FDA seeks to speed development of 'regenerated' organs for medical use

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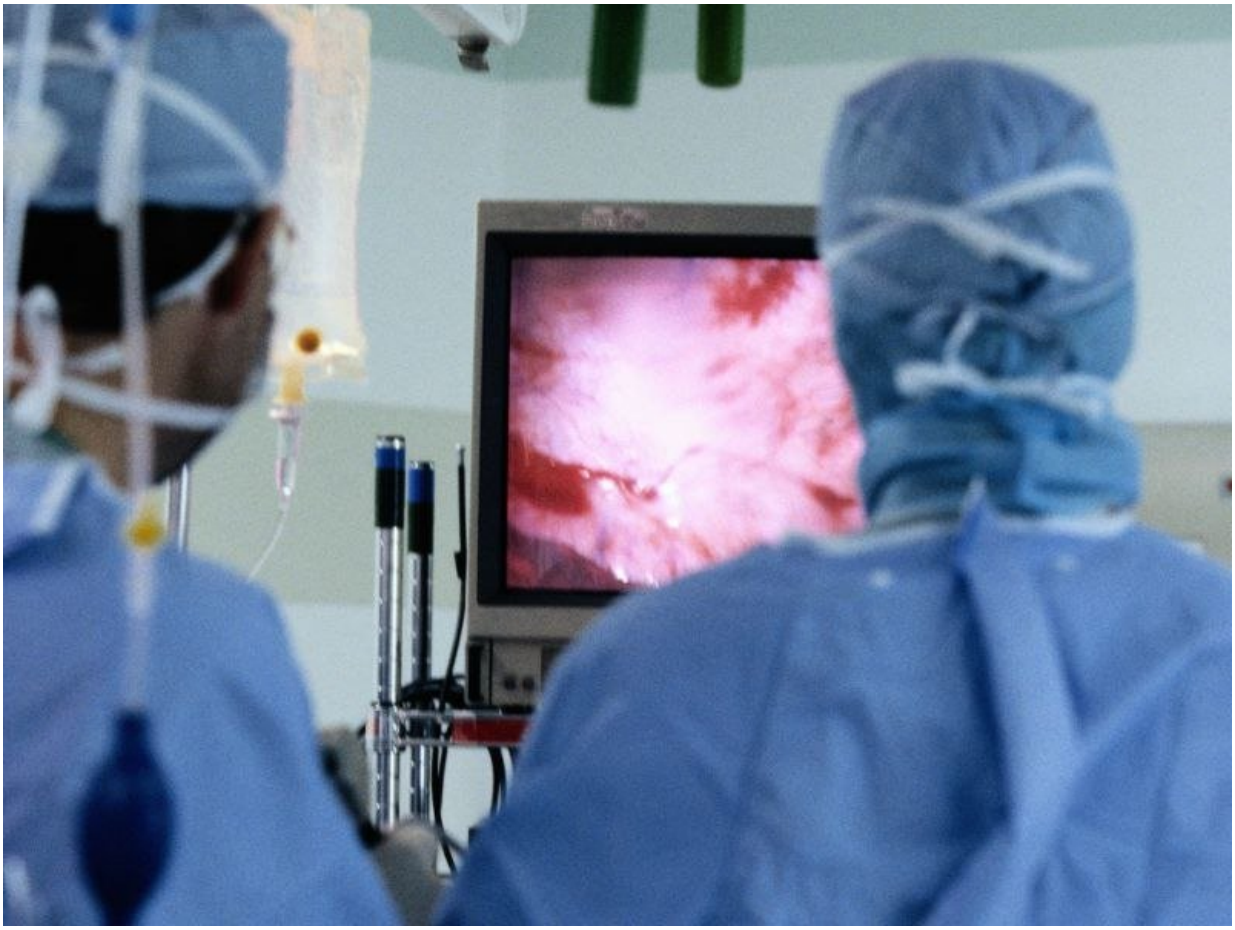

(HealthDay)—Using stem cells to grow new heart tissue, and even whole

organs, used to be the stuff of science fiction.

But the field of "regenerative medicine" is a reality now—and the U.S. Food and Drug Administration has its eye on it, the agency's head said Thursday.

"In the last decade, we've seen improbable advances that hold out great hope for patients," FDA Commissioner Dr. Scott Gottlieb said in an agency news release. "I believe that with the ability to facilitate the regeneration of parts of the human body, we're bearing witness to the beginning of a paradigm shift in the practice of medicine."

For example, over the past few years scientists and physicians have developed tissue-engineered skin for transplant; bladders grown from a patient's own cells; and tissues grown to repair ailing hearts or failing knees, according to the U.S. National Institutes of Health.

But Gottlieb said that along with all this good comes the bad. Companies seeking to exploit consumers are already popping up across the United States—stem cell "clinics" promising pricey cures that they can't deliver to desperate patients.

"The rapid growth and promise of this field has increasingly sowed the ground for the entry of some unscrupulous actors, who have opportunistically seized on the clinical potential of regenerative medicine to make deceptive claims to patients about unproven and, in some cases, dangerous products," Gottlieb said.

"By exploiting the lack of consumer understanding of this area, as well as the fear and uncertainties posed by the diseases these bad actors claim to treat, they're jeopardizing the legitimacy and advancement of the entire field," he explained.

So, Gottlieb says his agency is rolling out a new "regulatory framework" aimed at encouraging and speeding legitimate development of regenerative therapies that *do* work, while stamping out firms offering bogus treatments.

He said the FDA intends to promote the "least burdensome" rules for companies big and small that are seeking to develop new therapies, "while ensuring patient safety."

"Our policy will allow product manufacturers that time to engage with the FDA to determine if they need to submit a marketing authorization application and, if so, seek guidance on how to submit their application to the FDA for approval," Gottlieb said.

The new rules are in keeping with provisions from the 21st Century Cures Act, passed by Congress in December. That legislation earmarked $6.3 billion in funding, mostly for the U.S. National Institutes of Health, towards groundbreaking medical research.

According to Gottlieb, the bottom line is to allow patients "access to safe and effective regenerative medicine products as efficiently as possible. We are also committed to making sure we take action against products being unlawfully marketed that pose a potential significant risk to their safety."

More information: There's more on regenerative medicine at the U.S. National Institutes of Health.

regenerated-medical.html