



*For Patients Needing Transplants,
Hope Arrives on Tiny Hooves*

Some scientists are confident that organs from genetically modified pigs will one day be routinely transplanted into humans. But substantial ethical questions remain.



By Roni Caryn Rabin

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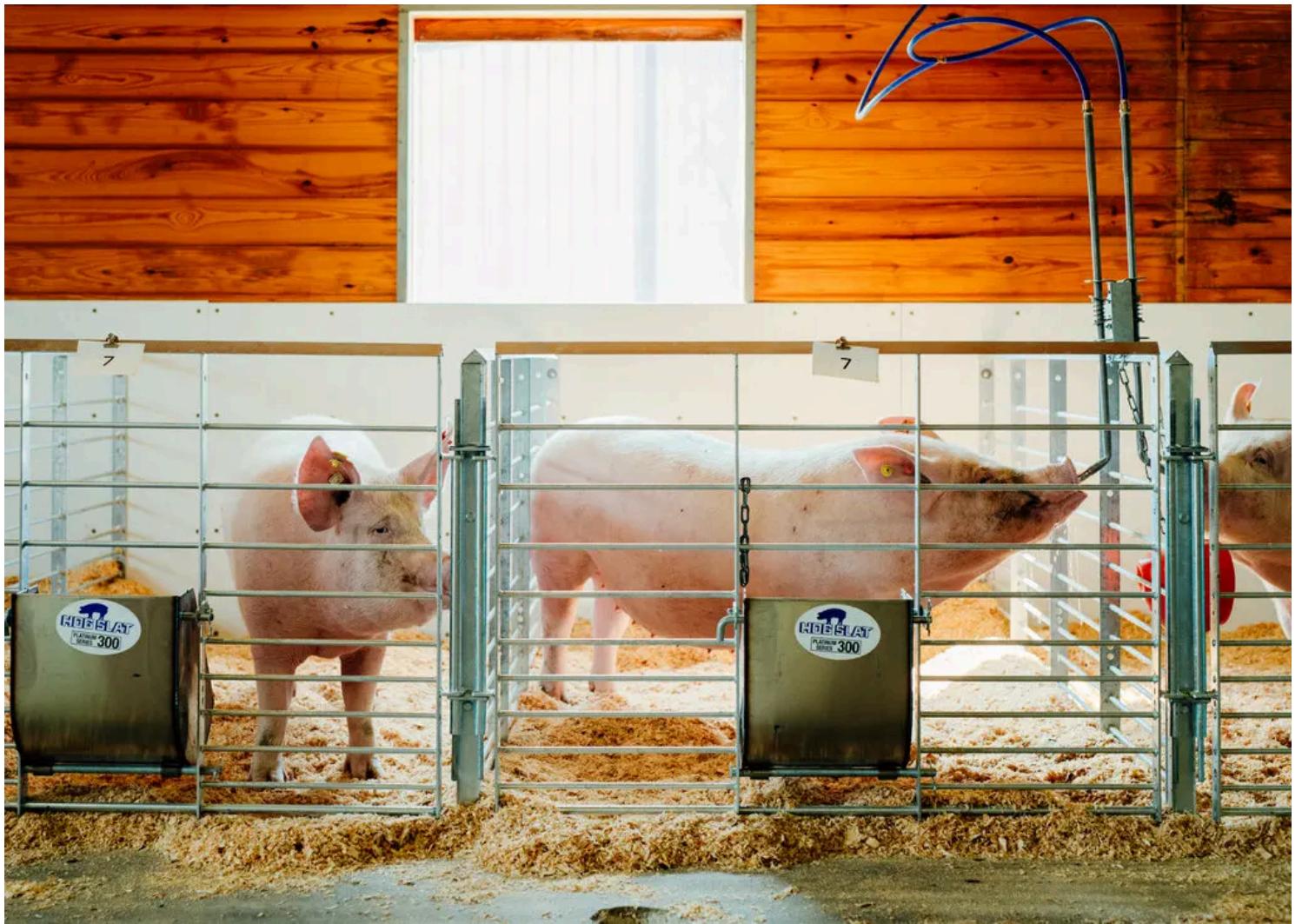
On a 300-acre farm in an undisclosed location in rural Wisconsin, surrounded by fields dotted with big red barns and bordered by wild blue chicory and goldenrod, live some of the most pampered pigs in the world.

