeonhole his motives, just as it confounded any easy reading of his interests from 1901 to 1906.” CARPENTER, *supra* note 2, at 260. “The debate also centered on Dr. Harvey W. Wiley, USDA’s chief chemist. Food manufacturers were wary of the section of the bill authorizing Dr. Wiley to establish food standards binding on the courts. They argued that this section would authorize Dr. Wiley to dictate to the food industry what could be produced, and many objected to Dr. Wiley because of his flamboyant conduct . . . Having Dr. Wiley as the chief enforcement officer was not in the interest of many food manufacturers and proved to delay consideration of the measure.” Litman & Litman, *supra* note 2, at 318.

¹⁵⁶ VEIT, *supra* note 77, at 187.

¹⁵⁷ BLUM, *supra* note 2, at 17; *see generally* CARPENTER, *supra* note 2, at 7.

¹⁵⁸ REES, *supra* note 2, at 59. At the time, the supply of sugar was uncertain and expensive for consumers. *See generally* William Lloyd Fox, *Harvey W. Wiley’s Search for American Sugar Self-Sufficiency*, 54 AGRIC. HIST. 516 (Oct. 1980).

¹⁵⁹ *See* REES, *supra* note 2, at 59 (citing BENJAMIN R. COHEN, *PURE ADULTERATION: CHEATING ON NATURE IN THE AGE OF MANUFACTURED FOOD* 156 (Univ. of Chicago Press, 2019)).

¹⁶⁰ *See* BLUM, *supra* note 2, at 43, 113. Indeed, such approaches later became standard practice for FDA and were central to FDA efforts in seeking legislation to strengthen the 1906 Act in the 1930s. *See generally* REES, *supra* note 2; Gwen Kay, *Healthy Public Relations: The FDA’s 1930s Legislative Campaign*, 75 BULL. HIST. MED. 446, 446–87 (2001).

¹⁶¹ KEVLES, *supra* note 3, at 61; SOUTHERN, *supra* note 77, at 52–53 (“Race science was everywhere on display at the fairs, justifying white economic and political control of dark-skinned people at home and abroad.”). Notably, Black Americans were excluded from the Columbian Exposition, and activist journalist Ida B. Wells distributed copies of a protest pamphlet (with contributions from Frederick Douglass, among other prominent reformers) at the entrance, entitled “The Reason Why the Colored American Is Not in the

After years of struggle over the interpretation and implementation of the 1906 Act, Harvey Wiley finally left office in 1912. While he was disgruntled by what he believed were efforts to diminish his contributions and thwart proper enforcement of the 1906 law, he retained wide public admiration.¹⁶² Various politicians and business interests resented his positions and approach—or believed he was primarily interested in “promoting Harvey Wiley”—but he was considered by many “a scientist and administrator of the highest integrity.”¹⁶³ Yet Wiley was much more than a tireless and controversial former bureaucrat: he remained a national celebrity, cultural force and public health authority in the United States for many decades after he left government.¹⁶⁴ As a former FDA Chief Counsel noted, “Harvey Wiley was the greatest lightning rod in American history.”¹⁶⁵

But Wiley’s views were often unpredictable, and from a scientific perspective, at times “seriously deficient.”¹⁶⁶ And, as evidenced by his various statements and writings detailed below, Wiley—like many others in the Progressive Era coalition of activists—was a supporter of eugenics. In many respects, Harvey Wiley’s relationship to eugenics was tied to his role as a Progressive Era public health advocate: his thinking about purity and hygiene was largely consistent with eugenic thinking, and his focus on preventing and removing “adulteration” was typical of the eugenic movement of the time. Indeed, pure food was a particular focus of the progressive eugenic agenda—and for Progressives like Wiley, a “favorite metaphor . . . was the human engine” or “the human animal.”¹⁶⁷

Wiley’s famous Poison Squad was a curious experiment on the “human animal”—particularly for a figure that would later contribute to the development of the notion of

World’s Columbian Exposition.” Barbara J. Ballard, *A People Without a Nation*, CHICAGO HISTORY, at 27–28 (1999) http://livinghistoryofillinois.com/pdf_files/African%20Americans%20at%20the%201893%20Worlds%20Columbian%20Exposition,%20A%20People%20Without%20a%20Nation.pdf.

¹⁶² Wiley wrote an entire book on the development of the Pure Food and Drug Act and his belief that the proper implementation of the law was “perverted to protect adulteration of food and drugs.” HARVEY W. WILEY, *THE HISTORY OF A CRIME AGAINST THE FOOD LAW* (1929).

¹⁶³ REES, *supra* note 2, at 105; see generally Donna J. Wood, *The Strategic Use of Public Policy: Business Support for the 1906 Food and Drug Act*, 59 BUS. HIST. REV. 403 (1985).

¹⁶⁴ See generally BLUM, *supra* note 2; REES, *supra* note 2.

¹⁶⁵ Interview by Akila Saravanan with Peter Barton Hutt, FDA Chief Counsel (Apr. 3, 2015), in *Leading the Pure Foods Movement: Dr. Harvey Washington Wiley and His Legacy of Food & Drug Safety*, <http://93628669.weebly.com/>.

¹⁶⁶ “He argued that any chemical that is harmful in large amounts must be harmful in small amounts, and therefore should be banned. He rejected the dose/response paradigm, well-known to scientists at the time. He therefore advocated banning such common food substances as sodium benzoate, bleached flour, caffeine, and saccharin—all of which remain on the market today and are regarded as safe . . . His policy on food toxicology was thus completely and irretrievably wrong.” Peter Barton Hutt, *A Perspective on Dr. Wiley*, in FDLI, *A CENTURY OF CONSUMER PROTECTION*, *supra*, note 2, at 49.

¹⁶⁷ VEIT, *supra* note 77, at 56, 102–03. Eugenic healthy eating and “biologic living” proponent John Kellogg “compared the regulatory digestive function of the individual body to immigration officers at U.S. consulates and Ellis Island who probed the backgrounds of prospective immigrants to reject those whose blood they thought would pollute the bloodstream of the national body.” COGDELL, *EUGENIC DESIGN*, *supra* note 68, at 134.

“rational therapeutics” in drug development.¹⁶⁸ The Hygienic Table studies were “as much a political experiment as a scientific one.”¹⁶⁹ As has been recounted many times:

Volunteers were fed high-quality meals with doses of the preservative under study gradually increased until effects were evident Sanctioned by Congress, . . . these experiments made the daily papers The overall results of the study were scientifically questionable, since the Bureau used no “control” group and Wiley took to giving the men preservatives in capsules after they began avoiding the butter laced with Borax.¹⁷⁰

Wiley’s Poison Squad was not labeled a eugenic experiment, and eugenics was just beginning to grow as a “scientific” movement in the United States when the Poison Squad first convened. However, it is interesting to consider Wiley’s Hygienic Table through a eugenic lens—essentially as a cross between a challenge study and the anthropometric exhibitions that later became common tools of eugenics. Wiley and his staff “decided to limit applicants to the presumably upright people who had passed the civil service exam, ‘so they came to us with a good character.’”¹⁷¹ All white men, the participants, who signed a liability waiver, were “the largest group ever yet used in a human health experiment of its kind.”¹⁷² Wiley wanted “young robust fellows, with maximum resistance to the deleterious effects of adulterated foods.”¹⁷³ While there is no direct evidence of Wiley having eugenic intent in 1902, and it is quite possible that Wiley recruited these volunteers for reasons unrelated to race or heredity, the actual scientific value of the hygienic table was questionable in that “[t]here was . . . little statistical analysis; only short-term effects were observed, and most of those were subjective.”¹⁷⁴

Wiley was reticent about publicizing the study too early, fearing “that too much showy attention might bias the study and rob it of scientific dignity” and worrying “that things would go wrong and he wouldn’t be able to manage the resulting bad news.”¹⁷⁵ When news of the Squad’s activities leaked to a *Washington Post* reporter, Wiley blamed the Poison Squad’s Black chef, S.S. Perry, whom he had caught “chatting cordially” with the reporter “through a basement window.”¹⁷⁶ Overall, while the Poison Squad has at times been depicted as a serious scientific effort, and the risks taken by its participants should not be discounted, in retrospect the experiment’s

¹⁶⁸ For a general history of those developments, see HARRY M. MARKS, *THE PROGRESS OF EXPERIMENT: SCIENTIFIC AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900–1990* (Cambridge Univ. Press, Charles Rosenberg, ed., 1997).

