FDA device regulator faces critics from both sides

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(AP) -- The Food and Drug Administration is approving medical devices too slowly. Or too quickly - depending on whom you ask.

House lawmakers heard both arguments Thursday at a hearing examining the FDA's regulation of U.S. medical devices, a $120-billion industry that includes everything from hospital beds to heart pumps.

FDA leadership are in the process of overhauling the 35-year old system used to clear most devices, triggering a slew of reports and analyses aimed at influencing the agency's plans.

On the one side are device manufacturers, who charge that FDA reviews have gotten longer and less predictable, forcing some companies to launch their devices overseas to stay in business. They say American patients no longer have access to the latest medical treatments, forcing some to fly to Europe for surgery.

But consumer safety advocates say just the opposite: FDA is clearing too many devices, too quickly, jeopardizing patient safety.

Can they both be right?

"Not unless we're in an episode of Star Trek with parallel universes," said FDA device director Dr. Jeffrey Shuren, in a recent interview with the Associated Press.

Shuren said the U.S. system is not inherently slower than Europe's, though it does require an extra level of evidence. European regulators require that a device be safe and perform as described on its label. The FDA has those standards but also requires that the device be proven to successfully treat a disease. Shuren points to a handful of devices that were rejected by the FDA and approved in Europe, only to later be recalled for safety reasons.

"Just because a technology is available in another country doesn't mean it works, or even that it's necessarily safe," he said.

The main problem the FDA has encountered in recent years, according to Shuren, is the declining quality of applications from device makers. According to Shuren, more than 50 percent of applications for conventional medical devices are missing key information, leading to delays that should have been avoided.

"We're stepping up to the plate to do our part to get this right. But if it's going to work we need industry to do their part," Shuren told members of the House Energy and Commerce Committee's Health Subcommittee.

Seated with Shuren at the witness table was a trio of device industry entrepreneurs, who argued that the pace and unpredictability of FDA reviews is driving some companies into bankruptcy.

"Investment is drying up, companies are moving overseas or closing their doors and U.S. patients are being denied timely access to safe and effective new medical products," said Dr. Josh Makower, a medical device inventor and consulting professor at Stanford University.

Makower and the others pointed out that venture capital, which is critical to start-up companies, has dropped 37 percent across the device sector since 2007. While some of that decline is unquestionably due to the

recession, entrepreneurs insist the FDA's regulatory stance is also to blame.

Makower hammered home a key argument of device companies: that it typically takes companies two years longer to get devices approved in the U.S. than in Europe.

That figure and others came from a survey sent to 750 device companies, in which only 17 percent responded. PricewaterhouseCoopers released a similar report last month and its conclusions relied on a survey of just 13 companies.

A committee room mostly filled with Republicans concentrated their questions on the FDA device director and industry representatives.

Patient safety advocates were also present at the hearing to argue that U.S. device approvals are often too fast.

Dr. Steven Nissen reiterated data from a study published last week suggesting the FDA is clearing too many devices through a fast-track pathway designed for low-risk devices.

The analysis found that 70 percent of life-threatening recalls between 2005 and 2009 involved devices cleared through the fast-track method, rather than a more rigorous system that requires medical testing.

"There's a serious problem here when 112 million devices were recalled in less than five years," said Nissen, chairman of cardiovascular medicine at the Cleveland Clinic.

Devices approved through the fast-track, or 510k, method, are often approved within 90 days, provided they are similar to devices already on the market. Devices requiring "pre-market review" usually require

human testing that takes years and tens of millions of dollars.

But the FDA has questioned the significance of the numbers, since the devices recalled represent about 1 percent of those approved via 510k. Also, since the agency approves 90 percent of its devices through the fast-track program it's expected that more of those devices would be recalled.