Algorithmic Discrimination in M-Health: Rethinking the US Nondiscrimination Legal Framework Through the Lens of Intersectionality

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ABSTRACT: The diversity of AI-powered m-Health technologies creates challenges for their effective regulation. This, in turn, enhances the risk of potential harms for the patients, including discriminatory outputs. This paper submits that algorithms embedded in m-Health technologies are particularly likely to discriminate against patients based on a unique synergy of protected grounds, reinforcing intersectional patterns of disadvantage. Based on the analysis of Section 1557 of the Patient Protection and Affordable Care Act, the main US non-discrimination provision applicable in the area of healthcare, the contribution highlights regulatory gaps in the protection of intersectional claimants who face automated discrimination. Lastly, the paper critically analyzes the Biden Administration's latest proposal for the revised Section 1557 rule, focusing particularly on a new provision dealing with algorithmic discrimination in healthcare.

KEYWORDS: M-Health; algorithmic discrimination; intersectional discrimination; software as a medical device; Section 1557 ACA

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1. Introduction

The concept of intersectional discrimination was brought to the legal discourse in 1989 by Kimberlé Williams Crenshaw who described how distinctive patterns of disadvantage can arise based on multiple identities, highlighting the experiences of Black women in the US.[1] In her recent report on racism and health the UN Special Rapporteur on the right to health underlines that "intersectionality is the bridge to substantive equality and must be placed at the centre of the operationalization of the right to health".[2] Nevertheless, despite these developments, patterns of exclusion based on a combination of grounds such as gender, racial or ethnic origin, disability, sexual orientation, or socio-economic status persist in healthcare.

The rise of mobile healthcare during the COVID-19 crisis has sparked discussions about how m-Health solutions could minimize health disparities by enhancing the prevention of diseases, early diagnosis, and monitoring of chronic health conditions.[3] Modern mobile technologies that serve to improve population health and well-being have been increasingly developed with the use of artificial intelligence (AI) algorithms which can significantly enhance their performance, for example by analysis of real-time medical data. However, algorithms are not neutral and can entrench and exacerbate intersecting axes of inequality at various points of their life cycle – from data collection, through development to deployment.[4] Addressing this problem requires comprehensive regulatory solutions, including both *ex-ante* protections, such as regulation of medical devices, and *ex-post* protections, such as anti-discrimination law. Unfortunately, the latter, being predominantly based on specific protected grounds considered in isolation, largely fails to accommodate intersectional claims. In the US, the overly complicated enforcement mechanisms under Section 1557, the anti-discrimination provision of the Patient Protection and Affordable Care Act (ACA), prevent patients from successfully bringing claims, especially those based on a combination of grounds. Thus, this contribution argues that non-discrimination law in the area of healthcare should be urgently revised to allow intersectional claims by patients who face human or automated discrimination.

The rest of the article proceeds as follows: section 2 revisits the concept of intersectional discrimination and discusses it in the context of healthcare; section 3 explores how algorithmic discrimination in m-Health technologies can disproportionately impact intersectional groups; section 4 offers an analysis of anti-discrimination legislation on the federal level, in particular Section 1557 ACA, examining the

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[1] K. W. CRENSHAW, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, in *University of Chicago Legal Forum*, 1989, 139-167.

[2] OHCHR | A/77/197: Report by the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health – Racism and the right to health *https://www.ohchr.org/en/documents/thematic-reports/a77197-report-special-rapporteur-right-everyone-enjoyment-highest* (last visited 20/12/2023).

[3] O. POLLICINO, L. LIGUORI, E. STEFANINI, *M-Health at the Crossroads between the Right to Health and the Right to Privacy*, in E. STEFANINI ET AL. (eds.), *The Cambridge Handbook of Information Technology, Life Sciences and Human Rights*, 2022, Cambridge, 11.

[4] H. SURESH, J. GUTTAG, *A Framework for Understanding Sources of Harm throughout the Machine Learning Life Cycle*, in *Equity and Access in Algorithms, Mechanisms, and Optimization*, 2021, New York, Association for Computing Machinery (EAAMO '21), 1. *https://doi.org/10.1145/3465416.3483305* (last visited 20/12/2023).

scope of protection offered to patients facing algorithmic discrimination on the intersection of protected grounds; section 5 comments on the Biden Administration's proposal for Section 1557 Regulations which introduces a new provision dealing with algorithmic discrimination in healthcare; section 6 concludes.

2. The concept of intersectional discrimination in healthcare

Crenshaw's academic commentary showed how anti-discrimination jurisprudence fundamentally misunderstood the nature of intersectional oppression.[5] One of the cases she analyzed was *DeGraffenreid v. General Motors*[6] in which the plaintiffs alleged that the "last hired first hired policy" disproportionately disadvantaged Black women, whom General Motors started to employ only 15 years prior. The Court refused to conduct an assessment based on a combination of race and sex, discussing the two categories separately. It thus found no sex discrimination because other, mostly white, women employees enjoyed favorable hiring statistics. Likewise, the Court refused to recognize that the plaintiffs had been discriminated based on race, since doing so would create a "special class", namely a Black woman.[7] This outcome showed the inadequacy of anti-discrimination law that focused on strictly single-axis discrimination, sparking debate about the groups that fall through the cracks of legal protections.

In the modern legal debate, Shreya Atrey argues that intersectionality involves tracing patterns of sameness and difference in group disadvantage and considering them as whole, having regard to the socio-economic, cultural, and political context.[8] She further underlines that the purpose of intersectional analysis is inherently transformative, aiming to rectify historical disadvantages suffered by intersectional groups.[9]

Conceived in this manner, intersectionality is a particularly useful tool for understanding and analyzing discrimination in healthcare. Far from being a purely biological phenomenon, health reflects prevailing patterns of power and exclusion in society, including racism, sexism, and classism. For instance, understanding the nature of discrimination faced by a Black gay man in the provision of healthcare requires an appreciation of his experience as a Black person and as a person belonging to a sexual minority. Both of these groups have distinct patterns of disadvantage and associated stereotypes. These are marked both by racism, such as high pain resistance,[10] and homophobia, such as the burden of HIV.[11] The experience of a Black gay person is at the same time similar to the experience of Black persons and gay persons and qualitatively different from both of them. Thus, it has to be understood as integrity, in the relevant socio-historical context.

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[5] K. W. CRENSHAW, *op. cit.*
[6] *DeGraffenreid v. General Motors* 413 F Supp 142 (E.D. Mo. 1976).
[7] *DeGraffenreid*, *op. cit.*, 143.
[8] S. ATREY, *Intersectional discrimination*, Oxford, 2019, 36.
[9] S. ATREY, *op. cit.,* 36.
[10] S. HAMED ET AL., *Racism in healthcare: a scoping review*, in *BMC Public Health*, 22, 1, 2022, 988.
[11] M.L. HATZENBUEHLER, C. O'CLEIRIGH, K.H. MAYER, M.J. MIMIAGA, S.A. SAFREN, *Prospective associations between HIV-related stigma, transmission risk behaviors, and adverse mental health outcomes in men who have sex with men*, in *Annals of Behavioral Medicine*, 42, 2, 2011, 227-234.

A growing number of studies use intersectionality to highlight complex health inequalities in the US. For instance, it has been confirmed that Black and other racial minority women experience complex patterns of discrimination when accessing healthcare and social determinants of health.[12] Similarly, persons with disabilities belonging to racial or ethnic minorities face particular challenges in the context of healthcare.[13]

While public health and social science study the nature of the intersectional disadvantages, the law should work on ways to address them, particularly in light of the rise of disruptive technologies that can both ease and enhance healthcare inequalities.

3. The rise of algorithms in m-Health – discrimination risks for intersectional groups

The World Health Organisation (WHO) defines the term m-Health as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".[14] Other definitions are broader, recognizing that technologies falling under the scope of m-Health are diverse and can include both devices and software applications used to monitor and augment not only the health but also the general well-being of patients.[15]

The m-Health technologies can be either "patient-facing" or "provider-facing".[16] The former are usually marketed directly to consumers to meet their self-identified needs, while the latter are destined to serve as diagnostic and prognostic aid to medical professionals. Such m-Health solutions are progressively incorporated into the healthcare systems around the world. For instance, the German Digital Healthcare Act integrates m-Health tools into traditional care by creating a system of "apps on prescription".[17]

3.1. AI-powered m-Health – applications

Many of the m-Health software applications rely on algorithms, a series of computational instructions that transform the input value into the output value.[18] Algorithms are building blocks of AI, a term that refers to a system's ability to learn and mimic human decision-making. AI systems can range from explicitly programmed expert systems to machine learning (ML) systems that can learn automatically from data, detecting patterns.

