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Between innovation and prohibition: the European legal and ethical framework on human germline genome editing and the role of criminal law as a safeguard

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ΠΡΩΤΟΤΥΠΗ ΕΡΓΑΣΙΑ

Μεταξύ καινοτομίας και απαγόρευσης: το ευρωπαϊκό νομικό και δεοντολογικό πλαίσιο για την επεξεργασία του γονιδιώματος της ανθρώπινης βλαστικής σειράς και ο εγγυητικός ρόλος του ποινικού δικαίου

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ΠΕΡΙΛΗΨΗ

Το άρθρο εξετάζει το ευρωπαϊκό νομικό πλαίσιο που διέπει την επεξεργασία του γονιδιώματος της ανθρώπινης βλαστικής σειράς (HGGE) και αξιολογεί κριτικά τον ρόλο του ποινικού δικαίου ως ειδικού μέσου προστασίας. Προχωρώντας πέρα από τις γενικές ηθικές συζητήσεις σχετικά με την ασφάλεια, τη βελτίωση και την ακεραιότητα της έρευνας, υποστηρίζει ότι η ιδιαίτερη νομική πρόκληση που θέτει η HGGE έγκειται στον κληρονομικό και μη αναστρέψιμο χαρακτήρα της, καθώς και στις διαγενεακές επιπτώσεις της. Αυτά τα χαρακτηριστικά θέτουν υπό πίεση τα συμβατικά ρυθμιστικά μοντέλα που βασίζονται στην αυτονομία και την ευθύνη.

Αναλύεται πρώτα το σχετικό διεθνές και ευρωπαϊκό νομικό τοπίο, με ιδιαίτερη έμφαση στη Σύμβαση του Οβιέδο και την έμμεση αλλά σημαντική επίδραση της νομοθεσίας της ΕΕ, συμπεριλαμβανομένων των μορφών «λειτουργικής απαγόρευσης». Στη συνέχεια, παρουσιάζεται μια συγκριτική εξέταση του εθνικού δικαίου της Γερμανίας, της Γαλλίας, της Ιταλίας και του Ηνωμένου Βασιλείου. Παρά τις διαφορετικές συνταγματικές παραδόσεις, τα συστήματα αυτά συγκλίνουν στην απαγόρευση της HGGE και στην επιβολή ποινικών κυρώσεων για την κλινική εφαρμογή της, ενώ επιτρέπουν την έρευνα που δεν στοχεύει σε αναπαραγωγή υπό αυστηρές προϋποθέσεις.

Κεντρική συμβολή του άρθρου είναι η αποσαφήνιση της κανονιστικής διάκρισης μεταξύ της έρευνας σε έμβρυα και της επεξεργασίας του γονιδιώματος των ανθρώπινων αναπαραγωγικών κυττάρων. Υποστηρίζεται ότι η ποινική ευθύνη δικαιολογείται μόνο όταν η επεξεργασία του γονιδιώματος εισέρχεται σε κλινικές δοκιμές ή σε αναπαραγωγική χρήση με στόχο την εμφύτευση, προκαλώντας έτσι κληρονομική τροποποίηση, όχι όμως στην προκλινική ή μη αναπαραγωγική έρευνα. Τελικά, το άρθρο αντιλαμβάνεται το ποινικό δίκαιο σε αυτόν τον τομέα ως προστασία μιας δι-ατομικής και δια-γενεακής προσέγγισης της ανθρώπινης αξιοπρέπειας, με την κληρονομικότητα να λειτουργεί ως το αποφασιστικό όριο για την ποινική παρέμβαση.

Λέξεις-κλειδιά:

επεξεργασία του γονιδιώματος της ανθρώπινης βλαστικής σειράς, όριο κληρονομικότητας, ανθρώπινη αξιοπρέπεια, ποινικό δίκαιο, ευρωπαϊκή διακυβέρνηση της βιοηθικής

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ORIGINAL ARTICLE

Between innovation and prohibition: the European legal and ethical framework on human germline genome editing and the role of criminal law as a safeguard

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ABSTRACT

This article examines the European legal framework governing human germline genome editing (HGGE) and critically assesses the role of criminal law as a safeguard within that framework. Moving beyond general ethical debates on safety, enhancement, and research integrity, it argues that the distinctive legal challenge posed by HGGE lies in its heritable and irreversible character, as well as in its transgenerational implications. These features strain conventional autonomy-based and liability-based regulatory models and help explain the persistent resort to categorical criminal prohibitions across European jurisdictions.

The analysis first reconstructs the relevant international and European legal landscape, with particular attention to the Oviedo Convention and the indirect yet significant influence of EU sectoral regulation, including forms of "functional prohibition." It then provides a comparative examination of Germany, France, Italy, and the United Kingdom. Despite differing constitutional traditions, these systems converge in prohibiting reproductive germline modification and attaching criminal sanctions to its clinical application, while allowing tightly regulated non-reproductive research in certain circumstances.