¹⁶⁹ CARPENTER, *supra* note 2 at 264; FDLI, *A CENTURY OF CONSUMER PROTECTION*, *supra* note 2, at 35.

¹⁷⁰ FDLI, *A CENTURY OF CONSUMER PROTECTION*, *supra* note 2, at 52.

¹⁷¹ BLUM, *supra* note 2, at 88.

¹⁷² *Id.*

¹⁷³ FDLI, *A CENTURY OF CONSUMER PROTECTION*, *supra* note 2, at 53.

¹⁷⁴ *Id.*

¹⁷⁵ BLUM, *supra* note 2, at 92.

¹⁷⁶ *Id.*

ultimate value was more attributable to its political and media influence than the scientific data it produced.¹⁷⁷ But was it also an example of early eugenic influences at work?

Some may consider Wiley's eugenic beliefs to be more in the nature of "euthenics"—a so-called "sister science" of eugenics that focused on sanitation, exercise, and diet rather than heredity as factors affecting health, intelligence, and appearance.¹⁷⁸ No doubt, some of the groups focusing on euthenics and the purity of foods and drugs—including certain crusading women's organizations—did not emphasize eugenics and were focused solely on moral and public health goals.¹⁷⁹ But the eugenics movement more generally "mixed specifically genetic concerns with a much broader range of preventive health measures, including personal and public hygiene, diet and exercise."¹⁸⁰ Many Progressives "saw these softer 'euthenic' policies as shorter-term prescriptions to foster positive change while waiting for the longer-term policies of eugenics to take hold."¹⁸¹ Thus, many view euthenics as going well beyond mere home economics: eugenics was "hygiene for future generations" while euthenics was "hygiene for the present generation."¹⁸² Prominent promoters of euthenics claimed that the implementation of euthenics, such as "healthful surroundings, proper food, education and business opportunities" was "central to the eugenic betterment of society" because "much that has been gained through inheritance can be lost."¹⁸³ Thus, the concepts were "interwoven," and while there was a tension between eugenics and euthenists' notions of environmental rather than hereditary effects, euthenists "promised to do more than preserve members of diverse races; many of them aimed explicitly to improve the white race."¹⁸⁴

For Harvey Wiley, pure food and drugs was a moral crusade, and "Wiley mixed pure food advocacy with moral exhortations and eugenic beliefs."¹⁸⁵ Indeed, "the Pure Food and Drug Act was 'an archetype of how moral indignation could lead to progressive legislation'"¹⁸⁶ Eugenics was also considered a moral crusade to "save the

¹⁷⁷ A "common scientific criticism" of the Poison Squad experiments was a concern as to predetermined bias and lack of blinding. REES, *supra* note 2, at 88–89.

¹⁷⁸ VEIT, *supra* note 77, at 103.

¹⁷⁹ See generally GOODWIN, *supra* note 2.

¹⁸⁰ DUPUIS, *supra* note 90, at 86.

¹⁸¹ *Id.*; see also REES, *supra* note 2, at 173, 208 ("Over the course of many public appearances during the 1910s, Wiley occasionally strayed from his usual subject of food purity and expressed support for racial ranking, sterilization of 'imbeciles' and the insane, or other racist arguments then being normalized in some scientific circles" including advocating for the "public instruction of eugenics.").

¹⁸² DUPUIS, *supra* note 90, at 86. Ellen Richards, a leader in euthenics, described it as "the term proposed for the preliminary science on which Eugenics must be based." POPULAR EUGENICS, *supra* note 13, at 67 (citing ELLEN SWALLOR RICHARDS, EUTHENICS, THE SCIENCE OF CONTROLLABLE ENVIRONMENT: A PLEA FOR BETTER LIVING CONDITIONS AS A FIRST STEP TOWARDS HIGHER HUMAN EFFICIENCY (Whitcomb & Barrows, 1910)).

¹⁸³ POPULAR EUGENICS, *supra* note 13, at 48–49.

¹⁸⁴ VEIT, *supra* note 77, at 106.

¹⁸⁵ DUPUIS, *supra* note 90, at 87.

¹⁸⁶ FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 45–46 ("Long before the muckrakers, Wiley had approached the problems of food and drug adulteration and misbranding as fundamentally moral problems—problems of dishonesty. Whereas both the Biologics Act of 1902 and the Meat Inspection Act of 1906 required government inspection before the regulated products could be marketed, the Pure Food and Drugs Act did not.").

race,” and Wiley’s anti-adulteration efforts can also be seen as part of the overall eugenic “race betterment” movement of the time.¹⁸⁷

Wiley in fact later joined the Central Committee of the National Conferences on Race Betterment in 1914 and 1915, and he spoke on the topic of advertising at the Third Race Betterment Conference in 1928, all organized by the Race Betterment Foundation, founded in 1911 by breakfast cereal magnate John H. Kellogg.¹⁸⁸ These conferences were intended to advocate for “improvement of the race,” and the organizers worked with other eugenic organizations, such as the Eugenics Record Office, on eugenics registries and spreading the gospel of eugenic thinking to the public.¹⁸⁹ The conferences juxtaposed all of the strains of eugenic “race betterment” thinking: Wiley’s presentation on “The Commercial Advertisement as an Educational Influence”—while on the same agenda as the pathologist George Papanicolaou first describing the cytological basis for what would become known as the “Pap Smear” test for cervical cancer—was also “nestled among presentations such as ‘Who Outbreeds Whom, . . .’ ‘The Sterilization of the Feeble-Minded in Michigan, . . .’ and ‘The Menace of the Melting Pot Myth.’”¹⁹⁰ Attended by thousands, the Race Betterment conferences generated extensive media coverage.¹⁹¹

Importantly for the examination of potential traces of eugenics in food and drug regulation today, a central focus for Wiley was the development of standards, monographs, and specifications. In fact, Wiley had wanted specific numbers and measurements written into statute in order to define when food substances are

¹⁸⁷ And that movement saw a close association between cleanliness of race and cleanliness of food:

[M]eticulous attention to food purity became deeply laden with a tenor of imperative action in the face of looming danger that cross-pollinated easily with discourses of racial purity and nativist politics. It is not surprising, for example that in July 1925’s *Scientific American* a review of current scientific thinking on the question, ‘Which Races Are Best?’ . . . sandwiched between articles on sanitary baking and methods for the safe handling of fruit juices. In an era when white Americans were exposed as never before to immigrants and their strange new foods, urgent questions of diet were never far from racial anxieties. Indeed, as germ theories of disease gained increasing popular acceptance, it often became difficult to distinguish between descriptions of food-borne contagion and the terrifying prospects of racial contamination.

GEOGRAPHIES OF RACE AND FOOD: FIELDS, BODIES, MARKETS 273 (Rachel Slocum & Arun Saldanha, eds. 2016). Hygiene “was another important term linked to place in the history of eugenics.” THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 17. In fact, “[t]o many Americans,” the “comprehensive overhaul of U.S. food offered answers to a host of social questions including physical health, wage strife, women’s roles, racial fitness, Americanization, international welfare, and world peace.” VIET, *supra* note 77, at 3.

