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Two Paths for Medical Device Approval: FDA vs. CE

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Several factors influence the length of time it takes for a medical device, particularly a new device, to reach its end user. One is the time it takes medical manufacturers to navigate regulatory demands, proving a device's safety and effectiveness before it gets to market. In terms of these demands, companies routinely face one simple but weighty decision: should they seek the United States' Food and Drug Administration (FDA) approval or the European CE mark?

Two Approaches

The choice is not necessarily an either/or, of course, but many companies don't have the resources to pursue both approvals at once. The differences between the two approaches stem from a central divide: the U.S. approach assesses the device's effectiveness as well as its risk of harm; the CE mark, on the other hand, affirms simply that the product "meets high safety, health and environmental protection requirements" (European Commission 2015). Ideally then the U.S. approval would ensure not only that the product poses no harm to consumers, but also that it does what it claims to do. Critics of the FDA system argue instead that this goal adds time and unpredictability to the approval process without in fact establishing the effectiveness of the device.

Measurable Differences

Congress established the framework of the FDA's current regulatory system in the Medical Device Amendments of 1976, with major modifications occurring in the 1990s (Rados 2006). However, the last major change to the medical device review, the Medical Device User Fee and Stabilization Act (MDUFSA) of 2005, merely added the requirement of a fee for medical device manufacturers seeking FDA clearance. The proceeds of the fee were meant to hire additional staff to improve the process (Rados 2006). Critics say it is overdue for reform.
For medical devices, the FDA assigns new products a classification of I, II or III, with Class III devices requiring a far more stringent trial process, the Premarket Approval Process or PMA than those in Class I or II. The classification is based on the degree of harm the device might pose and the specificity of its indications for use (U.S. Food and Drug Administration 2014a). However, only the truly novel device will require a PMA. If the manufacturer can prove "substantial equivalence" to a product already on the market, the device needs only to gain a less rigorous form of clearance, the 510(k).
A 2014 paper in the Journal of the American Medical Association (JAMA) called out as well an

"underexamined third way for a device to reach the market [is] via the 'supplement' process, used for modifications of devices originally approved through a PMA" (Rome et al. 2014). They found that most "new device models are deemed safe and effective without requiring new clinical data", even when those new models "involve significant design changes" (Rome et al. 2014).
Indeed, a 2011 Institute of Medicine committee recommended that the FDA eliminate the 510(k) altogether: "Rather than continuing to modify the 35-year-old 510(k) process, the IOM concludes that the FDA's finite resources would be better invested in developing an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle" (Institute of Medicine of the National Academies 2011).

Timeframe

With its many exemptions and various tracks, the FDA's approval process is widely considered more cumbersome and less clear than the CE marking process. A 2012 report by the Boston Consulting group quantified as much, analysing approvals "for the most innovative and potentially risky medical technologies"
(those requiring PMA) from 2000 through 2011. They concluded that "the same devices have been approved and made available to patients in Europe three or more years before devices are approved in the U.S" (Boston Consulting group 2012).

Effects

Calling the FDA approval process for Class III devices "confusing and repetitive," the study's authors identified a troubling trend for the U.S. population: "sustained approval differences are encouraging companies to favour innovations that will serve European markets and reducing the incentive to innovate for the specific needs of the U.S" (Boston Consulting group 2012).
This very outcome has been tacitly acknowledged by the FDA. On 22 April 2014 the FDA proposed an expedited premarket approval process for devices addressing unmet medical needs (U.S. Food and Drug Administration 2014b). The FDA's Medical Device Reimbursement Task Force, created in December 2013, shares the goal of promoting innovation and getting important devices to market. The group aims to "shorten the time medical device manufacturers wait before health plans will pay for products after they're approved"—a critical barrier that manufacturers face even after completing their FDA submissions. "We recognize that the mere fact the FDA approves or clears a device is not equivalent with patients getting access to that device," said Murray Sheldon, associate director of technology and innovation at the FDA (Dickson 2013).

Additional Considerations

Still, while the CE mark is less onerous to obtain, it is a less powerful certification. FDA approval means that the device is approved for use in all parts of the world, while the CE mark has restrictions, sometimes even within the EU. As one medical device company founder says of the CE marking, "there is no guarantee that the device will be widely accepted by physicians or reimbursable by the government in each European country" (Chi 2012).
It is possible too that the FDA's strictness is seen as safer for consumers. Some argue that the breast implant scandal of the early 2000s, in which the French company PIP sold silicone implants, which were not medical grade, wouldn't have happened in the U.S. Indeed, the FDA announced a moratorium on silicone breast implants in 2000. A recent paper in JAMA challenges that confidence, noting that less than 1% of medical devices approved by the FDA have undergone Premarket Approval (PMA), the most rigorous path to market (Rome et al. 2014).

Remaining Questions

A medical company's decision to pursue one approval over the other has ramifications extending beyond its own bottom line. Indeed, the advantages and disadvantages of each system translate directly into which population— American or European—gains access to new medical technologies. With this in mind, the question remains: is the extra expense and cost (human as well as financial) in the FDA's
longer timeframe and more intricate process balanced by the presumed assurance of effectiveness that the EU's approval system lacks?
Key Points

- Overview of how the U.S. Food and Drug Administration's approval processes for new medical devices varies from the European CE marking process.
- While the CE mark takes less time to obtain and devices may be available earlier than in the

U.S., the FDA’s strict procedures may be seen as safer for consumers.

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