A central contribution of the article is the clarification of the normative distinction between embryo research and reproductive germline modification. It argues that criminal liability is justifiable only where genome editing enters clinical trials or reproductive use aimed at implantation, thereby triggering heritable modification. Extending penal sanctions to preclinical or non-reproductive research would undermine the principle of extrema ratio. Ultimately, the article conceptualises criminal law in this field as protecting a trans-individual and transgenerational conception of human dignity, with heritability operating as the decisive threshold for penal intervention.

Keywords:
human germline genome editing, heritability threshold, human dignity, criminal law, european bioethics governance

I. Introduction

The rapid development of human germline genome editing (HGGE), particularly following the advent of CRISPR-Cas technologies, has profoundly altered the legal and ethical landscape of biomedicine. What was once a largely speculative concern became, more than ever, a concrete regulatory challenge in 2018 when the birth of children whose genomes had been edited at the embryonic stage was publicly announced (Bu 2019; Johnson 2024). That episode exposed not only the technical feasibility of germline interventions, but also the fragility and fragmentation of existing legal frameworks at national and international levels. In its aftermath, a broad consensus emerged that human germline genome editing raises issues that cannot be adequately addressed by scientific self-regulation or ethical guidelines alone.

From a legal perspective, germline genome editing presents a distinctive challenge. Unlike most biomedical interventions, it affects individuals who cannot consent, produces effects that may extend across generations, and entails a degree of irreversibility that renders ex post remedies largely ineffective. These features strain regulatory paradigms traditionally grounded in individual rights, informed consent, and compensatory liability. Comparative analyses of national legal systems indicate that states have responded through diverse and, in many cases, pre-existing regulatory instruments that were not designed with contemporary genome editing technologies in mind. Despite this diversity, comparative scholarship suggests a recurring pattern: where germline genome editing involves reproductive use or results in heritable genetic modification, national legal systems frequently rely on criminal prohibitions or criminal sanctions (Boggio et al. 2020), either directly or as a backstop to administrative regulation.

The presence of criminal sanctions in this field is, however, far from self-explanatory. Criminal law is conventionally reserved for conduct that causes concrete harm to identifiable victims or threatens clearly defined public interests. HGGE, by contrast, is characterised by scientific uncertainty, long temporal horizons, and diffuse potential effects. Moreover, neither international human rights law nor European bioethics instruments establish an unequivocal and comprehensive prohibition of all forms of germline modification, leaving room for divergent interpretations and regulatory approaches (Beriain et al. 2019, Yotova 2020). This raises a question that has not yet been systematically examined from a criminal-law perspective: which legal good is criminal law seeking to protect in the context of human germline genome editing?

The existing literature on HGGE, while steadily expanding, remains comparatively limited from a legal perspective and has focused predominantly on questions of ethical permissibility, international human rights constraints, and comparative regulatory models (Vöneky 2018; Raposo 2019; Yotova 2020). These contributions have been essential in mapping the normative terrain and drawing attention to risks such as regulatory fragmentation, ethics tourism, and governance gaps. Yet they often leave implicit the rationale for criminalisation itself. Where criminal law is addressed, it is frequently treated as a technical enforcement tool rather than as a normative choice requiring independent justification, particularly in light of the principle of extrema ratio.

This article argues that a more satisfactory account of criminal law in this field requires a shift in perspective. In addition to asking whether germline genome editing is safe, consensual, or scientifically justified, it is necessary to examine which interest is regarded as sufficiently fundamental to warrant the most intrusive form of legal intervention available to the state. Considerations of public health, individual autonomy, and research ethics undoubtedly play an important role in the broader governance of biotechnology. However, taken individually, they do not fully explain why criminal prohibitions persist even in the absence of demonstrable and actual harm, why they are triggered primarily by heritability, or why they attach with particular severity to reproductive applications.

The central hypothesis explored in this article is that criminal law in the field of human germline genome editing is oriented towards the protection of a trans-individual legal good, which can be reconstructed as human dignity understood in a collective and transgenerational sense. On this reading, criminal

prohibitions are not primarily aimed at protecting present individuals, but at safeguarding humanity from irreversible forms of self-instrumentalisation associated with the technological redesign of human reproduction. This hypothesis does not presuppose uniform philosophical agreement, but seeks to provide a coherent doctrinal explanation for the structure and persistence of existing criminal norms within the European legal space.

Methodologically, the analysis adopts an interdisciplinary yet law-centred approach, combining ethical analysis, international and European legal interpretation, and comparative criminal law. After outlining the legally salient biomedical and ethical features of HGGE, the article examines the international and European framework governing such interventions. It then turns to a comparative analysis of selected national legal systems, before addressing criminal law as a safeguard and the identification of the protected legal good. The concluding section reflects on the implications of this analysis for European governance and the cautiously delimited role that EU criminal law might play in this domain.

