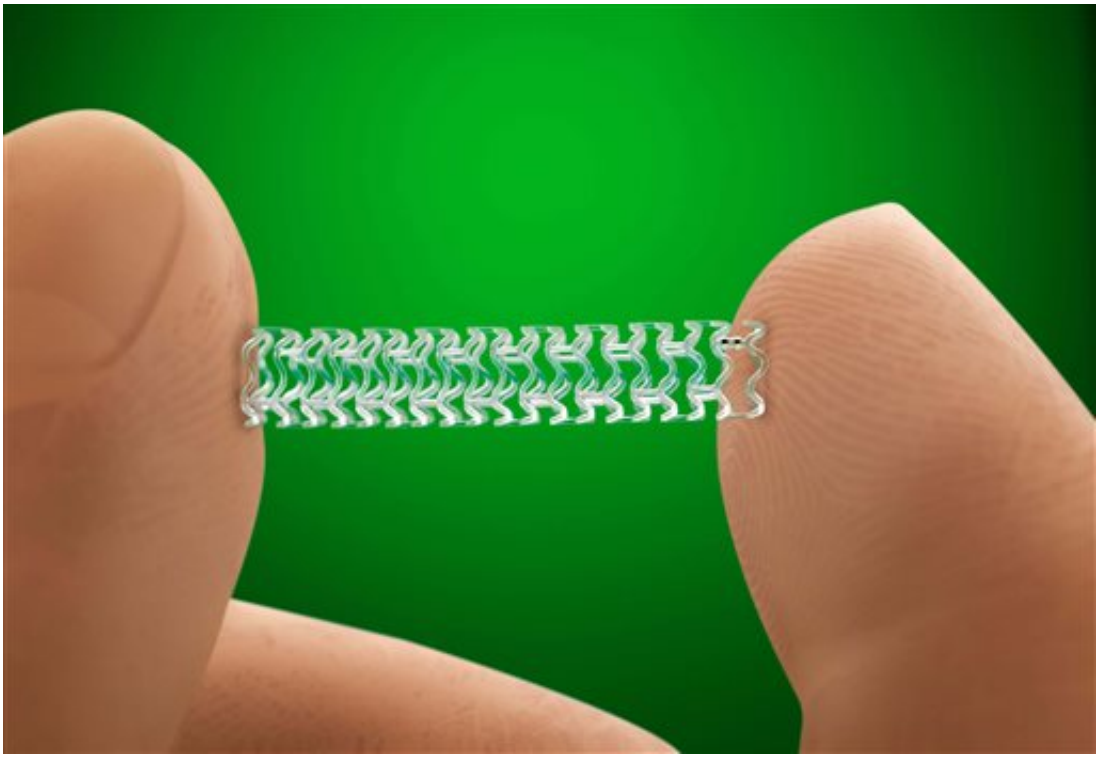
FDA advisers back first dissolving heart stent (Update)

March 15 2016, by Matthew Perrone



This undated image provided by Abbott shows their experimental heart stent "Absorb." The FDA holds a meeting Tuesday, March 15, 2016, to review Abbott Laboratories' first-of-a-kind heart stent that dissolves into the body after helping to clear fat-clogged arteries. (Weinberg-Clark Photography/Abbott via AP)

Federal health advisers overwhelmingly backed the safety and effectiveness of an experimental medical implant that dissolves into the body after doing its job.

A panel of Food and Drug Administration advisers voted unanimously Tuesday that the Absorb heart stent is effective for treating patients with narrowing arteries that can lead to heart attack and death. The same panel of cardiologists voted 9-1 in favor of the device's safety.

Abbott Laboratories has asked the FDA to approve its stent as an alternative to permanent, metal implants that have long been used to help brace arteries after they have been cleared of fatty plaque.

The vote is a nonbinding recommendation and the FDA will make its own decision on the device later this year.

Absorb is made of degradable material that's designed to stay intact for a year before gradually breaking down over the following two years.

Currently available stents are tiny, mesh-wire tubes used to prop open blood vessels. They have grown into some of the most lucrative medical implants ever developed, but use by cardiologists has been tempered by rare but risky complications.

Researchers first added drug-coatings to the devices in 2003 to prevent arteries from becoming reclogged due to scar tissue. But subsequent studies showed that the stented arteries could still develop blood clots, potentially triggering heart attack and death. To address that risk, Abbott and other device makers began developing dissolving stents that would slowly melt back into the body like stitches.

Abbott's stent managed to win a positive vote despite company studies that did not show superior outcomes for patients after one year, compared with older metal stents.

FDA scientists noted that rates of cardiovascular complications were actually slightly higher with Absorb than with Xience metal stents in a

company study. But that difference—1.7 percent—was not deemed statistically significant.

North Chicago, Illinois-based Abbott is tracking patients long-term to see if those with Absorb fare better several years later.

In a recent editorial, two prominent cardiologists pointed out that the Absorb stent has still not shown superior results to older models, even in a recent study that tracked patients for five years.

"'Here today, gone tomorrow' remains an incredibly intriguing concept that still needs further development and follow-up to reach its full potential," said Drs. David Holmes and Michael Mack, in last month's *Journal of the American College of Cardiology*.