They are delivered by C-section to protect them from viruses that sows can carry, and bottle-fed instead of nursed for the same reason. They are kept under warming lights and monitored around the clock for the first days of their lives, given toys and marshmallows as treats.

But they don't get to go outside and play in the dirt like other pigs. They are clones and constitutionally weak, genetically engineered to have kidneys, hearts and livers more compatible with the human body.

These miniature pigs are part of a bold scientific experiment that takes advantage of breakthroughs in cloning and gene editing to realize the centuries-old dream of xenotransplantation — the transfer of animal kidneys, hearts, livers and other organs into humans who need them.

Success could bring riches to the two biotech companies that are leaders in this space, the Cambridge, Mass.-based eGenesis and the Blacksburg, Va.-based Revivicor, owned by United Therapeutics Corporation. The demand for organs is huge.



Pregnant pigs at eGenesis. "They are the most spoiled pigs around," said one of their caretakers. Kevin Serna for The New York Times



E-Genesis staff outside the newborn piglet enclosures. Kevin Serna for The New York Times

More than 100,000 Americans are on waiting lists for donor organs, most needing a kidney. Only 25,000 human donor kidneys become available each year. Twelve Americans on the kidney list die every day on average.

Scientists first transplanted genetically engineered pig organs into other animals and then to brain-dead human patients. In 2022, researchers received permission to transplant the organs into a few critically ill patients, and then, last year, into healthier people.

Now, for the first time, a formal clinical study of the procedure is being initiated.

“Just imagine, you have kidney disease and know your kidneys are going to fail, and you have a pig’s kidney waiting for you — and you never see dialysis,” said Mike Curtis, president and chief executive at eGenesis.

He foresees a future in which genetic engineering will make pig organs so compatible with humans that patients won’t have to take powerful drugs that prevent rejection but make them vulnerable to infections and cancer.

Babies born with serious heart defects might be given a pig’s heart temporarily while waiting for a human donor heart. A pig’s liver could potentially serve as a bridge for those in need of a human liver.

Some scientists argue that there is a moral imperative to move forward.

“Is it ethical to let thousands of people die each year on a waiting list when we have something that could possibly save their lives?” asked Dr. David K.C. Cooper, who studies xenotransplantation at Harvard and is a consultant to eGenesis.

“I think it’s beginning to be ethically unacceptable to let people die when there’s an alternative therapy that looks pretty encouraging.”

But critics say xenotransplantation is a hubristic, pie-in-the-sky endeavor aiming to solve an organ shortage with technology when there’s a simpler solution: expanding the supply of human organs by encouraging more donation.

And xenotransplantation is freighted with unanswered questions.

Pigs can carry pathogens that can find their way to humans. If a deadly virus, for example, were to emerge in transplant patients, it could spread with catastrophic consequences.

It might be years or even decades before symptoms were observed, warned Christopher Bobier, a bioethicist from the Central Michigan University College of Medicine.

“A potential zoonotic transference could happen at any point after a transplant — in perpetuity,” he said. The risk is believed to be small, he added, “but it is not zero.”



Surgeons handling the genetically modified pig heart that would be transplanted into 57-year-old David Bennett. University of Maryland School of Medicine/EPA, via Shutterstock

Indeed, a post-mortem on a Maryland man who was the first patient to receive a pig's heart found a porcine cytomegalovirus in the organ that had not been detected before the transplant, despite rigorous testing. A closely related virus already infects humans.

No one knows how much an organ from a genetically engineered pig might cost, and whether insurance plans would cover it.

But many patients with organ failure, tethered to a dialysis machine four hours every other day, see in these small pigs hope for a return to normal life. "My hope for a xenotransplant is stronger than my fear of the risks," one dialysis patient said in a national survey.