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[12] P. HOMAN, T.H. BROWN, B. KING, *Structural Intersectionality as a New Direction for Health Disparities Research*, in *Journal of Health and Social Behavior*, 62, 3, 2021, 350-370.

[13] W. HORNER-JOHNSON, *Disability, Intersectionality, and Inequity: Life at the Margins*, in D.J. LOLLAR, W. HORNER-JOHNSON, AND K. FROEHLICH-GROBE (eds.), *Public Health Perspectives on Disability: Science, Social Justice, Ethics, and Beyond*, New York, 2021, 91-105.

[14] WHO Global Observatory for eHealth, *mHealth: new horizons for health through mobile technologies: second global survey on eHealth*, 2011, *https://apps.who.int/iris/handle/10665/44607* (last visited 20/12/2023).

[15] O. POLLICINO, L. LIGUORI, E. STEFANINI, *op. cit.*, 12.

[16] N.P. TERRY, L.F. WILEY, *Liability for Mobile Health and Wearable Technologies*, in *Annals of Health Law*, 25, 2, 2016, 62-97; N.P. TERRY, T.D. GUNTER, *Regulating Mobile Mental Health Apps*, in *Behavioral Sciences & the Law*, 36, 2, 2018, 136-44.

[17] O. POLLICINO, L. LIGUORI, E. STEFANINI, *op. cit.*, 19.

[18] T.H. CORMEN ET AL., *Introduction to algorithms*, Cambridge, 2022.

AI tools have been gradually transforming the healthcare landscape, especially in the emerging sub-field of m-Health: digital therapeutics. Digital therapeutics are defined as technologies offering "evidence-based therapeutic interventions to patients that are driven by software to prevent, manage, or treat a medical disorder or disease".[19] They can be deployed independently or accompanied by pharmacological therapy or medical and portable devices. An example is provided by ML-enabled wearable devices and implants which contain sensors allowing them to monitor the biomedical parameters of a patient to facilitate tasks such as the identification of ventricular arrhythmias,[20] detection of hypoglycemic events for diabetic patients[21] or prediction of the onset of seizures in patients with epilepsy.[22] As they continue to learn and adapt after their deployment, these algorithms can become increasingly personalized, offering a better quality of care to individual patients.[23]

Another example of AI's impact on m-Health involves the use of natural language processing (NLP), a sub-field of AI and linguistics that focuses on processing and interpreting text data. The state-of-the-art large language models are increasingly adapted to the medical domain, allowing analysis of large corpora of both structured and unstructured clinical data.[24] Models pre-trained on such data could be fine-tuned to a variety of m-Health applications based on the analysis of natural language. Moreover, their generative capabilities and ability to engage in human-like conversation allow for the development of more patient-friendly app interfaces or digital assistants.[25] For instance, digital voice assistant technologies, similar to Amazon's Alexa, could be developed for monitoring the cognitive functions of the elderly and early detection of diseases such as Alzheimer's.[26] Similarly, the incorporation of NLP

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[19] A. DANG, D. ARORA, P. RANE, *Role of digital therapeutics and the changing future of healthcare*, in J*ournal of Family Medicine and Primary Care*, 9, 5, 2020, 2207-2213, *https://doi.org/10.4103/jfmpc.jfmpc_105_20* (last viewed 20/12/2023).

[20] Z. JIA ET AL., *Personalized Deep Learning for Ventricular Arrhythmias Detection on Medical IoT Systems*, *https://doi.org/10.48550/arXiv.2008.08060* (last viewed 20/12/2023).

[21] M. PORUMB ET AL., *Precision Medicine and Artificial Intelligence: A Pilot Study on Deep Learning for Hypoglycemic Events Detection Based on ECG*, in *Scientific Reports*, 10, 1, 2020, 170, *https://doi.org/10.1038/s41598-019-56927-5* (last viewed 20/12/2023).

[22] See for instance: M.J. COOK ET AL., *Prediction of Seizure Likelihood with a Long-Term, Implanted Seizure Advisory System in Patients with Drug-Resistant Epilepsy: A First-in-Man Study*, in *The Lancet. Neurology*, 12, 6, 2013, 563-71; M.F. PINTO, *A Personalized and Evolutionary Algorithm for Interpretable EEG Epilepsy Seizure Prediction*, in *Scientific Reports*, 11, 1, 2021, 3415, *https://doi.org/10.1038/s41598-021-82828-7* (last visited 20/12/2023).

[23] J. HATHERLEY, R. SPARROW, *Diachronic and synchronic variation in the performance of adaptive machine learning systems: the ethical challenges*, in *Journal of the American Medical Informatics Association*, 30, 2, 2023, 361-366 *https://doi.org/10.1093/jamia/ocac218* (last visited 20/12/2023).

[24] L. RASMY ET AL., *Med-BERT: Pretrained Contextualized Embeddings on Large-Scale Structured Electronic Health Records for Disease Prediction*, in *NPJ Digital Medicine*, 4, 1, 2021, 86, *https://doi.org/10.1038/s41746-021-00455-y* (last visited 20/12/2023).

[25] R. BOMMASANI ET AL., *On the Opportunities and Risks of Foundation Models*, *https://doi.org/10.48550/arXiv.2108.07258* (last visited 20/12/2023).

[26] D.A. SIMON ET AL., *Should Alexa diagnose Alzheimer's?: Legal and ethical issues with at-home consumer devices*, in *Cell Reports. Medicine*, 3, 12, 2022, 100692, *https://doi.org/10.1016/j.xcrm.2022.100692* (last visited 20/12/2023).

solutions into mental health apps, which remain one of the most popular types of direct-to-consumer health apps,[27] could contribute to the early detection of mental health problems.[28]

3.2. The regulatory challenges of AI-powered m-Health

Mobile health devices and software applications, particularly those influencing clinical decisions made by physicians, should be subject to comprehensive regulatory oversight. However, across jurisdictions, challenges arise concerning the effective regulation of m-Health tools.[29] This is due to the breadth of the category which encompasses diverse technologies exhibiting varying degrees of risk to the patient. The degree of oversight depends primarily on whether an m-Health device or software will be classified as a medical device. This is determined based on its intended purpose, as specified by the manufacturer. In order or qualify as a device under section 201(h) of the Food, Drugs and Cosmetics Act (FD&C Act), the tool must be intended for "diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man." Moreover, even if the intended purpose is met, a software's function could be excluded from the device definition by section 520(o) of the FD&C Act. The recent guidelines issued by the Food and Drug Administration (FDA)[30] interpret the section, highlighting that software does not meet the requirements of a medical device if it *simultaneously* fulfills four conditions:

1) it does not acquire, process or analyze medical images, signals or patterns;
2) it is intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information normally exchanged between healthcare professionals;
3) it is intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition, also regarding an individual patient;
4) the recommendations that the software provides are accompanied by the basis that the healthcare professional can review, so that the clinical diagnosis or treatment decision regarding an individual patient is not guided directly by the recommendation.

Based on these criteria, a computer-aided diagnosis system receiving signals from wearables would likely be classified as a device, while applications that analyze general patient data to issue recommendations for the physician would not, as long as their output is accompanied by explanations. Finally, even if the software is classified as a medical device, the FDA can exercise enforcement discretion,

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[27] N.P. TERRY, T.D. GUNTER, *Regulating Mobile Mental Health Apps*, in *Behavioral Sciences & the Law*, 36, 2, 2018, 136-44.

[28] See, for instance: R.A. CALVO ET AL., *Natural Language Processing in Mental Health Applications Using Non-Clinical Texts*, in *Natural Language Engineering*, 23, 5, 2017, 649-85, *https://doi.org/10.1017/S1351324916000383* (last visited 20/12/2023); S. D'ALFONSO, *AI in Mental Health*, in *Current Opinion in Psychology*, 36, 2020, 112-17, *https://doi.org/10.1016/j.copsyc.2020.04.005* (last visited 20/12/2023); A. L. GLAZ ET AL., *Machine Learning and Natural Language Processing in Mental Health: Systematic Review,* in *Journal of Medical Internet Research*, 23, 5, 2021, e15708, *https://doi.org/10.2196/15708* (last visited 20/12/2023).

[29] O. POLLICINO, L. LIGUORI, E. STEFANINI, *op. cit.*; D. A. SIMON ET AL., *op. cit*.

