Congress of the United States
Washington, DC 20515

June 27, 2011

Mr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Berwick:

We are writing in response to concerns we have heard from patients and manufacturers regarding the proposed Accountable Care Organization (ACO) rule issued by the Centers for Medicare and Medicaid Services (CMS) on March 31, 2011. In particular, we are concerned about the potential unintended consequences of the proposed rule on medical innovation and patients' access to modern medical technology. We appreciate the complexity of the issues involved in designing an ACO regulation and urge you to thoroughly review these concerns and continue to seek stakeholder input as you work to finalize the ACO regulation.

While we share the goal of moving our nation's health care system away from paying for volume and toward paying for quality, we are concerned about potential unintended consequences of the regulation that could prevent some patients from receiving the care most appropriate for their needs, discourage medical progress, and possibly undermine economic growth and job creation.

First, while ACO shared savings incentives should spur providers to coordinate care, reduce costs and improve quality, stakeholders have communicated that these incentives could have the unintended potential to lead to stinting on care. This could include denial of needed specialty referrals or higher cost tests and interventions that are appropriate for the patient. While the proposed quality measures are necessary and provide some protection, they are limited in scope and cannot, by themselves, ensure that the quality of patient care is not compromised.

Second, the ACO model must continue to encourage advances in medical treatments for patients. Medical progress often occurs when cutting edge physicians and institutions are the early adopters of new treatments that, if proven successful, gradually diffuse until they become the standard of care. ACOs should be designed to support this process so we do not discourage the development and use of promising, innovative new therapies for patients.

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Finally, encouraging continued medical innovation is not only important for patients; it is important for economic recovery and growth at a time when America's leadership in the medical technology industry is increasingly challenged by foreign competitors. Without strategic government policies to support the medical technology industry's efforts to compete in world markets, jobs and the economic well being of constituents in our districts, as well as America's overall leadership in this industry, will be lost. As you may know, Pennsylvania and California both have a robust medical device manufacturing presence, and these companies are important contributors to each state's economy. The President has directed Federal agencies to seek means to achieve regulatory goals that are designed to promote innovation, and we ask that you consider the comments of the medical device community as you promulgate the final rule.

We urge you to consider unintended consequences to medical innovation and patients as you work to finalize the ACO regulation. We look forward to working with you to achieve the aim of improving quality and efficiency of health care delivery, while also assuring Medicare beneficiaries they will continue to have access to the highest quality medical care and American-made treatments that meets their individual needs.

Sincerely,

Jim Gerlach
Member of Congress

Mike Thompson
Member of Congress