

Congress of the United States

Washington, DC 20515

The Honorable Jack Lew
Secretary of the Treasury
U.S. Department of the Treasury
1500 Pennsylvania Ave
Washington, D.C. 20220

December 2, 2013

Dear Secretary Lew:

The Centers for Disease Control estimates that approximately 25.8 million Americans are affected by diabetes. According to some estimates, patients with diabetes have a 25% lifetime risk of developing a severe complication of diabetes, an ischemic diabetic foot ulcer or DFU.

DFUs affect more than two million Americans and result in approximately 70,000 lower limb amputations each year. Within two years of amputation, patients face a mortality rate of nearly 50% - a rate higher than many types of cancer, including breast and prostate cancer. In addition, it is estimated that over \$50 billion in annual direct medical costs are attributed to DFU patients. What's more, patients and physicians in the U.S. are frustrated, not only by the lack of an effective treatment, but by the lack of a readily available U.S. Pharmaceutical / Biotech effort at developing potential treatments for severe DFU sufferers in America.


A promising treatment offering a clear benefit over any existing therapy for severe DFU does exist. It has already been used in the treatment of more than 100,000 DFU patients with a high risk of amputation and is currently registered for use in 16 countries. The reason that Americans afflicted with diabetic foot ulcers cannot be treated with the only known effective treatment, Heberprot-P, is because this innovative treatment was developed by the Center for Genetic Engineering and Biotechnology, located in Havana, Cuba.

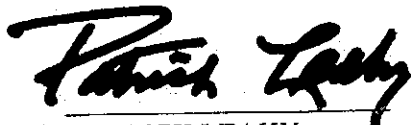
Since Heberprot-P is developed by a Cuban research institute, the Office of Foreign Asset Control (OFAC) must first grant a license under the Cuban Assets Control Regulations in order for Heberprot-P to be put to clinical trials in the United States, and, ultimately, made available to U.S. physicians for their treatment of patients with ischemic diabetic foot ulcers. Should a U.S. company make an application to OFAC for authorization, we urge its consideration. OFAC has granted similar authorizations in the past, for example, in 2004, OFAC granted a license to a U.S. company for a cancer vaccine developed by a Cuban research institute. It is our hope that an application for license to enable clinical trials of Heberprot-P will be afforded the same review and treatment.

The lack of access to an effective treatment for this life threatening condition, which afflicts millions of Americans and results in billions of dollars of direct medical costs, is a serious unmet medical need for the American people that should be viewed as a human issue and not as part of

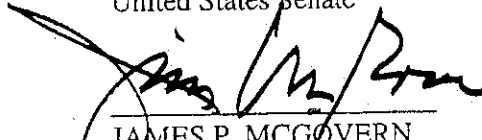
a Cold War era political one. We look forward to working with you to ensure Americans have access to life-saving biotech products and appreciate your attention and response to this letter.

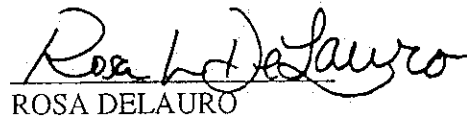
Cc: Secretary of State John Kerry
Adam Szubin, Director, Office of Foreign Asset Control



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Member of Congress



PATRICK LEAHY
United States Senate



MARK BEGICH
United States Senate



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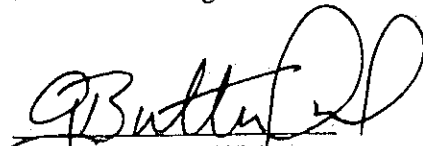

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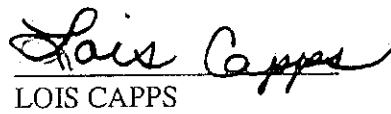

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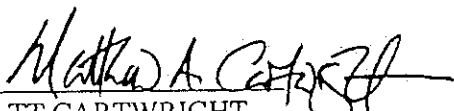

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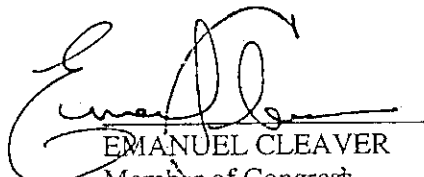

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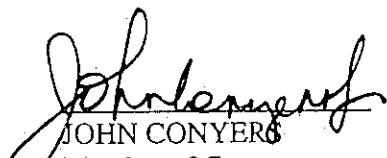

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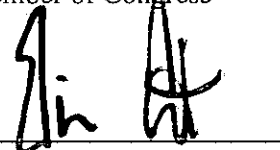

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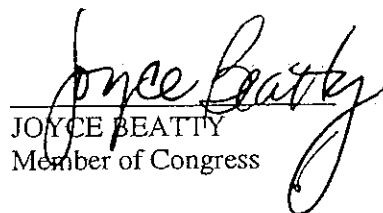

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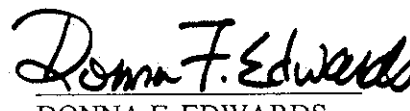