II. Ethical and Biomedical Background: Legally Relevant Features of Human Germline Genome Editing

II.1. Germline Genome Editing and the Centrality of Heritability

Human germline genome editing (HGGE) refers to genetic interventions performed on gametes, zygotes, or early embryos with the capacity to be transmitted to future generations. This heritable dimension distinguishes HGGE from somatic gene therapies, whose effects remain confined to the treated individual. Comparative scholarship treats the heritable dimension as legally salient and structures regulation along distinct stages of research and application (Boggio et al. 2020; Vöneky 2018).

From a regulatory perspective, heritability introduces a temporal extension of legal concern: interventions may affect individuals who do not yet exist as legal subjects and whose interests cannot be represented through conventional consent-based or rights-based mechanisms. This feature contributes significantly to treating HGGE as a distinct category within biomedical law, justifying differentiated legal treatment even before questions of safety or efficacy are addressed (Yotova 2020).

II.2. Irreversibility and Epistemic Uncertainty

HGGE combines two features that are legally salient: epistemic uncertainty and practical irreversibility. Scientific uncertainty persists with regard to off-target effects, pleiotropic interactions, and long-term consequences that may only emerge over generations. At the same time, once reproductive use has occurred, the intervention cannot be reversed without negating the very existence of the resulting individual. This combination limits the effectiveness of traditional regulatory tools such as ex post liability, post-market surveillance, or adaptive licensing (Boggio et al. 2020). Several commentators invoke the precautionary principle as a relevant governance framework. However, precaution is operationalised as a requirement of “due diligence” applied at each stage of development and through case-by-case assessment, rather than as a mandate for categorical prohibition (Cesa e Silva 2022). Importantly, unpredictability alone does not dictate criminal prohibition; many medical practices operate under comparable condition of incertitude without triggering penal sanctions (e.g. early-phase oncology trials). The relevance of uncertainty lies rather in its interaction with heritability and irreversibility, which together magnify the normative stakes of regulatory failure (Boggio et al. 2020, Almqvist 2020).

II.3. Consent, Parental Authority, and Future Persons

The absence of consent from those most affected by HGGE—future persons and subsequent generations—poses a structural challenge to autonomy-based justifications. While parental consent is widely accepted in pediatric medical decision-making, its legitimacy is more contested when decisions involve irreversible, heritable alterations that extend beyond the life horizon of the child (Boggio et al. 2020).

Some authors suggest that this "representation gap" weakens autonomy-based defences of HGGE and shifts attention towards collective or intergenerational interests (Yotova 2020; Raposo 2019). At the same time, scholarship cautions against overstating this point: lack of consent alone does not automatically justify criminalisation, as numerous prenatal medical decisions and reproductive practices affecting future persons are regulated through professional oversight rather than penal prohibition. Accordingly, consent analysis clarifies why HGGE raises distinctive concerns, but it does not, in isolation, explain the specific choice of criminal law as a regulatory response (Dukanovic 2019).

II.4. Enhancement, Instrumentalisation, and Social Meaning

Debates surrounding HGGE often invoke the distinction between therapeutic and enhancement-oriented interventions. While this distinction is analytically useful, the literature widely recognises its instability in practice. Even interventions framed as therapeutic may carry broader social meanings by introducing intentional design into human reproduction. From a legal perspective, concerns about enhancement often function as proxies for a deeper anxiety about instrumentalisation: the risk that future persons are treated as objects of optimisation rather than as subjects with an open future. This concern, while contested, recurs across ethical and legal scholarship and informs the perception of HGGE as a practice as a practice with implications for the genetic constitution and legal protection of future generations (Sergeev 2019). Taken together, heritability, irreversibility, uncertainty, and the limits of consent help explain why HGGE is persistently framed as a limit-case for law. These features do not, by themselves, mandate criminal prohibition. They do, however, clarify why legal responses tend to focus on reproductive and heritable applications and why governance debates repeatedly invoke collective and intergenerational interests. The next section examines how these concerns are translated into binding norms within the international and European legal framework.

III. The International and European Legal Framework Governing HGGE

III.1. International Soft Law and the Enforcement Gap

At the international level, governance of HGGE is characterised by strong ethical convergence and comparatively weak enforceability. Instruments such as UNESCO declarations articulate principles of human dignity, integrity of the human genome, and responsibility towards future generations, but remain formally non-binding. It's agreeable that such soft-law instruments play an important role in norm formation while relying on domestic implementation for effectiveness (Bu 2019; Sergeev 2019). The limitations of this framework have been illustrated by concrete cases in which actors exploited regulatory gaps, weak oversight, or jurisdictional fragmentation. Commentators describe these dynamics as forms of "ethics tourism" or regulatory arbitrage, facilitated by uneven national enforcement and the absence of centralised sanctions (Johnson 2024). These observations underscore the structural difficulty of protecting collective and future-oriented interests through soft law alone.

