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Houston Journal of Health Law & Policy

GENETICS, PUBLIC HEALTH, STATES, AND THE CLEAN AIR ACT

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ABSTRACT

The Precision Medicine Initiative began recruiting participants in 2017[1] to implement an innovative approach to disease treatment and prevention that takes each person's variability in "genes, environment, and lifestyle" into account.[2] Precision medicine is determined to "pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients."[3]

However, most of these efforts remain in the research phase, which, although necessary to improve disease detection and treatment efficiency, fail to encourage a clear plan of implementation into state health programs. This Comment presents an approach to implement these efforts into state programs through a comparative analysis of the Clean Air Act's (the "Act") standard-setting scheme for criteria

[1] Eric Dishman, NAT'L INSTITUTES HEALTH, *Beta Testing Begins for NIH's All of Us Research Program*, ALL US RES. PROGRAM (June 5, 2017), https://allofusnih.gov/news-events-and-media/announcements/beta-testing-begins-nihs-all-us-research-program.

[2] PRECISION MED. INITIATIVE (PMI) WORKING GROUP, THE PRECISION MEDICINE INITIATIVE COHORT PROGRAM—BUILDING A RESEARCH FOUNDATION FOR 21ST CENTURY MEDICINE 1 (2015), https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf.

[3] THE WHITE HOUSE, OBAMA WHITE HOUSE ARCHIVE *Fact Sheet: President Obama's Precision Medicine Initiative*, ARCHIVES.GOV (Jan. 30, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

pollutants and by using the complex interplay between the federal and state governments set out by the Act as a reference.

Furthermore, fears of discrimination are still present among potential participants, fueled by this country's history of eugenics and sterilization.[4] More specifically, fears of employment and insurance genetic discrimination are prevalent among many.[5] These fears, along with an extensive history of eugenics in states promoting the elimination of certain inherited traits, have contributed to the underuse of genetic information.[6] Finally, this Comment addresses those fears and the various challenges that the integration of genetic information into public health entails.

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[4] Jessica L. Roberts, *The Genetic Information Nondiscrimination Act as an Antidiscrimination Law*, 86 NOTRE DAME L. REV. 597, 607-08 (2011).

[5] *See* discussion *infra* Part II (describing in detail concerns regarding employment and insurance discrimination).

[6] *See* discussion *infra* Part II(A) (describing in detail the history of eugenics).

INTRODUCTION

Genetic factors are known to play a role in nine out of ten leading causes of death in the United States.[7] Further, genetics represents a significant risk factor for premature death in the United States.[8] Hence there is no disputing the need for greater understanding of the implications of genetic characteristics in our daily lives.

Despite this, the United States is falling behind other countries when it comes to the implementation of genetic services.[9] Unlike American scientists, Asian scientists have the full support of their governments in genetic research.[10] The prevailing ethical and religious beliefs in the United States, and other Western governments, have led to the placement of heavy restrictions on genetic work.[11]

Nevertheless, since 2011, the United States has sought to move forward in the implementation of new understandings, as asserted by the National Institute of Health (NIH), "the time is right."[12] Advances in science now allow us to have a greater understanding of human genes due to the flood of genomic, transcriptomic, proteomic, and epigenomic data, which offer potential to better understand these molecular interactions.[13] Furthermore, an increasingly large number of people are now engaged in healthcare research because research

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7 Muin J. Khoury, *Geography, Genetics & Leading Causes of Death*, CENTERS FOR DISEASE CONTROL & PREVENTION: GENETICS & HEALTH IMPACT BLOG (May 15, 2014), https://blogs.cdc.gov/genomics/2014/05/15/geography/.

8 *See* Steven A. Schroeder, *We Can Do Better—Improving the Health of the American People,* 357 NEW ENG. J. MEDICINE 1221, 1222 (2007).

9 *See* RONALD M. GREEN, BIOTECHNOLOGY: OUR FUTURE AS HUMAN BEINGS AND CITIZENS 63 (Sean D. Sutton ed., 2009).

10 Dennis Normile & Charles C. Mann, *Asia Jockeys for Stem Cell Lead*, 307 SCI. 660, 660 (2005).

11 *Id.*; *see* Andrew Pollack, *Cancer Therapy Dropped in U.S. is Revived in China*, N.Y. TIMES (Feb. 25, 2005), http://www.nytimes.com/2005/02/25/business/worldbusiness/cancer-therapy-dropped-in-us-is-revived-in-china.html ("China is plowing ahead in certain areas of medicine that are regarded more cautiously in the United States.").

12 NAT'L INSTITUTES HEALTH, ALL OF US[SM] RESEARCH PROGRAM (2016), https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/allofus-inforgraphic-20161117.pdf.

13 *Id.*; Brandi Davis-Dusenbery, *Big Data: Precision Medicine Research in the Million-Genome Era*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Jan. 15, 2017), http://www.genengnews.com/gen-articles/big-data-precision-medicine-research-in-the-million-genome-era/5944.

technologies have improved dramatically and we now have the tools to track this vast amount of health information through large databases.[14]

In 2005, the Centers for Disease Control and Prevention (CDC) created the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) initiative.[15] The EGAPP initiative was "created in order to support the translation of scientific evidence from genomic testing into clinical practice."[16] In 2014, this group published a report titled *The EGAPP Initiative: Lessons Learned,* in which they summarize key limitations on the analytic validity of genomic tests.[17] The group emphasized the limited availability of evidence due to economic constraints—evidence that is nonetheless needed in order to accurately assess the clinical implications of a specific genetic result.[18]

More recently, the potential effects of genomic conditions inspired President Obama when he announced, during his 2015 State of the Union Address, the Precision Medicine Initiative (PMI).[19] As part of this initiative, the National Institute of Health now leads the effort to build a national, large-scale research enterprise with one million or more volunteers to extend precision medicine to all diseases, including the merging of electronic medical records and genomic information.[20] This type of research relies on large sets of data.[21] The more samples

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14 *See, e.g.*, NAT'L INSTITUTES HEALTH, *supra* note 12.

15 EVAL. OF GENOMIC APPLICATION IN PRACT. AND PREV. (EGAPP) WORKING GROUP, *The EGAPP Initiative: Lessons Learned*, 16 GENETICS MED. 217, 217 (2014).

16 *Id.* at 218.

17 *Id*. at 223-24.

18 *See id*. ("Economic conditions brought both critical federal budget concerns and a need for additional focus in public health programs.").

19 THE WHITE HOUSE, OBAMA WHITE HOUSE ARCHIVE, *Precision Medicine Initiative*, ARCHIVES.GOV, https://obamawhitehouse.archives.gov/precision-medicine (last visited Feb. 18, 2017).

