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# The Role of Exceptionalism in the Evolution of Bioethical Regulation

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## Abstract

The paper aims to present a critical analysis of the phenomenon and notion of exceptionalism in bioethics. The authors demonstrate that exceptionalism pertains to phenomena that are not (yet) entirely familiar to us and could potentially bear risks regarding their regulation. After an overview of the state of the art, we briefly describe the origins and evolution of the concept, compared to exception and exclusion. In the second step, they look at the overall development debates on genetic exceptionalism, compared to other bioethical debates on exceptionalism, before presenting a detailed analysis of a specific case of early regulation of genetic screening. In the last part, the authors explain the historical background behind the connection between exceptionalism and exclusion in these debates. Their main conclusion is that while the initial stage of the discussion is shaped by the concept of exceptionalism and awareness of risks of exclusion, the later development centers around exceptions that are needed in detailed regulatory procedures.

**Keywords:** Exceptionalism; exceptions; exclusion; HIV; genetic screening

## Exceptionalism in Bioethics Debates: A Brief Overview

The notion of exceptionalism occupies a remarkable but somewhat uncertain position in bioethics. There are several ongoing debates on exceptionalism, including genetic exceptionalism, HIV exceptionalism, and neuro exceptionalism. Each is focused on a need for specific normative engagement with some new phenomenon or biomedical practice. The term itself usually emerges at a relatively late point when the already established exceptionally rigorous forms of regulation are directly criticized as obsolete. In other words, exceptionalism as a specific regulative approach exists before the explicit appearance of the corresponding term in bioethical debates.

The uniqueness of regulation is mainly justified through peculiar risks of social exclusion: due to hereditary features, HIV status, or behavioral traits essentialized in neuroscientific terms. The arguments favoring exceptionalism frequently involve dramatic plots—often of the kind that led to the Nuremberg Code. The code and the prevention of the revival of Nazi eugenics programs are the cornerstones of bioethics (pre)history. The institutionalization of bioethics is also linked to a series of negative events, where recollections of Nazi eugenics have usually accompanied the public discussion. The founding fathers of bioethics saw the condemnation of cancer cell experiments at the Jewish Chronic Disease Hospital (1962), the Henry K. Beecher study (1966), and the Tuskegee syphilis study (in the 1970s) as parts of the same story.<sup>1</sup> All phases of this history involved Nazi analogies. Such arguments highlighted that eugenic practices are compatible with modern liberal society, and the development of certain new biomedical technologies may bring their comeback closer.<sup>2</sup> Since general strategies to protect human rights did not work in these cases, such technologies required exceptional regulation.

The term “exceptionalism” frequently appears in academic texts about healthcare policy when authors intend to criticize superfluously restrictive regulation of a significant field. Even the early articles that headline the term speak of the “end of exceptionalism” – in relation to HIV<sup>3</sup> or genetics.<sup>4</sup> Alternatively, exceptionalism is often questioned,<sup>5</sup> as its use requires a systematic revision.<sup>6</sup> Nevertheless, there are also papers presenting general arguments in favor of exceptionalism<sup>7</sup> or describing individual cases demonstrating its validity,<sup>8</sup> mostly in an attempt to present sound counterarguments to those who criticize the notion.

Exceptionalism may be motivated *inter alia* by the peculiar scope of ethical problems or by the unknown side effects of a specific biomedical technology. The collision between individual bioethical principles often results in exceptional regulations. For instance, the tension between beneficence and nonmaleficence produces exceptions related to terminal sedation and relief of refractory pain in the legislation of countries that prohibit euthanasia.<sup>9</sup> In other cases, the conflict between the patient’s autonomy and the beneficence of their family members can lead to exceptions in privacy regulation, ultimately rethinking the foundational concept of autonomy.<sup>10</sup> There are also situations where a person can exercise autonomy through free and deliberate acceptance of the health risks but is not likely to benefit from the proposed intervention, because it is experimental and not designed to help the medical research subject.<sup>11</sup>

Social issues can play a crucial role in exceptionalism, be it the problem of trust for research exceptionalism,<sup>12</sup> stigmatization and social exclusion in the case of genetic tests and HIV,<sup>13</sup> or job discrimination for neuro exceptionalism.<sup>14</sup> These social concerns initially evoke images of a severe social exclusion requiring exceptional regulation but afterward gradually evolve into a more nuanced system of regulatory exceptions.