¹⁸⁸ See Colette Leung, *Race Betterment Foundation*, EUGENICS ORGANIZATIONS, EUGENIC ARCHIVE, <http://eugenicsarchive.ca/discover/tree/553e95f955b4ad032600001> (last visited Aug. 13, 2022).

¹⁸⁹ See *id.*; THE RACE BETTERMENT FOUNDATION, *Proceedings of the First National Conference on Race Betterment, January 8, 9, 10, 11, 12, 1914—Battle Creek, Michigan*, <https://babel.hathitrust.org/cgi/pt?id=ucw.ark:/13960/t4cn7gr5k&view=lup&seq=15&q1=wiley> (Emily F. Robbins, ed.); THE RACE BETTERMENT FOUNDATION, *Official Proceedings of the Second National Conference on Race Betterment, August 4, 5, 6, 7, and 8, 1915*, <https://catalog.hathitrust.org/Record/100334793>; THE RACE BETTERMENT FOUNDATION, *Proceedings of the Third Race Betterment Conference, January 2–6, 1928, Under the Auspices of the Race Betterment Foundation—Battle Creek, Michigan* (1928), <https://wellcomecollection.org/works/ex9tb25e/items?canvas=21>.

¹⁹⁰ See generally Alexa L. Swailes, Carrie E. Hossler & Joshua P. Kesterson, *Pathway to the Papanicolaou Smear: The Development of Cervical Cytology in Twentieth-Century America and Implications in the Present Day*, 154 GYNECOL. ONCOL. 3 (2019).

¹⁹¹ KLINE, *supra* note 8, at 15.

“injurious to health.”¹⁹² His efforts in this area were vast and unprecedented. Wiley was President of the U.S. Pharmacopeial Convention, despite not being a pharmacist or practicing physician, while also serving as the Chief of the Bureau of Chemistry.¹⁹³ With the enshrinement of the USP in the 1906 Act, the US Pharmacopeia “had suddenly become a most important book of standards.”¹⁹⁴ He was a founder of the Association of Official Agricultural Chemists (AOAC) in 1884, and he supported its work with Division of Chemistry funding.¹⁹⁵ He served as AOAC’s second president, and as its secretary for twenty-five years, focusing their work on food adulteration. As a network of state officials and professionals, the AOAC had enormous and lasting impact, including in the legislative development of the 1906 Act and beyond.¹⁹⁶

Wiley also served on the American Medical Association Council on Pharmacy and Chemistry, created in 1905.¹⁹⁷ The Council was intended to shore up the scientific basis underlying the development of “rational therapeutics” supporting drug products. While the results of the Council’s efforts were “meager” at first, the “standards of evidence articulated by the council were widely endorsed within academic medicine.”¹⁹⁸

Like his views about toxicology and dosing, Wiley had distinct ideas about food and drug law, including a particular point of view on the role of labeling that had a long-term effect:

Deleterious adulteration and commercial fraud in food and drugs converged in the issue of accurate labeling—the consumer’s right to know what he or she was purchasing. Even Harvey Wiley, the devoted advocate of pure food and drug legislation, did not deny people the right to consume poisonous or inferior goods, if they chose to do so. “I would be in favor

¹⁹² BLUM, *supra* note 2, at 157; CARPENTER, *supra* note 2 at 261. On the development of food standards generally, see Suzanne White Junod, *U.S. Federal Food Standards: The Case of the Peanut Butter and Jelly Sandwich*, in FOOD, SCIENCE, POLICY, AND REGULATION IN THE TWENTIETH CENTURY: INTERNATIONAL AND COMPARATIVE PERSPECTIVES 167–88 (David F. Smith and Jim Phillips, eds., Routledge 2000), <https://www.fda.gov/media/110474/download> [hereinafter Junod, *Food Standards*]. Eventually, more specific requirements were enacted, including, in 1913, the first mandatory food labeling law—the Gould Net Weight Amendment to the 1906 Pure Food and Drugs Act. See Suzanne White Junod, *Proscribing Deception: The Gould Net Weight Amendment and the Origins of Mandatory Nutrition Labeling*, in SETTING NUTRITIONAL STANDARDS: THEORY, POLICIES, PRACTICES (Cambridge Univ. Press 2018) (Elizabeth Neswald, David F. Smith & Ulrike Thoms, eds., 2017) (The Gould Amendment required all packaged foods to “have the ‘quantity of their contents plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count.’ The United States thereby became the first country in the modern world to enact mandatory food labeling in lieu of voluntary compliance with published standards, and paved the way for the twentieth-century adoption of mandatory nutrition labeling.”).

¹⁹³ *Harvey Washington Wiley*, 9 J. AM. PHARM. ASSOC. § 5 (May 1920).

¹⁹⁴ *Id.*

¹⁹⁵ CARPENTER, *supra* note 2, at 203, 261.

¹⁹⁶ *Id.* at 203, 262.

¹⁹⁷ *Id.* at 204. MARKS, *supra* note 168, at 25; see generally David L. Edsall, *The Work of the Council on Pharmacy and Chemistry*, 55 JAMA § 20, 1701 (1910).

¹⁹⁸ MARKS, *supra* note 168, at 41.

of putting benzoic acid in a salt-cellar . . . and letting the people use it if they want to,” Wiley told a Senate committee.¹⁹⁹

This was also central to his political strategy for the 1906 Act: “Wiley avoided stirring up opposition from the working class and the poor by designing the legislation generally to preserve the option to sell and buy cheap substitute foods properly labeled.”²⁰⁰ Like many of Wiley’s activities, that perspective was enduring. Beyond his investigations, the standards he helped set, and the regulations he wrote, Wiley also influenced the course of food and drug regulation for decades beyond his departure in 1912—four individuals that he hired and supervised continued to lead the agency until 1951.²⁰¹

Wiley’s national profile did not diminish substantially after he left the Bureau of Chemistry. He immediately doubled his pay by becoming *Good Housekeeping* magazine’s director of “food, health and sanitation.” He wrote a regular column for the magazine, and instituted the *Good Housekeeping* Seal—which still exists today—thus extending his reach into the American home, including *Good Housekeeping*’s 400,000 subscribers, in new and highly influential ways.²⁰² This was a very serious endeavor: Wiley had veto power over advertisers and sought to utilize the work of *Good Housekeeping* to empower subscribers to evaluate the purity of products at home, essentially acting as their own food inspectors. He also answered questions, “advocating that women take responsibility for the health of their households through pure home cooking and reap the rewards of a “‘peaceful, happy, and unbroken’ domestic life.”²⁰³ In so doing, Wiley became “one of the prime popular didactic voices on food and health in the mass media.”²⁰⁴

Wiley also had a contract with the same speakers’ bureau as other Progressive Era luminaries, giving hundreds of speeches across the country.²⁰⁵ As described by his colleagues at the USP, Wiley was “[a] man of great personal magnetism, a brilliant after-dinner speaker, a witty and entertaining conversationalist,” noting that in addition to pure foods and drugs, he focused on “the scientific raising of the two lusty boys of whom he is a proud father.”²⁰⁶

IX. WILEY’S EUGENICS

Like many leading thinkers of his time, Wiley’s public health eugenics focused on the purity of the race overall, and he believed in ranking the genetic propensities of

¹⁹⁹ Wood, *supra* note 163, at 411.

²⁰⁰ FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 59; *see also* Junod, *Food Standards*, *supra* note 192.

²⁰¹ CARPENTER, *supra* note 2, at 273.

²⁰² BLUM, *supra* note 2, at 261; *see The History of the Good Housekeeping Institute*, THE GOOD HOUSEKEEPING INSTITUTE, <https://www.goodhousekeeping.com/institute/about-the-institute/a17940/good-housekeeping-institute-timeline/> (last visited Aug. 13, 2022).