III.2. The Oviedo Convention and the Legal Salience of Heritability

Within Europe, the Convention on Human Rights and Biomedicine (Oviedo Convention) constitutes the most significant binding instrument. Article 13 permits genome interventions for preventive, diagnostic, or therapeutic purposes only insofar as they are not aimed at introducing modifications in the genome of descendants. The provision has generated extensive scholarly debate. Some authors interpret Article 13 as establishing a firm prohibition on heritable germline modification, grounded in respect for human dignity and the protection of future generations (Yotova 2020; Vöneky 2018). Others argue for a more flexible interpretation, suggesting that the text leaves room for future reconsideration, particularly with respect to research or hypothetical therapeutic applications (Beriain et al. 2019; Boggio et al. 2020). Despite this disagreement, there is broad consensus that the structure of Article 13 assigns decisive normative weight to heritability as the legal threshold.

III.3. European Union Law and "Functional Prohibition"

The European Union has not adopted a comprehensive legal framework specifically regulating HGGE. Nevertheless, EU law constrains clinical translation through sectoral instruments, including rules on clinical trials, funding eligibility, and biomedical research governance. This strategy can be described as a form of "functional prohibition", whereby a practice is effectively blocked by denying authorisation pathways, financial support, or lawful market access, without the adoption of an explicit EU-level criminal offence. While effective in limiting institutional research and clinical application, this approach has inherent limits. It does not fully address private conduct occurring outside regulated settings, nor does it ensure uniform enforcement across Member States. As a result, EU law indirectly reinforces national prohibitions while leaving criminal enforcement primarily to domestic legal systems.

III.4. Precaution, Due Diligence, and the Choice of Regulatory Instruments

European human rights scholarship increasingly frames HGGE as an area in which states may have positive obligations to prevent foreseeable harm under conditions of scientific uncertainty. Precaution can thus be understood as part of a broader duty of due diligence. However, the literature also emphasises that precaution does not entail absolute prohibition and is operationalised as due diligence, leaving regulatory choice open. States may fulfil precautionary obligations through a range of measures, including licensing, moratoria, and enhanced oversight (Cesa e Silva 2022). This observation is critical for the analysis that follows. The decision to employ criminal law cannot be inferred automatically from precautionary reasoning; it requires additional normative justification. The persistence of criminal sanctions in national frameworks therefore calls for closer examination of the legal good they are intended to protect. The international and European framework governing HGGE reveals a combination of ethical convergence and institutional fragmentation. While binding norms emphasise the impermissibility of heritable reproductive modification, enforcement remains predominantly national and uneven. This structural context explains why domestic legal systems play a central role in translating shared values into enforceable prohibitions. The next section examines how selected national frameworks operationalise these commitments and what this reveal about the role of criminal law as a safeguard.

IV. Comparative National Approaches to Human Germline Genome Editing

IV.1. Germany: Human Dignity, Constitutional Absolutism, and Penal Boundary-Setting

Germany is frequently cited as the paradigmatic example of a dignity-centred and prohibition-oriented approach to human germline genome editing. The German regulatory framework is primarily grounded in the Embryo Protection Act (Embryonenschutzgesetz, ESchG) of 13 December 1990, which criminalises a wide range of conduct involving the creation, manipulation, and use of human embryos. Section 5 ESchG, in particular, prohibits artificial modification of human germline cells, while other provisions criminalise the creation of embryos for purposes other than bringing about a pregnancy. The doctrinal background of this framework is inseparable from the constitutional status of human dignity (Art. 1(1) of the Basic Law), which German constitutional jurisprudence has consistently interpreted as an objective value forming the foundation of the legal order. Within this paradigm, human dignity is not merely an individual subjective right but a normative principle that constrains legislative and technological choices. Germline genome editing is therefore regarded as incompatible with the dignity of future human beings, insofar as it risks transforming them into objects of intentional genetic design rather than subjects with an open future. A salient feature of the German approach is that criminalisation does not depend on empirical assessments of safety or proportionality balancing between risks and benefits. Instead, the decisive legal trigger is the intentional modification of heritable genetic material, irrespective of whether the intervention is framed as therapeutic or enhancement-oriented. Even hypothetical improvements in safety would not necessarily alter the normative assessment, because the objection concerns

the permissibility of altering the genetic foundations of human life as such. Criminal law thus operates as a constitutional safeguard, designed to protect the integrity of humanity against instrumentalisation rather than to manage biomedical risk. In this sense, Germany provides a clear illustration of criminal law functioning as a categorical boundary-setting mechanism, closely aligned with constitutional values and resistant to incremental regulatory adaptation.