There are also many cases when we can reasonably characterize the specific regulation of certain practices as exceptional, although the concept of exceptionalism does not make an explicit appearance in relevant documents. For instance, according to pre-2000 versions of the Declaration of Helsinki, nontherapeutic research was regulated specifically and with maximum strictness. It mainly referred to “healthy volunteer” research, and the exceptional strictness was related to the lack of direct benefit to the subject.<sup>15</sup> Robert Levine was the voice of physicians pushing for a more nuanced approach to the Declaration. He pointed out that medical research is a long and multistage process that typically includes both therapeutic and nontherapeutic interventions.<sup>16</sup> Therefore, distinguishing nontherapeutic research as an area of exceptional regulation did not correspond to the logic of the process. It was replaced by nuances in the regulation of specific procedures and the remaining exceptional regulation of all medical research. However, this specific regulation was much broader in coverage and not so rigorous.

The mentioned type of research exceptionalism is a subject of debate as well. Some of the arguments against it are based on the need for more rapid approval of research, for example, to find new antibiotics.<sup>17</sup> There have also been proposals to replace the rigorous research regulation with risk payment, as established for workplaces with comparable risks.<sup>18</sup> Recognizing the problem of public trust, scholars propose to pay exceptional attention to transparency in the allocation of risk-based payment.<sup>19</sup>

In short, “exceptionalism” has frequently played a crucial role in bioethical regulations and related debates, at least since the 1960s. Unfortunately, there is still no theoretical framework that could be useful not only to understand the evolution of certain debates involving exceptionalism but also to provide aid in confronting the gap between the emergence of a new phenomenon or challenge and the formulation of detailed regulatory procedures. In what follows, we will develop this framework by outlining the boundaries and relations between the notions of exceptionalism, exception, and exclusion.

### Theoretical Ramifications: Exceptionalism–Exception–Exclusion

The brief glimpse into various uses of the notion of exceptionalism in bioethics, which serves as an introduction to the closer analysis of a specific case of “genetic exceptionalism,” shows us that there is a necessity for a clear differentiation between “exceptionalism,” “exception,” and “exclusion.” This differentiation should serve as a methodological connection between several crucial debates, providing a clear orientation in answering the ever-present question of whether we (still) need the notions of exceptionalism and/or exception in our description of a particular case.

When dealing with a new (or not entirely familiar) phenomenon that we consider “exceptional,” we face the crucial question of what could go wrong. While trying to find out if the existing regulatory cases, standards, and procedures can be (at least partially) helpful in this situation, we also recall the worst cases that serve as a basis for the precautionary principle. This precautionary principle helps us gradually find the necessary instruments (including a variety of possible exceptions) we have to apply to avoid the risk of exclusion of new information and/or particular social groups to which this information pertains. In other words, “exceptionalism” primarily accompanies our analysis at an early stage, while “exception” plays a more prominent role later in time, as soon as we delve into the details of particular procedures. In turn, “exclusion” plays a vital role at both stages since it is needed to assess potential or actual negative scenarios. Before discussing the relations between the three notions in bioethical regulation, let us look at their origins and evolution.

### Exceptionalism

From the perspective of Western philosophy, the origins of the notion of exceptionalism lie in the seventeenth- and eighteenth-century development of historical research (and of related sciences, such as geography and ethnology) due to a series of geographical discoveries and the growing interest in regions outside Europe. Most important in this regard are the debates between those who wanted to provide a general system of all new knowledge about foreign nations, races, and cultural traditions (while often trying to promote the idea that all European nations, or a particular European nation, were in some way superior to others) and those who insisted on their unique character which cannot and should not be made part of such system. This difference can be exemplified by the debates between Immanuel Kant and Johann Gottfried von Herder on the definition and goals of anthropology,<sup>20</sup> predating the early twentieth-century crisis and split of the discipline into philosophical and cultural anthropology. Kant’s anthropology was closely connected to his system of critical philosophy, particularly to his ethics with its categorical imperative. While this approach was advantageous for Kant’s practical philosophy (his political philosophy, in particular), it also had its downsides, as Kant used his ethical principles in controversial, discriminatory descriptions of human races during the 1770s and 1780s, which included a vertical classification according to their motives (*Triebfeder*) and capability to make rational decisions. Herder, on the contrary, challenged the necessity of using the concept of race, defending the idea of looking at each nation separately. While a very effective instrument in the debates against the misuse of the notion of race, this approach also had its weaknesses, as it was focused on the uniqueness of nations (and “national spirits”), defying any systematic attempts to drive essential conclusions from the similarities between them. Both Kant’s and Herder’s views on the phenomenon of exceptionalism, namely the discriminatory idea of European moral exceptionalism and the exceptionalist approach to each nation, significantly impacted the subsequent intellectual tradition.

