
Recent Developments in Health Law

The Genetic Information Nondiscrimination Act of 2008: “First Major Civil Rights Bill of the Century” Bars Misuse of Genetic Test Results

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About This Column

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Introduction

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA) became the first federal law to prohibit employers and health insurers, both group and individual, from denying employment or insurance to a healthy individual based solely on his or her genetic predisposition to develop a disease. In legislation that passed with significant bipartisan support, Congress determined that tremendous advances in human genome sequencing and genetics “give rise to the potential misuse of genetic information to discriminate in health insurance and employment.”¹ GINA amends the Employee Retirement Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code and the Social Security Act to prohibit a group health plan from adjusting premium or contribution amounts on the basis of genetic information, while employers are restricted from using genetic information to make personnel decisions surrounding hiring, firing, and promotion.² However, genetic test results are not entirely off-limits to insurers and employers pursuant to GINA. Under the new law, insurers may request voluntary genetic tests for research purposes, and employers may use tests to assess the biological effects of toxins in the workplace. It remains to be seen if GINA will help individuals overcome the discrimination “fear factor”— a major obstacle to participation in research studies that collect genetic information and hold the potential to advance the development of personalized medicine.³ Personalized medicine is the use of an individual’s genomic profile to develop the most effective preven-

tion, diagnosis, and treatment strategies for that individual.⁴

Background: Genetic Antidiscrimination Protection Pre-GINA

State statutes, the Health Insurance Portability and Accountability Act (HIPAA), and the Americans with Disabilities Act (ADA) provided a patchwork quilt of inconsistent protection against genetic discrimination in employment and insurance decisions prior to GINA. States first addressed the use of genetic information in the workplace in the 1970s and 1980s by outlawing discrimination against job applicants with the sickle cell trait.⁵ Statutes continued to develop steadily over the years, but the contents varied widely across states. All genetic nondiscrimination legislation prohibited differential access to employment on the basis of genetic test results, and many laws barred employers from requesting, requiring or obtaining genetic information.⁶ However, significant oversight and enforcement mechanisms were not incorporated into most genetic antidiscrimination statutes, and only a small minority of state policies explicitly levied penalties against employers who discriminated on the basis of genetic information.⁷ GINA addresses the variation in state law by creating a national baseline for safeguards against discrimination; it does not preempt state statutes that offer more extensive coverage against employer misuse of genetic information.

State genetic nondiscrimination policies aimed at individual and group health insurance plans are similar in scope to those geared towards employers and equally in-

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consistent. State policy generally makes it illegal for health insurers to use genetic information to determine eligibility or set premiums, require genetic testing of applicants, or disclose genetic information without consent.⁸ The power of state insurance commissioners to enforce these restrictions ranges from the ability

prohibition of discrimination on the basis of disability,¹⁶ but its language does not explicitly protect individuals from discrimination on the basis of genetic predisposition to disease. In 1995, the Equal Employment Opportunity Commission (EEOC) issued a statement that people with a genetic disorder “may” fall under the ADA’s

order possesses the genetic marker of a disease and thus has an increased chance of developing the illness at some point in his or her future.²² Absent any signs or symptoms of disease, it may be difficult to demonstrate that an employer “regarded [an] individual as having a genetic defect” and acted in a discriminatory fashion on

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to suspend an insurer’s license to the authority to impose heavy administrative fines that range in value from \$1,000 to \$150,000 depending on the scope and duration of violations.⁹ Some states have chosen to grant individuals a cause of action against insurers who discriminate on the basis of genetic test results.¹⁰ However, no state law in place prior to GINA extended to cover the actions of employer-sponsored health plans.¹¹ Employer-sponsored insurance is the leading source of health insurance in the country, and its exclusion left a significant gap in protection.¹²

Prior to GINA, the only federal legislation that directly addressed genetic discrimination was the Health Insurance Portability and Accountability Act (HIPAA).¹³ HIPAA explicitly states that genetic predisposition in the absence of a current diagnosis of illness cannot be considered a preexisting condition.¹⁴ HIPAA also makes it unlawful for insurers to use genetic information to limit eligibility or increase premiums, but it only applies to group health plans. This limitation to group plans left people seeking health insurance on the individual market open to different premiums and eligibility based on their genetic test results.¹⁵