Edited DNA

Scientists chose to use organs from genetically modified pigs, rather than chimps or baboons, for a simple reason: Pigs are easier to raise and mature in six months, and the size of their organs is compatible with adult humans.

At eGenesis, pig cells are collected by clipping notches from the pig's ear. Scientists edit the DNA in these cells as one might edit a manuscript: adding some genes, deleting others and altering still more.

The pigs at eGenesis have received dozens of gene edits. Revivicor produces pigs with 10 gene edits, and others with a single gene edit.

The companies clone embryos from the modified cells, implanting them in sows, where they gestate for about four months before birth.

Scientists at eGenesis first transplanted the pig kidneys into macaque monkeys. The organs came from pigs that had undergone 69 genetic edits, a number that skeptics had thought was not possible.

"They said, 'You can't do that many edits, you'll turn the genome into Swiss cheese,'" Dr. Curtis said. "We showed you could."

The scientists soon proved that monkeys with kidneys from gene-edited pigs lived longer than those receiving kidneys from untouched pigs. One macaque survived for more than two years after the transplant.



A pig closely monitored as it recovered from a C-section. Kevin Serna for The New York Times



Piglet births celebrated on a board at eGenesis. Kevin Serna for The New York Times

It was “proof of principle” that the organ was “safe and supports life,” said Wenning Qin, senior vice president for innovation at eGenesis.

But would it work in humans?

In 2021, scientists tried to find out, taking a radical approach that seemed plucked from a sci-fi novel. With the consent of the families, the researchers transplanted pig kidneys into patients who were brain-dead and maintained on ventilators, then tracked how their bodies responded.

The novel idea has been attributed to Dr. Thomas Starzl, widely known as the father of modern transplantation, who died in 2017. Two pioneering surgeons tried it, though neither knew what the other was up to.

One was Dr. Robert Montgomery, a charismatic surgeon at NYU Langone in New York City who is himself alive thanks to a heart transplant. He used an organ from a Revivicor pig with a single gene knocked out and thymus gland tissue attached.

The second surgeon was Dr. Jayme Locke, then at the University of Alabama at Birmingham, who trained under Dr. Montgomery.

Dr. Locke didn't make a public announcement, waiting until her paper was published in a medical journal. She used a kidney from a pig with six added human genes and four of its own silenced to prevent rejection.

Soon after the pig kidneys were attached to the brain-dead patients, the organs started functioning as a human's would — making urine and clearing a waste product called creatinine from the blood.

Dr. Montgomery maintained one brain-dead patient with a pig's kidney on a ventilator for two months. The so-called decedent studies yielded a trove of data. Blood samples and biopsies could be taken as often as needed, without disturbing a live patient.



Pig eggs prepared for an injection of genetic modifications at Revivicor Laboratories in Blacksburg, Va. Andrew Caballero-Reynolds/Agence France-Presse — Getty Images

The information is critical, because kidneys perform important functions besides making urine: They filter blood, removing waste and extra fluid, and help maintain healthy balances of water, salts and minerals like potassium. They produce hormones that control blood pressure, keep bones strong and help make red blood cells.

“Part of what we were able to answer with the two-month decedent was, ‘Can the pig kidney do all these things?’” Dr. Montgomery said.

The answer? “Not all of them. But most of them.”

As for the other functions, he said, “We have medications.”

In early 2022, a 57-year-old patient in Maryland became the first human to receive a heart harvested from a genetically modified pig, produced by Revivicor.

David Bennett had a life-threatening arrhythmia and had been hooked up to a heart-lung bypass machine. But he had run out of treatment options and was not even allowed on the waiting list for a human donor heart because of his history of not following doctors' orders.

When Dr. Bartley Griffith, a surgeon at the University of Maryland Medical Center, offered him the pig's heart, he wasn't sure that Mr. Bennett understood.

Then Mr. Bennett asked, "Will I oink?"

The new heart started pumping after it was implanted, and Mr. Bennett's body didn't turn on it, at least not right away. But his immune system eventually mounted a very aggressive response, and he died about two months later.

The official cause of death was heart failure, but his poor health had limited the use of anti-rejection drugs, Dr. Griffith and his colleague Dr. Muhammad Mohiuddin said.