Despite being a significant implicit part of the debates of the European Enlightenment, the notion has not made its explicit appearance in philosophical works until the nineteenth century. In the wake of the rise of national ideologies and movements across the world, “exceptionalism” found its way into the mainstream tradition of political philosophy, for instance, in the form of the concept of “American exceptionalism” that goes back to the works of Alexis de Tocqueville.<sup>21</sup> During the twentieth century and into the twenty-first century, the notion was and still is regularly used in theory of law, most notably in debates on “constitutional exceptionalism”<sup>22</sup> and “criminal law exceptionalism.”<sup>23</sup>

In bioethics, the notion was adapted and modified to describe the initial situation of many debates, such as those on genetic information,<sup>24</sup> health policy,<sup>25</sup> HIV treatment, and neuroethical issues.<sup>26</sup> In this new role, “exceptionalism” defines the limitations of the existing methods, marking a new (still mostly uncharted) territory and deterring us from all too readily using old instruments instead of looking for new ones. It applies to a situation when it is impossible to slightly adjust a previous approach while further work is necessary to find a new working method. However, its usefulness becomes very limited as a new approach takes shape, as “exceptionalism” *per se* defies systematic analysis by questioning and undermining it at each step. After a systematic framework is set,

“exceptionalism” does more harm than good, as it can confuse scholars and non-scholars alike, impeding them from reaching any clear, empirically relevant conclusion. In short, the notion of “exceptionalism” has its window of opportunity when confronting new phenomena as a core element of the precautionary principle. However, it can be counterproductive for later stages of research that systematize the theoretical findings and lead to practice-oriented conclusions. Contradictions between principles create the conditions for special regulation, but they are not always enough for exceptionalism. Such conflicts can create individual regulatory exceptions or urge exceptionalism at a particular stage of the field’s evolution.

### Exception

The notion of exception has a much longer history which is more complex but also often overlooked by philosophers who tend to limit its genealogy primarily to Giorgio Agamben, Carl Schmitt, Søren Kierkegaard (as Schmitt’s source), and Walter Benjamin (as Agamben’s source).<sup>27</sup> We first encounter it in Cicero’s speech *Pro Balbo*, as part of his examination of the relations between rules and exceptions in Roman law. During the Middle Ages, the vast majority of cases of its use are commentaries to the famous Code of Justinian, which included a sophisticated classification of different types of exceptions that can deny the applicability of a claim in some instances.<sup>28</sup> During the period between the fifteenth and the seventeenth centuries, the notion played a significant role in theological arguments and disputes, but also in philosophical debates on natural law and regularities in nature (in works of Francis Bacon, Rudolf Goclenius, and Theodor Zwinger), before finally finding its way into Leibniz’s philosophy of law which integrated theological, legal, and philosophical questions into one systematic approach.<sup>29</sup> More than a century later, the notion was used in Kant’s ethics and philosophy of law.<sup>30</sup> Starting with Kant, “exception” gradually develops from a strictly legal notion to a broad concept of utmost importance for many sciences, from history and philosophy to sociology and political theory.<sup>31</sup> Part of this development is its implementation in twentieth-century bioethics.

