## **Xenotransplantation**

Approved on June 20, 2024 by a vote of 18-0-0. Voting in favor: Rabbis Aaron Alexander, Jaymee Alpert, Pamela Barmash, Emily Barton, Suzanne Brody, Nate Crane, Elliot Dorff, David J. Fine, Joshua Heller, Barry Leff, Daniel Nevins, Matthew S. Nover, Micah Peltz, Joel Pitkowsky, Rachel Safman, Robert Scheinberg, Miriam T. Spitzer, Meir Szames. Voting against: None. Abstaining: None.

הַגָּר הַגָּר אִתְּכָם וְאָהַבְתָּ לוֹ כָּמוֹדָ

The alien who lives with you – love him like yourself Leviticus 19:34

# עעלה (Question)

Is the use of non-human animal tissues, organs, and glands for grafts and transplantation in humans, called xenografts and xenotransplantation, permissible by Jewish law? If permissible, are there any restrictions or concerns?

# (Response) תשובה

# Background

According to recent data, 17 people die each and every day in the United States awaiting organ transplants. More than 103,000 people are currently on the donor waiting list.<sup>1</sup> Public health experts point out that many patients don't even make it on to the waiting list, so the actual number of daily deaths due to the shortage of organs is significantly higher.<sup>2</sup> Moreover, the organ gap between need and availability is widest for children and neonates. "Xenografts could be made available in various sizes and would constitute a tremendous resource for pediatric transplantation.... Organ failure is the proximate cause for most pediatric deaths in the West."<sup>3</sup> Given the recent increases in diabetes, obesity, and hypertension—all contributing factors to organ distress--medical professionals expect the incidence of organ failure to continue climbing.<sup>4</sup>

<sup>2</sup>"Transplant Update," <u>https://www.pennmedicine.org/updates/blogs/transplant-update/2022/march/6-quick-facts-about-organ-donation</u>, accessed March 1, 2023, and OPTN, <u>OPTN: Organ Procurement and Transplantation Network - OPTN (hrsa.gov)</u>, accessed March 1, 2023.

<sup>4</sup> "UCI Health," <u>https://www.ucihealth.org/blog/2021/04/need-for-kidney-transplants-grows-dramatically</u>, accessed March 1, 2023.

The Committee on Jewish Law and Standards of the Rabbinical Assembly provides guidance in matters of halakhah for the Conservative movement. Individual rabbis, however, are authorized to interpret and apply halakhah for their communities.

<sup>&</sup>lt;sup>1</sup> "<u>Organ Donation Statistics | organdonor.gov,</u> accessed June 6, 2024.

<sup>&</sup>lt;sup>3</sup> Martine Rothblatt, *Your Life or Mine: How Geoethics Can Resolve the Conflict between Public and Private Interests in Xenotransplantation* (Surrey, UK: Ashgate Publishing 2004; rep. 2018), pp. 108f.

Judaism has an unequivocal imperative to heal, and this teshuvah will examine the permissibility of using new sources and technologies for xenografts and xenotransplants. These procedures involve cultivating non-human animal tissues, organs, and glands for therapeutic use in humans.

Our teachers, Rabbi Elliot N. Dorff and Rabbi Joel Roth, mentioned the permissibility of using non-kosher animal parts for transplants already in 1998 and 1999, respectively, when the prospects for such therapies were far on the horizon.<sup>5</sup> This present responsum, written in the wake of the first pig-to-human heart transplant in January of 2022, pig-to-human kidney transplant in March of 2024, and pig-to-human liver transplant in May of 2024, will consider the relevant halakhic concerns in light of the latest data.

When Rabbis Dorff and Roth wrote in the late 1990s, the most pressing medical challenge for xenotransplantation was the likelihood of humans rejecting non-human organs. By 2015, when Rabbi Daniel Nevins addressed the issue of genetically modified organisms, researchers were much closer to understanding how genetic engineering might neutralize the human autoimmune response that would normally reject non-human organs. In that teshuvah, Rabbi Nevins explicitly, although briefly, concurred that xenotransplantation, even with a pig organ, "would be justifiable in halakhah under the rubric of *pikuach nefesh*, an action that might save human life."<sup>6</sup>

Since July of 2019, CRISPR gene editing has been used to knock out deleterious genes and insert salutary genes for a variety of medical therapies. In 2021, CRISPR was used to facilitate the first pig-to-human kidney xenotransplant;<sup>7</sup> and in January 2022, the first pig-tohuman heart xenotransplant was performed using 10 gene modifications.<sup>8</sup> The xenoheart recipient, David Bennett, Sr., survived over eight weeks, and the cause of death could not immediately be linked to the xenotransplant given his other comorbidities.