²⁰³ IHB Marker Review: Harvey Washington Wiley, at 2 (May 7, 2014), <https://www.in.gov/history/files/39.1981.1review.pdf> [hereinafter IHB Marker].

²⁰⁴ DUPUIS, *supra* note 90, at 82.

²⁰⁵ BLUM, *supra* note 2.

²⁰⁶ *Harvey Washington Wiley*, *supra* note 193.

various races.²⁰⁷ Indeed, Wiley, his suffragist spouse, Anna Kelton Wiley, and their sons were deemed a eugenic ideal, attaining “near-celebrity status as an example of a modern, clean-living, white American family.”²⁰⁸

According to historian Jonathan Rees, “the influence of Wiley’s racial thinking . . . would be clear only later in his career”—and in fact he appears to have publicly voiced racist and eugenic views only after he left his government position in 1912.²⁰⁹ First, in a jarring example in the November 1913 *Good Housekeeping* magazine, Wiley continued the battle against rectified whiskey that he had waged at USDA in an article entitled “The Pure Food Law and N*gger Gin: Fixing the Responsibility of Our Most Basic Intoxicants.”²¹⁰ While Rees notes that “[n]ot coincidentally, Wiley made this claim about the same time he became enamored with the new racist pseudoscience of eugenics,” it seems quite unlikely that Wiley had suddenly adopted these beliefs at the age of sixty-nine and only after his departure from government.²¹¹ Given that Wiley had worked for decades as a central figure at USDA, a hotbed of committed eugenicists who had founded key eugenic institutions (the Eugenics Section of the American Breeder’s Association and the Heredity Commission) six years earlier, it is perhaps more likely that Wiley’s views had developed during his time at the Bureau of Chemistry, and that his departure from government allowed greater latitude in expressing his perspective.

In 1915, Wiley provided important support for Dr. Harry Haiselden, a surgeon who had publicized his practice of hastening the death of babies born with birth defects, including displaying the dying infants to reporters, allowing the mothers to be photographed and interviewed, writing a series of articles in the *Chicago American*, delivering lectures, and posing for newsreels.²¹² Haiselden’s public statements “riveted the attention of the nation” and “made page-one headlines for days on end.”²¹³ Ultimately, Haiselden worked with a muckraking journalist to write and star in a movie, *The Black Stork*, that dramatized his refusal to perform an operation on a baby with birth defects needing immediate surgery. The film, at times also titled *Are You Fit to Marry*, “was shown commercially in movie theaters from 1916 through the 1920s.”²¹⁴ In its initial version, the link between Dr. Haiselden’s eugenic practices and race was quite clear: the film traced the baby’s impairments “to his grandfather’s liaison with a slave—a vile filthy creature who was suffering from a loathsome disease.”²¹⁵ That depiction was later changed to a white servant—although a Black

²⁰⁷ Pernick, *Eugenics and Public Health*, *supra* note 20, at 1770.

²⁰⁸ IHB Marker, *supra* note 203, at 2 (citing 66-Year-Old “Dad Wiley’s” *Eugenic Babies Now Romping, Husky American Youngsters*, PHILADELPHIA EVENING PUB. LEDGER, Oct. 19, 1922, at 18. Harvey and Anna Kenton Wiley were married when he was almost sixty-seven and she was thirty-three. *Id.*

²⁰⁹ See REES, *supra* note 2, at 59.

²¹⁰ *The Pure Food Law and “N*gger Gin,”* GOOD HOUSEKEEPING, Nov. 1913, at 693, 696, https://www.google.com/books/edition/Good_Housekeeping/6-omAQAAIAAJ?hl=en&gbpv=1&bsq=n*gger. For a detailed discussion of Wiley’s war against rectified whiskey, see Rees, *supra* note 2, at 107–20.

²¹¹ REES, *supra* note 2 at 267 n.49.

²¹² See PERNICK, *THE BLACK STORK*, *supra* note 50, at 6, 56, 74.

²¹³ *Id.* at 5.

²¹⁴ *Id.* at 6.

²¹⁵ *Id.* at 56. This notion of eugenic purity versus “syphilitic taint” was a common theme among the eugenicists, who advocated for laws that required sexually transmitted disease screenings before marriage.

child with birth defects remained depicted—after controversy over film Director D.W. Griffith’s racist *Birth of a Nation*, and concerns that “any depiction of miscegenation would outrage southern whites.”²¹⁶ Of course, the name of the film continued to evoke “associations between blackness and genetic deficiency.”²¹⁷

This strange and deeply troubling movie brought a eugenic debate into the open, and among Haiselden’s supporters was national celebrity Harvey Wiley, who, while lauding Haiselden’s pursuits, “called for ‘gradual’ expansion of the eugenic target population only after extensive propaganda had prepared the public for each widening of the net.”²¹⁸ Such a communications strategy echoes Wiley’s adept approach to the use of propaganda in his famous pure food and drug pursuits. In fact, the audience for eugenics had considerable overlap with the coalition that Wiley built in his crusade, including the women’s social reform organizations of the time.²¹⁹

Ultimately, in a 1922 *Good Housekeeping* article, Wiley published his thoughts on “The Rights of the Unborn”—a document that is in essence a eugenic social engineering manifesto, in which he argued for “matrimonial selection limited by law.”²²⁰ He begins by noting his own pedigree:

I consider it the greatest asset which has ever been active in my own career to have been the son of moral, intelligent, and physically perfect parents . . . [m]y forebears on my father’s side were Irish Protestants residing near Belfast. On my mother’s side they were Scotch-Presbyterians, members of the Maxwell clan, and thoroughly imbued with the doctrinal principles of that favored race. I say “favored” because it is universally acknowledged that descendants of the Scotch and Irish Presbyterians, or Protestants in the general sense, in Great Britain, and of the Huguenots of France, have always shown themselves to be a superior people. Not only are they a healthy race, long lived, and industrious, but their children had been brought up with strict discipline.²²¹

Paul A. Lombardo, *A Child’s Right to Be Well Born: Venereal Disease and the Eugenic Marriage Laws, 1913–1935*, 60 *PERSPECTS. BIOL. & MED.* 211 (Spring 2017).

²¹⁶ PERNICK, *THE BLACK STORK*, *supra* note 50, at 57.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ KLINE, *supra* note 8, at 27–28; see CARPENTER, *supra* note 2, at 265 (“The first and most significant force was the two principal women’s federations of the period, the Women’s Christian Temperance Union and the General Federation of Womens’ Clubs.”). Oddly, Wiley also provided “invaluable” and “enthusiastic” support for eugenic evangelist Paul Popenoe’s campaign advocating that Americans eat their pets. Whether this was driven by Wiley’s otherwise eccentric views or support for Popenoe specifically is unclear: there is no evidence that Wiley directly interacted with Popenoe, but notably, Popenoe had access to an array of “influential contacts” and “purposefully included government scientists among his cat feast guests.” VEIT, *supra* note 73, at 54. Wiley himself proposed pet eating in lectures in the winter of 1917–18, promoting the notion that the public “[k]ill all your pet dogs and cats, but save their hides” and recounted “an old woman he knew” who kept “a mangy, short-winded pup with a bad disposition that eats enough to keep three healthy babies.” VEIT, *supra* note 73, at 55. For Wiley at least, it may be that concerns about soaring food prices and a desire to send surplus food to starving Europeans were the driving factors here—pets typically ate human food at the time, and Americans clearly had a very different relationship with their pets in that era. VEIT, *supra* note 73, at 54.

²²⁰ Harvey W. Wiley, *The Rights of the Unborn*, 75 *GOOD HOUSEKEEPING*, at 32, Oct. 1922.