Finally, the Americans with Disabilities Act offered some protection against discriminatory use of genetic information. The ADA was created to establish “clear and comprehensive

definition of disability as persons “regarded as having an impairment.”¹⁷ Relying upon this interpretation in *EEOC v. Burlington Northern Santa Fe Railroad*, the EEOC filed a genetic discrimination claim under the ADA against Burlington Railroad for secretly testing its employees for a rare genetic condition that causes carpal tunnel syndrome.¹⁸ Burlington argued that the test was a means of determining whether the high incidence of repetitive-stress injuries among its employees was work-related.¹⁹ However, in addition to testing for the carpal-tunnel syndrome gene, doctors were instructed to screen for several other medical conditions such as diabetes and alcoholism, and at least one employee who refused testing was threatened with termination.²⁰ The EEOC argued that the tests were unlawful because they were not job-related, and the lawsuit was settled quickly when Burlington agreed to stop requesting genetic samples and to stop punishing employees who chose not to be tested.²¹

In light of the EEOC statement and the *Burlington* settlement, the ADA arguably provides some protection against genetic discrimination by employers. However, it was not clear to proponents of federal antidiscrimination legislation that it went so far as to cover asymptomatic individuals who have late-onset genetic disorders. A presymptomatic individual or someone who has a late-onset genetic dis-

that basis.²³ The limited protection of the ADA was thus a motivation in the extended effort to develop a more uniform standard of protection.

GINA 2008: “First major civil rights bill of the new century”²⁴

The first two titles of the Genetic Information Nondiscrimination Act of 2008 outline how insurers and employers may and may not use genetic test results. Genetic tests include tests that assess genotypes, mutations, or chromosomal changes. *Title I: Genetic Nondiscrimination in Health Insurance* prohibits individual and group health plans of all sizes from requesting or requiring that a covered individual or a member of his or her family undergo genetic testing.²⁵ Further, health plans are restricted from requesting, requiring, or purchasing genetic information for underwriting purposes or for evaluating an individual prior to enrollment.²⁶ Failure to comply with restrictions would result in financial penalties that may be reduced or waived if the insurer can demonstrate reasonable diligence in its efforts to avoid inappropriate use of genetic information.²⁷ The Secretaries of Health and Human Services, Labor and the Treasury are charged with coordinating their enforcement efforts to ensure consistent interpretation and application of the regulations set forth in the Act.²⁸

Health plans are permitted to request that a plan participant or ben-

eficiary undergo a genetic test for “research purposes” if the following conditions are met: (a) the plan clearly indicates that compliance is voluntary and that noncompliance will have no effect on enrollment status; (b) no genetic information is used for underwriting purposes; and (c) the plan notifies the Secretary of Health and Human Services that it is conducting activities pursuant to this exception and includes a description of the activities.²⁹ Finally, Section 105 of Title I extends HIPAA privacy regulations to genetic information.

needed to comply with certification requirements of family and medical leave laws; (b) the information is to be used for genetic monitoring of the biological effects of toxic substances in the workplace; or (c) the employer conducts DNA analysis for purposes of law enforcement or human remains identification.³⁴

Nondiscrimination Legislation and Personalized Medicine

It remains to be seen if the restrictions outlined in GINA will provide the ideal degree and type of protec-

crimination “fear factor” in turn decreased patient willingness to participate in biomedical research that was necessary to explore the potential of personalized medicine.³⁸ Proponents argued that nondiscrimination legislation would be key to allaying these concerns and speeding entry into a new era of medical treatment where drugs are designed to work with the specific genes of a patient.³⁹

Moreover, although GINA incorporates most of the major policy recommendations developed by the National Institutes of Health National

GINA prohibits health insurers and employers from discriminating on the basis of genetic test results. Premiums and enrollment status cannot be based on genetic information in the health insurance context; nor can hiring, firing, and promotion decisions be linked to genetics in the job arena. These straightforward restrictions are at the heart of nondiscrimination legislation that appears to have roots in concern about employer and insurer practices and the progress of novel approaches to medicine.