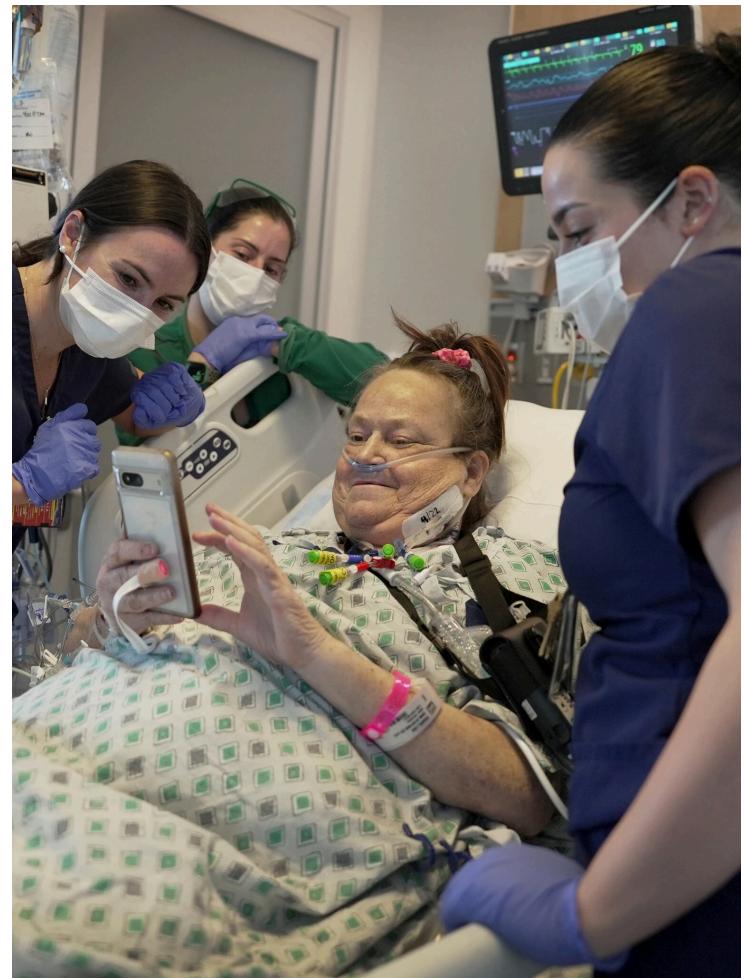
In September 2023, a second terminally ill man opted to receive a pig's heart. Lawrence Faucette, of Frederick, Md., had advanced heart failure. Mr. Faucette, 58, survived for only six weeks after the procedure, but his wife, Ann Faucette, said she had no regrets.

"It's like you're in the middle of the ocean, and you have a choice of staying there to be eaten by sharks or having pirates rescue you, and then at least you have a chance," Ms. Faucette said.

The deaths may have signaled failure to the general public, but the xenotransplant community was optimistic. Neither of the patients experienced a dreaded outcome, hyperacute rejection, when the body attacks and destroys a transplanted organ, turning it black within hours, even minutes.

Last year, the pace of development picked up.

In March 2024, Richard Slayman, 62, a transportation department supervisor from Weymouth, Mass., known as Rick, became the first patient to have a genetically engineered pig's kidney transplanted.





Pig kidney recipients Rick Slayman, Lisa Pisano, Tim Andrews and Towana Looney. Michelle Rose/Massachusetts General Hospital; Shelby Lum/Associated Press; Billy Hickey for The New York Times; Jackie Molloy for The New York Times

He had suffered from kidney failure for over a decade, and a human donor kidney had failed. He developed heart disease and vascular problems. His kidney doctor at Massachusetts General Hospital, Dr. Winfred Williams, said he “was growing despondent.”

Within days of the xenotransplant, Mr. Slayman was walking around the hospital. A week later, he was discharged — the first patient to go home with an internal pig’s organ making urine and clearing creatinine. The kidney was produced by eGenesis.