²²¹ *Id.*

While, unlike some eugenicists, Wiley goes on to hold out hope for those who are not from such ancestry, he proceeds to propose that:

[I]t will be necessary for the state to exercise control over marriage to a much greater degree than it has yet been done. Mating of the human animal is based almost solely upon sentimental principles. The true philosophy of life does not seek to obliterate sentiment. Its purpose is only to control and direct it. Nevertheless, it is the business of the state to inject a little common sense into matrimony.²²²

....

[B]ased upon the established principle that the state has a right to protect and perpetuate itself, an inquiry into the possibilities of the future citizens is entirely justified. This inquiry need not be pushed to any annoying extent, but it should cover the moral and physical aspects of the future citizen. The welfare of the state does not depend alone upon the number of its inhabitants but upon their character. Imbeciles, epileptics, syphilitics and tuberculines are undesirable. Therefore the state has a right to limit their number, as far as possible.²²³

....

[I]f we are really to get the people of this country interested in the greatest of all problems, namely, a happy, healthy life, we must in some way reach their inner conscience with the feeling that proper preparation for life is the supreme duty of the present generation. If we just take a casual survey, what do we find? Hospitals, supported largely at public expense for the blind, for the deaf, for the insane. All of these disasters—I say “all” in not too strict a sense, might have been avoided by the proper selection of husband or wife.²²⁴

He also noted:

[T]he organization of poor houses where the flotsam and jetsam of humanity are collected; men and women who have made a failure of life from every point of view, but who are neither insane nor necessarily the subject of hereditary disease, but simply lacking in those qualities of industry and judgment which marked the dividing path between success and failure. Thus, from an economic point of view, and that should never

²²² *Id.*

²²³ *Id.*

²²⁴ *Id.*

be lost sight of, the prevention and bringing of the imperfect and defective into the world is a factor of tremendous public importance.²²⁵

Wiley goes on to examine a famous eugenic case study of the “degenerate” Jukes family by Richard Dugdale, a typical eugenicist approach to “proving” the importance of race and good heredity.²²⁶ Like his former USDA colleague Willet Hays, he then draws a direct comparison between animal breeding—a central USDA concern—and human breeding for racial improvement. After describing how a breeder of cows deeply understands the pedigree of his Holsteins, he contrasts that knowledge with the cattle breeder’s own son:

His little boy who accompanies him into the yard and plays about his feet while his father is discoursing on the pedigree of his cow, is himself a scrub. His forbearers have never been selected for any desirable physical or lacteal property. They have come by chance. They have never had any examination to show their fitness. They have never been tested to discover if they have in their blood the ineradicable taint of a bad heredity. If we could introduce into the breeding of human beings those dynamic facts and principles illustrated by . . . the breeding of domesticated animals, we would lay the foundation of a future state whose splendor efficiency and fame would be the outstanding glory of history.²²⁷

Despite such writings calling for governmental eugenic management of the population, historian Jonathan Rees argues that “Wiley’s flirtation with eugenics indicates an underlying racism, but that racism was never central to his work as a food reformer.”²²⁸ Rather:

His interest in eugenics was . . . a reflection of his willingness to speak and write about science of which he had little understanding. Wiley was prone to follow scientific fads of all kinds—whether right or wrong—because he wanted to appear to understand more science than he actually did. His willingness to leave the realm of food left him open to what in retrospect seem like serious lapses in judgment.²²⁹

Yet, eugenics was much more than a fad, and the arc of Wiley’s career at USDA and beyond makes that conclusion hard to justify. In its essence, Wiley’s long fight for food and drug purity was largely consistent with eugenic ideology, and it was fought from his senior and high-profile role at the government agency—USDA—most

²²⁵ *Id.*

²²⁶ *Id.* (citing Richard Dugdale, *The Jukes: A Study of Crime, Pauperism, Disease and Heredity*, GEORGIA STATE UNIV. COLL. OF L. READING ROOM, *Buck v. Bell Documents: Faculty Publications* (Jan. 1, 1969)).

²²⁷ *Id.*

²²⁸ REES, *supra* note 2, at 210.

²²⁹ *Id.*

associated with, and supportive of, the growing eugenics movement. And the war against adulteration was one that Wiley and many other Progressive Era eugenicists believed must be waged with respect to *both* the “human engine” and the composition of U.S. society as a whole—through laws, regulation, and standard-setting.

X. ROYAL COPELAND

The eugenics believers of the Progressive Era did not simply disappear with their views in the 1920s. Although largely forgotten today, the homeopathic physician and Senator Royal Copeland served as the primary author and sponsor of the Federal Food, Drug, and Cosmetic Act of 1938, where a critical reference to homeopathy remains enshrined in the drug definition.²³⁰ Copeland had been steeped in the public health world for many years—until his election to the Senate in 1923, Copeland had served five terms on the New York City Board of Health and was the New York Public Health Commissioner.²³¹ His views were typical of eugenicists of the time, but he focused his efforts on the potential for replacement of the historical U.S. population by immigrants. He pointed to:

“[A]n alarming decrease in American babies” and warned that the country’s racial makeup had begun to lean dangerously toward, “black hair, black eyes, and . . . swarthy complexion.” While for Copeland, jazz music and the automobile played a pivotal role in declining white birth rates, impure milk also threatened the survival and vigor of white babies. Not surprisingly, for public health officials like Copeland food-borne diseases were often associated with eastern Europeans, Mexicans, and other “dirty” groups. Thus the dangers of racial and dietary contamination demanded authoritarian intervention.²³²

Yet the impact and influence of eugenics was not limited to USDA and key individuals involved in the 1906 and 1938 Acts. Eugenics was also an important factor in the development and activities of the other thread of modern FDA’s origins: the entities and statutes creating the Public Health Service.

XI. THE PUBLIC HEALTH SERVICE AND EUGENICS

Like the history of the food and drug aspects of FDA, the history of the regulation of biologics has been well-chronicled, including in this Journal.²³³ That history is complex, with the 1902 Act spurred not by Harvey Wiley’s coalition-building, but by safety scandals: contaminated biologic products killed two dozen children, resulting

²³⁰ See generally Suzanne White Junod, *An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation*, 55 FOOD & DRUG L.J. 161 (2000); Ole Salthe, *A Brief Review of the Legislative History of the Federal Food, Drug, and Cosmetic Act*, 3 FOOD DRUG COSMETIC L. Q. 148, 253–63 (June 1948).

²³¹ *Id.*

²³² Bobrow-Strain, *supra* note 73, at 26.

²³³ Coleman, *supra* note 115, at 544.

in the rushed enactment of the 1902 Biologics Act, negotiated by manufacturers of biologics with the Public Health Service to achieve their “urgent desire” to institute a regulation and licensing regime and restore confidence in their products.²³⁴ Under that statute, what became the Public Health Service implemented certain standards for manufacturing and products, and exercised lot approval and recall authorities.²³⁵

The Public Health Service (PHS) evolved from the Treasury Department’s Marine Hospital Services over time, and ultimately incorporated various public health functions, from research, to product manufacture and testing (the “Hygienic Laboratory”), to evaluation of immigrants at Ellis Island and other ports of entry. The Hygienic Laboratory was renamed the National Institute of Health (later changed to “Institutes” in 1948), “the unit directly involved with biologics [which] became the Division of Biologics Control in 1937, the Laboratory of Biologics Control in 1944, and the Division of Biologics Standards in 1955,” before later becoming part of FDA.²³⁶ Initially, rules under the 1902 Act were issued by a board composed of the Surgeon General and two military surgeons general, and administered by the PHS and “a layer of assistant surgeons general supervising the various units.”²³⁷

Is there evidence that eugenics was pivotal in the enactment of the 1902 or 1944 Acts? No. However, there is no doubt that certain critical figures in the leadership of the Public Health Service in that era, including the Surgeon General, were committed to eugenics as an integral part of the national public health agenda.²³⁸ Public health in the Progressive Era and beyond remained “closely entwined with the politics of social order and the policing of the dangerous classes” and “the line between wellness and sickness closely followed established hierarchies of social difference: class, ethnicity, and race.”²³⁹ Dr. Rupert Blue, whose tenure as Surgeon General ran from 1912–1920, supported eugenic laws, and he became a member of the Eugenics Committee of the American Genetic Association. His successor, Hugh Cumming (Surgeon General from 1920–1936), sat on the American Eugenics Society Advisory Council and helped organize the Second International Eugenics Congress in 1921. He became president of the American Public Health Association in 1931.²⁴⁰

Given its leadership’s views and its various roles, it is not surprising that the Public Health Service’s activities became deeply entangled in eugenics priorities and activities.²⁴¹ This involvement was so pervasive at the time that the Public Health Service offered:

²³⁴ *Id.* at 551.