More complicated xenotransplants occurred at Massachusetts General Hospital and NYU Langone Health in March of 2024. At Mass General, a 62-year-old man received a modified pig

 <sup>&</sup>lt;sup>5</sup> Elliot N. Dorff, *Matters of Life and Death: A Jewish Approach to Modern Medical Ethics* (Jewish Publication Society of America: Philadelphia, 1998), p. 217. Joel Roth, "Use of Animal Organs," *Responsa: 1991-2002* (New York: The Rabbinical Assembly, 2002), 208-211.
<sup>6</sup> Daniel S. Nevins, "Halakhic Perspectives on Genetically Modified Organisms," p. 37. 
Halakha and GMOs (rabbinicalassembly.org)>

When the time arrives, another teshuvah will be in order to discuss the considerations of xenotransplants when the category of *pikuach nefesh* is not operative.

<sup>&</sup>lt;sup>7</sup> Robert A. Montgomery, et. al. "Results of Two Cases of Pig-to-Human Kidney

Xenotransplantation," *New England Journal of Medicine* 386;20, May 19, 2022. N Engl J Med 2022;386:1889-98. DOI: 10.1056/NEJMoa2120238

<sup>&</sup>lt;sup>8</sup> See Martine Rothblatt's brief history of the process. "Commentary on achievement of first lifesaving xenoheart transplant." *Xenotransplantation*, March 23, 2022. DOI: 10.1111/xen.12746. "The pig used in the recent xenotransplantation had 10 genetic interventions: 3 knockouts to eliminate hyperacute rejection, 1 knockout to eliminate continued growth of the implanted heart, and insertion of 6 human genes to reduce immunological rejection." Entwistle, John W. "Clinical xenotransplantation seems close: Ethical issues persist," *Artificial Organs*, March 23, 2022, p. 4. doi.org/10.1111/aor.14255

kidney with sixty-nine genetic edits. He died within two months of the transplant. And at NYU, a 54-year-old woman received a porcine kidney as well as a porcine thymus gland while relying on a previously implanted mechanical heart pump.<sup>9</sup> Although the organ was not rejected, it was removed after 47 days due to a problem with blood flow from the heart pump. In May of 2024, another barrier was broken: a 71-year-old man in China became the first living person to receive a porcine liver transplant.<sup>10</sup> We seem to be on the cusp of a new era in the realm of xenotransplantations.

#### Extra-Halakhic Regulation

"Extra-halakhic regulations" refer to rules governing procedures that are relevant to the general public. Although traditional halakhah should be mined for discussions of any topic, even the most technologically advanced, jurists are not always sufficiently informed with the latest data and/or aware of the latest ethical concerns within the research community to make a determination on the viability of any given medical procedure. We are blessed to be living in a society that strictly regulates all aspects of xenotransplantation, from animal welfare to the informed consent of the recipient and the necessary safeguards to ensure that zoonotic diseases are not inadvertently unleashed on an unsuspecting public. Thus, prior to determining the halakhic permissibility of xenotransplantations, the research and medical communities must approve the procedure. Only afterwards will we be able to determine if a given practice or procedure is compatible with the world of Jewish values.

Beyond the question of whether  $\aleph$  is halakhically permissible, there is the question of whether  $\beth$  might be a better use of our limited resources—particularly if there are halakhic advantages to  $\beth$ . In our case, synthetic organs would obviate our concern with animal welfare attendant to xenotransplantation.<sup>11</sup> Should that advantage inform our halakhic decisions? Given that the preservation of human life is a primary goal of both halakhah and medical research, it would be prudent for the medical experts to determine how best to pursue our shared goal. Moreover, given the urgency of the need for organs and the lethal consequences of the lack of available donors, if xenotransplantation is halakhically permissible, it should be utilized to save lives today. Tomorrow, with more data to consider, we can consider the pursuit and utilization of synthetic organs.