Specifically, genetic information is to be treated as health information and health insurers are not allowed to disclose genetic tests results for underwriting purposes.³⁰

Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information designates discrimination against an employee because of genetic information as an unlawful employment practice.³¹ Employers are prohibited from failing to hire, discharging, or failing to promote on the basis of genetic information, while employment agencies are barred from making referral decisions using genetic criteria.³² Title II makes it unlawful for employers, employment agencies, labor organizations, or joint-labor management committees to limit, separate, or classify employees by genetic profile. These same entities are also prohibited from purchasing employees’ or members’ genetic information.³³ However, employee genetic information may be accessed for the following reasons: (a) such information is

tion against genetic discrimination and address a major concern of bill proponents: patient participation in biomedical research and the advance of personalized medicine. The Genetic Information Nondiscrimination Act of 2008 took more than a decade to become law as the legislation had been debated in Congress since 1995. Policymakers critical of GINA considered the incidence of genetically motivated discrimination by employers and health insurers to be relatively low and were generally unconvinced that additional legislative measures were necessary to address the issue.³⁵ Members of the health care, research, and policy communities cited the results of multiple studies and reports to refute these criticisms and demonstrate growing concern among Americans that genetic information would be used against them by employers and insurers.³⁶ This fear was shown to be particularly acute where tests revealed that an individual was presymptomatic or at heightened risk for developing a condition.³⁷ This dis-

Human Genome Research Institute (NHGRI),⁴⁰ a notable difference is the absence of a private right of action for individuals who can demonstrate disparate impact on the basis of genetic information.⁴¹ Section 208 of Title II explicitly removes a private right of action based on disparate impact while remaining silent on whether or not a cause of action exists where an individual can prove intentional discrimination.⁴² This is significant insofar as it will substantially limit the venues through which individuals can seek relief in the event of genetic discrimination.⁴³

The GINA Effect?

The personalized medicine component of the argument in favor of GINA raises interesting questions about the relationship between regulation and behavioral response. Will patients and potential study participants view GINA as adequate protection against employer and insurer discrimination in the event that a genetic marker for disease is detected?

How will the enrollment rate in clinical trials change in states that had more and less extensive protections in place prior to GINA? And, perhaps most importantly, will employers and health insurers stop engaging in genetics-based discrimination? Insurers opposing the law argued that genetic information is another form of health information that allowed for “fair discrimination” such that those with the lowest risk pay the lowest premiums.⁴⁴ Employers argued that there are relatively few documented cases of genetic discrimination and that restrictions on testing would limit their ability to reduce costs associated with insurance claims.⁴⁵ These unanswered questions and the resistance of insurers and employers suggest that GINA’s success must be evaluated with data on reported cases of genetic discrimination and rates of participation in biomedical clinical trials.

Conclusion

GINA prohibits health insurers and employers from discriminating on the basis of genetic test results. Premiums and enrollment status cannot be based on genetic information in the health insurance context; nor can hiring, firing, and promotion decisions be linked to genetics in the job arena. These straightforward restrictions are at the heart of nondiscrimination legislation that appears to have roots in concern about employer and insurer practices and the progress of novel approaches to medicine. Referring to individual concerns about genetic discrimination in the health insurance context, Representative Judy Biggert, co-sponsor of GINA in the U.S. House of Representatives, stated that “[t]his bill unlocks the great promise of the Human Genome Project by alleviating the most common fear about genetic testing.”⁴⁶ The dual purpose of the new law should make its success at curbing discriminatory practices and encouraging genetic testing a serious inquiry for its proponents.

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18. *EEOC v. Burlington N. Santa Fe R.R.*, No. CO1-4013 (N.D. Iowa filed February 9, 2001).
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24. U.S. Senator Ted Kennedy (D-MA) as quoted in Hudson et al., “Keeping Pace with the Times — The Genetic Information Nondiscrimination Act of 2008,” *New England Journal of Medicine* 358, no. 25 (2008): 2661-2663, at 2662.
25. See *Genetic Information Nondiscrimination Act of 2008*, *supra* note 1, at “Title I: Genetic Nondiscrimination in Health Insurance.” The “family member” of an individual includes dependents and first-, second-, third- and fourth-degree relatives.
26. *Id.* “Genetic information” refers to an individual’s genetic test results, the genetic test results of family members, and the manifestation of disease or disorder in family members of the individual. If the insurer comes across this information incidentally, then there is no violation of Title I.
27. *Id.*
28. *Id.*
29. *Id.*
30. See *Genetic Information Nondiscrimination Act of 2008*, *supra* note 1, at Title I, Sec. 105.
31. *Id.*, at Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information.
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43. W. M. Carter, Jr., “A Thirteenth Amendment Framework for Combating Racial Profiling,” *Harvard Civil Rights and Civil Liberties Law Review* 39 (2004): 17. Carter discusses the limited and ineffective avenues to seek relief from harms associated with racial profiling when the Supreme Court ruled in *Alexander v. Sandoval* that regulations pursuant to Title VI prohibiting disparate-impact discrimination did *not* create an implied private cause of action.