²³⁵ FDLI, A CENTURY OF CONSUMER PROTECTION, *supra* note 2, at 200.

²³⁶ Coleman, *supra* note 115, at 558 n.83.

²³⁷ *Id.* at 558.

²³⁸ Paul Lombardo, *Eugenics and Public Health: Historical Connections and Ethical Implications*, in THE OXFORD HANDBOOK OF PUBLIC HEALTH ETHICS § 55, 647 (eds. Anna C. Mastroianni, Jeffrey P. Kahn & Nancy E. Kass, eds., Oxford Univ. Press, 2019) (“Officers of the Service supported the conclusion that social problems could be cured by eugenic interventions, and argued that ‘eugenics is a science. It is a fact, not a fad.’”), <https://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780190245191.001.0001/oxfordhb-9780190245191-e-56?print=pdf> (publ. online Mar. 2019); THE GUARDED GATE, *supra* note 141.

²³⁹ WILLIAM J. NOVAK, THE PEOPLE’S WELFARE: LAW AND REGULATION IN NINETEENTH-CENTURY AMERICA 216 (Univ. of N.C. Press 1996).

²⁴⁰ Lombardo, *Eugenics and Public Health*, *supra* note 237, at 647.

²⁴¹ *Id.*

[O]fficial certification to individuals who wished to prove their eugenic suitability for marriage. Its first certificate was granted to architect Homer B. Terrill of Washington, after the Surgeon General's office put him through "the most approved line of investigation known to the science of eugenics and pronounced him fit."²⁴²

The Public Health Service's manufacturing of vaccines and vaccine regulation was one of its most important early achievements, and the most direct predecessor regulatory function relative to the current FDA. However, the nexus of eugenics to public health debates over vaccines at the time was also clear. Remarkably, in the 1927 decision in *Buck v. Bell*, Justice Holmes cited *Jacobson v. Massachusetts*, the 1905 Supreme Court decision validating compulsory vaccination, without distinguishing between the public health protection goals of vaccination versus involuntary sterilization.²⁴³ Rather, Holmes wrote that "the principle that sustains compulsory vaccination is broad enough to cover cutting the fallopian."²⁴⁴

Perhaps the most important eugenic involvement of Public Health Service personnel was their training and responsibilities as "eugenic gatekeepers" at the border, resulting in numerous scenarios in which PHS officers explicitly implemented eugenic policies. Starting as the Marine Hospital Service, what became the Public Health Service increasingly became involved in the inspection of immigrants at the border and even at foreign ports.²⁴⁵ And the eugenic impetus behind these activities was important: "[t]he process of health inspection on arrival by the U.S. Public Health Service (and in some circumstances at the point of departure) was driven simultaneously by fiscal (the cost of welfare), health, and eugenic rationales, with the distinction between the latter increasingly imperceptible."²⁴⁶ For eugenicists, "barring genetically inferior immigrants before they stepped on the mainland was the necessary counterpart to sterilizing and secluding defective Americans."²⁴⁷

²⁴² ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER* 98 (W.W. Norton & Co. 2008) ("its work fit well with the beliefs of many American eugenicists that hygiene and sanitation had eased the rigors of natural selection and allowed more weakened specimens to prevail. Groups such as the Race Betterment Foundation mixed genetic concerns with preventive health measures, and eugenicists who advocated thinning out the unfit often won the support of public health officials.").

²⁴³ *THE GUARDED GATE*, *supra* note 141, at 171.

²⁴⁴ *Buck v. Bell*, 274 U.S. at 207 (citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)).

²⁴⁵ *Id.*; see generally PAUL A. LOMBARDO, *THREE GENERATIONS, NO IMBECILES: EUGENICS, THE SUPREME COURT AND BUCK V. BELL*, 104, 116 (Johns Hopkins Univ. Press, Oct. 1, 2010) (Lombardo notes that "the real story of the Bucks was much more complex: Carrie herself had been raped, her daughter Vivian was perfectly normal, and the case itself was a fraud."); see also Paul A. Lombardo, *Disability, Eugenics, and the Culture Wars*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 57 (2008).

²⁴⁶ The history of the Public Health Service's involvement in addressing disease outbreaks is also rife with eugenic and race-related controversies. See generally DAVID K. RANDALL, *BLACK DEATH AT THE GOLDEN GATE: THE RACE TO SAVE AMERICA FROM THE BUBONIC PLAGUE* (eds. W.W. Norton & Co. 2019); *Plague in San Francisco—1900, Year of the Rat*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES (Aug. 28, 2012, <https://www.niaid.nih.gov/about/joseph-kinyoun-indispensable-man-plague-san-francisco>). For a general organizational history of the Public Health Service, including the medical inspection of immigrants, see LAURENCE F. SCHMECKEBIER, *THE PUBLIC HEALTH SERVICE: ITS HISTORY, ACTIVITIES, AND ORGANIZATION*, INST. OF GOV. RSCH., Monograph No. 10, (Johns Hopkins Press, 1923).

²⁴⁷ *THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS*, *supra* note 8, at 159.

Among those trained in eugenics at the Eugenics Record Office at Cold Spring Harbor were Public Health Service Medical Examiners from Ellis Island.²⁴⁸ And Henry Goddard, a eugenics researcher (and segregationist), was invited by the Public Health Service to Ellis Island—where seventy percent of immigrants were entering the country at the time—to see if he could devise a method of identifying mentally deficient immigrants that was more reliable than the eye-ball test in use at the time.²⁴⁹ He then moved on to use of intelligence testing, and Public Health Service doctors “proudly announced how IQ tests would be enlisted in the Ellis Island screening process to identify ‘mental enfeeblement’ and ‘protect our racial stock.’”²⁵⁰ Predictably, such testing was unscientific, finding that virtually all immigrants were “morons.”²⁵¹ And, based on such arbitrary conceptions of race and fitness, laws were enacted to ensure that immigrants from Africa and Asia (and ultimately those deemed “inferior stock” from parts of Europe) need not apply.²⁵²

Research conducted by Public Health Service physicians was also in many cases driven by eugenic ideas that were pervasive in their medical schooling. The notorious Tuskegee Syphilis Study is perhaps the most shocking and long-lasting example. Surgeon General Hugh Cumming and PHS physicians Taliaferro Clark and Raymond Vonderlehr played central roles in initiating the study, which lasted from 1932 to 1972. Throughout that period, “the PHS continually assessed the health of some four hundred infected black men while intentionally withholding treatment.”²⁵³ As the eugenics scholar Paul Lombardo wrote:

Three critical features link these men. First, they had learned a brand of “racial medicine” that had evolved beyond medical folklore, finding “scientific” validation in eugenic theory. That theory provided a scientific overlay that legitimated long-standing medical and cultural prejudices toward African Americans Second, this learning took place at the University of Virginia’s medical school; the resulting personal alliances and interpersonal affinity as alumni of a single institution help to explain a pattern of appointments at the PHS, which became a stronghold of

²⁴⁸ Anne-Emanuelle Birn, *Six Seconds Per Eyelid: The Medical Inspection of Immigrants at Ellis Island, 1892–1914*, 17 DYNAMIS: ACTA HISPANICA AD MEDICINAE SCIENTARUMQUE HISTORIUM ILLUSTRANDAM 281, 288 (1997); KEVLES, *supra* note 3, at 95 (“A cardinal point of the American eugenics program had come to be the restriction of immigration from Eastern and Southern Europe. Eventually the program was enlarged to permit the immigration only of pure Caucasians; to require a minimum grade of ‘C’ the presumed average grade of the American population—on the Army intelligence-test scale; and to require certification, based on an assessment of near kin, that the prospective immigrant would become a biological asset to the United States.”).