There are other issues related to xenotransplantation that are also of Jewish concern but beyond halakhic reach. Until there are enough xenohearts, xenokidneys, and xenolivers<sup>12</sup> for all

<sup>10</sup> <u>First pig-to-human liver transplant recipient 'doing very well' (nature.com)</u>, article access on June 6, 2024.

<sup>&</sup>lt;sup>9</sup> <u>Mass. patient who received pig kidney leaves hospital, continues recovery at home | WBUR News; Second Patient Receives Gene-Edited Pig Kidney Transplant in Breakthrough Surgery | Smart News| Smithsonian Magazine; articles accessed on May 6, 2024.</u>

<sup>&</sup>lt;sup>11</sup> Daniel S. Nevins, "The Kashrut of Cultured Meat," p. 24. <<u>kashrut\_of\_cultured\_meat\_responsum\_final\_version\_march\_2018.pdf</u> (rabbinicalassembly.org)>

<sup>&</sup>lt;sup>12</sup> "Because the liver has more than 500 vital functions, xenotransplantation of this organ is very complex, even more so than xenotransplantation of the kidneys or heart. With this complexity

those in need, for example, the fair distribution of xeno-organs will be a vexing question.<sup>13</sup> Even after the supply of xeno-organs rises to the demand, equitable access to xenotransplantations will likely constitute yet another challenge to our health system. Insurance coverage for xenotransplant recipients and other financial concerns also go beyond the parameters of this teshuvah but are issues of Jewish concern and central to the Jewish principle of the sanctity of life.

## Contagion

The possibility of "transmitting viral disease from the donor animal to the human host and the potential for zoonotic transmission to other people is a major concern."<sup>14</sup> Protocols for experimentation and lifetime surveillance of xenotransplant recipients were initially discussed at the Asilomar Conference Center in Pacific Grove, California, in February of 1975.<sup>15</sup> Since zoonotic infections could arise years after the xenotransplant, special restrictions must be agreed upon by the recipient prior to the procedure. For instance, in addition to lifetime surveillance, accomplished through a contract by which the patient agrees to waive all rights of withdrawal, the recipient must agree to never donate blood or have biological children.<sup>16</sup> The halakhah's prohibition on exposing others to danger, in this case, is being supervised and regulated by specialists within the medical and public health fields.<sup>17</sup>

As it happens, weeks after the death of the first xenoheart recipient, it was discovered that his xenoheart had been infected with porcine cytomegalovirus, a pathogen known to have catastrophic consequences in transplant patients.<sup>18</sup> Although the donor pig had been tested earlier for this virus, the testing "appears to have tested the pig's snout for the virus, but often it is lurking deeper in the tissues."<sup>19</sup> According to Dr. Joachim Denner of the Institute of Virology at the Free University of Berlin, "If you test the animal better, it will not happen. The virus can

and limited survival in nonhuman primate trials, pig-to-human research is behind." Raphael Miyashiro Nunes dos Santos, "Insights into Pig Liver Xenotransplantation," *Gastroenterology and Hepatology*, Vol. 18, No. 4 (April 2022), p. 218. My thanks to Dr. Rebecca Cherry for this reference.

<sup>&</sup>lt;sup>13</sup> Rothblatt, *Your Life*, pp. 150-156; Sade, "Ethical Issues," p. 712; and Loike, John D. and Alan Kadish, "Ethical Rejections of Xenotransplantation?" EMBO Reports 19 (2018), p. 2. doi: 10.15252/embr.201846337

<sup>&</sup>lt;sup>14</sup> Entwistle, p. 2. See also Rothblatt, Your Life, pp. 47-69.

<sup>&</sup>lt;sup>15</sup> Rothblatt, Your Life, pp. 122-137.

<sup>&</sup>lt;sup>16</sup> Sade, Robert M. and Rupak Mukherjee. "Ethical Issues in Xenotransplantation: The First Pigto-Human Heart Transplant," *Annals of Thoracic Surgery* 2022; 113 (3):712-4. doi: 10.1016/j.athoracsur.2022.01.006

<sup>&</sup>lt;sup>17</sup> Sh. Ar., Hoshen Mishpat 427.