20 *See* Omri Gottesman et al., *The Electronic Medical Records and Genomics (eMERGE) Network: Past, Present, and Future*, 15 GENETICS MED., 761, 761 (2013) (defining eMERGE as a "consortium tasked with developing methods and best practices for the utilization of the electronic medical record (EMR) as a tool for genomic research"); *Scientific Opportunities,* NAT'L INST. HEALTH, https://allofus.nih.gov/about/scientific-opportunities (last visited Oct. 6, 2017).

21 Jill U. Adams, *Big Hopes for Big Data*, 18 NATURE 108, 108-09 (2015) ("Big-data researchers believe that analyzing the data of the thousands of tumors that have come before will reveal

collected, the more genetic variants that can be found and detected in a person.[22] Therefore, to move these initiatives forward and translate the research results into actual effects in Americans' lives via public health policies, key actors must address the questions, concerns, challenges, and fears that are raised by genetic testing to attract participants and increase the availability of data.

This Comment advances the idea that the integration and practical implementation of precision medicine in a public health setting are yet to be addressed. In other words, many of these programs focus on the research end of the spectrum——i.e., investigation, correlation of genotypes/phenotypes, and study of diseases——but miss a form application into the daily lives of Americans. Only 50% of Americans say they have heard or read about genetic testing.[23]

This Comment argues that public health policy has much to gain from the increasing amount of genetic and genomic information that is available and argues that the Clean Air Act offers a useful paradigm for integrating genetic and genomic data into public health.

This Comment will address (I) the current efforts led by the United States government in the gathering of genomic information; (II) the significant concerns that must be addressed in implementing the knowledge of genomic testing into states' programs; and lastly, (III) an innovative approach to the applicability of the generalizations of genomic information to public health policy, more specifically, a comparative analysis with the Clean Air Act.

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patterns that can improve screening and diagnosis, and inform treatment.").

22 Davis-Dusenbery, *supra* note 13.

23 Sharon Begley, *Consumers Aren't Wild About Genetic Testing—Nor Are Doctors*, STAT NEWS (Feb. 12, 2017), https://www.statnews.com/2016/02/12/consumers-arent-wild-genetic-testing-doctors/.

I. CURRENT EFFORTS IN GATHERING OF GENOMIC INFORMATION

The United States government is currently engaging in programs that collect various types of personal information, including medical records and genomic information.[24] The purpose of these programs vary, but their collective end goal is to provide patients with a broader understanding of their medical conditions, faster treatment response, and treatment effectiveness.[25] As a way of introduction, this section will briefly address five recently implemented programs that embody the characteristics of gathering large sets of patient data and their usage in providing benefits to specific groups through research. These programs are: The Electronic Medical Records and Genomics (eMERGE),[26] FDA's Sentinel Data Network,[27] the Million Veteran Program,[28] FDA's *Guidance on Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics*,[29] and the All of Us Research Program (formerly called the "PMI Cohort Program").[30]

The eMERGE Network is a National Human Genome Research Institute-funded program "tasked with developing methods and best practices for the utilization of the electronic medical record (EMR) as a

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24 *See* discussion *infra* Part I.

25 *See, e.g.*, U.S. DEP'T VETERAN AFF., OFF. RES. & DEV., *Million Veteran Program (MVP)*, VA.Gov, http://www.research.va.gov/MVP/default.cfm (last visited Jan. 20, 2017) (noting that "[t]he goal of MVP is to partner with Veterans receiving their care in the VA Healthcare System to study how genes affect health."); PRECISION MED. INITIATIVE (PMI) WORKING GROUP, *supra* note 2, at 1; U.S. FOOD & DRUG ADMIN. *FDA's Sentinel Initiative - Background*, http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149340.htm (last updated Oct. 5, 2016) [hereinafter *Sentinel Initiative*] (explaining that "the FDA launched the Sentinel Initiative to create a national electronic system, the Sentinel System, for medical product safety surveillance.").

26 Gottesman, et al., *supra* note 20, at 761.

27 *See generally Sentinel Initiative*, *supra* note 25.

28 *See generally* U.S. DEP'T VETERAN AFF., *supra* note 25.

29 *See generally* U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR STAKEHOLDERS AND FOOD AND DRUG ADMINISTRATION STAFF: USE OF PUBLIC HUMAN GENETIC VARIANT DATABASES TO SUPPORT CLINICAL VALIDITY FOR NEXT GENERATION SEQUENCING (NGS)-BASED IN VITRO DIAGNOSTICS (July 8, 2016), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM509837.pdf.

30 *See* NAT'L INSTITUTES HEALTH, ALL OF US[SM] RESEARCH PROGRAM, *supra* note 12.

tool for genomic research."[31] The network combines longitudinal phenotypic data already contained in EMRs with genomic data for the discovery of genotype-phenotype associations.[32] Once these discoveries are validated, they are introduced back into the EMR to improve clinical care.[33]

In 2007, the Food and Drug Administrative Amendments Act (FDAAA) authorized the creation of a 100-million-person health data network known as the Sentinel Network.[34] The Sentinel Network is a national electronic system, created by the Food and Drug Administration (FDA), designed to monitor the safety of FDA-regulated medical products including drugs, vaccines, biologics, and medical devices.[35] When the Sentinel Network reaches its fully operational state, it will offer a rich database of health information.[36] The implementation of the Sentinel Network will include patients' Medicare, military, and private insurance claims, health records, pharmaceutical purchase data, and "other data as the Secretary [of Health and Human Services] deems necessary."[37]

The non-inclusion of genetic data in the Sentinel Network is not of consequence because the Sentinel Network's objective focuses on analyzing the safety and effectiveness of specific FDA-regulated products.[38] In contrast, as part of the 2011 White House Precision Medicine Initiative, the Million Veteran Program "combines genomic data, health and treatment records, and baseline and follow-up surveys that track veterans' military experiences, health, and lifestyles."[39] Unlike the Sentinel Network's focus on FDA-regulated',

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31 Gottesman, et al., *supra* note 20, at 761.

32 *Id*.

33 *Id*.

34 Barbara J. Evans, *Authority of the Food and Drug Administration to Require Data Access and Control Use Rights in the Sentinel Data Network*, 65 FOOD DRUG L.J. 67, 67 (2010).

35 *Sentinel Initiative*, *supra* note 25.

36 Evans, *supra* note 34, at 68.

37 Barbara J. Evans, *Congress' New Infrastructural Model of Medical Privacy*, 84 NOTRE DAME L. REV. 585, 588 (2009) (citing FDAAA § 905(a), 21 U.S.C § 355(k)(3)(C)(i)(III)(aa)-(cc)).

38 *Sentinel Initiative*, *supra* note 25.

