OBAMA-BIDEN TRANSITION PROJECT

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December 8, 2008

The Honorable Thomas A. Daschle
Chair, Health Care Policy Working Group
Obama-Biden Transition Project
451 6th Street, NW
Washington, DC 20001

Dear Mr. Daschle:

As you turn from the historic elections of 2008 to the task of governing in 2009 and the critical issue of health care reform, the members of the Coalition for Competitive Pharmaceutical Market (CCPM), advocate for access to safe, effective and affordable biogeneric drugs for millions of Americans in need of these critical medicines.

CCPM is an organization of large national employers, health plans, PBM's, chain pharmacies, generic drug manufacturers, biopharmaceutical companies and others representing more than 200 million beneficiaries. While recognizing that biopharmaceuticals provide great hope for many who suffer from life-threatening and chronic illnesses, the prices of these medications- as much as $300,000 per patient per year- impose significant financial burdens on the entire healthcare system and threaten the economic sustainability of many families and businesses alike.

CCPM shares the belief of many in Congress and the incoming Administration that the time has come to pass legislation giving the FDA authority to implement a workable pathway for approval of biogenerics. Meaningful legislation must include:

A rational and economically justifiable market exclusivity provision. The 5 years of exclusivity provided under Hatch Waxman (PL 98-417) for chemical drugs successfully fostered innovation and significant return on investment. We see no justification for any additional exclusivity beyond Hatch Waxman in a competitive biologic market.

An approval process that allows the FDA to determine, on a case-by-case basis, what data it requires to approve comparable and interchangeable products. This pathway must be free of administrative barriers that impede the FDA's ability to approve safe and effective biogenerics, based on science and not legislative mandate; and

A patent dispute resolution process that provides a clear and timely resolution of patent disputes to prevent frivolous and unnecessary delays of access to biogeneric competition. CCPM fully supports patent protection but opposes the continuation of a system that allows brand manufacturers to conceal patents as a business model for delaying competition.

Thank you for your interest and attention to the issue of biogenerics. We look forward to working closely with you on this critical issue.

Sincerely,

Katie Huffard

Katie Huffard
Executive Director

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