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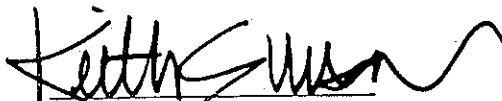

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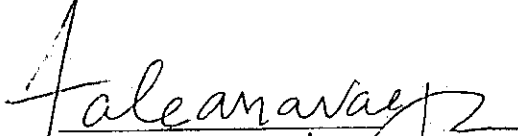

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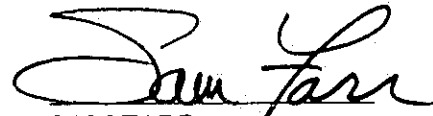

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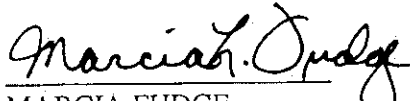

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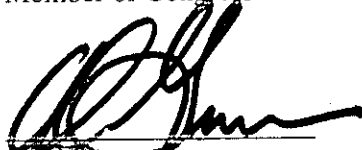

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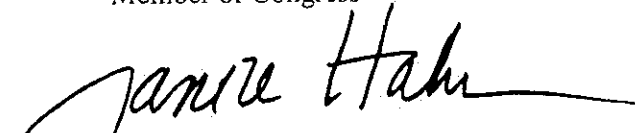

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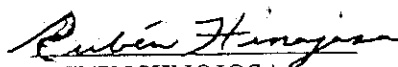

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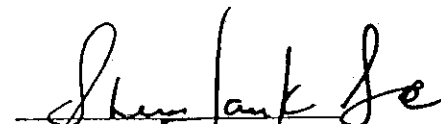

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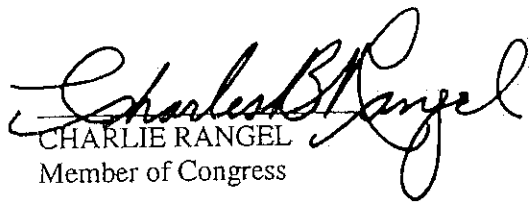

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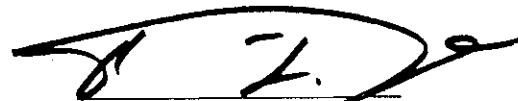

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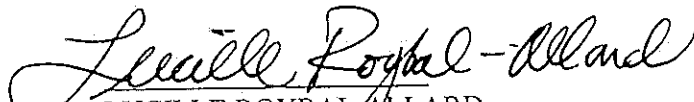

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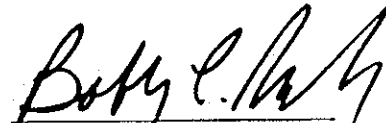

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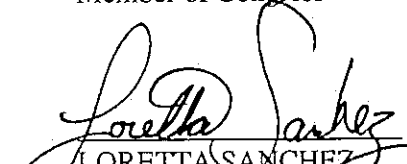

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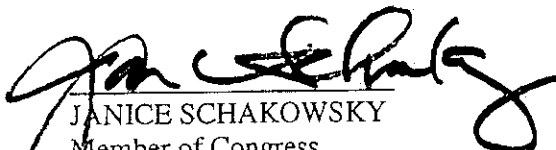

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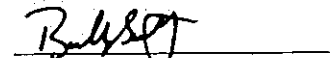

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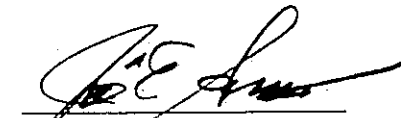

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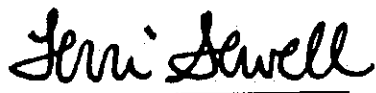

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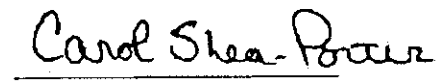

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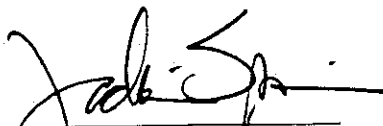

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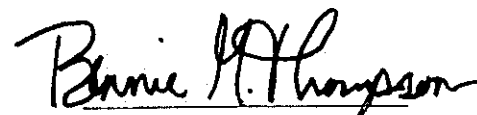

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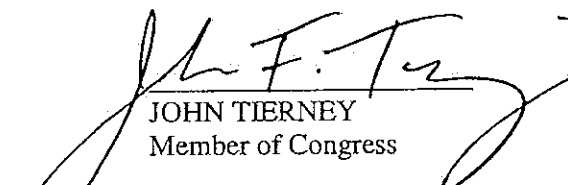

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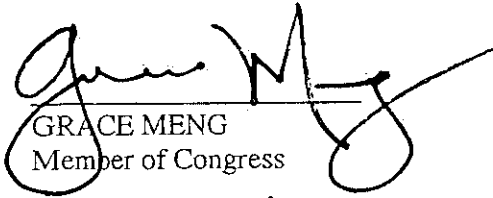

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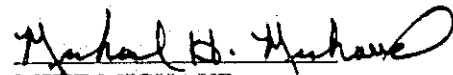