39 John D. Curtis, *Million Veterans Program Now World's Largest Genomic Biobank*, YALE SCH. MED. (Aug. 12, 2016), https://medicine.yale.edu/news/article.aspx?id=13225.

the Million Veteran Program aims to accelerate understanding of disease detection, progression, prevention, and treatment by combining its rich clinical, environmental, and genomic data.[40]

In July 2016, the FDA issued draft guidance for the development of public human genetic variant databases[41] to establish the clinical validity of the different NGS-based (Next-Generation Sequencing) in vitro diagnostic tools being developed.[42] The guidance defined a "genetic variant database" as a "publicly accessible database of human genetic variants that aggregates and curates reports of human phenotype-genotype relationships to a disease or condition with publicly available documentation of evidence supporting those linkages."[43]

While many organizations have developed these databases, the FDA seeks to standardize "evidence aggregation, curation, and interpretation practices" to support FDA premarket submission.[44] The guidance expands on the required characteristics of such databases[45] and represents an important step in centralizing interpretative methods of NGS-produced data. Although ultimately the employment of the database would allow NGS-based tests to provide more accurate (clinically valid) information,[46] the guidance does not provide for a clear route that states can follow in order to benefit from the newly available information.

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40 *Id*.

41 U.S. FOOD & DRUG ADMIN., NOTICE OF AVAILABILITY: DRAFT GUIDANCE, 81 FR 44611, 44611 (proposed July 8, 2016); *see also* U.S. FOOD & DRUG ADMIN., *supra* note 29. *See generally* U.S. FOOD & DRUG ADMIN, *Proposed Regulations and Draft Guidances,* FDA.GOV, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/ (last updated Sep. 25, 2016) ("Draft regulations and guidances are documents that have been proposed, but FDA has not made a decision as to whether the proposal will be adopted in whole, in part, or not at all. Each FDA draft document lists how to submit comments to the agency concerning the draft.").

42 U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE, *supra* note 29, at 2.

43 *Id*.

44 *Id*. at 7.

45 *Id*. at 5-6.

46 *Id*. at 2.

The All of Us Research Program is the largest longitudinal study[47] in the history of the United States.[48] It represents an innovative approach to health care development that involves the combination of genes, environments, and lifestyles.[49] As part of the PMI, the program will create a cohort of one million volunteers who will contribute their health data and biospecimens to a centralized national database to support precision medicine research.[50] The program hopes to allow researchers to achieve a number of goals, including: (1) develop ways to measure risk of a range of diseases based on environmental exposures, genetic factors, and interactions between the two; (2) identify the causes of individual differences in response to commonly used drugs (pharmacogenomics); (3) discover biological markers that signal increased or decreased risk of developing common diseases; (4) use mobile health technologies to correlate activity, physiological measures and environmental exposures with health outcomes; (5) develop new disease classifications and relationships; (6) empower participants with data and information to improve their own health; and (7) create a platform to enable trials of targeted therapies.[51]

These programs, created as early as 2007, demonstrate a general trend towards big-data collection and collaboration among different players.[52] However, their actual implementation is still unclear. Furthermore, to continue driving their goals, the federal government must develop a proper route for implementation as they depend on the continued collection of medical records and participation.

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47 INST. WORK & HEALTH, *What Researchers Mean by . . . Cross-sectional vs. Longitudinal studies*, (2015), https://www.iwh.on.ca/wrmb/cross-sectional-vs-longitudinal-studies (defining longitudinal study as one in which researchers conduct several observations of the same subjects over a period of time, sometimes lasting many years).

48 Pamela L. Sankar & Lisa S. Parker, *The Precision Medicine Initiative's All of Us Research Program: An Agenda for Research on Its Ethical, Legal, and Social Issues*, 19 GENETICS MED. 743 (2017).

49 *Id*.

50 *Id*.

51 NAT'L INSTITUTES HEALTH, *Program FAQ,* NIH.GOV, https://www.nih.gov/allofus-research-program/frequently-asked-questions (last visited Jan. 20, 2017).

52 *See* discussion *supra* Part I.

II. SIGNIFICANT CONCERNS THAT MUST BE ADDRESSED IN IMPLEMENTING THE NEW GENETIC KNOWLEDGE INTO PUBLIC HEALTH PROGRAMS

Many fears, concerns, and challenges await further development of genetic services. From genetic discrimination, high costs, big data technical challenges, to ethical dilemmas, all of these looming concerns constantly clash with the possible benefits genetic services can provide. This section briefly explores and describes such concerns, which must be addressed before seeking greater engagement from the general population.

A. The Genetic Information Nondiscrimination Act May Not Be Enough

Beyond the context of childbearing, people are fearful that genetic information will be used to deny them and their relatives access to health insurance and employment.[53] Furthermore, ethnic groups like American Indians and Ashkenazi Jews have also expressed concern that genetic research and testing will cause them to be perceived as unusually healthy, and a burden to society.[54] These fears are not in vain. In part, they stem from the United States' history of eugenics-based laws and policies.[55] Starting in the 1900s, many states sanctioned forced sterilization to eliminate "unfavorable" traits, such as in the case of Carrie Buck.[56] Buck was eighteen-years-old when a court ordered the Virginia State Colony for Epileptics and Feeble Minded to sterilize her without her consent.[57] The US Supreme Court held that "society can prevent those who are manifestly unfit from continuing their kind . . . . Three generations of imbeciles are enough."[58] Between

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53 *See* Roberts, *supra* note 4, at 603-07.

54 Ellen Wright Clayton, *Genetics, Public Health, and the Law*, *in* GENETICS AND PUBLIC HEALTH IN THE 21ST CENTURY 489, 494 (Muin J. Khoury et al. eds., 2000).

55 *See* Roberts, *supra* note 4, at 607.

56 *Id*. at 608.

57 *Id*. (citing Buck v. Bell, 274 U.S. 200 (1927)).

58 *Id*. at 608 (quoting Buck v. Bell, 274 U.S. 200, 207 (1927)).

1921 and 1964, states sterilized over 60,000 people in the United States without their consent.[59]

Before 2008, these worries were only partially addressed by the Health Insurance Portability and Accessibility Act (HIPAA).[60] It was not until May 2008, after thirteen years of debate,[61] that Congress passed the Genetic Information Nondiscrimination Act (GINA) as civil rights legislation "intended to outlaw a burgeoning form of discrimination."[62] GINA was introduced with two related arguments: research justification (geared towards alleviating fear surrounding genetic testing) and an antidiscrimination justification.[63]

GINA prohibits "discrimination on the basis of genetic information in health insurance and employment."[64] Title I prohibits health insurers from using genetic information to determine eligibility or premiums, and from requiring genetic testing.[65] Section 202 states:

It shall be an unlawful employment practice for an employer:

to fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee; or

to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee.[66]

Thus, "Title II prohibits employers from hiring, firing, classifying, or otherwise disadvantaging employees based on genetic

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59 *Id*. at 608 (citing JACQUELINE VAUGHN SWITZER, DISABLED RIGHTS 36 (2003)).

60 *See supra* note 54, at 497.

61 *See* Roberts, *supra* note 4, at 599.