44. See Benton, *supra* note 17, at 309.

45. *Id.*

46. See Hudson et al., *supra* note 24, at 2662.

Reversing the “Irreversible”: Heart Donation after Cardiac Death

Inga Chernyak

I. Introduction

A medical team at Denver Children’s Hospital performed three infant heart transplants using donors who had died from cardiocirculatory death. This was the first challenge to the tradition of performing heart transplants using only donors who had been declared brain dead.¹ The Uniform Determination of Death Act, adopted by Colorado in 1981, states that an individual can be declared dead if he has sustained irreversible cessation of either his circulatory and respiratory functions or of his entire brain.² The controversy about the Denver transplants has centered on the issue of whether or not a donor can be declared dead using the “irreversible cardiocirculatory death” definition if his or her heart can, and is, restarted in the organ recipient.

If it is found that donors whose hearts can be successfully restarted in recipients do not meet the criteria for irreversible cardiocirculatory death, then heart transplants from donors who have died of cardiocirculatory causes may violate the “dead donor” rule, which states that patients must be dead before the removal of any vital organs for transplantation.³ This would mean that patients for whom further treatment is futile, or whose quality of life is so poor that they or their families have decided to discontinue life support measures, would be barred from offering their hearts for transplantation. To decide the issue, courts must consider not only the technical meaning of the term “irreversible” but also the repercussions of disallowing a form of organ donation that has the potential to significantly increase organ availability and thus save more lives at arguably little or no cost.

II. The Clinical Trial

Between May 2004 and May 2007, Dr. Mark M. Boucek led an institutional clinical trial on infant heart transplants at the Denver Children’s Hospital.⁴ In this trial, three infants underwent transplantation of hearts from donors who had died of cardiocirculatory causes. All three infants who underwent the experimental transplantation are still alive and have functional and immunologic outcomes similar to those of the surviving control infants. Physicians who were not involved in the care of the recipients made the medical decision to withdraw life support from the potential donors independently of any considerations of organ donation. In all three cases, the decision to withdraw life support was based on the futility of ongoing care and the dependence on life support to maintain viability. The families of the potential donors were then given the option to allow consent to the use of the infants’ organs for transplantation.

III. Medical Background of Non-Heart-Beating Organ Donation

Since 1968, the majority — down to 90% in 2006 from 98% in 1995⁵ — of organ donors have been individuals declared brain dead with continuing cardiocirculatory functioning following the brain-based definition of death widely accepted in the medical community. Organ donation is now classified into two sorts of procedures: heart-beating organ donation (HBOD) and non-heart-beating organ donation (NHBOD). When the donor has ceased to have any brain function, but continues to have normal cardiocirculatory activity, the procedure is classified HBOD; a donor with a cessation of cardiocirculatory and cardiorespiratory activity is classified as NHBOD.⁶ Today, NHBODs usually involve patients who are on life support due to devastating brain injuries, spinal cord injuries, or end-stage musculoskeletal disease.⁷ They are not brain dead while they remain on life support, and thus may only be declared dead once life support has been removed and cardiocirculatory activity stops.

NHBOD is especially attractive for pediatric or infant organ donation because of the specific vulnerabilities of the pool of potential recipients and potential donors. Infants awaiting a cardiac transplant face the highest risk of death — up to 25% waitlist mortality — and increased waiting time before transplantation, which can adversely affect neurological development.⁸ Potential infant donors are particularly suited to NHBOD because mechanical circulatory support is generally unavailable for infants, meaning those who die will do so due to the withdrawal of life support rather than the cessation of brain function. The only way that these patients could serve as organ donors would be in NHBOD procedures. The use of organs from donors who died from cardiocirculatory causes presents an opportunity to reduce waiting time and waitlist mortality among children whose survival depends on a heart transplant.

preme Court, in *Lovato v. District Court In and For Tenth Judicial Dist.*, acknowledged Colorado's adoption of the UDDA dual standard of death in a state statute, adding that the court's "recognition of this concept of brain death does not preclude continuing recognition of the standard of death as determined by traditional criteria of cessation of respiration and circulation."¹¹ This dictum indicates that the acceptance of brain death as an alternative statutory definition of death does not undermine the continuing relevance of the traditional cardiocirculatory death definition. However, whether the Denver trial heart donors could be found to have sustained irreversible cessation of circulatory and respiratory functions under the UDDA will depend upon how a given court interprets the requirement of irreversibility. To date, no court has directly addressed this issue.

The UAGA is a model act first drafted, approved, and recommended for enactment in all the states by the

cable anatomical gift law of another state is not liable for the act in a civil action, criminal prosecution, or administrative proceeding.¹⁵ The official comment for this provision in the 1968 act stated that the purpose of this provision was to encourage and facilitate organ donation. According to the official comment in the 2006 act, "immunity was intended to be extended to persons which generally and substantively act in accordance with the 1968 Act, with honesty of intent."¹⁶ A liberal reading of the provision on limitation of liability would be beneficial to the Denver Children's Hospital: since the medical team was clearly acting in good faith, the provision may shield the physicians and hospitals involved from civil action or criminal proceedings.

The purpose of the limitation of liability provision of the UAGA — to indemnify those who make good faith efforts to facilitate organ donation — was elucidated in *Williams v. Hoffmann*.¹⁷ In this case, the plaintiff's

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IV. Legal History

Two acts serve as the main tools for analyzing the legality of NHBOD: the Uniform Determination of Death Act (UDDA) and the Uniform Anatomical Gifts Act (UAGA). The UDDA is a model act drafted, approved, and recommended for enactment in all the states by the National Conference of Commissioners on Uniform State Laws in August 1980. The purpose of the Act was to provide "comprehensive bases for determining death in all situations."⁹ According to section 1 of the UDDA, "[a]n individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead."¹⁰ In 1981, the Colorado Su-

National Conference of Commissioners on Uniform State Laws in 1968, amended in 1987, and then revised once again in 2006. The 2006 revisions were made to "address in part the critical organ shortage by providing additional ways for making organ, eye, and tissue donations."¹² The UAGA relies on the UDDA for its definition of "death" and does not itself define the term. Colorado adopted the 2006 UAGA in July 2007.¹³ In addition to Colorado, 19 states have adopted the 2006 UAGA.¹⁴ The statute establishes the scope of liability for physicians, hospitals, and other personnel involved in the transplantation.

A person or institution that acts, or attempts to act in good faith in accordance with the UAGA or the appli-

wife died after being admitted to the Milwaukee County General Hospital for a brain hemorrhage. The plaintiff then consented to the removal of the decedent's kidneys for transplantation, based upon the decedent's doctor's assurance that she was dead. The plaintiff later discovered that the decedent had been kept on life support after the declaration of death and was only taken off life support shortly before the kidney removal operation took place. The plaintiff then sought to recover damages for negligence on the part of the doctor and the county, alleging negligent conduct both before and after his wife's death. The judge held that in the immunity provision of the UAGA, the phrase "terms of this section" concerns the mechanics of giving and receiving anatomi-

cal gifts, the determination of time of death, and procedures following death; the immunity provision in this case did not extend to treatment of the donor prior to death.¹⁸ Therefore, although the doctor and county could use the liability limitation offered in the UAGA as an affirmative defense to any claim involving “(a) the mechanics of giving and receiving anatomical gifts, (b) the determination of time of death, and (c) procedures following death,”¹⁸ they could not rely on that

the determination of death, then the Denver team’s informed consent procedure may still shield the team from liability. Unlike in *Williams*, after the families of the potential donors made the decision to withdraw life support, the Denver doctors informed them about the organ donation process before the families gave their consent to the heart donations. That means that the families of the donors knew that the infants would remain on life support until the time of the transplanta-

question. In that case, the defendant shot his victim in the head, resulting in the victim’s brain death. After the victim was declared brain dead, his mother signed a consent form allowing for his kidneys and spleen to be removed for donation. The defendant argued that if the court subscribes to the common law definition of death only, then the victim did not die until he was taken off life support and his kidneys were removed “by the independent intervening acts of the

The legal permissibility of NHBOD for heart transplantation surgeries will ultimately depend on the determination courts make about whether organ donors whose hearts can be successfully restarted in the bodies of recipients can satisfy the statutory definition of cardiocirculatory death.

provision of the UAGA as an affirmative defense to any claim concerning mistreatment of the plaintiff’s wife when she was still legally living — before the doctor’s pronouncement of a time of death. A footnote in this opinion cautiously points out that it is unclear whether the immunity provision of the UAGA was meant to apply to liability arising from determination of death, and that no clarification is found in this case since plaintiff’s complaints have not alleged injury arising from any wrongdoing connected with the determination of death itself.¹⁹

The holding of *Williams* implies that Denver Children’s Hospital and Dr. Boucek may avoid liability through the limitation clause of the UAGA for any conduct occurring after the donor infants were declared dead, so long as the conduct was performed in good faith. However, it is unclear whether they could be held liable for injuries arising from the determination of death itself. If the limitation clause were found to apply to the determination of death, a demonstration of good faith by the Denver medical team would most likely be sufficient to secure indemnity in a civil action or criminal proceeding. If, on the other hand, the UAGA immunity provision were later found *not* to apply to

tion surgery, and that after the withdrawal of life support, no effort would be made to restart organ function. These two stages of consent by the donors’ families — first, to withdraw life support, and second, to permit this particular process of organ donation — could help Denver Children’s Hospital to demonstrate that the infant donors were going to die of cardiocirculatory causes, catalyzed by the withdrawal of life support measures, irrespective of whether they were going to serve as organ donors. The fact that the decedents’ organs were then harvested for transplantation should not undermine the statutory validity of cardiocirculatory death.

If the Denver Children’s Hospital medical team is not indemnified under the limitation clause of the UAGA for wrongful determination of death and a court finds that the donor infants did not satisfy the statutory definition of death before organs were harvested for transplantation, then the question remains as to whether the actual removal of the organs by the medical team would be determined to be the proximate cause of death; if it is not, then the causation element in civil lawsuits would not be satisfied and the team would be protected from further liability. A criminal case, *People v. Bonilla*,²⁰ addresses this very

hospital physicians.”²¹ The judge held that although it would be a determination of fact whether a bullet wound to the head was a proximate cause of the victim’s death, “it is enough that defendant’s conduct forged a link in a chain of events which brought about the death” and the “intervention of a secondary agency constitutes a defense only if the death is solely attributable to it.”²² Since the defendant’s actions brought about the victim’s brain death, it would be incorrect to say that the death of the victim can be legally attributed to the organ removal performed by the surgeons. This holding suggests that if the infant donors in the Denver Children’s Hospital trial were taken off life support because of the decision made by their families and physicians, then the proximate cause of death from a legal perspective would be cardiocirculatory death — failure of the heart and lungs to function without mechanical support — and not the removal of the organs themselves by the transplantation team, as this latter step occurred after the decision to terminate the life via withdrawal of life support was made.

V. Competing Theories of “Irreversibility”

The UDDA defines cardiac death as the “irreversible cessation of circulatory and respiratory functions.” The ideological conflict between those who believe that the Denver clinical trial was legally and medically sound and those who believe that it was problematic hinges on two alternative interpretations of the word “irreversible”: impossible to reverse, or not to be reversed.

The interpretation most favorable to the Denver Children’s Hospital, and most likely the one relied upon by the Boucek medical team in a potential suit, was proposed in a report from the *American Journal of Transplantation* based on the 2005 National Conference on Donation after Cardiac Death. The following explanation of the condition of irreversibility appeared in the report:

Irreversibility is recognized by persistent cessation of function during an appropriate period of observation.... If data show that autoresuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.²³

According to this definition, “irreversible” means, effectively, that the cessation of function *will not* be spontaneously or artificially reversed in the potential donor. It does not speak to whether it would be theoretically possible for the heart to be restarted in any body — that of the donor or a potential recipient — but only to whether there is an actual “attempt at artificial resuscitation.” In the Denver Trial, the families of the donors decided for reasons independent of organ donation to withdraw life support from the patients and forgo artificial resuscitation. Under this definition of “irreversible,” once the life support measures were removed, the donors could be declared dead due to irreversible cessation of circulatory and respiratory functions

as required under the UDDA unless cardiocirculatory function restarted spontaneously during the observation period.

Dr. Robert Veatch, a professor of medical ethics at the Kennedy Institute of Ethics at Georgetown University, challenges the reliance on whether or not the heart *will* be restarted in the donor and argues instead that “irreversibility” must include both actual and theoretical cessation. He writes, “If someone is pronounced dead on the basis of irreversible loss of heart function... it would not be possible for heart function to be restored in another body.”

²⁴ According to Veatch’s definition, for loss of function to be irreversible, it must be *impossible to reverse* in any context. Responding to the definition offered in the 2005 convention report, Veatch says, “Calling such a heart ‘irreversibly stopped’ may be defensible if no attempt will be made to restart the heart. However, one cannot say a heart is irreversibly stopped if, in fact, it will be restarted.”²⁵ For Veatch, it is doubly problematic if there is not only a theoretical possibility of reversal but also an actual reversal of the loss of function. If a donor’s heart is both *possible to restart* and *will be restarted*, argues Veatch, it is logically impossible for the donor to have satisfied the definition of cardiac death.

Veatch’s argument, while compelling logically, fails to acknowledge the practical implications of the decision to disallow heart transplants from donors who died of cardiac death (NHBODs), which are typically catalyzed by the withdrawal of life support measures. Patients for whom further treatment is futile, or whose families have made the voluntary decision to withdraw life support, even in the absence of brain death, would be prevented from being heart donors, for purely theoretical reasons. Irrespective of whether the donation of the heart will be permitted, the patient *will die* because the decision to withdraw life support has been made. The loss of cardiocirculatory function will not be reversed in the donor because of the decision of the patient and his/her family. If the patient or family

wishes to donate a healthy, viable heart, it is not sensible for the law to disallow the donation on the technicality that the cardiocirculatory function was not *irreversibly* ceased at the time of the declaration of death.

VI. Conclusion

The legal permissibility of NHBOD for heart transplantation surgeries will ultimately depend on the determination courts make about whether organ donors whose hearts can be successfully restarted in the bodies of recipients can satisfy the statutory definition of cardiocirculatory death. If these donations are allowed and NHBOD becomes a viable alternative to HBOD, then the availability of organs will rise, potentially saving many thousands of lives. Donors who died from cardiocirculatory death catalyzed by the withdrawal of life support measures would legally be able to serve as organ donors. If courts determine that such donors do not meet the statutory definition of cardiocirculatory death, then one valuable source of much-needed organs will be eliminated. If courts are concerned with increasing the availability of organs and accommodating the wishes of organ donors, then patients who die from cardiocirculatory causes and their families should be legally allowed to lawfully donate their hearts for transplantation.

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9. *Unif. Determination of Death Act Prefatory Note* (1980).
10. *Colo. Rev. Stat. Ann.* § 12-36-136 (1981).
11. *Lovato v. Dist. Court In and For Tenth Judicial Dist.*, 198 Colo. 419, 433 (1979). See also *New York City Health & Hospitals Corp. v. Sulsona*, 367 N.Y.S.2d 686, 691 (Sup. Ct. 1975) (finding that brain death, the definition of death consistent with the generally accepted medical practice of doctors, is an acceptable alternative to the common law definition of cardiocirculatory death); *In re Welfare of Bowman*, 94 Wash.2d 407, 416 (1980) ("brain death is the legal equivalent of death because-under current medical science-the capacity for life is irretrievably lost when the entire brain, including the brain stem, has ceased functioning"); *In re Haymer*, 115 Ill.App.3d 349, 355 (App. Ct. 1983) ("person is legally dead if he or she has sustained either (1) irreversible cessation of total brain function, according to usual and customary standards of medical practice, or (2) irreversible cessation of circulatory and respiratory functions, according to usual and customary standards of medical practice").
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