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LEGISLATIVE ALERT!

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May 2, 2008

The Honorable Frank Pallone, Jr., Chairman
Committee on Energy and Commerce
Subcommittee on Health
Washington, D.C. 20515

The Honorable Nathan Deal, Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
Washington, D.C. 20515

Dear Chairman Pallone and Ranking Member Deal:

Thank you for the opportunity to provide our views on legislative efforts to create a pathway to allow the Food and Drug Administration (FDA) to approve generic biologic products. We believe such legislation is necessary to help slow the rapid rate of growth in health care costs.

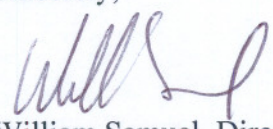
With the development and broader use of biologic drugs, we have seen health care costs grow enormously for our members and the health plans that provide their health benefits. For more than a year, we have worked in coalition with stakeholders as diverse as consumers, purchasers, labor and employers to push for enactment of legislation that will lead to lower cost biologic drugs through competition. We also recognize that compromise will be necessary to achieve legislation. However, we believe it is more important that legislation be done right than that it be done now.

Safety must be the primary goal of any legislation enacted and we won't advocate for any bill that doesn't meet that goal. The FDA should be empowered to use its expertise to determine on a case-by-case basis what scientific evidence is needed to approve comparable and interchangeable products. Any process that is overly prescriptive will create administrative barriers that impede the FDA's ability to approve safe and effective biogenerics. At the same time, we believe the FDA should be adequately financed, through direct appropriations and user fees, to have the resources necessary to make those case-by-case determinations and ensure safety.

In addition, innovators should be granted a period of market exclusivity to reward their investment and innovation, but legislation must protect against an unreasonable period of exclusivity that will stifle competition and innovation. A balanced, workable pathway that is clinically based will both reward that innovation and provide consumers and purchasers with the competition and choice necessary to rein in health care costs without impeding access to life-saving treatments.

Thank you for the opportunity to comment on the health subcommittee's work in this important area.

Sincerely,



William Samuel, Director
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