[30] US Food and Drug Administration (FDA) Center for Devices and Radiological Health, *Clinical Decision Support Software*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software* (last visited 20/12/2023).

abandoning regulatory requirements in case of software that poses minimal risk to the patient. For instance, a digital assistant that analyzes symptoms against patient characteristics such as age, sex, or behavioral risk to advise whether to consult a doctor would likely fall under this discretion.[31]

This complex regulatory system creates many grey areas, as certain m-Health tools can be particularly difficult to classify. Moreover, manufacturers of mobile health applications often purport to avoid regulatory oversight by marketing them as general wellness tracking products or "experimental tools" for clinicians.[32] Nevertheless, these applications, if inaccurate or inappropriately utilized, can still cause harm to patients, for instance by suggesting inappropriate medical interventions. Thus, some scholars criticize over-reliance on auto-certification of purpose, highlighting that certain m-Health solutions can in practice be used contrary to the manufacturer's intended purpose, or their intended purpose might evolve without the legal classification being rectified.[33] The gaps and uncertainties in the regulatory framework of medical devices can negatively affect the safety of patients, causing harm, including discriminatory treatment.

Recent regulatory developments could help to fill in those gaps in the case of provider-facing technologies. Even if certain m-Health tools fall outside of the scope of medical device regulation, they can still be subject to requirements established by the Office of the National Coordinator for Health Information Technology (ONC), in particular, the ONC Health IT Certification Program. Participation in the program is voluntary for the providers of Health IT (HIT), such as electronic health records (EHR).[34] However, since the adoption of certified HIT by healthcare institutions is a prerequisite for participation in numerous governmental and non-governmental programs, the technology providers have a strong incentive to comply. In December 2023, the ONC finalized a new rule (HTI-1 Rule)[35] that introduced transparency requirements for predictive decision support interventions (PDSI)[36] which form part of certified HIT systems.[37] The preamble argues that the provision of information relevant to health equity concerns will enable clinical users to determine, based on their judgment, whether the

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[31] US Food and Drug Administration (FDA) Center for Devices and Radiological Health, *Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion*, *https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion* (last visited 20/12/2023).

[32] S. GILBERT ET AL., *Large language model AI chatbots require approval as medical devices*, in *Nature Medicine*, 29, 2023, 2396-2398.

[33] H. YU, *Regulation of Digital Health Technologies in the European Union: Intended versus Actual Use*, in C. SHACHAR ET AL. (eds.), *The Future of Medical Device Regulation: Innovation and Protection*, Cambridge, 2022, 103-114.

[34] According to the ONC, HIT refers to "electronic systems health care professionals – and increasingly, patients – use to store, share, and analyze health information". See HIT Factsheet: *https://www.healthit.gov/sites/default/files/pdf/health-information-technology-fact-sheet.pdf* (last visited 20/12/2023).

[35] Office of the National Coordinator for Health Information Technology (ONC), US Department of Health and Human Services (HHS), *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (HTI-1) Final Rule, *https://www.healthit.gov/sites/default/files/page/2023-12/hti-1-final-rule.pdf* (last visited 20/12/2023).

[36] The HTI-1 Rule distinguishes between evidence-based and predictive decision-support interventions. It defines the latter as "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis" (ONC, *op. cit.*, § 170.102).

[37] ONC, *op. cit.*, § 170.315(b)(11).

PDSI are fair.[38] While transparency and fairness are inextricably linked, the provision of information might not always be sufficient to ensure health equity. For instance, a recent study has found that image-based explanations did not help clinicians improve the accuracy of decisions taken with the use of a systemically biased AI system.[39] This result suggests that explanations, even in a user-friendly form, might not be enough to mitigate bias.

3.3. Algorithmic bias in healthcare – the effect on intersectional groups

As acknowledged by the Blueprint for the AI Bill of Rights, a non-binding policy agenda published by the White House Office of Science and Technology Policy, one of the risks associated with the deployment of algorithms in the health sector is the entrenchment of bias underlying the healthcare system, leading to discrimination against vulnerable groups of patients.[40] This type of discrimination is difficult to detect and remedy, since, as noted by scholars, algorithmic discrimination patterns are very different from human discrimination.[41]

In their study of algorithmic discrimination in healthcare, Sharona Hoffman and Andy Podgurski distinguish three major types of bias.[42] The first is measurement bias, associated with poor quality of training data.[43] Algorithms trained on flawed datasets that contain errors and gaps are likely to yield poor, often discriminatory results. Thus, much of the scholarly debate has been focused on eliminating bias by increasing the quality of data.[44] The second type is selection bias which occurs when the algorithm is trained on data that does not adequately represent the target patient population.[45] The prevailing patterns of social exclusion cause limited availability of health data concerning minorities that continue to face structural, socio-economic, and linguistic barriers to accessing healthcare. For instance, scholars have underlined how digital ageism causes the lack of reliable data concerning older adults, one of

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[38] ONC, *op. cit.*, 159.

[39] S. JABBOUR ET AL., *Measuring the Impact of AI in the Diagnosis of Hospitalized Patients: A Randomized Clinical Vignette Survey Study*, in *Journal of the American Medical Association*, 330, 23, 2023, 2275-2284.

[40] The White House, *Blueprint for an AI Bill of Rights*, https://www.whitehouse.gov/ostp/ai-bill-of-rights (last visited 20/12/2023).

[41] For a discussion of differences between human and algorithmic discrimination see C. NARDOCCI, *Artificial Intelligence-Based Discrimination: Theoretical and Normative Responses. Perspectives from Europe*, in *DPCE Online*, 60, 3, 2023, 2367-2394, https://doi.org/10.57660/dpceonline.2023.1981 (last visited 15/02/2024).

[42] S. HOFFMAN, A. PODGURSKI, *Artificial Intelligence and Discrimination in Health Care*, in *Yale Journal of Health Policy, Law, and Ethics*, 19, 3, 2020, 1-49.

[43] S. HOFFMAN, A. PODGURSKI, *op. cit.*, 13.

[44] A. GERYBAITE, S. PALMIERI, F. VIGNA, *Equality in Healthcare AI: Did Anyone Mention Data Quality?*, in *BioLaw Journal – Rivista di BioDiritto*, 4, 2022, 385-409.

[45] S. HOFFMAN, A. PODGURSKI, *op. cit.*, 13. Some scholars propose data donation and sharing mechanisms as a strategy to increase the representativeness of data. See, for instance: G. R. FERRÈ, *Data donation and data altruism to face algorithmic bias for an inclusive digital healthcare*, in *BioLaw Journal – Rivista di BioDiritto*, 1, 2023, 115-129; M.A. WÓJCIK, *Towards fair AI in healthcare – the impact of the European Health Data Space Proposal on data poverty*, in *Droit & Santé – Revue luxembourgeoise*, 15, 2023, 14-21; Y. YOUSEFI, *Data Sharing as a Debiasing Measure for AI Systems in Healthcare: New Legal Basis*, in *Proceedings of the 15th International Conference on Theory and Practice of Electronic Governance*, ICEGOV '22, New York, 2022, 50-58, https://dl.acm.org/doi/10.1145/3560107.3560116 (last viewed 20/12/2023).

the main target groups of m-Health tools.[46] The third type of algorithmic discrimination is feedback loop bias.[47] An algorithm fed with data tainted with historic bias is likely to perpetuate inequalities, reflecting existing patterns of discrimination entrenched in data. For example, discrimination can occur by proxy, when seemingly neutral variables used by the algorithm become an indicator for a specific protected group. Anya E. R. Prince and Daniel Schwartz illustrate how the use of AI systems has changed the character of proxy discrimination, historically associated with intentional conduct aimed at masking disparate treatment based on protected characteristics.[48] They argue that AI's ability to detect correlations reinforces unintentional proxy discrimination, which might appear "rational."[49] A good example is provided by the Impact Pro algorithm which was used to identify patients with complex health problems, suitable for high-risk care management. The algorithm, which used healthcare spending as a proxy for illness, falsely attributed a lower risk of serious disease to Black patients. Although the proxy appeared "rational", it triggered disparate impact resulting from bias embedded in historical data which reflected unequal access to healthcare experienced by people of color.[50]

Ivana Bartoletti and Raphaële Xenidis argue that algorithmic bias is particularly likely to affect groups that already suffer intersectional disadvantages.[51] This is particularly true in the case of ML algorithms that detect patterns, profiling individuals into distinct sub-groups. The output of such algorithms is typically not based on a single characteristic, but rather on "a combination of characteristics and behavior that is unique to a particular person, or perhaps to a small group of persons".[52] Thus, scholars warn that the use of algorithms causes a paradigm shift in discrimination patterns, whereby discrimination is not limited to traditionally protected groups, such as sex, but extends to "algorithmic groups" that can encompass attributes not protected by antidiscrimination law, for instance, older women-smokers who own a dog.[53]

Because of AI's propensity to encode social injustices, algorithmic groups can often overlap with historically disadvantaged intersectional groups. For example, Joy Boulamwini and Timnit Gebru have shown how facial recognition algorithms used by leading tech companies underperform in the case of

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[46] H. VAN KOLFSCHOOTEN, *The AI cycle of health inequity and digital ageism: mitigating biases through the EU regulatory framework on medical devices*, in *Journal of Law and the Biosciences*, 10, 2, 2023, 1-23.