Compared to more homogeneous “exceptionalism,” “exception” can be used in various ways. From the legal perspective, which still, since Antiquity, plays a dominant role in the use of the concept, some exceptions are included in rules, expanding them and making them more resilient in the face of challenges from new phenomena. Such is the case with clauses in laws that are meant to be a “safety mechanism” against a possible state of exception (which can quickly occur during crisis periods like the epidemic of coronavirus disease [COVID-19]). On the other hand, many exceptions cannot fit into existing theories or practices. In the latter case, given that we try to preventively define the boundaries of a rule or practice against all kinds of exceptions, “exception” (e.g., in collocations “with the exception of” and “except from/to”) can indicate that something is excluded from the rule or a particular practice.<sup>32</sup> However, such preventive measures only apply to a number of cases, as some occurrences—and discoveries—cannot be predicted. In the latter case, “exclusion,” sometimes coupled with “exceptionalism” as a signal to exert caution in dealing with the uncertain, can immediately tackle the problem. At the same time, “exceptionalism” is not an apt instrument for finding a long-term solution, as such a goal needs instruments of systematization.

If we look at exceptions from another angle, namely not before they take place but after they have already occurred, we can also differentiate between several kinds. There are, first, one-time exceptions that do not have lasting consequences apart from immediate ones in a concrete situation. Other exceptions can transform rules and mainstream practices. Finally, there are some hybrid cases where exceptions have a limited impact, not by changing fundamental tendencies but rather by making minor modifications to the treatment of specific range of cases that still fall under a general rule, thus playing a stabilizing role. As we will show in the specific example of the debate on genetic exceptionalism, there are cases with a whole set of different kinds of exceptions that can be used to make the mainstream practice more stable in the long term. Unlike “exceptionalism,” “exception” is much more versatile and is applicable to various stages of the development of specific theoretical approaches, debates, and practices. While individual exceptions may eventually become obsolete, the overall concept of exception always retains its usefulness in formulating and applying regulatory standards.

## Exclusion

In comparison to the other two notions, the boundaries of the notion of exclusion are significantly vaguer. This is partly due to its historical closeness to “exception,” as the meanings of exception and exclusion were included in the semantical field of the Latin *exceptio* (cf. also the German *Ausnahme*). From the Late Middle Ages, the word was present in various legal studies<sup>33</sup> and other texts but did not gain such theoretical significance as exception and exceptionalism. In the twentieth century, exclusion was part of several prominent concepts in various fields (from the “causal exclusion problem” in analytical philosophy to “social exclusion” in sociology, political theory, and psychology). In recent philosophical studies, the notion has, for instance, gained much presence in the debates on immigration.<sup>34</sup> In bioethical theories, for instance, in disability bioethics, “exclusion” is primarily used to describe the situation of certain groups that are or have been subjected to discrimination.<sup>35</sup>

In light of the genealogy of the notion, it is not surprising that the idea of exclusion can often accompany the notion of exception, as they complement and explain each other. However, it is also essential to understand the differences between these two concepts—which are, unfortunately, often either overlooked by scholars from various fields or left without sufficient clarification, as the authors are primarily focused on the concept of the state of exception.<sup>36</sup> On the one hand, labeling something as exceptional means excluding it from all usual theoretical approaches in order to start our search for new methods and instruments. On the other hand, excluding something from our considerations does not necessarily mean including it in the field that is or will eventually be covered by another approach. Exclusion can also be a process of separation of something that is (with or without justification) deemed unnecessary or even harmful for the whole. Excluded elements (information, social groups, or something else) can remain marginal for a considerable time without good prospects of altering their status. In contrast to phenomena with “exceptional” status, they usually are not given special attention, as they are considered (or painted as) relatively unimportant. We assume that the forms of exclusion highlighted during the construction of a bioethical theory can shape exceptionalism and, consequently, the range of regulatory exceptions. However, the nature of this connection requires further research. In our subsequent analysis of the debates on genetic exceptionalism, we will emphasize the role of exclusion as the counterpart of inclusion, in the same sense it is used in sociology, anthropology, and disability studies.

As shown above, the notions of exceptionalism, exception, and exclusion are related to each other but have specific traits that should be appropriately recognized to use these terms at a proper time and place. In the next part, we will demonstrate how these notions can be applied to the analysis of the development of the debates on genetic exceptionalism.