IV.2. France: Bioethics Legislation and the Expressive Function of Criminal Law

The French regulatory framework governing human germline genome editing is characterised by the close integration of bioethics legislation and criminal law. The central normative instruments are the Bioethics Laws (Lois de Bioéthique), periodically revised since 1994 and codified primarily in the Code de la Santé Publique, in conjunction with criminal provisions contained in the Code Pénal. These instruments prohibit interventions aimed at modifying the human germline for reproductive purposes and attach criminal sanctions to violations involving embryos and genetic modification. Unlike the German model, the French approach does not rely explicitly on constitutional absolutism. Instead, it reflects a republican bioethical tradition that emphasises respect for the human body, non-commercialisation, and the integrity of the human species. Criminal law plays a predominantly symbolic and expressive role, reinforcing ethical boundaries established through legislative deliberation and democratic debate rather than through judicially entrenched constitutional principles (Boggio et al. 2020; Schweikart 2020). Notwithstanding the periodic revision of bioethics legislation to accommodate scientific and social developments, the prohibition of heritable germline modification has remained comparatively stable. Even as French law has shown openness towards revisiting rules on embryo research or medically assisted reproduction, reproductive germline interventions continue to be excluded from permissible biomedical practice. This persistence suggests that heritability functions as a normative red line that resists recalibration through ordinary legislative balancing (Yotova 2020). From a comparative perspective, the French case demonstrates how criminal law may serve as an instrument of ethical consolidation, translating broadly shared bioethical commitments into enforceable prohibitions without invoking the language of absolute constitutional constraints. Yet the outcome converges with the German position: criminal sanctions mark the point at which technological intervention in human reproduction is deemed incompatible with fundamental values.

IV.3. Italy: Law No. 40/2004, Constitutional Review, and the Persistence of Penal Extrema Ratio

Italy presents a more fragmented and contested regulatory landscape, shaped by the interaction between legislative prohibition and constitutional adjudication. The central statute is Law No. 40 of 19 February 2004 on medically assisted reproduction, which introduced restrictive rules on embryo creation, research, and genetic intervention, accompanied by criminal sanctions. Several provisions of Law No. 40/2004 were subsequently challenged before the Italian Constitutional Court, leading to significant modifications, particularly with regard to access to reproductive techniques and embryo-related practices. Despite this progressive judicial recalibration, the prohibition of heritable germline genome modification has not been normalised or authorised. While constitutional case law has relaxed certain aspects of the original framework—often invoking proportionality, health rights, and reproductive autonomy—it has refrained from legitimising interventions that intentionally alter the genetic inheritance of future generations (Dukanovic 2019; Boggio et al. 2020). This selective persistence of criminal prohibition is analytically significant. It suggests that Italian constitutional jurisprudence distinguishes between restrictions that unduly burden present individuals and interventions that affect the genetic foundations of future persons. In the latter case, criminal law continues to operate as extrema ratio, justified by the irreversible and transgenerational nature of the conduct at issue. The Italian experience thus illustrates how criminal law can survive constitutional balancing and rights-based scrutiny when the protected interest is framed as extending beyond individual autonomy to encompass collective and intergenerational concerns. Heritability again emerges as the decisive legal threshold.

IV.4. United Kingdom: Regulatory Flexibility and the Criminal Backstop

The United Kingdom adopts a regulatory model that is often described as comparatively permissive and innovation-friendly. The legal framework is centred on the Human Fertilisation and Embryology Act (HFE Act), which establishes a sophisticated licensing and oversight regime administered by a specialised authority. Under this system, certain forms of embryo research, including genome editing for research purposes, may be authorised subject to strict conditions and institutional supervision. However, this regulatory flexibility is structurally limited. The implantation of a genetically modified embryo for reproductive purposes remains prohibited and constitutes a criminal offence under the HFE Act. Thus, while administrative discretion allows for case-by-case evaluation within the research domain, criminal law defines the outer boundary of permissible conduct. The UK model is particularly instructive from a comparative standpoint. It demonstrates that even where governance relies primarily on administrative licensing rather than categorical prohibition, criminal law retains a decisive role at the heritability threshold. Regulatory flexibility operates within a legally delimited space; once conduct crosses into reproductive germline modification, discretion ends and penal enforcement begins. This undermines the view that criminalisation is merely a feature of rigid or conservative legal cultures. Instead, it suggests that criminal law functions as a common safeguard mechanism across divergent governance styles, reserved for interventions perceived as raising fundamental normative concerns.