62 *Id*.

63 See Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 VAND. L. REV. 439, 471-80 (2010).

64 Roberts, *supra* note 4, at 617.

65 *See* 42 U.S.C. § 300gg-53 (2012).

66 42 U.S.C. § 2000ff-1(a) (2012).

information."[67] Additionally, Title II prohibits the requesting, requiring, or purchasing of genetic information of an employee or a family member of the employee with a few exceptions.[68]

Fears based on the history of eugenic policies and the possibility of harmful discrimination has led to the underuse of genetic technology.[69] This underuse, in turn, has led to negative effects for both researchers and individuals.[70] Linking genetic variations to health outcomes requires large sample sizes.[71] Consequently, in order to have significant statistical information, scientists must gather a large number of cases.[72] If individuals do not use genetic technology or indirectly hinder advances, patients will likely suffer the consequences by not receiving the best care possible that could potentially be provided by genetic advancement.[73]

GINA represents the "first predominantly forward-looking antidiscrimination statute" as "no socially recognized group of genetically disadvantaged people exists at present."[74] That is, GINA does not react to past discrimination on the basis of genetic information, but instead anticipates future discrimination.[75]

However, as Professor Jessica Roberts describes, GINA still has many weaknesses.[76] Under the current provisions, entities could still

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67 Roberts, *supra* note 554, at 599.

68 42 U.S.C. § 2000ff-1(b) (2012) (prohibiting the acquisition of genetic information by the employer).

69 Roberts, *supra* note 4, at 604-05.

70 *Id.* at 605.

71 GENETICS & PUBLIC POL'Y CTR, U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION & GENETIC DISCRIMINATION 1 (2007).

72 Eun Pyo Hong & Ji Wan Park, *Sample Size and Statistical Power Calculation in Genetic Association Studies*, GENOMICS INF. 117, 117-22 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3480678/; *see also,* Roberts, *supra* note 4, at 605 ("Without test subjects, researchers cannot design and run studies, and—consequently—genetic technology cannot advance.").

73 *See* Hong, *supra* note 72, at 117-22.

74 *Id.* at 600-01.

75 *Id.* at 600 (citing Roberts, *supra* note 63, at 441) (explaining further the preemptive nature of GINA that bases protection on future, rather than past or present, discrimination).

76 *See* Roberts, *supra* note 4, at 644.

use genetic information as a way of limiting available opportunities.[77] Potential discriminators would just have to wait until the conditions manifest as GINA does not protect manifested genetic health conditions.[78] Furthermore, once the condition is manifested, it does not constitute "genetic information," and thus, falls outside the reach of the statute.[79] Similarly, statutes like the Americans with Disabilities Act (ADA) would not be able to reach many conditions because a manifested condition is not necessarily a disability under the ADA.[80] Additionally, because GINA only prohibits facially discriminatory actions, it fails to acknowledge facially neutral policies with a disparate impact.[81] Therefore, employers may still introduce "policies that screen out undesirable genetic traits using other signals, either intentionally or unintentionally."[82] Consequently, as Professor Roberts advances, because GINA fails to protect manifested genetic conditions and other statutes like the ADA do not provide these protections, GINA needs incorporation of antisubordination protections.[83] A pure anticlassification approach, as currently provided, leads to the treatment of people with genetic disabilities exactly like their non-disabled counterparts, which could lead to undesired results.[84]

The United States' history of eugenic-based policies as well as fears arising out of the use of genetic information have led to underuse

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77 *Id.* at 634.

78 *Id.*

79 *Id.* at 634-35.

80 *Id.* at 635.

81 *Id.* at 639-40.

82 *Id.*

83 *Id.* at 635, 639-43.

84 *Id.* at 638-39 ("Take, for example, a genetic predisposition to developing carpal tunnel syndrome. GINA's prohibition on classifying on the basis of genetic information would prevent an employer from treating employees with that variant differently than employees with another variant. However, treating both groups identically could result in the carriers' developing carpal tunnel and needing to leave their jobs or take time off to recover while the group without the variant continues working. Alternatively, if the employer could consider genetic information, the employees with the genetic predisposition could work longer hours but with more breaks to allow their joints to rest or could switch positions throughout the day.").

of genetic services.[85] Due to the nature of the field, this underuse leads to less advancement,[86] and thus, two groups are disadvantaged: patients and researchers.[87] Before implementing measures that incorporate the use of genetic information in the area of public health services, states must ensure that these fears are further addressed. Otherwise, lack of advancement and innovation may lead to less than optimal care.

B. Are Insurance Companies Willing to Pay for Genetic Tests?

High costs present an additional challenge to the implementation of genetic information into public health programs.[88] Genomic medicine has the capacity to revolutionize clinical practice, but if private insurance companies and public payers, such as Medicare, are unwilling to pay for genetic testing, the process will likely be stalled.[89] Health insurers observe the availability of genetic tests when deciding which tests to include as part of their coverage,[90] and their decisions to cover these new genetic tests impact the use of the tests and their potential integration to state programs.[91] This presents a circular dilemma: the coverage of the tests by insurance companies depends on their availability, which in turn depends on their usage. The answer to this dilemma appears to rely on whether Medicare will begin covering genetic tests for its beneficiaries.[92] Therefore, the implementation of these programs will remain uncertain until the time

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85 *Id.* at 607.

86 *See supra* note 71, at 1.

87 Roberts, *supra* note 4, at 605.

88 Toby Tabachnick, *Cost, Coverage Remain Hurdles to Standard Genetic Testing*, JEWISH CHRON., Sep. 30, 2010, at 1; Alex Kacik, *Genetic Testing Not Living Up to Its Promise in Cancer Treatment*, MOD. HEALTHCARE (Sep. 11, 2017), http://www.modernhealthcare.com/article/20170503/NEWS/170509957.

89 NAT'L HUM. GENOME RES. INST., *Coverage and Reimbursement of Genetic Tests*, GENOME.GOV, https://www.genome.gov/19016729/ (last updated May 2, 2016).

90 AMANDA K. SARATA, GENETIC TESTING: BACKGROUND AND POLICY ISSUES 12 (Congressional Research Serv. 2015).

91 *Id.*

92 *Id.*

comes when Medicare and insurance companies decide to provide coverage for genetic testing.

C. Big Data Technical Challenges

Precision Medicine inherently involves the generation of large amounts of data. The scale and complexity of large population samples "require innovative and efficient approaches to analysis."[93] It is estimated that by 2025 we will be generating approximately two exabytes (or two million terabytes) of data per year.[94] Storing, accessing, and analyzing this data will be a difficult challenge.[95]

Furthermore, collection of genomic data not only involves genomes, but also involves "other types of data like RNA sequencing, proteomic, imaging, and clinical data."[96] That is, not only has the number of samples increased, but the dimensions of analysis have also increased.[97]

One solution involves portable analysis workflows that travel to the data, such as those employed in the Million Veteran Program.[98] A researcher within the VA research site can write a description of an analysis he wants to do and submit it to another VA research site using only kilobytes of data.[99] Analysis is in turn done across the network and the data itself is not transported.