## Debates on Genetic Exceptionalism

Before examining one specific case, let us look at the overall development of the debates. In the early 1990s, the term “exceptionalism” began to appear in the debates on biomedicine regulation.<sup>37</sup> At that time, it referred to the AIDS epidemic; at the end of the decade, it began to deal with the prospects of genetic testing.<sup>38</sup> In the discussions at that time, ethical issues closely intertwined with questions about the legal status of HIV or gene-related information. These discussions tended to begin with applied regulatory issues, immediately involving historical examples of stigmatization and cases of personal data misuse.<sup>39</sup>

HIV and genetic exceptionalism refer to the specific regulation of relevant medical tests and health information because of the distinctive risks of discrimination against patients or persons closely connected with them.<sup>40</sup> However, HIV and genetic exceptionalism differ in explicitness and contestability of the link between specific regulation and discrimination. The “HIV exceptionalism” label appeared “to distinguish the policies that had emerged in the face of the AIDS epidemic from more conventional approaches to public health issues.”<sup>41</sup> The AIDS epidemic put the public health community in a situation requiring unprecedented levels of medical testing. Since the deadly danger of the virus puts HIV-positive people at risk of highly distressing, pervasive exclusion, HIV or AIDS exceptionalism was

about implementing necessary health policy, not about the perspectives of new biomedical fields and technologies, as in the case of genetic exceptionalism.

Neuro exceptionalism is sometimes called a third generation of exceptionalism. Arisen after HIV and genetic exceptionalism, it continues to highlight ethical concerns on privacy and identity. The paper comparing genetic and neurotechnologies in terms of these risks is one of the texts marking the birth of neuroethics as a special discipline.<sup>42</sup> Its authors, Judy Illes and Eric Racine, see parallels in the technical difficulty of discriminating between rare variables in genes or neuroimaging and those related to pathology. However, they attribute the ethical exceptionality of neuroimaging not to this complexity itself but to the fact that cultural presuppositions will interfere with the processing and interpretation of the neuroimages.

The article's commentators agreed that the development of neurotechnology has provided additional practical relevance to philosophical questions about personal identity. However, they contested the need to separate neuroethics from bioethics, attacking the uniqueness of neuroimaging.<sup>43,44</sup> In the next few years, Judy Illes, one of the paper's authors and founders of neuroethics, paid more attention to the role of neuroimaging in overcoming the stigma of psychiatric patients than to the debates about the uniqueness of information generated by neurotechnologies.<sup>45</sup>

The debates about generic exceptionalism were also mainly built around the question of the uniqueness of genetic information. All arguments in favor of this view have been dismissed. The Task Force on Genetic Information and Insurance pointed out back in 1993 that genetic information is not exclusive: 1) in terms of its importance to the patient's future (there are other medical tests with comparable predictive power); 2) in terms of its importance to other family members (information about infectious diseases, for example, may have the comparable importance); and 3) in terms of the possible stigma associated with genetics (there are other, more apparent social fragmentation factors like race or gender).<sup>46</sup>

In a later study, legal scholars Lawrence Gostin and James Hodge largely agreed with the conclusions of the Task Force. However, they highlighted the risks of nonmedical use of genetic information by employers, educational institutions, the police, and others.<sup>47</sup> Tom Murray supported these arguments against genetic exceptionalism, showing their bioethical relevance.<sup>48</sup> Michael Green and Jeffrey Botkin, while rejecting the special status of genetic information, recommended focusing on stigma, including the intrafamilial stigma associated with genetic information.<sup>49</sup> Despite reaching a relative consensus, debates about exceptionalism returned in the 2010s, already in the post-genomic era. Garrison et al. criticized the questioning of the uniqueness of genetic information.<sup>50</sup> By introducing the notion of genomic contextualism as a replacement for genetic exceptionalism, they proposed starting with the types of stigma and exclusion that could be associated with specific genomic tests. It implies that genetic testing is no longer a field of exceptional regulation. Some, but not all, tests, hereditary diagnoses, and counseling situations may be of great ethical concern. Therefore, specific — sufficiently rigorous — guidelines may be proposed for them.

Nowadays, genetic exceptionalism denotes a much less monolithic thing than HIV exceptionalism, be it on the level of theory or practical regulation. The term “genetic exceptionalism” is mainly used to indicate the vector of criticism. For example, it has recently been used to show that considerations of justice do not speak unequivocally against the use of genetic test results in insurance.<sup>51</sup> In many countries, life insurance is an area with an exclusive ban on the use of genetic data.<sup>52</sup> The arguments criticizing the total ban usually include some limited exceptions undermining rigorous regulation, which is considered to be related to genetic exceptionalism.