[47] S. HOFFMAN, A. PODGURSKI, *op. cit.*, 15.

[48] A.E.R. PRINCE, D. SCHWARCZ, *Proxy Discrimination in the Age of Artificial Intelligence and Big Data*, in *Iowa Law Review*, 105, 2020, 1257-1318.

[49] A.E.R. PRINCE, D. SCHWARCZ, *op. cit*.

[50] Z. OBERMEYER ET AL., *Dissecting racial bias in an algorithm used to manage the health of populations*, in *Science*, 366, 6464, 2019, 447-453, *https://doi.org/10.1126/science.aax2342* (last viewed 20/12/2023).

[51] I. BARTOLETTI, R. XENIDIS, *Study on the impact of artificial intelligence systems, their potential for promoting equality, including gender equality, and the risks they may cause in relation to non-discrimination*, Council of Europe, 2023, 58-59, *https://edoc.coe.int/en/artificial-intelligence/11649-study-on-the-impact-of-artificial-intelligence-systems-their-potential-for-promoting-equality-including-gender-equality-and-the-risks-they-may-cause-in-relation-to-non-discrimination.html#* (last viewed 20/12/2023).

[52] J. GERARDS, R. XENIDIS, *Algorithmic discrimination in Europe: challenges and opportunities for gender equality and non-discrimination law: a special report*, European Commission, Directorate General for Justice and Consumers, 2021, 76, *https://data.europa.eu/doi/10.2838/544956* (last viewed 20/12/2023).

[53] S. WACHTER, *The Theory of Artificial Immutability: Protecting Algorithmic Groups Under Anti-Discrimination Law*, in *Tulane Law Review*, 97, 2, 2023, 149-204.

women of color.[54] Similarly, in the area of healthcare, Black women suffer from intersecting patterns of disadvantage, since both women and Black persons are under-represented in medical datasets.[55] Moreover, it has been shown that NLP applications are likely to entrench intersectional stereotypes.[56] For instance, the state-of-the-art large language models, which are trained on the Internet corpora, can replicate discriminatory patterns for intersectional groups, such as Muslim women.[57] Furthermore, there is evidence suggesting that language models can reinforce harmful stereotypes in healthcare.[58] While an increasing number of computer scientists explore the question of intersectional fairness, emerging de-biasing strategies do not fully account for intersectional disadvantages, focusing on sub-group fairness without analyzing the socio-historical context.[59]

4. Intersectional algorithmic discrimination claims under Section 1557 – examining legal criticalities

The gaps in the regulatory regime concerning m-Health technologies diminish *ex-ante* protection against bias in AI-enabled digital health tools, risking the entrenchment of intersectional health disparities. When a doctor makes a clinical decision based on a biased algorithmic output, his patient can seek redress through *ex-post* legal tools, including anti-discrimination law. Introduced in 2010, Section 1557 of the Patient Protection and Affordable Care Act (ACA) offers explicit protection against discrimination in healthcare settings. It states that "an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." Regarding prohibited grounds of discrimination, Section 1557 incorporates protections offered by Title VI of the Civil Rights Act of 1964 (race, color, national origin), Title IX of the Education Amendments of 1972 (sex), Section 504 of the Rehabilitation Act of 1973 (disability) and Age Discrimination Act of 1975 (age). The Department of Health and Human

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[54] J. BOULAMWINI, T. GEBRU, *Gender Shades: Intersectional Accuracy Disparities in Commercial Gender Classification*, in *Proceedings of Machine Learning Research*, 81, 2018, 1-15.

[55] See, for instance: A.S. ADAMSON, A. SMITH, *Machine Learning and Health Care Disparities in Dermatology*, in *JAMA Dermatology*, 154, 11, 2018, 1247, *https://doi.org/10.1001/jamadermatol.2018.2348* (last viewed 20/12/2023); M.S. LEE, L.N. GUO, V.E. NAMBUDIRI, *Towards gender equity in artificial intelligence and machine learning applications in dermatology*, in *Journal of the American Medical Informatics Association*, 29, 2, 2022, 400-403, *https://doi.org/10.1093/jamia/ocab113* (last viewed 20/12/2023).

[56] E.M. BENDER, ET AL., *On the Dangers of Stochastic Parrots: Can Language Models Be Too Big?*, in *Proceedings of the 2021 ACM Conference on Fairness, Accountability, and Transparency*, New York, 2021, 610-623, *https://doi.org/10.1145/3442188.3445922* (last viewed 20/12/2023); W. GUO, A. CALISKAN, *Detecting Emergent Intersectional Biases: Contextualized Word Embeddings Contain a Distribution of Human-like Biases*, in *Proceedings of the 2021 AAAI/ACM Conference on AI, Ethics, and Society*, 2021, 122-133, *https://doi.org/10.1145/3461702.3462536* (last viewed 20/12/2023).

[57] A. ABID, M. FAROOQI, J ZOU, *Persistent Anti-Muslim Bias in Large Language Models*, 2021, *http://arxiv.org/abs/2101.05783* (last viewed 20/12/2023).

[58] H. ZHANG ET AL., *Hurtful Words: Quantifying Biases in Clinical Contextual Word Embeddings*, 2020, *https://doi.org/10.48550/arXiv.2003.11515* (last viewed 20/12/2023).

[59] A. OVALLE ET AL., *Factoring the Matrix of Domination: A Critical Review and Reimagination of Intersectionality in AI Fairness*, in *AAAI/ACM Conference on AI, Ethics, and Society* (AIES '23), Montréal 2023, *https://dl.acm.org/doi/10.1145/3600211.3604705* (last viewed 20/12/2023).

Services' Office of Civil Rights (HHS OCR) is responsible for enforcing Section 1557 and drafting interpretative rules.

This section explores to what extent Section 1557 accommodates claims of intersectional discrimination by algorithms, discussing three major interconnected problems. The first one regards the protected grounds. Although the LGBT community is often subject to harassment and stereotypes that can be exacerbated by AI, it is unclear whether the ACA protects claimants who are discriminated against based on their sexual orientation and gender identity. The second problem pertains to the possibility of bringing a disparate impact claim under Section 1557. Generally, unless an algorithm is explicitly designed to discriminate against certain groups, algorithmic discrimination is likely to fall under the ambit of disparate impact rather than disparate treatment theory. Disparate impact can be described as a facially neutral practice that disproportionately disadvantages certain protected groups, and thus is functionally equivalent to intentional discrimination. Unfortunately, the possibility of bringing a disparate impact claim under ACA is subject to controversies. Finally, the third problem is about the possibility of bringing an intersectional claim under the ACA. Although algorithms can draw complex and unforeseeable correlations between different protected groups, the anti-discrimination law in general, and Section 1557 in particular, create barriers for intersectional claimants.

4.1. Who is protected? The uncertain status of gender identity and sexual orientation as prohibited grounds of discrimination

By virtue of the statutes it incorporates, Section 1557 prohibits discrimination based on race, ethnicity, national origin, sex, disability, and age. It is, however, unclear whether the ground of "sex" includes sexual orientation and gender identity. In *Rumble v. Fairview Health Services*,[60] the first case involving the interpretation of the ACA nondiscrimination clause, the District Court of Minnesota interpreted "sex" as encompassing individuals who do not conform to standard gender expectations. Thus, the Court allowed the claim by a transgender man who alleged to have received inferior care because of his sexual identity. The Court found this interpretation consistent with the case law under Title IX and the interpretation put forward by the OCR in an agency opinion letter. Throughout the years, several other district Courts reached similar conclusions, holding that Section 1557 extends to claims of gender identity.[61]

Presenting a similar view, the first interpretative regulations promulgated by the Obama Administration in 2016[62] interpreted "on the basis of sex" to include, among others, "sex stereotyping and gender identity".[63] However, while the OCR explicitly clarified that transgender claimants are protected, its position was less clear concerning discrimination based on sexual orientation. Because of varying judi-

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[60] *Rumble v. Fairview Health Services*, No. 14-CV-2037, 2015 WL 1197415 (D. Minn. 2015).