Another solution would be to centralize storage.[100] Cloud computing providers offer storage and infrastructure, that, when combined with biomedical software and service providers, will give organizations the ability to create streamlined genomic analysis.[101]

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93 Davis-Dusenbury, *supra* note 13.

94 *Id.*

95 *Id.*

96 *Id.*

97 *See id.*

98 *Id.*

99 Davis-Dusenbery, *supra* note 13.

100 *Id.*

101 *Id.*

Other challenges related to big data involve making data more useful and visual.[102] These issues, along with the management of large data generation challenge, must be addressed to allow a more efficient use of resources and time.

D. Ethical Concerns

The development of the Human Genome Project by the NIH and the Department of Energy brought attention to the ethical issues involved in sequencing the genome and applying that knowledge.[103] Particular angst, however, is directed at physicians being able to diagnose a genetically-determined disease or a genetic predisposition to a disease when there is no effective preventive or therapeutic treatment available to the individual.[104] That is, whether to use genetic testing involves complex questions about informed consent, confidentiality, privacy, and duty to warn.[105] Although these would partially be addressed at the normative assessment step in the implementation of the public health policy development,[106] the ethical challenges are only going to increase, so the establishment of a credible process for public discourse and respectful consideration of diverse views will be critical to the development and application to public health agencies.[107]

Although many of these concerns are rooted deeply within our country's history,[108] such as the fears of genetic discrimination, others fall within areas of new legislation opposed by states, such as the area of ethical concerns.[109] Furthermore, the fear of high costs and big data challenges will not be solved until the use of this information becomes

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102 *Id*.

103 Gilbert S. Omenn, *Genetics and Public Health: Historical Perspectives and Current Challenges and Opportunities*, *in* GENETICS AND PUBLIC HEALTH IN THE 21ST CENTURY 25, 41 (Muin J. Khoury et al. eds., 2000).

104 *Id*. at 42.

105 *Id*.

106 *See infra*, at 46-47 (explaining what the normative step is).

107 Omenn, *supra* note 103, at 42.

108 *See* discussion *supra* Section (II)A, at 16 (explaining the Unites States' history of eugenics-based laws and policies, including many state-sanctioned forced sterilization laws).

109 *See infra* Section (II)D, at 28.

more prevalent. Therefore, it is not the time to stop innovation and let those fears hamper our progress. Instead, it is time to address and implement a new place for genetics in society.

III. AN INNOVATIVE APPROACH IN THE IMPLEMENTATION OF THE USE OF GENOMIC INFORMATION INTO PUBLIC HEALTH POLICY DEVELOPMENT

A. Complex Interplay of Powers Between State and Federal Government

While some modern political philosophers argue that public health is an inherent function of the government, one thing is true: "[W]ithout healthy citizens, there can be no state. . . ."[110]

Although the federal government often conditions funds and exercises its regulatory powers of interstate commerce to influence public health policies within a state,[111] the power to promote and maintain public health has historically been reserved to the states under the Tenth Amendment[112] of the Constitution.[113] Furthermore, the US Supreme Court has admitted that states' powers in this area of law are far-reaching.[114] Accordingly, states often delegate some of their authority to local governments.[115]

Reconsiderations of the reach of the federal government's Commerce Clause in terms of public health have led to more limitations.[116] As a result, Congress must be careful when legislating if

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110 *See supra* note 54, at 490.

111 *Id*. at 491.

112 U.S. CONST. amend. X (stating that "[t]he powers not delegated to the United States by the Constitution… are reserved to the States respectively," meaning that because public health regulation was not explicitly delegated to the federal government, it is up to the states to maintain).

113 Clayton, *supra* note 54, at 490.

114 *Id*. at 490-91.

115 *Id*. at 491.

116 *Id*.

it wishes to accomplish national public health objectives.[117] This involves subjecting practically every bill that Congress wishes to pass through the political process.[118]

Nevertheless, even if we assume that the government's policy powers in terms of public health are broad, a number of rights constrain these powers and narrow the reach of any such law. These rights include the right to privacy, which includes the right to make decisions free from governmental interference. Such decisions include the right to bear children and the right to refuse life-sustaining medical treatment.[119] Additionally, the right to privacy also includes the "right to avoid disclosure of personal matters."[120] Equally, the right to due process and equal protection of the laws play important roles in preventing government overreach.[121]

Finally, while the implementation of genetic information into public health policy conjures a picture of the federal government gathering large sets of data on citizens, most of its actual implementation would be at the state level. Therefore, as previously stated, the development and implementation of public health policies typically arise from a complex interplay between state and local governments.

B. Innovative Approach Through a Comparative Analysis with the Clean Air Act

Dense, visible smog in many cities contributed to the passing of the Clean Air Act in 1970.[122] Although it has undergone various reviews to improve its effectiveness and to target new sources of air

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117 James G. Hodge, Jr., *Implementing Modern Public Health Goals Through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. HEALTH L. & POL'Y 93, 117 (1997).

118 Clayton, *supra* note 54, at 491.

119 *Id*.

120 *Id*. (citing Whalen v. Roe, 429 U.S. 589 (1977)) ("Another aspect of the right to privacy is the 'right to avoid disclosure of personal matters' by the government.").

121 *Id*. at 491-92.

122 U.S. ENVTL. PROTECTION AGENCY, *Clean Air Act Requirements and History*, EPA.GOV, https://www.epa.gov/clean-air-act-overview/clean-air-act-requirements-and-history (last updated Jan. 20, 2017).

pollution since its enactment,[123] it involves a situation surprisingly similar to the one caused by the implementation of genetic factors into the public health policies within the United States.

Sections 7408 through 7409 of Title 42 require that the Environmental Protection Agency (EPA) Administrator prepare a list of air pollutants that may be contributed to or caused by emissions and may endanger public health or welfare.[124] Furthermore, the EPA Administrator must also publish regulations prescribing a national primary ambient air quality standard to these listed air pollutants.[125] Once the EPA sets the national standards of emissions for those listed air pollutants, states are required to adopt enforceable plans to achieve and maintain air quality by meeting the air quality standards.[126] Although at first, this process seems distant from the implementation of public health policies, certain characteristics in its implementation could help guide states in developing public health policies.

This section will propose two analogies as models of comparative analysis to Title I of the Clean Air Act. Subsection (a) will address the adaptation of the federal-state relationship of the Clean Air Act into a state-county relationship ensuring a respect to the complex interplay between the federal and state powers in matters of health policy development. Subsection (b) will address the interplay of specific provisions of the Clean Air Act and their implementation into health policy through an innovative form of goal-setting for counties.