Despite the semantic blurring, we assume the presence of genetic exceptionalism not only as a field of debate but also as a rigorist approach to ethical regulation. When the debate about genetic exceptionalism began, this rigorism had already begun to override itself through a nuanced approach toward the issue of disclosing genetic information. This approach was embodied in increasingly precise ethical guidelines and in the unique role of genetic counselors who aim to prevent social exclusion and stigmatization.<sup>53</sup> In this light, the appeal to retire the notion is justified, not because “genetic exceptionalism” was not aptly used in the initial stages of the debates, but because it is no longer needed

at the current stage, as the focus of current discussions shifts to individual exceptions and problems of exclusion.

### The Case of Early Regulation of Genetic Screening

It would not be unreasonable to say that genetic exceptionalism began with the declaration of an emergency related to the genetic decline of the human population. Exceptionalism in the regulation of genetic tests was a response to this alarm. Invoking historical and theological arguments, it was directed against possible forms of exclusion of “defective” genomes. In the 1960s, Hermann Müller, a biologist who had previously been involved in (non-Nazi) eugenic research, publicly shared his “genetic pessimism” about the decline of biological heredity. Other scientists have criticized eugenics for its ineffectiveness and failure to prevent the degradation of the human gene pool.<sup>54</sup> Initially, the ethical arguments against this view were theologically colored. Paul Ramsey pointed out that the Christian understanding of responsibility is not about genetic control or preventing genetic deterioration, even when it occurs.<sup>55</sup> In May 1970, a small conference “Early Diagnosis of Human Genetic Defects: Scientific and Ethical Considerations” was convened. Hastings Center staff participated in a face-to-face discussion of the ethical challenges of genetic testing. Robert Morison, the conference’s chairman, emphasized negative historical examples of eugenic discrimination.<sup>56</sup>

At that time, a group for genetic counseling was already working at the Hastings Center. It consisted of theologian James Gustafson and scientists Richard Roblin and Marc Lappé. Their article was one of the major early sources on the ethics of genetics. The text mentions possible forms of stigma and discrimination, proposes a specific set of principles for regulating the field, and outlines a move toward more nuanced regulation. In our view, this article contains a vision of genetic testing as a field of exceptional regulation. It can be considered illustrative of the role of social exclusion for exceptionalism and the future dissolution of exceptionalism into a set of more specific rules.

The article published in 1972 in *The New England Journal of Medicine* summarizes an agenda for developing ethical regulations of genetic screening.<sup>57</sup> The authors proposed an extended list of ethical principles for screening programs. Despite the accurate ethical regulation, the authors’ approach was not casuistic. The principles they propose apply to any genetic screening program, regardless of its scope, the diseases detected, or the technical tools used. They also identify a core ethical challenge and propose a program for dealing with it. Judging by the fact that there is “a flood tide of ill-considered programs in genetic screening,”<sup>58</sup> this program has been accepted by decisionmakers in the field.

First, the authors identified the reduction of the frequency of apparently deleterious genes as a both practically and morally unacceptable objective of genetic screening.<sup>59</sup> According to them, each significant screening program should be aimed at supporting the decisionmaking of a pregnant woman and improving the well-being of affected individuals while the affected community should guide the design and implementation of a significant program. At the same time, Lappé et al., referring to equal access to screening, specifically mention the two groups most affected by eugenics programs in Europe and the United States: Ashkenazi Jews and African Americans. They stress that the community involved in the screening program prevents the exclusion of individuals as potential carriers of apparently deleterious genes and ensures the program’s focus on improving the health of people who suffer from genetic disorders. At the same time, health policymakers make sure that particular communities are not excluded from a screening program.

The article concludes by outlining possible types of exclusions based on the sickle-cell traits identified by screening, the most frequent focus of genetic screening at that time. In that case, disclosure of genetic information may cause problems with life insurance for adults. Moreover, even confident knowledge about such risks may make parents unnecessarily restrict physical activity of the affected child.<sup>60</sup> This can be understood as an attempt to look into the future from 1972. The named risks of stigmatization may require special regulatory exemptions, even after genetic testing becomes a routine procedure.