[61] See: *Tovar v. Essentia Health*, 342 F. Supp. 3d 947 (D. Minn. 2018); *Flack v. Wis. Dept. of Health Servs*., 328 F. Supp. 3d 931 (W.D. Wis. 2018); *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020), *Prescott v. Rady Children's Hospital-San Diego*, 265 F. Supp. 3d 1090 (S.D. Cal. 2017), *Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018).

[62] US Department of Health and Human Services, *Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg., 2016, 31375-31473, *https://www.federalregister.gov/documents/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities* (last viewed 20/12/2023).

[63] Nondiscrimination in Health Programs and Activities (2016), *op. cit.*, §92.4.

cial interpretations of whether Title IX covers this type of discrimination, the OCR refrained from explicitly resolving the issue in the regulation, contending that the position will be gradually revised in light of judicial developments.[64] The extension of nondiscrimination protection to transgender individuals was successfully challenged by religious-based healthcare providers, leading to an injunction against the sex-defining provision of the rule.[65]

The regulations enacted under the Trump administration in 2020[66] effectively eliminated the protection for non-heterosexual and transgender patients by interpreting the ground of "sex" as referring only to male or female as determined by biology.[67] However, this interpretation came under criticism, as the same year the Supreme Court in *Bostock v. Clayton County*[68] held that the prohibition of sex discrimination in employment under Title VII of the Civil Rights Act includes the prohibition of discrimination based on sexual orientation and gender identity. Based on the *Bostock* decision, the Biden administration issued a notification on an updated enforcement position, holding that the OCR will interpret and enforce Section 1557 as protecting against discrimination based on both sexual orientation and gender identity.[69]

Recently, however, the *Bostock* notification has been successfully challenged as unlawful in the Texas district Court. In *Neese v. Becerra,*[70] two healthcare providers whose patients include persons with gender dysphoria asked the Court to set aside the OCR Notification, claiming that it would obscure the necessary treatment of patients based on their biological differences. The Court agreed with the plaintiffs, holding that the rule in Bostock does not extend beyond the statute that was the subject matter of the decision, namely Title VII of the Civil Rights Act. In particular, the Court underlined that the interpretation of Title VII cannot influence the interpretation of Title IX of the Education Amendments,

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[64] Nondiscrimination in Health Programs and Activities (2016), *op. cit.*, 31389-31390.

[65] *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016). The plaintiffs argued that sex discrimination under the Obama Administration rule should not be construed to encompass gender identity discrimination and that following Title IX, exemptions should apply to religious entities. The District Court for the Northern District of Texas issued a preliminary injunction. Proceedings were stayed due to the request of the new-coming Trump Administration that announced a revision of the ACA rule. Following a delay in enacting the new rule, the Court issued a permanent injunction in *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d. 928 (N.D. Tex., 2019). For a commentary on the litigation see: A. POST, A. STEPHENS, V. BLAKE, *Sex Discrimination in Healthcare: Section 1557 and LGBTQ Rights after Bostock*, in *California Law Review Online*, 11, 2020-2021, 545-556; W. FORE, *Trans/Forming Healthcare Law: Litigating Antidiscrimination under the Affordable Care Act,* in *Yale Journal of Law and Feminism*, 28, 2, 2017, 243-270.

[66] US Department of Health and Human Services, *Nondiscrimination in Health and Health Education Programs or Activities*, Delegation of Authority, 85 Fed. Reg, 2020, 37160-37248, *https://www.federalregister.gov/documents/2020/06/19/2020-11758/nondiscrimination-in-health-and-health-education-programs-or-activities-delegation-of-authority* (last viewed 20/12/2023).

[67] Nondiscrimination in Health Programs and Activities (2020), *op. cit.,* 37178.

[68] *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731, 207 L. Ed. 2d 218 (2020).

[69] US Department of Health and Human Services, *Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 (2021) Federal Register*, 86 Fed. Reg., 2021, 27984-27985, *https://www.federalregister.gov/documents/2021/05/25/2021-10477/notification-of-interpretation-and-enforcement-of-section-1557-of-the-affordable-care-act-and-title* (last viewed 20/12/2023).

[70] *Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022). The case is currently pending appeal before the Fifth Circuit Court of Appeals (Docket No. 23-10078)

and thus, the interpretation of Section 1557 of the ACA, because of different statutory language - while Title VII prohibits discrimination in employment "because of sex", Title IX prohibits discrimination in education "on the basis of sex". Thus, according to the Court, the causation rule in Title VII cannot apply to Title IX. Moreover, the Court found that the prohibition of discrimination based on gender identity and sexual orientation is contrary to the purpose of Title IX, which aims to promote equality of opportunity for biological women. Similarly, the Court reasoned that Congress purposively did not include gender identity and sexual orientation as protected grounds under Section 1557 because doing so would lead to conflicts and contradictions, such as preventing providers from tailoring care to the biological differences between men and women.

Since, as mentioned above, other Courts reached the opposite conclusion regarding the inclusion of gender identity as a protected ground under Section 1557, until the question reaches the Supreme Court, LGBT patients who face discrimination will have varying chances of success, depending on the jurisdiction. At the same time, studies have shown that up to 70% of LGBT respondents in the US reported "discrimination, refusal of care, bias, erroneous assumptions and derogatory statements" by healthcare professionals.[71] The health disparities are particularly wide on the intersection of age and gender identity/sexual orientation, as LGBT elders often face increased trauma and fear of stigmatization when accessing healthcare services due to the sociohistorical context in which they had lived.[72] In light of these significant disparities, the lack of clear legal protection is very concerning, particularly from the point of view of algorithmic discrimination. Researchers argue that gender and sexuality identities are often very complex and thus particularly difficult to grasp in demographic data, including health and clinical research data that tends to focus on the binary classification of sex.[73] Inadequate representation of LGBT individuals in the sources of big data can entrench existing stereotypes and amplify algorithmic bias against non-hetero-normative patients.

4.2. The scope of protection against disparate impact in healthcare

Section 1557 Regulations proclaimed by the OCR cannot conclusively define whether a private right of action exists under ACA. As held by the Supreme Court in *Alexander v. Sandoval*,[74] this depends solely on Congressional intent. Thus, upon finding evidence of such intent, the Courts can imply a cause of

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[71] American Geriatrics Society Ethics Committee, *American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement*, in *Journal of the American Geriatrics Society*, 63, 3, 2015, 423-426, *https://doi.org/10.1111/jgs.13297* (last viewed 20/12/2023); K. HAVILAND, C. BURROWS WALTERS, S. NEWMAN, *Barriers to palliative care in sexual and gender minority patients with cancer: A scoping review of the literature*, in *Health & Social Care in the Community*, 29, 2, 2021, 305-318, *https://doi.org/10.1111/hsc.13126* (last viewed 20/12/2023); S. MCCRONE, *LGBT Healthcare Disparities, Discrimination, and Societal Stigma: the Mental and Physical Health Risks Related to Sexual and/or Gender Minority Status*, in *American Journal of Medical Research*, 5, 1, 2018, 91.97.

[72] M. LECOMPTE ET AL., *Inclusive Practices toward LGBT Older Adults in Healthcare and Social Services: A Scoping Review of Quantitative and Qualitative Evidence*, in *Clinical Gerontologist*, 44, 3, 2021, 210-221, *https://doi.org/10.1080/07317115.2020.1862946* (last viewed 20/12/2023).

[73] R. RUBERG, S. RUELOS, *Data for queer lives: How LGBTQ gender and sexuality identities challenge norms of demographics*, in *Big Data & Society*, 7, 1, 2020, *https://doi.org/10.1177/2053951720933286* (last viewed 20/12/2023).

[74] *Alexander v. Sandoval*, 532 U.S. 275, 280 (2001).

action. In 2022, the Supreme Court in *Cummings v. Premier Rehab Keller*[75] clarified that a private right of action exists under Section 1557 for intentional discrimination. However, given the ambiguous construction of Section 1557, which incorporates four pre-existing statutes, the extent to which it accommodates private disparate impact claims is subject to contrasting judicial interpretations. The Courts are divided on whether the Congress intended to create a new, single standard for non-discrimination in healthcare or merely extend the existing anti-discrimination law to the area of healthcare.