IV.5. Comparative Synthesis: Convergence, Divergence, and Legal Significance

The comparative analysis reveals a striking convergence across Germany, France, Italy, and the United Kingdom. Despite profound differences in constitutional traditions, legislative techniques, and regulatory architectures, all four jurisdictions prohibit reproductive heritable germline genome editing and support this prohibition with criminal sanctions. This convergence cannot be fully explained by uniform assessments of scientific risk or by shared positions on enhancement, consent, or research ethics. At the same time, important divergences persist with regard to the scope of offences, oversight mechanisms, and enforcement capacity. These differences are not merely formal. They may affect the credibility of sanctions, the detectability of violations, and the incentives faced by researchers and clinicians operating in a transnational environment (Boggio et al. 2020). From the perspective of criminal-law theory, the comparative picture supports the inference that criminal law intervenes at a specific normative threshold: heritability. Across systems, criminal sanctions appear not as a default response to biomedical innovation, but as a targeted safeguard against interventions that risk altering the genetic inheritance of future generations. This empirical grounding prepares the way for the theoretical analysis developed in the following section, which examines criminal law as a safeguard and reconstructs the protected legal good underlying these convergent prohibitions. A brief comparison with the regulatory experience of assisted human reproduction (AHR) further clarifies the boundary-setting function of criminal law in biomedical governance. Comparative scholarship on AHR shows that criminal law has often been employed to mark ethical red lines - such as prohibitions on reproductive cloning, the commercialisation of reproductive material, or certain embryo-related practices - while proving ill-suited as a comprehensive framework for the routine governance of medically embedded techniques (Snow 2015). Across different legal systems, broad criminalisation in the field of assisted reproduction has been criticised for its rigidity and for its limited capacity to accommodate evolving medical practice and constitutional scrutiny, whereas more targeted criminal prohibitions have been regarded as retaining greater legitimacy when confined to clearly delimited practices perceived as crossing fundamental ethical or legal thresholds (Caulfield 2001, Lee 2012). This experience suggests that criminal law performs its most defensible role not as a general regulatory tool, but as a residual safeguard—a pattern that closely mirrors its function in national responses to human germline genome editing.

V. Criminal Law as a Safeguard in Human Germline Genome Editing

V.1. The Recurring Resort to Criminal Law: Preliminary Observations

The comparative analysis undertaken in the previous section suggests that criminal law occupies a recurrent position in national frameworks governing human germline genome editing (HGGE), particularly with respect to reproductive and heritable applications. This recurrence is not self-evident. HGGE is characterised by scientific uncertainty, evolving technologies, and, at least in the short term, a limited number of concrete cases. In many other areas of biomedical innovation, such features have led legislators to favour administrative regulation, professional oversight, or civil liability rather than criminal sanctions.

Nevertheless, a significant strand of the legal literature suggest that states have repeatedly opted for criminal prohibitions in this field, even where regulatory alternatives are available (Boggio et al. 2020; Dukanovic 2019). This choice suggests that criminal law is not employed merely as a default enforcement mechanism, but rather as a safeguard reserved for a specific category of conduct, namely interventions that intentionally introduce heritable genetic modifications into the human germline. At the same time, scholars have cautioned against interpreting this pattern as evidence of a coherent or uniform theory of criminalisation. Instead, criminal law appears to fulfil multiple functions simultaneously: deterrence, symbolic boundary-setting, and the protection of interests that are not easily accommodated within traditional risk-based regulatory models (Schweikart 2020). The following subsections examine whether commonly proposed legal goods can adequately explain this resort to criminal law.

V.2. Public Health and Risk Prevention: An Incomplete Justification

One possible justification for criminal prohibitions on HGGE is the protection of public health and safety. Germline genome editing involves uncertain risks, including off-target effects, epigenetic interactions, and long-term consequences that may only manifest across generations. From a precautionary perspective, some scholarship frames HGGE governance in terms of due diligence under uncertainty rather than categorical prohibition (Cesa e Silva 2022). However, legal analysis suggests that this explanation encounters difficulties. First, criminal sanctions attach even in the absence of demonstrated harm or immediate risk to identifiable individuals. Second, if risk prevention were the decisive criterion, it would be difficult to explain why the legal trigger is heritability rather than the level of scientific uncertainty or the magnitude of potential harm (Raposo 2019). Many biomedical practices involve comparable uncertainty without being criminalised. Moreover, risk-based reasoning would suggest a regulatory model capable of adaptation as scientific knowledge evolves. By contrast, criminal prohibitions on heritable germline modification tend to be framed categorically and persist despite advances in safety claims. This persistence suggests that risk prevention alone does not fully account for the structure of existing criminal norms (Boggio et al. 2020).

Accordingly, while public health considerations are undoubtedly relevant to HGGE governance, they appear insufficient to explain why criminal law, rather than administrative or civil mechanisms, is repeatedly employed as the ultimate safeguard.

V.3. Autonomy, Consent, and the Limits of Individual-Centred Legal Goods

A second candidate for the protected legal good is individual autonomy. Germline genome editing affects persons who cannot consent—namely future children and subsequent generations—and therefore challenges the centrality of informed consent in medical law. It is arguable that this absence of consent undermines the legitimacy of germline interventions and may justify stringent legal constraints. However, autonomy-based justifications also encounter structural limitations. Parental consent is routinely accepted in many areas of paediatric medicine, even where decisions have long-term consequences. While the irreversibility and heritability of HGGE complicate this analogy, autonomy alone does not explain why criminal sanctions, rather than enhanced oversight or judicial review, are considered necessary. More importantly, autonomy-based accounts struggle to explain why the law targets

reproductive heritable outcomes rather than the decision-making process itself. Criminal prohibitions do not focus on defective consent or coercion; instead, they attach to the act of introducing heritable genetic change. This suggests that the interest protected by criminal law is not reducible to the autonomy of present or future individuals, but extends beyond individual-centred legal goods.