We should note that the risks of stigmatization were not the product of the imagination of the bioethicists. Drs. Robert Murray and Michael Kaback, who shared their experiences with the Hastings

Center research group, reported cases of employment discrimination against adult African Americans involved in the sickle-cell screening. Also, the majority of the programs targeted preschool children who could not benefit directly from the test results. These programs were tied to school admission and marriage licensing.<sup>61</sup>

In the early stages of the debates on genetic screening, the complexity of possible exclusion made it necessary to treat genetic screening as an experimental practice since it involved “untried testing procedures” and was “vitaly concerned with the acquisition of new knowledge.”<sup>62</sup> Hence, it required the highest degree of protection for human subjects provided by its regulation as a form of human experimentation, not a routine clinical procedure. Such regulation was the fencing tape, showing an area of probably severe but unknown risks. In this case, genetic exceptionalism was not based on judgments about the uniqueness of genetic information. Instead, the Hastings Center research group asserted exceptionalism as a temporary barrier preventing possible misuse of genetic information, exclusion, and stigma.

The movements from exclusion through exceptionalism to a set of exceptions can be seen as the swinging of the historical pendulum between more and less strict regulation. Nevertheless, historical examples of social exclusion, or their interpretations, are aggregated when formulating exceptionally rigorous regulations. Notions of specific forms of exceptionalism more often arise when the need for specific regulation of a particular area is called into question. Terms of HIV, genetic and neuro exceptionalism emerged to denote the object of criticism.

Several decades can pass between the emergence of exceptionalism as an approach to regulation and the introduction of the term in academic papers, as in the case of genetic exceptionalism, or it can happen almost simultaneously, as in the case of neuro exceptionalism.<sup>63</sup> Lappé et al. proposed specific ethical principles for genetic tests in the early 1970s while genetic exceptionalism became a subject of discussion only in the late 1990s, as shown in the previous section.

Regardless of this time lag, exceptionalism as an approach to regulation provides a site for understanding the social impact of new biomedical technologies. Once this work is done, exceptionalism begins to be called by its name, emerging as an object of criticism. After that, the strictness of regulation can be weakened without fear of being accused of insensitivity to social exclusion or discrimination.

### Social Exclusion Shaping Regulatory Exceptionalism

The connection between genetic technologies and eugenics-driven exclusion is neither necessary nor obvious. It takes a considerable amount of work to construct historical arguments to make this connection an essential element of bioethical discussions. Silke Schicktanz et al. identified six types of historical arguments in bioethics (slippery slope-, analogy-, continuity-, knockout/taboo-, ethical progress-, and accomplice arguments).<sup>64</sup> In doing so, the arguments tend to draw from biomedical experiments implicating discrimination and exclusion, from Nazi eugenics to the Tuskegee syphilis study.

The current myth of the origins of bioethics partly explains the propensity for such eugenic parallels. Nevertheless, there is a controversy over why modern Germany rigidly regulates medical procedures, which are most often compared to eugenic practices. As we point out below, Nazi eugenics separated lives that were not worth living, so Preimplantation Genetic Diagnosis (PGD) here is strictly regulated today. In the Soviet Union, geneticists were repressed and excluded from the academy, so today, their colleagues can more openly claim free regulation of what is called “liberal eugenics.”

The rules guiding PGD in contemporary Germany are much stricter than in other European countries.<sup>65</sup> One explanation for this phenomenon is that the political elite here is more religious than the general public. However, the proponents of this explanation admit that strict PGD regulation is much more often linked to Germany’s Nazi past.<sup>66</sup> German public speakers have done definite semantic work<sup>67</sup> to associate Third Reich eugenics with the medical manipulation of embryos.<sup>68</sup> Concerns of a repetition of Nazi history have been assembled through reference to practices of exclusion having an unambiguous



moral assessment. As Catherine Braun argues, a universalist and inclusive understanding of human dignity led to the exceptional regulation of reprogenetics in Germany.<sup>69</sup>

The impossibility of excluding someone's life as not worthy of being lived led to the prohibition of the instrumentalization of life. Thanks to this, the German regulation combines a woman's right to abortion with rigorous PGD regulation. The German Stem Cell Act distinguishes between biological cell life and life endowed with human dignity. Ingrid Metzler regards this distinction as analogous to Agamben's distinction between *zoe* and *bios*.<sup>70</sup> Thus, the forms of exclusion taken into account have also nuanced the repertoire of exceptions in German regulation. In contrast, Catholic bioethicists in Italy defended the sanctity of life, leading to restrictions on the right to abortion and the limitation of stem cell research.<sup>71</sup>