The District Court in *Rumble* followed the first view.[76] The Court found that while the integrated statutes provide the basis for the prohibition of discrimination, Section 1557 creates a new cause of action and a single standard of proof. Taking a purposive approach, the Court opined that interpreting Section 1557 in a fragmented manner would be absurd and undermine the ACA's commitment to combating discrimination in healthcare. Under this interpretation, every Section 1557 plaintiff can use any enforcement mechanism available under any of the four incorporated statutes. Therefore, Section 1557 allows bringing a claim of both disparate treatment and disparate impact.

On the contrary, the District Court in *Briscoe v. Health Care Service Corporation* favored a more strict, textual interpretation of Section 1557.[77] Following the language of the law, which states that the enforcement mechanisms available under Section 1557 are those provided for and available under the relevant incorporated statutes, the Court underlined that the express reference to specific civil rights statutes precludes the Congress' intention to create a single standard for healthcare discrimination claims. Therefore, depending on the ground of discrimination on which the plaintiff seeks to rely, different enforcement mechanisms and standards apply under Section 1557. Hence, the *Briscoe* Court held that plaintiffs cannot bring the disparate impact claim based on sex under Section 1557, because Title IX of the Education Amendments of 1972 does not allow private disparate impact claims. Likewise, the District Court in *Southeastern Pennsylvania Transportation Authority v. Gilead Sciences (SEPTA)*[78] confirmed that no disparate impact claim is available under Section 1557 for patients discriminated against on the basis of race, ethnic origin or nationality, as the Supreme Court explicitly excluded the possibility of disparate impact litigation under Title VI of the Civil Rights Act in *Alexander v. Sandoval*. The Courts are likely to reach a similar conclusion in the case of age, as the Age Discrimination Act of 1975 is interpreted as barring private disparate impact claims.[79] In the case of disability, there is a circuit split regarding the possibility of bringing a disparate impact claim under the Rehabilitation Act of 1973. The Eleventh and Fifth Circuit have suggested that disparate impact claims are permissible under the Rehabilitation Act.[80] However, in *Doe v. BlueCross BlueShield of Tenn.*,[81] the Sixth Circuit

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[75] *Cummings v. Premier Rehab Keller*, P.L.L.C., 142 S. Ct. 1562, 1576 (2022).

[76] Rumble, *op. cit*.

[77] *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 727 (N.D. 11. 2017).

[78] *Southeastern Pennsylvania Transportation Authority v. Gilead Sciences* 102 F. Supp. 3d 688 (E.D. Pa. 2015).

[79] S. HOFFMAN, A PODGURSKI, *op. cit.,* 29. Two cases recently brought for age discrimination under Section 1557 ACA have been dismissed for the failure to exhaust administrative remedies: *Papa v. Diamandi*, No. CV 19-846, 2020 WL 762372 (E.D. Pa. 2020); *Galuten on behalf of Estate of Galuten v. Williamson Cnty. Hospital District*, No. 3:18-CV-00519, 2020 WL 7129022 (M.D.Tenn., 2020) upheld on appeal in *Galuten v. Williamson Cnty. Hosp. Dist.*, No. 21-5007 (6th Cir. Jul. 20, 2021).

[80] *Geor. State Conf. of Branches of NAACP v. Georgia*, 775 F.2d 1403, 1428 (11th Cir. 1985); *Prewitt v. U.S. Postal Serv.*, 662 F.2d 292 (5th Cir. 1981).

[81] *Doe v. BlueCross BlueShield of Tennessee, Inc*., 926 F.3d 235 (6th Cir. 2019).

rejected a disparate impact claim based on disability under Section 1557, holding that no such claim is possible under the integrated statute. Similarly, in *Doe v. CVS Pharmacy,[82]* the Ninth Circuit held that no disparate impact claim is available under the Rehabilitation Act, and consequently under Section 1557. Although the Supreme Court issued a writ of certiorari in the case,[83] the parties decided to settle before oral arguments. Thus, the uncertainty around Section 1557 disparate impact claims based on disability persists.

Much like Section 1557 jurisprudence, the interpretative regulations adopted under the Obama and Trump administrations provide a contrasting interpretation regarding the possibility of bringing disparate impact claims under ACA. The former regulation seemed to align with the reasoning of the *Rumble* Court, affirming that Section 1557 authorizes "a private right of action for claims of disparate impact discrimination".[84] By contrast, the current regulations, introduced by the Trump administration follow the view that ACA's nondiscrimination provision merely reinstates pre-existing legal protections and thus follows the enforcement structure for each civil rights statute identified in Section 1557.[85] Under this interpretation, the possibility of bringing disparate impact claims remains severely curtailed for the majority of plaintiffs. This is highly worrying given the reported inefficiency of OCR's enforcement of Section 1557.[86] Moreover, as pointed out by Solon Barocas and Andrew D. Selbst, because of the centrality of intent in the disparate treatment doctrine, most of the cases of algorithmic discrimination will fall under disparate impact.[87] This puts patients challenging discriminatory algorithms at a particular disadvantage compared to claimants alleging human discrimination under Section 1557 ACA.

4.3. Protection against intersectional discrimination in healthcare

Before analyzing whether intersectional claims are possible under Section 1557 ACA, it is necessary to briefly examine the extent to which the American nondiscrimination law addresses the phenomenon of intersectional discrimination. After *DeGraffenreid* failed to address a combined claim based on more than one discrimination ground, Courts progressively moved away from single-axis analysis to acknowledge intersecting patterns of disadvantage. In *Jefferies v. Harris County,[88]* a case concerning discrimination against a Black woman in the context of employment, the Fifth Circuit recognized that discrimination could be based on multiple protected grounds at the same time. Moreover, the Court

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[82] *Doe v. CVS Pharmacy, Inc.,* 982 F.3d 1204 (9th Cir. 2020).

[83] *CVS Pharmacy, Inc. v. Doe*, 141 S. Ct. 2882, 210 L. Ed. 2d 990 (2021).

[84] Nondiscrimination in Health Programs and Activities (2016), *op. cit.,* 31440.

[85] Nondiscrimination in Health Programs and Activities (2020), *op. cit.,* 37204.

[86] S. TAKSHI, *Unexpected Inequality: Disparate-Impact From Artificial Intelligence in Healthcare Decisions*, in *Journal of Law and Health*, 34, 2, 2021, 215; A. TINSEY, *Private Right of Action Jurisprudence in Healthcare Discrimination Cases*, in *Richmond Public Interest Law Review*, 20, 3, 2017, 305-318.

[87] S. BAROCAS, A.D. SELBST, *Big Data's Disparate Impact*, in *California Law Review*, 104, 3, 2016, 671-732. Barocas and Selbst name only two circumstances in which algorithmic discrimination is likely to fall under the disparate treatment doctrine. Firstly, the human decision-maker might intentionally use a biased algorithm to "mask" discriminatory intent. Secondly, the decision-maker might use protected characteristics as a proxy for a desired target, engaging in the so-called "rational racism" (see pages 694-701).

[88] *Jefferies v. Harris County*, 615 F 2d 1025 (5th Cir 1980).

underlined the distinctive character of such a disadvantage, opening a way to recognize "distinct pro-tected subgroups," such as Black females.[89] In *Judge v. Marsh*,[90] the District Court of Columbia followed *Jefferies* but, at the same time, limited its scope. While recognizing the existence of protected sub-groups, the Court warned against turning anti-discrimination law into a "many-headed Hydra." It thus specified that the reasoning applies only to "decisions based on one protected, immutable trait or fundamental right, which are directed against individuals sharing a second protected, immutable char-acteristic."[91] This effectively limited intersectional claims to only two grounds, leading to the develop-ment of what is described as "sex-plus" and "race-plus" jurisprudence. This limit does not sit well with the nature of algorithmic bias, as AI algorithms can draw correlations between several protected groups.