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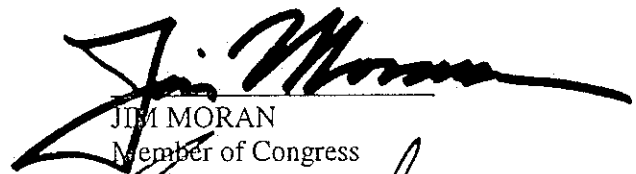

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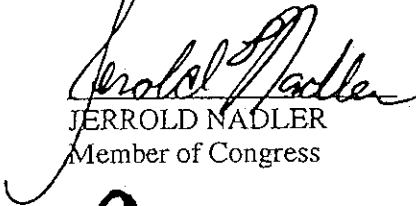

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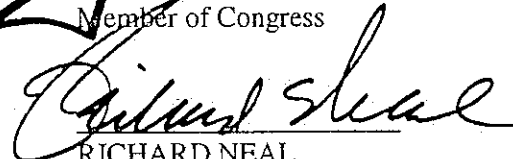

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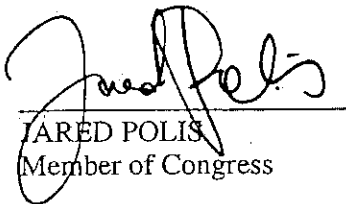

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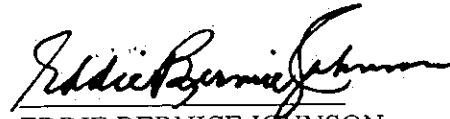

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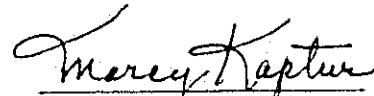

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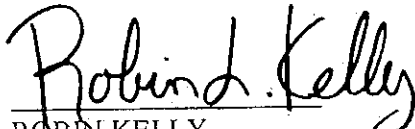

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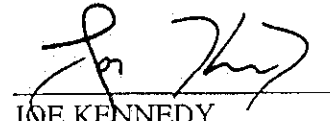

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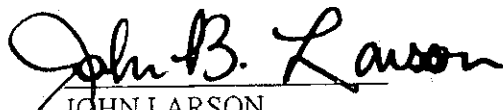

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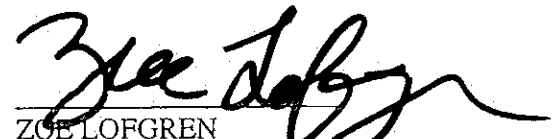

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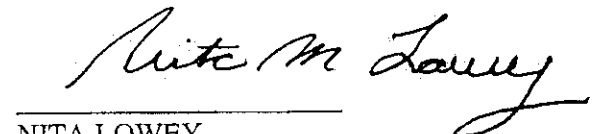

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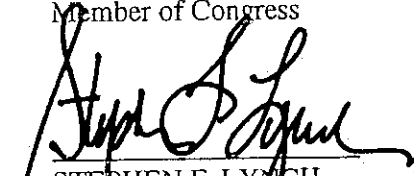

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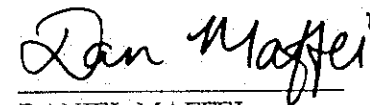

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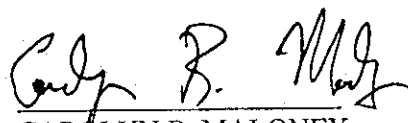

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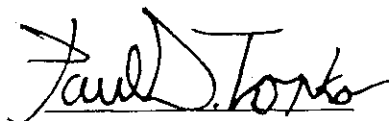

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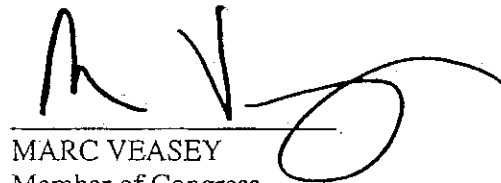
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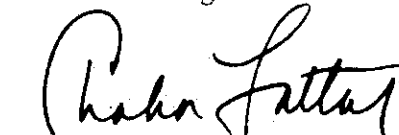
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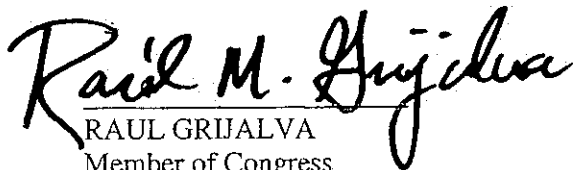
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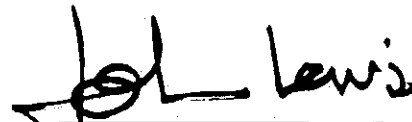
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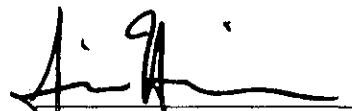
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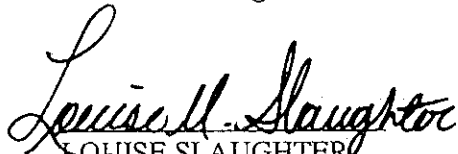
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