

U.S. Proposes Regulating Face, Hand Transplants

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The government wants to start regulating face and hand transplants just as it does now with kidneys, hearts and other organs. This would mean waiting lists, a nationwide system to match and distribute body parts, and donor testing to prevent deadly infections. It's a big step toward expanding access to these radical operations, especially for wounded troops returning home. A dozen U.S. hospitals already do face or hand transplants and more are preparing to offer the operations. More than 1,000 troops have lost an arm or leg in Afghanistan or Iraq, and the government estimates that 200 troops might be eligible for face transplants. "These body parts are starting to become more mainstream, if you will, than they were five or 10 years ago when they were first pioneered in this country," said Dr. James Bowman, medical director of the Health Resources Services Administration, the government agency that regulates organ transplants. The agency has proposed new rules that expand the regulation of transplants to include faces, hands and other body parts. Waiting lists for these body parts are informal and local now. The new rule would make such transplants part of the nationwide matching system run by the United Network for Organ Sharing, or UNOS.

The rules would regulate transplants of feet, ankles, legs, fingers, windpipes, voice boxes, the abdominal wall and possibly even a uterus or a penis — operations tried at least once in other countries. "When you think about the human body, there is really nothing that could not be replaced by transplantation. Almost nothing," said Dr. Bohdan Pomahac, who has done four face transplants at Brigham and Women's Hospital in Boston.

At least 18 face transplants have been done around the world, starting in 2005 with a French woman mauled by her dog. The Cleveland Clinic did the first face transplant in the U.S. in 2008. The U.S. Department of Defense is providing money for more of these surgeries in Cleveland and Boston in hopes of helping soldiers disfigured in battle. The University of Pittsburgh, the University of California, Los Angeles, and other medical centers plan to offer face or hand transplants soon.

The first successful hand transplant in the United States was performed in 1999, and more than three dozen have been done worldwide. The proposal to treat these like organ transplants "is terrific" and is supported by leading transplant surgery groups, Pomahac said. "It's a huge step forward in the right direction. It will make it easier for programs to get started," Pomahac said. The federal agency will accept public comments on the rules until February 14 before making a final decision. The rules are expected to take effect later this year or early next year.

The change would not affect regulation of heart valves, bone and other tissue implants or transplants, which are overseen by the Food and Drug Administration. Instead, it would cover transplants of complex tissues such as a combination of

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bone and muscle involving blood vessels — like a hand or face. Many doctors and bioethicists long objected to face and hand transplants because patients must take drugs for the rest of their lives to prevent rejection, which can raise their risk of cancer and other problems. The risk wasn't considered worth the benefit for operations that are not life-saving as heart or liver transplants are.

However, the objections have softened as face transplants have been so successful and greatly improved quality of life. The most recent recipient is Charla Nash, a Connecticut woman mauled by a chimpanzee. She had a face transplant last May. Now, "she's feeling a lot of the face. She can start to move on one side. She's able to talk better. Her spirits are great," said Pomahac, her surgeon. Other face transplant recipients go out in public, enjoy eating normal food for the first time in years, and some have even become advocates for the procedure.

So far, only two face transplant-related deaths have been reported. One was a Chinese man who reportedly was not given or did not take medicines to prevent his body from rejecting his new face. The other was in Paris, a man who received a face and a double hand transplant. He suffered a heart attack during surgery.

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