Subsequent case law underlined the unique character of combined discrimination. For instance, in *Lam v. University of Hawaii*,[92] the Ninth Circuit Court held that Asian women are subject to specific stereo-types that are shared neither with Asian men nor with White women. Therefore, such claimants could succeed even in the absence of evidence of discrimination against Asian men and White women. High-lighting differences in group disadvantage can be seen as a positive development, breaking with *DeGraffenreid*'s flat construction of protected identities. However, at the same time, the *Lam* Court proceeded to diminish the value of similarities in group disadvantage, requiring an intersectional claim to present proof of discrimination based strictly on a "combination of factors."[93] Thus, when proving discrimination against an Asian woman, evidence of discrimination against White women and Asian men can be used but is not conclusive in establishing the intersectional claim. Therefore, as noted by the District Court of Maryland *in Jeffers v. Thompson*, "the more specific the composite class in which the plaintiff claims membership, the more onerous the ultimate burden (of persuasion) becomes".[94]

In particular, plaintiffs typically struggle to find a suitable comparator in intersectional claims, which has to be the "negative mirror image".[95] For instance, in cases of gender plus discrimination, the Tenth Circuit Court requires proof that women with an additional protected characteristic are treated less favorably than men with the same protected characteristic. In *Frappied v. Affinity Gaming Black Hawk,*[96] a case concerning an intersectional claim based on gender and age, the Court rejected evi-dence comparing the treatment of older women to younger women, and the overall treatment of men to the overall treatment of women as irrelevant, demanding only comparison between older women and older men. The problem with this approach is that it excludes similarities in group disadvantage (e.g. older women sharing some forms of disadvantage with women in general), and thus fails to cap-ture the essence of intersectionality which is preoccupied with patterns of both sameness and differ-

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[89] Jefferies, *op. cit.*, 1034.

[90] *Judge v. Marsh* 649 F Supp 770 (D. D. C. 1986).

[91] Judge, *op. cit.*, 780.

[92] *Lam v. University of Hawaii* 40 F 3d 1551 (9th Cir. 1994).

[93] Lam, *op. cit.*, 1562.

[94] *Jeffers v. Thompson* 7 264 F Supp 2d 314, 327 (D. Md. 2003).

[95] S.B. GOLDBERG, *Discrimination by Comparison*, in *Yale Law Journal*, 120, 4, 2011, https://www.yalelawjour-nal.org/article/discrimination-by-comparison (last viewed 20/12/2023).

[96] *Frappied v. Affinity Gaming Black Hawk, LLC*, 966 F.3d 1038, 1058 (10th Cir. 2020).

ence in group disadvantage. For this reason, intersectionality jurisprudence has been criticized for being intersectional in name only.[97] Scholars have thus proposed departing from the comparator-based analysis, to embark on a contextual analysis that is better suited to capturing interactions between different protected grounds.[98]

The difficulties in construing a successful intersectional claim are further exacerbated in the case of Section 1557. The interpretation of the *Briscoe* Court, followed by the rule introduced by the Trump administration, affirms the fragmentation of enforcement mechanisms which does not reflect the real experience of discrimination in healthcare. Instead, it creates an artificial framework under which intersectional claimants, particularly those alleging disparate impact, need to choose between their identities to increase their chances of succeeding. Let us consider the case of a Black disabled woman experiencing indirect discrimination by a healthcare provider. Her ability to bring a claim that fully captures her intersectional experience would be curtailed by: (1) the *Jefferies* rule that allows a combined claim based on only two grounds and (2) the impossibility of bringing a disparate impact claim based on sex or race under Section 1557. Thus, in practice, the claimant could rely solely on her identity as a disabled person to bring a disparate impact claim under the ACA. However, as discussed above, the success of this claim would also likely depend on the jurisdiction. Although patients who allege disparate treatment would be able to claim intersectional discrimination based on any of the two protected grounds, they are likely to face different evidentiary standards and burdens of proof for each of the grounds. This, in essence, pushes the Court to analyze the two alleged grounds completely separately, guided by the particular requirements of incorporated statutes. For instance, in *SEPTA*, the plaintiffs claimed that a pharmaceutical company that set high prices on their Hepatitis C drug discriminated against people with disabilities (Hepatitis C patients) and racial minorities that are particularly affected by the disease. The Court analyzed the grounds of disability and race in isolation, immediately dismissing the racial discrimination claim based on the impossibility of bringing disparate impact cases under Title VI of the Civil Rights Act. Interpreted in this manner, Section 1557 fails to capture the plaintiff's identity as a whole by reinforcing a *de facto* single-axis framework that tackles only intentional discrimination. Thus, patients who face discrimination by algorithm, in particular, based on a combination of different protected characteristics, are very unlikely to succeed before the Court. It is worth recalling that one of the arguments against a fragmented enforcement mechanism cited by the plaintiff in *Rumble* was that it would leave the Court with "no guidance about what standard to apply for a Section 1557 plaintiff bringing an intersectional discrimination claim".[99] In a similar vein, a lawsuit challenging the Trump administration's ACA rule underlined that the elimination of the uniform enforcement scheme will make it more difficult to bring claims of intersectional discrimination.[100] Scholars raise similar concerns, arguing that the fact that Section 1557 contains a disclaimer that nothing in the provision intends to alter the interpretation of the incorporated statutes implies that ACA creates a

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[97] S. ATREY, *op. cit.*, 117.

[98] S.B. GOLDBERG, *op. cit*.

[99] Rumble, *op. cit.*, 12.

[100] *Boston Alliance of Gay, Lesbian, Bisexual and Transgender Youth and Others v. United States Department of Health and Human Services and Others* 557 F.Supp.3d 224 (D. Mass. 2021). The Court held that the plaintiffs lacked standing to assert the claim because they had not shown sufficient evidence that the current enforcement mechanism is inadequate to address intersectional discrimination.

new, independent right of action, whose main purpose is precisely the accommodation of intersectional claims.[101] The above considerations make clear that the solution to the lack of effective protection against intersectional discrimination under Section 1557 must necessarily involve a move towards a single standard for health discrimination.

5. Towards addressing algorithmic discrimination in clinical decision making – the Biden Administration Rule Proposal

In August 2022 the HHS released a new proposed Rule on Section 1557.[102] The Biden Administration committed to reverse many of the limitations introduced by the Trump Administration. For instance, the proposed rule reaffirms the *Bostock* Notification, interpreting the ground of "sex" to include gender identity and sexual orientation.[103] Moreover, it broadens the scope of covered entities to include, for the first time, healthcare providers who receive funding through Medicare part B program which, until now, has not been considered to constitute federal financial assistance.[104]

However, perhaps the most interesting development from the point of view of this paper is that the OCR decided to explicitly address the topic of algorithmic discrimination. The rule proposes a new provision that states that "a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decisionmaking."[105] The rule clarifies that although healthcare providers will not be held liable for discriminatory algorithms that they did not design, they remain liable for the decisions taken in reliance on such algorithms.[106] At the same time, the proposed rule contains a presumption against fully substituting clinical judgment with algorithmic tools.[107] While the proposal can be praised for its timely acknowledgment of the emerging problem of algorithmic bias in the context of healthcare, it suffers from several deficiencies.

Firstly, there is an ambiguity surrounding the definition of clinical algorithms which makes it unclear to what extent AI and ML-powered solutions would fall under their scope. The Department defines clinical algorithms as: "tools used to guide health care decision-making" ranging in form "from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models."[108] This definition is broad and could, in principle, encompass algorithms derived from AI and ML. In fact, in explaining the necessity to introduce the prohibition of algorithmic discrimination, the

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[101] M.D. LEGNINI, *An Unfulfilled Promise: Section 1557's Failure to Effectively Confront Discrimination in Healthcare Notes*, in *William & Mary Journal of Race, Gender, and Social Justice*, 28, 2, 2021, 487-516.

[102] US Department of Health and Human Services, Office for Civil Rights, *Notice of Proposed Rulemaking, Nondiscrimination in Health Programs and Activities*, 87 FR 47824, 47880 (Aug. 4, 2022), *https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities* (last viewed 20/12/2023).

[103] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, §92.101(2).

[104] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47887.

[105] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, §92.210.

[106] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47880.

[107] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47882.

[108] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47880.

proposal refers to studies that discuss bias in automated systems.[109] Nevertheless, in inviting comments on the draft regulatory proposal, the OCR asks whether the provision "is appropriately limited to clinical algorithms or should include additional forms of automated or augmented decision-making tools or models, such as artificial intelligence or machine learning."[110] This signals that the proposed rule in its current state must be understood as excluding algorithms based on these technologies.

There is a strong argument in favor of explicitly including automated systems in the provision: it would be simply unreasonable to protect patients against discrimination solely in the case of non-automated systems, especially in light of the overwhelming evidence of bias that AI/ML models can exhibit. This solution would contribute to the further fragmentation of the ACA protection framework. It would work to the detriment of intersectional groups that, as emphasized throughout this paper, are particularly likely to be the target of automated discrimination by ML.