<sup>&</sup>lt;sup>18</sup> "Yet, the precise basis for the recipient's death continues to be uncertain and remains under evaluation." F.H.F. Galvao, "Bioethics and xenotransplantation from pig to human," in *Clinics* 78 (2023). https://doi.org/10.1016/j.clinsp.2023.100170

<sup>&</sup>lt;sup>19</sup> https://www.technologyreview.com/2022/05/04/1051725/xenotransplant-patient-died-received-heart-infected-with-pig-virus/

be detected and easily removed from pig populations, but unfortunately they didn't use a good assay and didn't detect the virus."<sup>20</sup> Although this particular pathogen appears to be innocuous for healthy humans not undergoing transplants, the fear is that a different virus might infect a xenotransplant patient who then becomes patient zero of a highly contagious, lethal pandemic.

## Animal Welfare

The final extra-halakhic issue was raised by Rabbi Roth in his 1999 teshuvah: צער בעלי Although the halakhah has much to say about the treatment of non-human animals, the researchers involved in thinking through the ethics of animal research have gone beyond anything the halakhah currently requires. "To minimize the transmission of infections to humans, animals will need to be housed in a strictly controlled environment, unlike animals bred for human consumption."<sup>21</sup> Dr. Rothblatt, who was integrally involved in the first xenoheart transplant, pledged that the researchers "respected the animals' quality of life to the extent that it can be discerned.... [and that] sensitive and humane animal care practices, such as clean and appropriately stimulating environments [were employed]."<sup>22</sup>

Although concerns have been raised about keeping the animal research subjects in isolation, they are treated better than their cousins in factory farms awaiting slaughter, whether under kosher supervision or not.<sup>23</sup> It would be farcical to discuss cruelty to animals in this context when "kosher" slaughterhouses operate with such disregard for the living conditions of their "product." Indeed, scrutiny of the protocols for animal welfare within the medical research community challenges what current halakhah deems acceptable within kosher slaughterhouses. Given contemporary halakhah's tolerance for the relatively inhumane treatment of these animals for gastronomic satisfaction, the acceptability of animal research for *pikuach nefesh* is a foregone conclusion.<sup>24</sup>

Notwithstanding Judaism's prohibition against wanton cruelty to animals, Judaism is "speciesist." We unapologetically hold that human life is of higher value than non-human animal life. But such recognition of value distinctions among species in the animal world is not to be confused with license to mistreat God's non-human creatures. God's compassion is upon

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Entwistle, p. 6.

<sup>&</sup>lt;sup>22</sup> Rothblatt, "Commentary," p. 1 and Rothblatt, *Your Life*, pp. 72-90. The FDA also has strict guidelines that can be reviewed at:

https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Source-Animal--Product--Preclinical--and-Clinical-Issues-Concerning-the-Use-of-Xenotransplantation-Productsin-Humans--Guidance-for-Industry.pdf.

<sup>&</sup>lt;sup>23</sup> See Rabbi Pamela Barmash, "Veal Calves" <<u>Veal teshuvahfinal+pic NB Job 1.pdf</u> (<u>rabbinicalassembly.org</u>)>

The ASPCA, an advocacy group for animal welfare, provides a skeletal overview of the cruelty involved in factory farming. <u>Animals on Factory Farms | Chickens | Pigs | Cattle | ASPCA</u><sup>24</sup> It is true that only a very small fraction of these animals will actually be donors for xenoorgans, although that is the goal of the research. See J. David Bleich, "Judaism and Animal Experimentation," *Tradition: A Journal of Orthodox Jewish Thought*, Vol. 22, No. 1 (SPRING 1986), pp. 1-36.

all His works (Psalm 145:9). I look forward to the day when our standard for certifying animals for consumption considers an animal's whole life and not only the instant of its death.<sup>25</sup>

In his 1999 teshuvah, Rabbi Roth wondered if the prohibition of צער בעלי היים could ever "outweigh the use of an animal organ to save or prolong a human life."<sup>26</sup> Rabbi Roth was concerned with the practical issues such as the actual living conditions of the animal subjects. Given the *current conditions* under which animal subjects are maintained for purposes of xenotranplants, my answer is that there is no limit to how many non-human animals we can experiment upon, and possibly kill, in order to potentially save a human life.<sup>27</sup>