1. Adaptation of Clean Air Act's Federal-State Relationship to State-County in a Setting of Public Health Policy

The legislators who participated in the 1970 amendments of the Clean Air Act contemplated the increasing role of the federal government at the expense of the states.[127] However, "[e]ven a cursory

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123 *Id*.

124 42 U.S.C. § 7408 (2012).

125 42 U.S.C. § 7409 (2012).

126 42 U.S.C. § 7410 (2012).

127 John P. Dwyer, *The Practice of Federalism Under the Clean Air Act*, 54 MD. L. REV. 1183, 1191 (1995).

review of the Clean Air Act shows that the states are important actors in the implementation and enforcement of air pollution policy."[128] Similarly, the states' exercise of the police powers in the area of public health policies "depend[s] on non-interference of the national government in a decentralized, state-based framework."[129] This was confirmed in *Acorn v. Edwards*,[130] where the Fifth Circuit struck down a provision of the Lead Contamination Control Act "requiring states to establish remedial action programs for the removal of lead contaminants from school and day-care water fountains."[131] The Fifth Circuit reasoned that the "requirement that states develop a program to further federal government's purposes, or be subject to a civil suit 'is no choice at all.'"[132] The Fifth Circuit held that in theory, it is "an attempt by Congress to force states to regulate according to Congressional direction."[133]

Although this Comment advances this centered approach to public health policy development at the state level, by no means does it dismiss the idea that public health duties must not be prioritized at the national level.[134] In fact, this interplay between the federal government's capabilities in developing large, nationally-based cohorts of information that combine genomic, environmental, and medical records information, with states' police powers to implement the new understandings is what must drive public health policy development.

Nonetheless, due to this state-focused framework, the federalist principles adopted in the Clean Air Act must be adapted into local principles of public health policy. Again, as mentioned *supra*, states

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128 *Id*. at 1193.

129 James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 312 (1998).

130 *Id*. at 355 (citing *Acorn v. Edwards*, 81 F.3d 1387 (5th Cir. 1996)) (explaining that Acorn v. Edwards illustrates how the federal government is constrained from intruding upon the states' exercise of police power in the public health field).

131 *Id*.

132 *Id.*

133 *Id.*

134 *Id.* at 355-56.

often delegate some of their public health authority to local governments.[135]

For example, in Texas, the state legislature has delegated a number of functions to local governments.[136] Chapters 121 and 122 of the Texas Health & Safety Code[137] developed this infrastructure. These chapters depict the close interplay between the state and local governments. Section 121.002(1) defines "essential public health services" as, among others, services to: monitor the health status of individuals in the community to identify community health problems; diagnose and investigate community health problems and community health hazards; inform, educate, and empower the community with respect to health issues; develop policies and plans to support individual and community efforts to improve health; and evaluate the effectiveness, accessibility, and quality of personal and population-based health services in a community.[138] Section 121.0065 allows the Texas Department of Health and Human Services to administer grants to counties, municipalities, and public health districts to provide or pay for the essential public health services.[139] That is, the state government may condition funds specifically for the provision of those essential public health services.

The Texas Department of State Health Services' website lists, among others, the following services that local public health organization currently provide: disease surveillance and tracking services; environmental health services through water, sewage, and air quality; and health and public health education and promotion.[140]

The integration of genetics into these services could enhance the local government's effectiveness as more accurate information could lead to a more accurate understanding of residents' medical

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135 *See* discussion *supra* Section (III)(A); *see also* Clayton *supra* note 54.

136 *See generally* Tex. Health & Safety Code §§ 121.003, 122.001 (2015).

137 Tex. Health & Safety Code §§ 121 & 122 (2015) (also known as the Local Public Health Reorganization Act).

138 *Id.* at § 121.002(1).

139 *Id.* at § 121.0065.

140 TEX. DEP'T STATE HEALTH SERVS., DIV. FOR REGIONAL & LOC. HEALTH SERVICES, *Texas Local Public Health Organizations*, http://www.dshs.texas.gov/rls/localservices/ (last visited on Nov. 11, 2017).

conditions, faster treatment response, and treatment effectiveness—the goals of the Precision Medicine Initiative.[141]

The Clean Air Act represented a challenge for the federal government in implementing, enforcing, and funding such a complex Act.[142] Furthermore, legislators viewed the concept of state autonomy and principles of federalism with suspicion because "states had failed to impose adequate air pollution controls."[143] Yet, it ultimately became a law that relied on these principles by allowing states to set up their own implementation plans to achieve the federal standards.[144] Because the federal government's public health powers are greatly limited, the focus of a plan that proposes the development of health policy must be centered on the states.[145] This provides an interesting opportunity to apply the lessons learned from the Clean Air Act at a much smaller level between state governments and local governments.

This relational adaptation is further supported by the infrastructure already in place in many states.[146] For example, the Texas state government delegates public health authority to local governments.[147] The implementation of public health policies is just a further step down the road. However, putting the federalist relationship discussion aside, this analogy is practically incomplete without discussion of the ways the Clean Air Act achieved its goals.

Once a proper infrastructure is in place, one that involves genetic data, the development of public health policies would follow the Clean Air Act's standard-setting approach.

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141 U.S. DEP'T VETERAN AFF., OFF. RES. & DEV., *supra* note 25, at 2; PRECISION MED. INITIATIVE (PMI) WORKING GROUP, *supra* note 2; *Sentinel Initiative*, *supra* note 25, at 1; Naoyuki Tsuchiya, *Human Immune System Diversity and its Implications in Diseases,* 60 J. HUM. GENETICS, 655-56 (2015) ("The majority of autoimmune or immune-related diseases are complex diseases, where a combination of multiple genetic and non-genetic factors is thought to play a role.").

142 Dwyer, *supra* note 127, at 1192.

143 *Id.* at 1192-93.

144 *Id.*

145 *See* Hodge, Jr., *The Role of New Federalism and Public Health Law*, *supra* note 129 (maintaining that the states' exercise of police powers "depends on non-interference of the national government in a decentralized, state-based framework.").

146 Tex. Health & Safety Code §§ 121.002(1), 121.0065.

147 Clayton, *supra* note 54, at 491; Tex. Health & Safety Code § 121.0065.

2. *The Clean Air Act's Standard-Setting Approach in a Public Health Policy Development Context*

This subsection will give a brief background on the pertinent parts of Title I of the Clean Air Act's standard-setting approach, which will then be adapted into the public health context incorporating genetic services.

a. Background on the Clean Air Act's Standard-Setting Approach.