V.4. Research Integrity and Professional Misconduct: A Partial Account

Some commentators frame criminalisation in the field of human germline genome editing (HGGE) primarily as a response to failures of research integrity, pointing to cases in which genome editing has been pursued in violation of ethical guidelines, approval procedures, or institutional oversight. On this view, criminal law operates as a backstop against rogue research and professional misconduct, intervening where existing mechanisms of self-regulation and ethical review have failed (Bu 2019). While this explanation captures an important aspect of the regulatory landscape, it remains incomplete. Systems of research governance - such as ethics committees, licensing authorities, and professional disciplinary regimes - are already specifically designed to address misconduct within institutional research settings. As recent scholarship has emphasised, regulatory reform in this area should therefore avoid conflating embryo research conducted under strict non-reproductive conditions with reproductive germline modification, as these activities raise qualitatively different legal and ethical concerns (Vidalis 2023). In this perspective, the need for legislative amendment arises not from embryo research as such, but from the prospective clinical translation of germline editing technologies into reproductive use. This distinction also bears directly on the scope of criminal liability. Criminal prohibitions on HGGE extend beyond breaches of research protocol and apply irrespective of whether conduct occurs within or outside formal research institutions (Boggio et al. 2020). However, extending criminal liability to preclinical or non-reproductive research phases - such as laboratory experimentation or authorised embryo research - would risk undermining the principle of extrema ratio. Criminal law appears normatively justified only where research activity crosses into unauthorised reproductive application or clinical trials involving implantation and heritable genetic modification, thereby affecting the genetic identity of future persons. This confirms that the protected interest underlying criminal intervention is not merely professional integrity, but a more fundamental concern linked to the transgenerational consequences of germline modification.

V.5. Human Dignity as a Trans-Individual and Transgenerational Legal Good

Against this background, a growing body of scholarship suggests that the most plausible reconstruction of the protected legal good is human dignity, understood not solely as an individual right but as an objective, trans-individual value linked to the integrity of humanity across generations (Vöneky 2018; Yotova 2020; Sergeev 2019). This interpretation finds support in the architecture of European legal instruments and national legislation. The consistent focus on heritability—rather than on intent, enhancement, or risk—indicates that what is at stake is the permissibility of altering the genetic conditions under which future human beings come into existence. Criminal law, in this reading, aims to prevent the instrumentalisation of future persons by subjecting their genetic identity to deliberate design choices. Importantly, this account should be understood as a doctrinal reconstruction, not as a claim that all legislators or courts explicitly endorse the same philosophical conception of dignity. The literature reflects significant disagreement about the scope and content of dignity-based arguments. Nevertheless, the convergence of criminal prohibitions around heritable germline modification suggests that dignity, operationalised through the heritability threshold, functions as a common normative denominator capable of explaining the resort to criminal law (Boggio et al. 2020; Beriain et al. 2019).

V.6. Criminal Law, Extrema Ratio, and the Need for Calibration.

Recognising human dignity as the protected legal good does not imply an endorsement of expansive or indiscriminate criminalisation. On the contrary, many authors emphasise the circumstance that criminal law

must remain an instrument of extrema ratio, particularly in technologically dynamic fields (Dukanovic 2019; Cesa e Silva 2022). This principle supports a calibrated approach that distinguishes between non-reproductive research under stringent oversight and reproductive applications resulting in heritable modification. Overly broad criminal norms risk chilling legitimate scientific research, undermining related values such as health, scientific freedom, and innovation (Raposo 2019). Conversely, a narrowly tailored criminal prohibition focused on the heritability threshold aligns more closely with the underlying dignity-based rationale. Such calibration also reinforces the legitimacy of criminal law by ensuring that it protects the conditions of responsible innovation, rather than opposing innovation as such. In this sense, criminal law functions as a safeguard of foundational values, not as a substitute for comprehensive biomedical regulation.