#### Halakhic Concerns

#### Kilayim

Rabbi Nevins, in his teshuvah on genetically modified organisms, addressed the prohibitions of mixing species and cross breeding, known as *kilayim*. Many of Rabbi Nevins' halakhic concerns had previously been discussed by Rabbi Avram Israel Reisner in his teshuvah on genetically engineered foodstuffs.<sup>28</sup> The Torah's silence concerning the rationale for the prohibitions of kilayim invited later commentators to speculate. Rabbis Reisner and Nevins used the rationales offered by post-biblical commentators in their discussions of different approaches to kilayim and differing philosophies of law. Rabbi Reisner concluded that the development of the laws of kilayim show "an extraordinary tendency toward leniency."<sup>29</sup>

Rabbi Nevins delved more deeply into competing philosophies of law which he designated as "formalism" and "values-informed" halakhah. Rabbi Nevins defined the latter as extrapolating from the function or purpose of a traditional law and applying that *telos* to contemporary questions. Rabbi Nevins did not offer a definition of formalism, but he presented the posture in contrast to a values-informed approach. Rabbi Nevins then advocated for the values-based approach to halakhah: "To apply the law without seeking to understand its values is literally to devalue the Torah, and to strip it of its purpose."<sup>30</sup> Although I demur from both Rabbi Reisner's and Rabbi Nevin's discussions concerning the philosophies of halakhah and kilayim, I

<sup>&</sup>lt;sup>25</sup> <u>Shmuly Yanklowitz: Why This Rabbi Is Swearing Off Kosher Meat - WSJ</u>, accessed March 1, 2023. Barmash, "Veal," p. 27.

<sup>&</sup>lt;sup>26</sup> Roth, p. 209.

<sup>&</sup>lt;sup>27</sup> Rabbi Roth's conclusion is the same: "....the primacy of human life over animal life will also be an halakhic given.... Lest there be any ambiguity whatsoever, we should make clear that if and when such [animal] transplants become frequent, there will also be no restriction whatsoever on the animals which can be used." "Organ Donation," pp. 208-11.

<sup>&</sup>lt;sup>28</sup> Avram Israel Reisner, "Curiouser and Curiouser: The Kashrut of Genetically Engineered Foodstuffs," *Responsa: 1991-2002* (New York: The Rabbinical Assembly, 2002), pp. 98-111. < reisner\_curiouser.pdf (rabbinicalassembly.org)>

<sup>&</sup>lt;sup>29</sup> Ibid., p. 110.

<sup>&</sup>lt;sup>30</sup> Nevins, "Halakhic Perspectives," 33.

concur with their conclusions.<sup>31</sup> Xenografts and xenotransplantations should not be halakhically inadmissible due to the prohibition of kilayim.<sup>32</sup>

The issues with xenotransplantation involve genetic manipulations. Given that Maimonides carved out an explicit exemption for kilayim when developing medical treatments,<sup>33</sup> and the fact that scientists are extracting and implanting strings of DNA sequences, rather than bringing two different animals species together to mate, the issue of kilayim is inapplicable in our case.<sup>34</sup> One can imagine, as science fiction writers are wont to do, a genetically manipulated chimera that might constitute a violation of kilayim, but the therapies under discussion do not approach the threshold of such concern.<sup>35</sup>

## Pastoral Issues

The most promising animal to serve as a donor for xenotransplantations is a pig. Their genetics, anatomy, and reproductive cycle make their organs strong candidates for human recipients—strong, but not ideal. For Jews and Muslims who may be squeamish about incorporating a porcine organ into their body, given the religious taboo of consuming pork, pastoral education might be required. There is some evidence from a study conducted in Turkey that there is discomfort among Muslims for receiving porcine xenografts.<sup>36</sup> Anecdotal evidence suggests that there are also Jews who would need to be taught that the prohibition concerning pork is restricted to consumption.<sup>37</sup> Furthermore, both the brutish associations with pigs and the romantic associations with hearts may require pastoral sensitivity and education.

<sup>&</sup>lt;sup>31</sup> My understanding of why the sages were extraordinarily lenient about kilayim can be gleaned from pages 7-44 and 368-373 of my *Coherent Judaism: Constructive Theology, Creation, and Halakhah* (Brookline: Academic Studies Press, 2020). A strictly academic treatment of the distinction of the two biblical philosophies of halakhah can be found in <u>Cherry Camouflage Motive (zeramim.org)</u>.