²⁴⁹ KEVLES, *supra* note 3, at 56.

²⁵⁰ THE GUARDED GATE, *supra* note 141, at 235.

²⁵¹ Lombardo, *Eugenics and Public Health*, *supra* note 237, at 647.

²⁵² THE GUARDED GATE, *supra* note 141, at 239. Although thousands of immigrants were turned away due to such testing, even Goddard was not confident in his findings and slow-walked the publication of the results. THE GUARDED GATE, *supra* note 141, at 239. Jews were a particular target: in 1913, Public Health Doctor J.G. Wilson wrote in *Popular Science Monthly* that “[i]f the science of eugenics deserves any practical application at all, it should insist upon a careful study of the . . . Jews[,]” who are “a highly inbred and psychopathically inclined race . . . almost entirely due to heredity.” J.G. Wilson, *A Study in Jewish Psychopathology*, 82 POPULAR SCI. MONTHLY 265 (1913).

²⁵³ See NBC NEWS, 1910s–1920s: *Immigration, Defining Whiteness* (May 27, 2008), <https://www.nbcnews.com/id/wbna24714378>; KEVLES, *supra* note 3, at 95.

Virginia physicians. Third, during their Public Health Service careers, all three men were associated with the American eugenics movement; the continuing role of these and other PHS officers within the movement provides additional evidence of how eugenic theory may have influenced public health programs.²⁵⁴

Obviously, the Public Health Service has produced many momentous and enduring public health achievements in this country. Nonetheless, early in its history this central national public health function was responsible for numerous damaging practices driven by spurious eugenic “science.”

XII. WHY WORRY ABOUT EUGENICS AND THIS EARLY FDA HISTORY?

Given the time that has passed, these eugenic beliefs and practices may appear to be a mere historical curiosity. As a Progressive Era historian noted, while “eugenics and race science are today discredited . . . expertise in the service of an administrative state . . . has survived the discredited notions once used to uphold it . . . indeed it has thrived.”²⁵⁵ And most of that expertise is highly beneficial—modern, science-based FDA regulation. But could remnants of eugenics and its faulty assumptions and practices be found in FDA regulation even today, despite the passage of time and the many intervening changes to FDA and the laws it administers?

In investigating “historical amnesia” associated with eugenics, one must “tease out the insinuation and reach of eugenic ideas and practices today.”²⁵⁶ In the food and drug field, one place to start is in the interplay between the practice of medicine and FDA regulation. A known legacy of eugenics is that “[d]octors schooled in eugenic theory” included “these ‘racial’ distinctions as part of their diagnostic expectation, understanding disease susceptibility and medical outcomes differently for black and white patients.”²⁵⁷ Critically, such distinctions proliferated over the years. Today, the use of “race-norming” and other race-related adjustments in medicine is under wide-ranging critical study. Medical specialties are now grappling with disturbing remnants of race-based medical algorithms and measurements, some of which can be traced to spurious distinctions established via eugenic anthropometric studies. Others are attributable to even earlier racial theories originating in slavery-era medicine and experiments, or later assumptions established by evaluating health and anatomy with a faulty racial lens. Such remnants—often “hidden in plain sight”—continue to be used in medical practice and are inevitably embedded in clinical databases.²⁵⁸ And, “[b]y embedding race into the basic data and decisions of health care . . . these algorithms

²⁵⁴ A CENTURY OF EUGENICS, *supra* note 8, at 294.

²⁵⁵ A CENTURY OF EUGENICS, *supra* note 8, at 292.

²⁵⁶ LEONARD, ILLIBERAL REFORMERS *supra* note 9, at xiv.

²⁵⁷ STERN, *supra* note 4, at 238.

²⁵⁸ Lombardo & Dorr, *supra* note 9, at 294.

guide decisions in ways that may direct more attention or resources to white patients than to members of racial and ethnic minorities.”²⁵⁹

Such algorithms also have a direct link to regulatory decision-making. The use of clinical endpoints incorporating measurements that may have been subject to race-norming or adjustment may be routine in the clinical development and use of certain categories of drugs and medical devices, thus potentially embedding eugenic and other mistakes in data from controlled studies and real-world evidence. These practices often persist in part due to a lack of close examination of the underlying basis for certain racial distinctions, as well as the historically relatively recent scientific acceptance that race, long used by eugenicists and others as a scientific factor based on skin color or self-declaration, is “not a reliable proxy for genetic difference.”²⁶⁰

The origins of these practices can seem obscure at first: “[s]ome algorithm developers offer no explanation of why racial or ethnic differences might exist” or “offer rationales, but when these are traced to their origins, they lead to outdated, suspect racial science or to biased data.”²⁶¹ While “[m]ost such race corrections implicitly, if not explicitly, operate on the assumption that genetic difference tracks reliably with race” such assumptions are in fact “exceedingly unlikely” because “[s]tudies of the genetic structure of human populations continue to find more variation within racial groups than between them” and “racial differences found in large data sets most likely often reflect effects of racism[.]”²⁶²

To date, perhaps the best-researched historical example of the eugenic “contribution” to continued medical race “correction” practices is found in the work of Dr. Lundy Braun, who has traced the practice of race adjustment in the use of spirometers to measure the lung capacity of Black Americans directly to racial lung function theories that originated with Thomas Jefferson and slavery in the United States and were later perpetuated and reified by the anthropometric studies of Francis Galton, the founder of eugenics.²⁶³ The medical practice of making such adjustments for patients identified as Black or Asian (for example, setting the standard of “normal” for Black Americans at a fixed percentage, typically ten to fifteen percent, below that of a norm based on studies of whites) can result “in the misclassification of disease severity and impairment for racial/ethnic minorities (e.g., in asthma and COPD)” — potentially skewing treatment decisions.²⁶⁴

Galton’s work in this area focused on testing the physical attributes of races in anthropometric studies, including utilizing the spirometer to measure breathing capacity. Such studies had a direct relationship to monitoring progress in addressing the eugenic concern of racial “degeneration.” “With a few simple measurements,” Galton believed he could assess “whether the nation was progressing, deteriorating, or remaining the same” and “would show that inherent capacity, rather than education,

²⁵⁹ See generally Darshali A. Vyas, Leo G. Eisenstein & David S. Jones, *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms*, 383 NEW ENG. J. MED. 874 (Aug. 27, 2020).

²⁶⁰ *Id.* at 874.

²⁶¹ *Id.*

²⁶² *Id.* at 879.