V.7. The European Dimension: Convergence, Fragmentation, and Cautious Prospects for EU Action

The analysis thus far highlights a tension within the European legal space. On the one hand, there is significant normative convergence around prohibiting reproductive heritable germline modification. On the other hand, differences persist in offence definitions, enforcement mechanisms, and oversight capacity. In an integrated environment characterised by cross-border research and medical services, such differences may facilitate regulatory arbitrage at the margins, even where headline prohibitions align (Boggio et al. 2020). Some authors have therefore suggested that limited EU involvement could be justified to protect shared fundamental values, particularly where fragmentation undermines effective enforcement. However, the literature also cautions against overextending EU criminal-law competence into ethically contested domains. Any potential EU action would need to respect subsidiarity, remain tightly circumscribed, and focus on minimum standards rather than comprehensive harmonisation (Schweikart 2020; Yotova 2020). Accordingly, the relevance of EU criminal law in this field should be framed not as an inevitable next step, but as a contingent possibility that depends on demonstrable enforcement gaps and a clear articulation of the protected legal good. Taken together, the doctrinal and comparative material supports a cautious conclusion: criminal law in the field of HGGE is most plausibly understood as safeguarding a trans-individual and transgenerational conception of human dignity, operationalised through the heritability threshold. This reconstruction does not exclude alternative readings, nor does it deny the relevance of risk, autonomy, or research integrity. It does, however, offer a coherent explanation for why criminal law appears repeatedly, and specifically, at the point where genetic intervention becomes heritable.

VI. Conclusion

Human germline genome editing confronts contemporary legal systems with a form of technological power that challenges foundational assumptions of biomedical regulation. Its transgenerational reach, irreversibility, and resistance to consent-based justification place it at the margins of established legal categories. As this paper has shown, the response of European legal systems to this challenge has been neither uniform nor accidental. Despite significant differences in constitutional traditions, regulatory techniques, and ethical cultures, national legal orders converge on one decisive point: the exclusion of heritable germline genome editing from permissible biomedical practice, typically reinforced through criminal law. This convergence cannot be adequately explained by reference to public health concerns, individual autonomy, or scientific uncertainty alone. While these considerations undoubtedly inform the broader governance of biotechnology, they do not fully account for the persistence and rigidity of criminal prohibitions, particularly in contexts where harm remains speculative, benefits are asserted, and safety claims continue to evolve. Nor can criminalisation be reduced to a mere extension of research ethics or professional discipline. Instead, the comparative analysis undertaken in this paper indicates that criminal law intervenes at a specific normative threshold: heritability. Across Germany, France, Italy, and the United Kingdom, heritable modification of the human genome functions as a legal red line that

triggers criminal liability irrespective of differences in regulatory architecture and degrees of regulatory flexibility. In this context, regulatory flexibility refers to the extent to which legal systems permit differentiated governance of biomedical practices through administrative licensing, ethical review, or judicial balancing—most notably in the domains of embryo research and assisted reproduction. Even where such flexibility exists, as in systems relying on licensing and case-by-case oversight, it consistently ceases once intervention crosses into reproductive applications resulting in heritable genetic modification. Whether criminal law operates as a constitutional shield, a symbolic reinforcement of bioethical norms, an expression of penal extrema ratio, or the backstop of an administrative licensing regime, its function converges on the same outcome. This empirical pattern provides the foundation for the paper's central claim: criminal law in the field of human germline genome editing protects a trans-individual legal good, which can be reconstructed as human dignity understood in a collective and transgenerational sense. As developed in Parts IV and V, this conception of dignity departs from purely individualistic or subjective accounts. It reflects an objective dimension of human dignity that constrains not only state action but also private technological choices capable of reshaping the conditions of human reproduction. Criminal law, in this context, does not aim to punish harm already caused. Rather, it seeks to prevent irreversible forms of self-instrumentalisation of humanity that no ex post legal mechanism could meaningfully remedy. Its legitimacy therefore derives not from risk management alone, but from boundary-setting: marking forms of conduct that the legal order deems incompatible with the continued recognition of human beings as ends rather than as products of design. At the same time, the analysis has emphasised the limits inherent in criminalisation. Criminal law remains an instrument of extrema ratio and must be carefully circumscribed to avoid freezing legitimate scientific research or conflating basic research with reproductive application. The distinction between non-reproductive research under stringent oversight and reproductive interventions resulting in heritable modification is therefore crucial. Criminal law can be justified only where the protected legal good—humanity's genetic integrity across generations—is directly at stake. These findings also bear implications for the European Union legal order. While the EU currently relies on indirect regulatory mechanisms and leaves criminal enforcement largely to Member States, the comparative evidence suggests that fragmentation may undermine the effectiveness and coherence of protection in an integrated legal and scientific space. Any move towards EU involvement in criminal law in this field, however, must remain limited, subsidiarity-sensitive, and anchored in the protection of fundamental values rather than in the harmonisation of bioethical choices. The analysis offered in this paper does not advocate expansive EU criminal competence, but rather provides a principled framework for assessing when limited and carefully circumscribed intervention might be justified. Ultimately, the contribution of this work lies in reframing the debate on human germline genome editing from a question of permissibility or safety to a question of legal goods and legitimacy. By identifying the protected legal good underlying criminal prohibitions, it seeks to bring conceptual clarity to a field often dominated by ethical intuition and regulatory pragmatism. In doing so, it aims to show that criminal law, when properly constrained, can function not as an obstacle to innovation, but as a safeguard of the normative foundations upon which any responsible innovation must rest.

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