The next month, in April 2024, NYU Langone surgeons transplanted a Revivicor pig kidney into Lisa Pisano, 54, a critically ill New Jersey woman who also had a mechanical heart pump implanted. Doctors had to remove the kidney because she developed complications.

Mr. Slayman died in May after a cardiac event, and Ms. Pisano, who never left the hospital, died in July.

Dr. Montgomery said doctors had learned from each procedure.

“We forget, but the first person to receive a human heart transplant also died within two weeks,” he said. (The first heart transplant was done in 1967 by Dr. Christiaan Barnard. The patient, 53-year-old Louis Washkansky, died after 18 days.)

‘A Win-Win’

In November, Towana Looney, 53, from Gadsden, Ala., was sitting in her dialysis chair when she got the call she had been waiting for ever since she heard news reports about pig kidneys years earlier.

Ms. Looney had kidney failure. But she also carried antibodies that made organ rejection likely, meaning she probably would not receive a donated human kidney.

Dr. Locke was calling to tell her that a pig’s kidney was waiting for her in New York.

“I said, ‘But what about Christmas?’” Ms. Looney recalled in an interview. “Dr. Locke said, ‘This is going to be the best Christmas present you ever got.’”

The new kidney changed Ms. Looney’s life. She no longer needed dialysis, and she could urinate again. Her blood pressure normalized, her nausea subsided, her appetite roared back to life, and she was able to walk nine or 10 city blocks at a clip.

“Dialysis took so much out of me, I felt like I had to fight to live,” she said over dinner recently. “Now my voice is strong, my energy is strong, I sound different — it’s a win-win.”

Ms. Looney was the first patient to make it to the three-month mark, and she flew home to Alabama last month.

In January, Mass General surgeons transplanted an eGenesis pig's kidney into 66-year-old Tim Andrews, of Concord, N.H. Mr. Andrews was taken to his first pre-surgical consultation in a wheelchair — and felt well enough to do a short tap-dance by the time he left the recovery room.

The Food and Drug Administration has given the green light to U.T.C., the parent company of Revivicor, to begin a formal clinical trial that could pave the way to routine approved use of pig kidneys. eGenesis also received the go-ahead to study a series of patients, of whom Mr. Andrews was the first.



Surgeons at work during Ms. Pisano's surgery at NYU Langone Health in April 2024.

Joe Carrotta/NYU Langone Health, via Associated Press

As routine pig organ transplants move closer to reality, researchers have begun wrestling in earnest with ethical dilemmas.

Bioethicists have asked how trial participants can be properly informed of the risks of the procedure when there are so many unknowns. Unlike participants in any other clinical trial, for example, xenotransplant patients must agree to lifelong

surveillance and cannot withdraw from the trial.

Relatives and caregivers would need to be informed of the potential risks, too, since they could be among the first infected if a pathogen crosses species.

To minimize the risk of an animal disease spillover, organs will be procured from pigs born and raised in pathogen-free facilities with much stricter regimens than those on the Wisconsin farm.

The companies will recruit kidney failure patients who depend on dialysis and are relatively healthy, but not eligible for a human donor organ because of their age or an additional medical condition.

Concerns about equity have also surfaced. Medical centers have been besieged by calls from patients begging to be next in line. But who will be first to get the pig organs? The burden of chronic kidney disease is disproportionately borne by Americans of color.

“When innovations are rolled out, it’s commonly those with money who get them before anybody else,” said Dr. Peter Reese, founding director of the Vanderbilt Center for Transplant Science, who has served as an unpaid adviser to eGenesis.