Secondly, the provision can be criticized for putting an undue burden on the healthcare providers, who would be responsible for the decision taken in reliance on a biased algorithm even if they did not design it or "do not have knowledge about how the tool works."[111] This would put an obligation on healthcare professionals to understand the functioning of very complex algorithms, especially if the provision was expanded to cover AI/ML solutions. Even though the OCR claims that its aim is not to prohibit the use of clinical algorithms, the practical outcome of the new rule can entail healthcare professionals refraining from using algorithmic tools due to the fear of liability.[112] This can result in stiffing innovation, including in the m-Health sector. For instance, doctors can be less eager to use data from wearables to help their diagnosis. In light of these concerns, the preferable solution would be to move towards a shared model of liability between the manufacturer and the healthcare provider, both of whom play a crucial role in ensuring the safe and effective usage of the technology. Thus, the rule should be supplemented by a clear division of responsibilities between the providers of a clinical algorithm and their users. It should therefore clarify the relationship between the regulation of software as a medical device, the HIT certification requirements, and the responsibility of healthcare providers.

A tiered approach to a doctor's liability for discrimination could be adopted depending on the classification of the tool in question. For instance, in the case of the software whose function is excluded from the device definition by section 520(o) of the FD&C Act, the duties of healthcare providers could be broader, since the physician can be presumed to have a reasonable understanding of the reasons behind a recommendation. Conversely, the legal responsibility for software that is classified as a medical device should rest primarily on the manufacturer, as the physician should not be expected to fully understand the functioning of a highly complex system. At the same time, researchers underline that, especially in the case of algorithms that continue to learn after deployment, cooperation between the manufacturer and the doctor is crucial, since the latter continues to tune and adapt the algorithm through usage.[113] This underlines the importance of transparency requirements for PDSI introduced

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[109] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47880-47881.

[110] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47884.

[111] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47883.

[112] C. SHACHAR, S. GERKE, *Prevention of Bias and Discrimination in Clinical Practice Algorithms*, in *Journal of American Medical Association*, 329, 4, 2023, 283-284.

[113] A. KISELEVA, *AI as a Medical Device: Is it Enough to Ensure Performance Transparency and Accountability?*, in *European Pharmaceutical Law Review*, 4, 1, 2020, 5-16.

by the HTI-1 Rule, providing healthcare professionals with tools to review whether the model has been adequately tested for fairness and whether it uses attributes relevant to health equity, including race, ethnicity, or sexual orientation.[114] However, as highlighted by several scholars, determining how the use of these attributes in the design of an algorithm affects equity concerns is a complex exercise.[115] Thus, more interdisciplinary cooperation is needed to develop common bias-evaluating standards for clinical algorithms, preferably including fairness metrics for intersectional groups. This should be one of the main concerns of the AI Task Force, which will be established by the Secretary of Health and Human Services according to President Biden's recent Executive Order.[116] Importantly, the strategic plan for the responsible deployment of AI in the health sector[117] should include provisions for the training of healthcare professionals on the sources of bias in algorithmic decision-making.

Thirdly, what follows from the previous point is that the rule should establish clear legal standards for assessing discrimination by the use of algorithms. The rule states that in investigating a claim of algorithmic discrimination against a healthcare entity, the OCR would assess, among others, what decisions were taken based on the algorithm and what measures did the entity take to ensure that its decision is not discriminatory.[118] This guidance appears very vague and needs clarification. For instance, the Department could establish separate standards for decisions made with the help of algorithms that use variables that directly correspond to protected groups and decisions aided by algorithms that do not use such variables. In the case of the former, including race-adjustment algorithms discussed by the rule, it will be generally easier to assess whether the impact is discriminatory. Thus, a clinician who decides without a proper assessment of the algorithm's fairness could be liable for intentional discrimination through deliberate indifference.[119] In the case of algorithms that do not use protected groups as variables, bias detection will generally be more difficult. These algorithms could discriminate against protected groups through proxies or feedback loops. Clinical decisions taken with the help of these algorithms are more likely to constitute disparate impact. In this case, a clarification of the steps that the covered entity should take to detect such bias is needed. For instance, in the case of race-blind and gender-blind algorithms, it could suffice for the doctor to ensure that the algorithm was properly tested for bias and that the testing sample of the dataset is representative of the patient's demographic data.

Finally, since many algorithmic discrimination cases are likely to constitute indirect discrimination, to offer meaningful protection to individuals seeking redress before the Court, the new provision should

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[114] HTI-1 Rule, *op. cit.*, § 170.315(b)(11)(iv)(A)(5)-(13).

[115] See, for instance: E.F. VILLARONGA ET AL., *Accounting for diversity in AI for medicine*, in *Computer Law & Security Review*, 47, 2022, 105735; M.A. WÓJCIK, *Assessing the Legality of Using the Category of Race and Ethnicity in Clinical Algorithms – the EU Anti-discrimination Law Perspective*, in *EWAF'23: European Workshop on Algorithmic Fairness*, 2023, Winterthur, *https://ceur-ws.org/Vol-3442/paper-51.pdf* (last viewed 20/12/2023).

[116] Executive Order 14110 of Oct 30, 2023, *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*, 88 FR 75191, 75191-75226, *https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24283.pdf* (last viewed 20/12/2023).

[117] Executive Order, *op. cit.*, Sec. 8(b)(i).

[118] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47883.

[119] Courts have established that a failure to address discriminatory conduct despite the knowledge of its potential existence can amount to disparate treatment. See: *Sunderland v. Bethesda Hosp., Inc.*, 686 F. Appx. 807, 815 (11th Cir. 2017); *Bax v. Doctors Medical Center of Modesto, Inc*., 393 F. Supp. 3d 1000 (E.D. Cal. 2019).

be accompanied by a well-established right of private action, including disparate impact claims. Although the rule explicitly confirms that Section 1557 contains a right to private action, it does not affirm the 2016 provision which provided that disparate impact claims are available to Section 1557 plaintiffs. Instead, the Department's view is that "it is important to preserve – and not expand – the longstanding treatment of disparate impact in the referenced statutes' implementing regulations."[120] This affirmation of the *status quo* can be seen as a missed opportunity to promote the meaningful elimination of discriminatory practices in healthcare.

6. Conclusion

New technologies can change the way care is delivered to vulnerable patients, increasing access and decreasing costs. However, to ensure patient safety, AI-powered m-Health tools should be comprehensively regulated. This includes effective steps for detecting, remedying and compensating for discriminatory outcomes. Unfortunately, the current US *ex ante* and *ex post* legal frameworks suffer from deficiencies, which can undermine effective protection for patients, especially those who are discriminated against based on a unique combination of protected grounds.

This contribution has focused on analyzing the role of antidiscrimination law in addressing intersectional discrimination by healthcare algorithms. It has argued that the current judicial and agency interpretation of Section 1557 suffers from gaps and uncertainties that effectively preclude intersectional claimants from succeeding in a private action before the Court. Firstly, despite the much-welcomed clarifications offered by the *Bostock* Notification and the recently proposed rule, considerable uncertainty regarding the inclusion of sexual orientation and gender identity under the ground of "sex" persists. Secondly, the fragmented enforcement mechanisms do not allow plaintiffs to bring a claim for disparate impact under most of the grounds protected under ACA, making it impossible to address the majority of cases of discrimination by the use of algorithms. Thirdly, in spite of its acknowledgment of combined discrimination, the case law fails to capture the nature of intersectionality by limiting the claim to only two grounds and overly focusing on differences in patterns of group disadvantage, while neglecting the similarities. Fourthly, the aforementioned fragmentation of enforcement mechanisms under ACA precludes intersectional claims, forcing the Court to analyze each ground in isolation.

Commitment to intersectionality requires a commitment to its transformative aim. Thus, tuning the antidiscrimination law to effectively address the problem of intersectional discrimination in healthcare, particularly by the use of algorithms, may require decisive solutions aimed at fostering substantive equality. Firstly, the antidiscrimination law should move beyond the "sex plus" and "race plus" paradigm, favoring a more contextual analysis that accurately traces the relationship between different patterns of exclusion. Secondly, to pursue ACA's goal of eradicating health disparities both the Courts and the OCR should abandon the fragmented enforcement mechanism in favor of establishing a single standard for health discrimination under Section 1557.

While the new regulatory provision directly tackling discrimination by the use of algorithms is a welcomed development, it warrants amendments and clarifications regarding the scope of covered algorithms, the division of responsibility between the manufacturers and users of algorithmic technologies,

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[120] Nondiscrimination in Health Programs and Activities (2022), *op. cit.*, 47860.

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and a clear designation of applicable legal standards. Moreover, the proposed rule does not address the contentious issue of disparate impact litigation. Without a right to such private action enshrined, the prohibition of discrimination by the algorithm will remain toothless.