The Clean Air Act's standard-setting approach consists of the following three steps: (1) setting of national ambient air quality standards; (2) evaluation of whether regions abide by the standards; and (3) the implementation of plans to maintain attainment to the standards or to reach attainment.[148]

As previously mentioned, 42 U.S.C. § 7409 requires the EPA Administrator to publish regulations prescribing a national primary ambient air quality standard to certain listed air pollutants.[149] Once these emission standards are set, the EPA evaluates which areas meet the standards.[150] Lastly, states work closely with the EPA by adopting enforceable plans to achieve and maintain air quality by meeting the air quality standards.[151]

As of today, the EPA has listed and required National Ambient Air Quality Standards (NAAQS) for six air pollutants.[152] However, air is polluted by a combination of natural and man-made substances.[153]

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148 U.S. ENVTL. PROTECTION AGENCY, *Process of Reviewing the National Ambient Air Quality Standards*, CRITERIA AIR POLLUTANTS, EPA.GOV (Feb. 1, 2018, 7:15 PM), https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards.

149 Nat'l Primary & Secondary Ambient Air Quality Standards, 42 U.S.C. § 7409 (2012).

150 U.S. ENVTL. PROTECTION AGENCY, *NAAQS Designations Process*, CRITERIA AIR POLLUTANTS (Feb. 1, 2018, 7:18 PM), https://www.epa.gov/criteria-air-pollutants/naaqs-designations-process.

151 U.S. ENVTL. PROTECTION AGENCY, *supra* note 148.

152 U.S. ENVTL. PROTECTION AGENCY, *Criteria Air Pollutants*, https://www.epa.gov/criteria-air-pollutants (citing six common air pollutants: ground-level ozone, particulate matter, carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide).

153 NAT'L INST. ENV'T HEALTH SCI., *AIR Pollution*, NIH.GOV, https://www.niehs.nih.gov/health/topics/agents/air-pollution/ (last visited Jan. 20, 2017.

These substances include, among others, fine particles produced by the burning of fossil fuels, noxious gases, ground-level ozone, tobacco smoke, building materials, mold, and pollen.[154] How could the EPA narrow down the large number of pollutants to just six criteria air pollutants? This dilemma is also encountered in the allocation of resources to a small amount of health conditions out of the vast number of health conditions currently present.

The Clean Air Act provides that in promulgating a new or revised NAAQS (i.e., narrowing the vast number of pollutants out in the environment), the EPA must draft a "Criteria Document" that reflects "the latest scientific knowledge" of the health effects of the relevant pollutant.[155] For example, in setting the national air quality standards for carbon monoxide, the EPA prepared a "Scope and Methods Plan for Health Risk and Exposure Assessment."[156] In this preliminary report,[157] the EPA discusses the adverse health effects that carbon monoxide causes in the human body.[158] The "greatest concern from [carbon monoxide] exposure is hypoxia induced by elevated [carboxyhemoglobin] levels."[159] The report particularly emphasizes the effects of carbon monoxide in vulnerable individuals: "reduced delivery of O_2 [caused by the presence of carbon monoxide] is of heightened concern for individuals with ischemic heart diseases. . . ."[160] Furthermore, the report takes into account available evidence from controlled human exposure, epidemiologic, toxicological studies, and emergency room visits.[161] The report concludes that the studies "support a direct effect of short-term [carbon monoxide] exposure on

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154 *Id.*

155 Cary Goglianese & Gary E. Merchant, *The EPA's Risky Reasoning,* 1 CATO J. 16 (2004); Air Quality Criteria & Control Techniques, 42 U.S.C. § 7408.

156 U.S. ENVTL. PROTECTION AGENCY, *Carbon Monoxide National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* EPA-452/R-09-004 (2009).

157 U.S. ENVTL. PROTECTION AGENCY, *supra* note 149 (analyzing the five steps outlined: Planning, Integrated Science Assessment (ISA), Risk/Exposure Assessment (REA), Policy Assessment (PA), and Rulemaking).

158 U.S. ENVTL. PROTECTION AGENCY, *supra* note 157, at 6.

159 *Id.*

160 *Id.*

161 *Id.* at 7.

cardiovascular morbidity at ambient concentrations below the current NAAQS level."[162] At this point, along with other pieces of information, the EPA sets the standard and applies a similar approach for the rest of the criteria pollutants.[163]

The determination of whether certain areas of the country meet the new standards set by the EPA requires data collection from monitors in urban and rural settings collecting information characterizing air quality, such as modeling.[164]

After working with the states and considering the information from air quality monitors, and/or models, the EPA will "designate" an area as attainment or nonattainment for the standard.[165] If an area is designated nonattainment, the EPA has interpreted section 110(a)(2) to require emission limits.[166] That is, the state environmental agency must submit a plan in which emission limitations are contemplated in order to attain the NAAQS in those areas designated as nonattainment.[167] Conversely, areas in attainment are required to maintain their emissions in a way that does not pass the limits imposed by the state implementation plan.[168]

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162 *Id.*

163 *See* U.S. ENVTL. PROTECTION AGENCY, *Clean Air Pollutants*, EPA.GOV, https://www.epa.gov/criteria-air-pollutants (last visited Oct. 22, 2017) (noting that the "Clean Air Act requires EPA to set National Ambient Air Quality standards (NAAQS) for six common air pollutants (also known as "criteria air pollutants") and that the rest of the reviewing information can be found online on the Environmental Protection Agency's website).

164 *NAAQS Designations Process*, U.S. ENVTL. PROTECTION AGENCY (Feb. 21, 2017), https://www.epa.gov/criteria-air-pollutants/naaqs-designations-process.

165 *Id.*

166 U.S. ENVTL. PROTECTION AGENCY, GUIDANCE ON INFRASTRUCTURE STATE IMPLEMENTATION PLAN (SIP) ELEMENTS UNDER CLEAN AIR ACT SECTIONS 110(A)(1) & 110(A)(2) (2013).

167 *Id.*

168 42 U.S.C. § 7410 (2012).

b. Implementing the Standard-Setting Approach into a Public Health Program that Incorporates Genetic Information

There are around 25,500 genetic tests available for rare and common conditions[169] and more than 500 laboratories where genetic testing is available.[170] The results of a genetic test can help determine a person's propensity of developing or passing a specific genetic disorder to future generations.[171] These discoveries present broad potential applications for improving health and preventing disease.[172] In fact, the field of public health genomics[173] uses population-based data on genetic variation and environmental interactions with the genes to develop, implement, and evaluate evidence-based tools for improving health and preventing disease.[174] The applicability of such tests is primarily divided into six types: therapeutic agents, diagnostic tests, pharmacogenomics tests, prognostic tests, screening tests, and risk assessment tests.[175]

In developing public health programs, states must account for the benefits brought by genetics. As previously mentioned, the current legal framework and infrastructural relationships allow for this to occur. However, "[i]n a time of tight budgets, difficult choices have to be made. We must make sure our very limited resources are spent on priorities."[176] Consequently, we must answer the question, how do we

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169 NAT'L CTR. FOR BIOTECHNOLOGY INFO., http://www.ncbi.nlm.nih.gov/gtr (last visited Jan. 20, 2017).