In Nazi Germany, eugenic exclusion reached unprecedented size, the memory of which has resulted in contemporary reprogenetic exceptionalism. Meanwhile, in the Soviet Union, genetics and the early "positive eugenics" were themselves subject to academic exclusion and a target for political repression.<sup>72</sup> Officials stigmatized geneticists as supporters of racism and Nazism, nicknaming them "flyovers-humanhaters." It may be one of the reasons why appeals to exclusively free regulation of genome editing have not met with serious opposition. For instance, Russian biotechnologist Denis Rebrikov dared to publicly propose a program of experimental human genome editing after the He Jiankui case had gathered negative ethical and legal appraisals.<sup>73</sup>

Although the mechanisms of exclusion's impact on exceptionalism remain a subject of debate, we need not emphasize just the correlation between them but also the substantive relationship between prior exclusion and subsequent exceptionalism. In a nutshell, the facts on who was previously excluded and how they were excluded shape contemporary exceptionalism.

## Conclusions

Given the origins and evolution of the notions of exceptionalism, exception, and exclusion, it is understandable that they are closely connected in bioethics, just like in law theory, philosophy, or political theory. Still, each notion has its meaning and scope. Exceptionalism pertains to phenomena that are not (yet) entirely familiar to us and could bear significant risks regarding their regulation. Among these risks is the exclusion of information or specific social groups, as we have demonstrated in several historical examples. In turn, exceptions are helpful in the formulation of detailed regulatory policies and procedures.

From this perspective, the development of the debates on genetic exceptionalism can be described as a movement from awareness of social exclusion through genetic exceptionalism to the set of particular regulatory exceptions. We consider this pattern to be rather common for the evolution of bioethical regulation in an emerging biomedical field.

In the early stage of debates on the regulation of genetic testing, the parties argued about the special status of genetic information. If genetic information is exceptional compared to other medical data, then special regulation is required to prevent a resurgence of eugenic discrimination.<sup>74</sup> Although genetic information often plays an essential role in family, social, and work stigma and exclusion, it does not necessarily contribute to these phenomena.<sup>75</sup> Over the decades of the evolution of medical genetics, bioethicists have realized that genetic information does not play a privileged role in exclusion. Ethical and social implications of genetic tests vary from case to case. For these reasons, a more nuanced approach to framing the problem has been adopted. It dealt with the effects of particular genetic tests on various forms of stigma and exclusion.<sup>76</sup> Particular genetic tests could amplify existing modes of exclusion and assemble new ones based on previously common ones. In fact, this approach has proven to be the most productive in the development of bioethical regulation. Debates about the uniqueness of genetic information have rather been dominated by the development of this nuanced approach than resolved by advances in biological knowledge and medical technology.

Looking at the bigger picture, one can conclude that the lack of a systematic understanding and analysis of the role of exceptionality and exceptions in the development of various bioethical approaches stems from the absence of a bioethical theory of novelty<sup>77</sup> which would use a limited number of clearly

defined instruments to describe entities that are partially or entirely new for an existing paradigm. While it is impossible to construct such a theory within the framework of a single paper, we believe that we have taken a step in this direction by studying the notions of exceptionality, exception, and exclusion that can potentially form its foundation.

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## Notes

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28. See lib. IV, tit. XIII: *De exceptionibus*.
29. In his *Méditation sur la notion commune de la justice* (presumably 1702), Leibniz states that we need exceptions from a strict rule (*jus strictum*), linking the exception with the idea of equality (*equitas*) and piety (*pietas*). Strict adherence to the strict rule without regard for equity could only lead to lawlessness, and so in justified cases, we have to make an exception from it in order to mitigate it.
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63. We could grasp exceptionalism also as an instrument of “boundary work” in the bioethical domain that, for instance, allowed neuroethics to become a separate field. However, regardless of the extent to which exceptionalism plays the role of a tool for (sub)disciplinary separation, it continues to play its role by providing a venue for reflecting on the ethical and social meaning of new biomedical technology (see Racine E, Sample M. Two problematic foundations of neuroethics and pragmatist reconstructions. *Cambridge Quarterly of Healthcare Ethics* 2018;27(4):566–77).
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