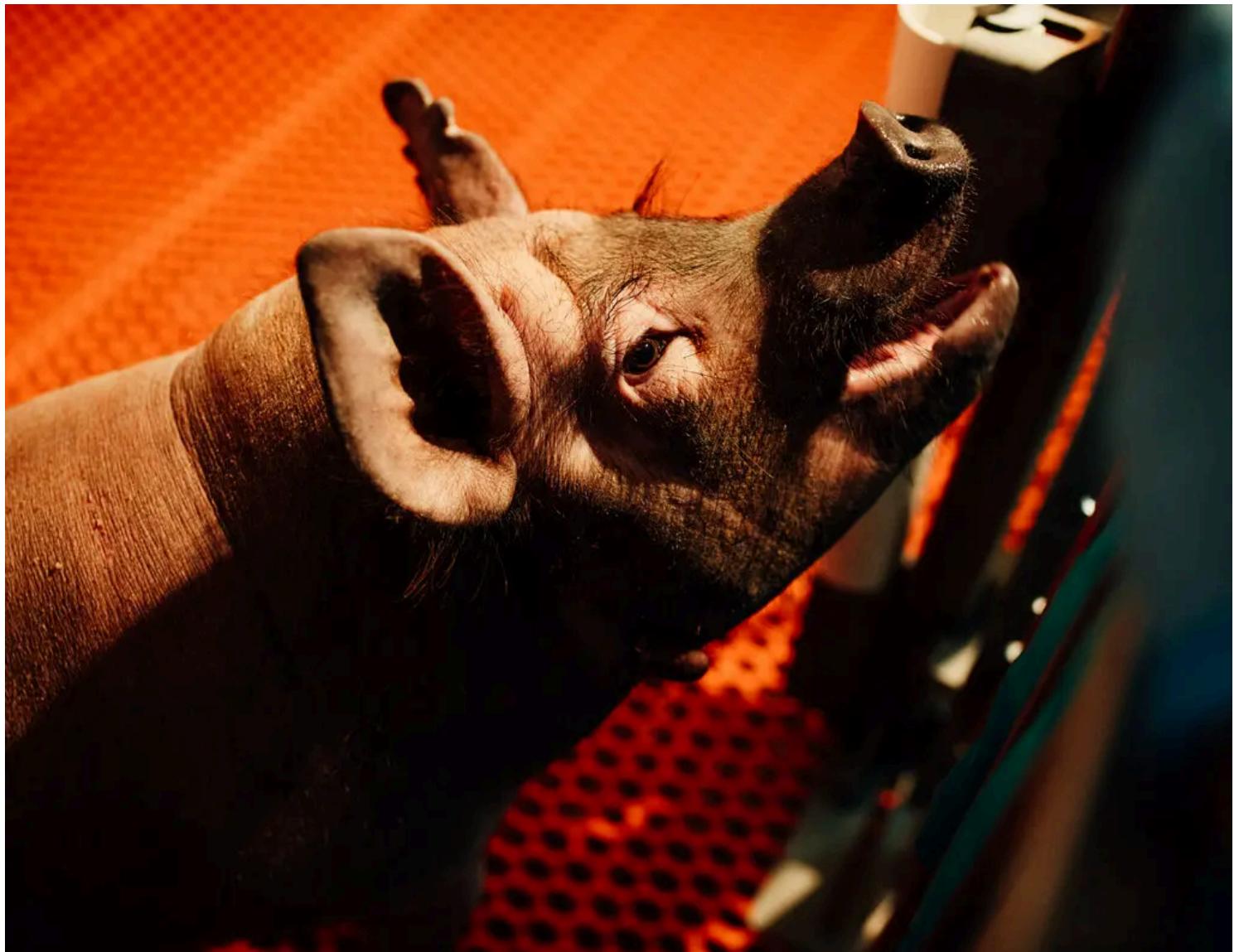
Some critics object to cloning animals for their organs as unethical. Still, the United States raises almost 150 million hogs for consumption each year.

For now, caregivers at the eGenesis facility in Wisconsin are making sure the coddled pigs live their best lives.

The animals, which are very social, always have “snout-to-snout” contact with other pigs. And they are well fed, even though they often pretend that they missed a feeding.

The caregivers, who grow attached to the pigs, know that most of them will be sacrificed for research or transplantation as soon as they mature, but they believe in the mission.

“We know what they’re being used for is so important,” said Haley Rymut, the manager of donor resources. “We know their lives are changing the world.”



Kevin Serna for The New York Times

Roni Caryn Rabin is a Times health reporter focused on maternal and child health, racial and economic disparities in health care, and the influence of money on medicine. More about Roni Caryn Rabin