²⁶³ *Id.*

²⁶⁴ See generally LUNDY BRAUN, *BREATHING RACE INTO THE MACHINE: THE SURPRISING CAREER OF THE SPIROMETER FROM PLANTATION TO GENETICS* (Univ. of Minnesota Press, 2014).

circumstances, or free will, drove the physical and psychological evolution of individuals and the race.”²⁶⁵ His faulty lung capacity “findings” were integrated into the literature, considered in standardization efforts, and globalized in medical and industrial practices relating to lung health and safety.²⁶⁶ Although now being reexamined, such race-adjustment practices could not be more relevant today, in that concerns have been expressed that race correction in spirometry, particularly in the recovery of COVID-19 patients, could conceivably bias “clinical reports of COVID-19 recovery, severity of lung damage, and subsequent recovery treatment plans.”²⁶⁷

Dr. Braun’s spirometry research is just one example. A range of long accepted race-related measures and adjustments are now under study or active revision in various clinical fields.²⁶⁸ While only some of these practices can likely be traced to the era of eugenics, the relevance of these findings to our FDA and Public Health Service founders most obviously lies in their deep preoccupation with measurements, standards, and specification-setting, in which figures such as Harvey Wiley were preeminent. To what extent do remnants of their historical eugenic biases and assumptions remain incorporated in measurements, standards, clinical practices, and

²⁶⁵ Vyas et al., *supra* note 259, at 878.

²⁶⁶ BRAUN, *supra* note 262, at 92.

²⁶⁷ *Id.* at 96.

²⁶⁸ *UW Medicine to Exclude Race from Calculation of eGFR (Measure of Kidney Function)*, UNIV. OF WASH. DIVISION OF NEPHROLOGY (June 5, 2020), <https://nephrology.uw.edu/news/excluding-race-calculation-egfr-measure-kidney-function> [hereinafter *UW Medicine to Exclude Race from Calculation of eGFR*]; Press Release, Am. Thoracic Soc’y, Removal of “Race Correction” in Pulmonary Function Tests Shows More Prevalent and Severe Lung Disease Among Black Patients (May 16, 2021), <https://www.thoracic.org/about/newsroom/press-releases/conference/removal-of-race-correction-in-pulmonary-function-tests.php>; Meredith A. Anderson, Atul Malhotra & Amy L. Non, *Could Routine Race-Adjustment of Spirometers Exacerbate Racial Disparities in COVID-19 Recovery?*, 9 THE LANCET 124, 125 and n.9 (Dec. 10, 2020) (citing Charles A. Odonkor, Rachel Esparza, Laura E. Flores, Monica Verduzco-Gutierrez, Miguel X. Escalon, Ryan Solinsky & Julie K. Silver, *Disparities in Health Care for Black Patients in Physical Medicine and Rehabilitation in the United States: A Narrative Review*, 13 AM. J. PHYSICAL MED. & REHAB. 180 (Oct. 8, 2020), <https://doi.org/10.1002/pmrj.12509> (“Spirometers are used in determining severity of ventilatory defects with the measure of forced expiratory volume—the amount of air expelled during the first 1 s of a forced exhalation. These measures can influence treatment plans—e.g., for patients with pulmonary fibrosis caused by COVID-19 induced pneumonia, pulmonary rehabilitation might be needed, including breathing exercises and continual monitoring of pulmonary function. These treatments might not be undertaken if the racial adjustment leads to misdiagnosis. This notion is of particular concern considering Black patients are already less likely than White patients to be referred to pulmonary rehabilitation, despite more frequent pulmonary-related hospitalizations.”)). Another example is the use of race as a factor in determining risk of acute heart failure, which “regards black patients as lower risk and may raise the threshold for using clinical resources for black patients.” Vyas et al., *supra* note 259, at 876. Also, the use of race in calculating a patient’s risk of complications and death in common cardiac surgeries, which uses adjusted scores for black patients and “could steer minority patients, deemed higher risk, away from these procedures.” *Id.* In nephrology, the focus is on adjustment estimated glomerular filtration rate (eGFR) MDRD and CKD-EPI equations, which reports higher eGFR values with the same creatinine measurement for patients identified as black, “potentially delaying referral to specialist care or listing for kidney transplantation.” *Id.*; *UW Medicine to Exclude Race from Calculation of eGFR*, *supra* note 268; Chi-yuan Hsu, Wei Yang, Rishi V. Parikh, Amanda H. Anderson, Teresa K. Chen, Debbie L. Cohen, Jiang He, Madhumita J. Mohanty, James P. Lash, Katherine T. Mills, Anthony N. Muir, Afshin Parsa, Milda R. Saunders, Tariq Shafi, Raymond R. Townsend, Sushrut S. Waikar, Jianqiao Wang, Myles Wolf, Thida C. Tan, Harold I. Feldman & Alan S. Go, *Race, Genetic Ancestry, and Estimating Kidney Function in CKD*, 385 NEW ENG. J. MED. 1750 (Nov. 4, 2021); Andrea Park, *NIH Vouches for New Kidney Disease Diagnostic That Doesn’t Rely on Faulty Race-Based Calculations*, FIERCE BIOTECH (Sept. 23, 2021), <https://www.fiercebiotech.com/medtech/nih-vouches-for-new-kidney-disease-diagnostic-doesn-t-rely-faulty-race-based-calculations>.

data intertwined with FDA regulation and policy even today? And what are the current and future implications of these remaining traces of eugenics, particularly in light of the enormous and magnifying power of current and developing technologies—from gene editing to artificial intelligence to implanted Brain–Computer Interface devices and transhumanism?²⁶⁹

The stakes associated with these questions may be growing in light of an ongoing debate over the “old” versus a “new” eugenics.²⁷⁰ In recent decades, various writers and researchers have argued that a resurrection of a sanitized version of eugenics—at times called “reprogenetics” or “neoeugenics”—is both possible and desirable in the era of molecular biology: “[t]heir conclusion is that we need not abandon the central motivation of eugenics—to endow future generations with genes that might enable their lives to go better—if this can be pursued and achieved justly.”²⁷¹ Others reject a revival of eugenics, but nonetheless call for a “new synthesis” that recognizes that ignoring the actual genetic differences among people also presents risks, and argue for using genetic data—delinked from socially constructed notions of race and hierarchy—in policies and interventions to improve outcomes.²⁷²

Thus, the early role of eugenics in the development of FDA’s central authorities and practices is not merely a troubling but remote historical curiosity, nor a wholly theoretical concern. In fact, there is a need to establish a better understanding of the subtle but potentially broad influence of eugenic history (and that of other historical strains of “scientific racism”) on data, regulation, and policy today and in the future.

²⁶⁹ U.S. FOOD & DRUG ADMIN., FDA-2014-N-1130, IMPLANTED BRAIN-COMPUTER INTERFACE (BCI) DEVICES FOR PATIENTS WITH PARALYSIS OR AMPUTATION—NON-CLINICAL TESTING AND CLINICAL CONSIDERATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATIVE STAFF (May 2021), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/implanted-brain-computer-interface-bci-devices-patients-paralysis-or-amputation-non-clinical-testing>; U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN (Jan. 2021), <https://www.fda.gov/media/145022/download>. Transhumanism “would augment or increase human sensory reception, emotive ability, or cognitive capacity as well as radically improve human health and extend human life spans” via technologies that “would be more or less permanent and integrated into the human body.” *Transhumanism*, ENCYCLOPAEDIA BRITANNICA, <https://www.britannica.com/topic/transhumanism> (last visited Aug. 7, 2022).

²⁷⁰ THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 540–41; Allen, *supra* note 106, at 59, 61; Calum MacKellar, *Gene Editing and the New Eugenics*, DIGNITAS § 1, at 3–9 (2018).

²⁷¹ THE OXFORD HANDBOOK OF THE HISTORY OF EUGENICS, *supra* note 8, at 541; see Linda L. McCabe & Edward R.B. McCabe, *Are We Entering a “Perfect Storm” for a Resurgence of Eugenics? Science, Medicine, and Their Social Context*, in A CENTURY OF EUGENICS, *supra* note 8, at 193.

²⁷² KATHRYN PAIGE HARDEN, THE GENETIC LOTTERY: WHY DNA MATTERS FOR SOCIAL EQUALITY 16, 21 (Princeton Univ. Press, 2021).