G. Richard Wagoner, Jr.
Chairman &
Chief Executive Officer

April 30, 2008

The Honorable Frank Pallone, Jr.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Office Building
Washington, D.C. 20515

The Honorable Nathan Deal
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Office Building
Washington, D.C. 20515

Dear Chairman Pallone and Representative Deal:

Thank you for allowing me to share our views on the importance of enacting legislation that would facilitate the availability of generic versions of biopharmaceuticals. General Motors Corporation has long supported competition in the pharmaceutical market, particularly for biologics, which for the most part enjoy no competition from generic or biosimilar alternatives. As an innovation, safety and technology leader, GM appreciates the importance of fostering innovation and ensuring safety. We believe strongly that the Committee can develop legislation that appropriately balances these interests, while enabling patients to have access -- sooner rather than later -- to more affordable biopharmaceutical choices. I am pleased that the Committee is committed to crafting legislation that would establish an abbreviated process for the Food and Drug Administration to use in approving safe generic biopharmaceuticals. Generic biopharmaceuticals would offer significant benefits to all patients, whether they are covered by private insurance, Medicare, Medicaid, other federal or state programs or are uninsured.

For purposes of background, GM is one of the largest private purchasers of health care in the United States. In 2007, GM spent $4.6 billion providing health care for approximately 1 million employees, retirees and dependents. Of this amount, approximately $1.3 billion was spent on prescription drugs.

GM is committed to helping improve the U.S. health care system and is working with both our salaried and union employees, as well as our retirees, to help them and their families become better health care consumers. We actively engage our beneficiaries in generic drug education, on ways to better manage their prescription drug use, and on methods to lower their out-of-pocket drug costs. We believe that they benefit from having choices of therapies and being equipped with information about these treatments so that they and their physicians can make more informed decisions about the best medications available.

General Motors Corporation Mail Code 482-C39-B50 300 Renaissance Center Detroit, MI 48265-3000

GM has been working with other employers, labor, patient groups, whealth plans and others to support measures that would allow the FDA to approve safe, equally effective generic biopharmaceuticals, whether comparable or interchangeable. With advancements in science and skyrocketing pharmaceutical costs, the time has come to address this issue.

Biopharmaceuticals hold great promise for our employees, retirees, and their families. However, biopharmaceuticals have a significantly higher cost than synthetic compounds, and that cost is growing at a rate much higher than that of synthetic compounds. According to the National Association of Chain Drug Stores, in Michigan alone, based on the number of prescriptions filled at Michigan pharmacies, including traditional drug stores, mass merchants and supermarkets, between the years of 2004 and 2007, biopharmaceutical prescription spending grew 64%, which is an average annual rate of 17.8%. These cost increases more than triple the rate of cost growth these same pharmacies experienced for brand synthetic drugs. If this trend continues, Michigan biopharmaceutical spending will increase from $378 million in 2007 to almost $2 billion by 2017.

Moreover, while we understand that today biopharmaceuticals account for only about 10% of the pharmaceutical market, going forward more and more patients will use biopharmaceuticals. This is because, as we have been advised, over 20% of drugs in the development pipeline are biopharmaceuticals, and these drugs will be used to treat more prevalent diseases, as well as chronic conditions, which require long term medication adherence. At GM, we are experiencing an increasing trend of patients moving from chemically-based drugs to biopharmaceuticals.

Our experience shows us that generic competition goes a long way to making prescription drugs more affordable for beneficiaries. For example in 2007, GM beneficiary generic drug usage resulted in a savings of $375 million. When generics are available, our generic substitution rate is 98.5%. In analyzing the combined Michigan presence for Chrysler, Ford and General Motors, our three companies saved over $553 million in 2007 with the use of generic drugs. Our beneficiaries also enjoyed significant savings because of the considerably lower out-of-pocket cost for the equally safe and effective generics. Based on these experiences, we believe that allowing safe generic competition in the biopharmaceutical arena will result in additional savings for our employees and retirees and the health care system generally. For

example, in Europe, Omnitrope, a generic version of the human growth hormone drug Genotropic, costs 20% - 25% less than the original brand version.

When considering legislation we believe that there are several key principles that should be followed:

1. <u>Protect and Promote Fair and Open Competition</u>

As a leader in innovation, GM understands the importance of encouraging and protecting intellectual property and in rewarding innovation. We believe strongly that there must be a balance between innovation and competition, as full and fair competition is what our beneficiaries and their physicians need to make the best and most affordable decisions on the right therapies. Today there is an effective open-ended monopoly on brand biopharmaceuticals, since FDA is not approving generic versions. This has the effect of undermining competition and innovation.

Our health care system cannot afford excessive patent extensions or multi-years of market or data exclusivities that substantially exceed the timeframes currently available for chemically-based drugs. These would unfairly delay competition and limit consumer access to more affordable generic biopharmaceuticals. It is preferable to allow the FDA the flexibility to determine on a case-by-case basis whether any additional exclusivity should be provided and, if so, how much. Equally important is the need for a clear and final resolution of patent issues and an expedited court process to determine the validity and applicability of patents in order to avoid unwarranted suits that restrict access to generic alternatives.

2. <u>Definitive Pathway for FDA Approval of Comparable and Interchangeable Biopharmaceuticals</u>

It is critical that the legislation establishes a meaningful regulatory pathway for the FDA to review and approve comparable and inter-changeable biopharmaceuticals, based on science and safety. Safety must be a paramount concern for FDA, and they should be provided adequate resources to do their job, and to do it well. The FDA, as the entity with scientific expertise and experience, is best positioned to determine what clinical safety and effectiveness data is necessary to approve the safety of all pharmaceutical drug products, and what

guidance and rulemaking may be appropriate. The FDA should be given the authority to approve safe comparable and interchangeable biopharmaceuticals, and should be given the flexibility to determine, on a case-by-case basis, what data that the agency needs to approve both comparable and interchangeable products.

3. <u>Uniform Terminology for Comparable and Interchangeable Biopharmaceuticals</u>

In order to promote transparency and simplicity for all beneficiaries, there should be uniform and consistent terminology when describing generic biopharmaceuticals, whether they are comparable or interchangeable. Differing names lead to confusion and inconsistencies for physicians, pharmacists, and patients, and inhibit their ability to make informed, value-driven decisions about what pharmaceutical treatments are most effective and affordable.

Thank you for your interest and attention to this critically important issue. We look forward to working closely with you and your Committee to pass meaningful legislation that will bring safe and affordable generic biopharmaceuticals to millions of patients across the country.

Sincerely,

G. R. Wagoner, Jr.

c: The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce

The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce