SBA Office of Advocacy
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Fact Sheet

Advocacy: the voice of small business in government

Advocacy Provides CMS and the FDA with the Medical Technology Industries' Concerns with the Parallel Review of Medical Products Request for Comments

On December 13, 2010, the Office of Advocacy (Advocacy) filed comments with the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) providing the agencies with the affected medical technology industries' comments on the parallel review of medical products request for comments. Advocacy also asked that the agencies analyze any economic impacts associated with parallel review pursuant to the requirements of the Regulatory Flexibility Act. A copy of Advocacy's letter may be accessed at http://www.sba.gov/advo/laws/comments**.**

On September 17, 2010, CMS and FDA published a notice in the *Federal Register* requesting public comment on the establishment of a parallel review process for medical products (75 Fed. Reg. 57045). The notice indicated that the agencies wanted to establish a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. The stated goal of the parallel review process was to reduce the time between FDA marketing approval or clearance decisions and CMS national coverage determinations (NCDs).

- Seed and early stage venture capital, medical device and biotechnology companies through their association with the National Venture Capital Association Medical Innovation and Competitiveness Coalition approached Advocacy and voiced support for the goal of the parallel review process. The stakeholders said that they wanted to make sure that it would not have the unintended consequence of making the approval process for medical technologies more burdensome and make it more difficult to get innovative technology to the public. The stakeholders also asked Advocacy to provide CMS and FDA with their comments and concerns with parallel review.

- Advocacy provided the small home health care agencies' concerns to CMS and FDA. Advocacy also asked the agencies to comply with the Regulatory Flexibility Act by analyzing the potential economic impacts associated with parallel review.

For more information, visit Advocacy's web page at www.sba.gov/advo or contact Linwood Rayford at (202) 205-6533.