<sup>&</sup>lt;sup>32</sup> Violations of Leviticus's Priestly Torah, such as kilayim (Lev. 19:19), can result in the land vomiting out the sinners (Lev. 20:22). Vomiting is an autonomic reflex that occurs without conscious intention. The transgressions detailed in Leviticus generate a natural response. The consequences for violations of Deuteronomy's laws, on the other hand, are punishments. No one any longer believes that the land of Israel reacts to violations of kilayim. Given that we reject the metaphysical foundation for these laws, when such a law conflicts with advances in our applications of science or our moral sensibilities (as in Lev. 18:22), we should not hesitate to bracket its halakhic relevance. I am committed to checking my clothing labels for *shaatnez*, but I will not allow an archaic metaphysics to hinder life-sustaining medical procedures or recognizing the potential holiness of homosexual relationships.

<sup>&</sup>lt;sup>33</sup> The exemption was for seeds, not animals. M.T. Kilayim 1:4.

<sup>&</sup>lt;sup>34</sup> See Nevins, "Halakhic Perspectives," p. 37.

<sup>&</sup>lt;sup>35</sup> See, for example, H. G. Well's 1895 *The Island of Dr. Moreau*.

<sup>&</sup>lt;sup>36</sup> "Effects of Religious Belief on Selecting of Graft Materials Used in Oral and Maxillofacial Surgery," Zeynep Gungormus, et. al. July 14, 2017. *American Association of Oral and Maxillofacial Surgeons*.

<sup>&</sup>lt;sup>37</sup> B. Shabbat 110b.

The life expectancy of a porcine xeno-organ is also less than ideal. Pigs are not expected to live more than twenty years. Pediatric recipients would be facing a series of transplants throughout their lives. The prospect of future surgeries, regardless of the recipient's age, is one factor among many that will need to be considered prior to an individual's decision to undergo a xenotransplantation. The burden of this teshuvah is to assure our community that xenotransplantations are halakhically permissible. There will always be reasons to decline such a therapy.

## **Conclusion**

The Jewish obligation to heal is both unequivocal and ambiguous.

נתנה התורה רשות לרופא לרפאות ומצוה היא ובכלל פיקוח נפש הוא ואם מונע עצמו הרי זה שופך דמים.

The Torah has given permission for a healer to heal, and it is a duty, and healing falls under the category of saving lives. One who prevents himself is as one who spills blood. (YD 336)

Many of the commentators express surprise that healing is somehow both "permissible" and a "duty." If healing is duty, it is obviously permissible. One modern commentator, Barukh HaLevi Epstein, offers a novel solution in his Torah commentary on Deuteronomy 22:2.

ואולי משום דאינה מפורשת מצוה זו במקומה רק כלולה במצות השבת אבידה.

Perhaps because the duty [of healing] is not explicit in the place (where the Torah discusses medical costs [Ex. 21:19]), it was included in the duty to return lost items. (Torah Temimah on Dt. 22:2)

Epstein explains that although *permission* was implicitly given to heal in the Torah's discussion of the liability for medical costs, the *mandate* to heal was included in the duty to return a lost object. The midrash in Sanhedrin 73a interprets the pronominal suffix in *vahashevoto* as "return *him*" rather than "return *it*." There is a duty to return him, i.e., to restore his health that he has lost.

This interpretation clarifies the ambiguity of the Shulchan Arukh and allows for patient autonomy. Just as one can despair of finding a lost object, one can also despair of regaining one's health and choose to forego medical treatment.<sup>38</sup> The duty to return a lost object falls upon the one who is able to return the lost item. He corresponds to the healer who can restore the

<sup>&</sup>lt;sup>38</sup> YD 336.

person to health. If *they* have the ability to heal and prevent themselves from doing so, *they* are the blood spillers. There is no obligation upon the one who lost the item or who is ill.

# פסק דין / Ruling

Once xenotransplants have been fully authorized by the appropriate medical and governmental bodies, Jews may avail themselves of the benefits of non-human tissues, organs, and glands for grafts and transplantations. The halakhic obligation to safeguard life *requires* the Jew to consider a xenograft or xenotransplant without any concern that such a procedure is in tension with Jewish law or tradition. It is not. Nevertheless, the decision to pursue such a therapy remains that of the patient and those within their immediate circle of concern.