170 NAT'L INSTITUTES HEALTH, *GENETIC TESTING: HOW IT IS USED FOR HEALTHCARE* (2010).

171 GENETICS HOME REFERENCE, https://ghr.nlm.nih.gov/primer/testing/genetictesting (last visited Jan. 20, 2017).

172 MUIN J. KHOURY ET AL., HUMAN GENOME EPIDEMIOLOGY: A SCIENTIFIC FOUNDATION FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE 3 (2004).

173 MUIN J. KHOURY ET AL., HUMAN GENOME EPIDEMIOLOGY: BUILDING THE EVIDENCE FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE 5-6 (2d. ed. 2010) ("'[P]ublic health genomics . . .' [is] a multidisciplinary field concerned with the effective and responsible translation of genome-based knowledge and technologies to improve population health.").

174 *Id.* at 6.

175 *Id.* at 5.

176 Bob Riley, *Bob Riley Quotes*, BRAINYQUOTES, https://www.brainyquotes.com/quotes/quotes/b/bobriley167775.html (last visited Oct. 10, 20 17).

prioritize our limited resources among the vast number of options available as a consequence of the incorporation of genetic information into public health development? As discussed *supra*, this dilemma is often encountered by the EPA in narrowing the number of pollutants to be listed.[177] That is, in this case, it presents the challenge of how to narrow the list of conditions that state governments will allocate resources towards.

Because of the concerns (which are to be discussed in Part iii of this Comment, *infra*) surrounding the use of genetic information, this Comment advances the idea that states must employ the evidentiary model of policy development in narrowing the listed conditions to be prioritized with the use of state resources for genetic services.

The evidentiary model relies on three main features: (1) understanding that empirical data is necessary prior to the development of any health policy decision; (2) acknowledgment that translation into health policy involves a normative assessment; and (3) that the normative assessment must be made not only by scientific professionals, but also by the public.[178] This is because such decisions (of which conditions to prioritize resource allocation) are value decisions that affect society as a whole.[179] Under the evidentiary model, the deliberately chosen standard of care would determine utilization of genetic resources and reimbursement.[180]

Examples of what may constitute as normative aspects include whether a particular disease is sufficiently common or severe to warrant a genetic testing program, or whether the benefits are justified by the costs.[181] This Comment further advances the need to incorporate the environment's influence in the development of a genetic-related condition as an additional normative aspect.

Once the normative aspects are weighed by the public and, thus, specific genetically-related conditions are narrowed down into "listed

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177 *See* discussion *supra* Section (III)(B)(2) (discussing background on the Clean Air Act's standard-setting approach).

178 Benjamin S. Wilfond & Elizabeth J. Thomson, *Models of Public Health Genetic Policy Development*, GENETICS & PUB. HEALTH 21ST CENTURY 61, 73 (Muin J. Khoury et al. eds., 2000).

179 *Id*.

180 *Id.* at 74.

181 *Id.* at 73.

criteria conditions," the states, in the utilization of their police power,[182] would set standards for the treatment of people suffering from criteria conditions by incorporating the provision of genetic services through local governments. That is, genetic information will be used to determine which conditions would be listed,[183] in turn improving treatment options, treatment effectiveness, and treatment response.[184]

Similar to the second and third steps of the Clean Air Act's standard-setting approach, state governments—now serving as the central goal-setting body—would evaluate whether different regions around the state would be considered in attainment or not. That is, state governments would assess whether the local governments (i.e., counties) of different regions abide or have implemented the provision of genetic services to specific conditions. If a region has not incorporated the provision of genetic services for certain criteria conditions and would in turn be considered in nonattainment, those regions must work with the state governments in the implementation of policy strategies budget expansion in order to abide by the set standard. In practice, local governments would incorporate genetic prevention and treatment services specifically targeting the listed criteria conditions.

Through the evidentiary model of policy development, genetic information can be implemented to expand the provision of state public health services. States would set standards of treatment and use genetic information in determining the "listed criteria conditions" to be targeted by employing the many tools available through efforts of

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182 Clayton, *see supra* note 54 (explaining that the power to promote and maintain public health was reserved to the states under the Tenth Amendment of the US Constitution).

183 Would be listed as "listed conditions" just like the Clean Air Act lists criteria pollutants.

184 *See supra* notes 29-32 and accompanying text (through the use of generalizations coming from centralized data, departing from federal efforts in addressing precision medicine. These programs are listed in section (i)); NAT'L INSTITUTES HEALTH, THE PRECISION MEDICINE INITIATIVE COHORT PROGRAM—BUILDING A RESEARCH FOUNDATION FOR 21ST CENTURY MEDICINE, https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf (last visited Oct. 20, 2017); Gottesman, et al., *supra* note 20, at 761; *See* U.S. DEP'T OF VETERAN AFF., OFF. OF RES. & DEV., VA.GOV, http://www.research.va.gov/MVP/default.cfm (last visited Jan. 20, 2017).

the federal government[185] and would also employ the use of genetic information in the treatment of the listed criteria conditions.[186]

CONCLUSION

We are entering a world in which parents can choose their baby's eye color and companies can offer genetic dating services.[187] Precision medicine seeks to maximize effectiveness by taking into account variability in genes, environment, and lifestyle. Precision medicine promises to redefine our understanding of disease onset and progression, treatment response, and health outcomes through the more precise measurement of molecular, environmental, and behavioral factors that contribute to health and disease.[188] In achieving this, the federal government has engaged in a number of efforts that aim to gather large amounts of data to be used in improving treatments. However, although participation is admittedly essential, neither program provides a direct avenue of implementation into state health programs.

The Clean Air Act Title I's complex interplay between the federal government and states provides an interesting analogous model. By design, the actors of this interplay, however, must be scaled down to one between states and counties or local governments. Furthermore, the Clean Air Act's standard-setting approach for criteria pollutants provides an additional opportunity of analogy for a system that requires the active participation of local governments.

Nevertheless, before these programs that incorporate genetic information are implemented into state public health programs, both the federal government and states must address the well-founded fears of genetic discrimination which have not been completely addressed by GINA, and technical and ethical challenges that will

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185 *See* discussion *supra* Section (I) (describing the current federal efforts in addressing the incorporation of genetic information. For example: The Precision Medicine Initiative, Sentinel Initiative, etc.).

186 Wilfond & Thomson, *supra* note 178 ("Expansion of state provided services to include genetic treatments. Incorporation of precision medicine.").

187 Roberts, *supra* note 4, at 647.

188 *See* Davis-Dusenbery, *supra* note 13.

continue to grow and become more complex with the passing of time. Even so, these challenges must not halt the development of personalized medicine. "We must not succumb to the complacency that says that the human organism has achieved its optimum state and we can now relax our efforts at health improvement. Above all, we must not lose our capacity to dream."[189]

[189] Green, *supra* note 9, at 63.