

Congress of the United States
Washington, DC 20515

February 5, 2018

The Hon. Alex M. Azar II
Secretary
Department of Health and Human Services
Hubert D. Humphrey Building
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Shulkin:

In 21st Century America, non-traumatic amputations simply should not have to occur. Yet, every year, tens of thousands of Americans, a disproportionate number of whom are racial and ethnic minorities, undergo non-traumatic amputation as a medical intervention for conditions such as peripheral artery disease (PAD). Unfortunately, these patients often suffer substantially higher mortality rates as a result of the amputation. Since a large share of these patients receive care through the Medicare and Medicaid programs, the Veterans Health Administration, and the Indian Health Service, this crisis is impacting taxpayers as well as patients and their families.

Currently, technologies exist to identify these patients early in their disease progression, when medical therapies and supervised exercise therapies can be utilized to prevent disease progression. In addition, even when peripheral artery disease has reached its end-stage (critical limb ischemia), minimally-invasive revascularization techniques are now available to avoid amputation of the leg and may offer a better treatment route for some patients.

Despite these capabilities, at-risk patients are not regularly screened for peripheral artery disease early in the disease's progression. In addition, peer-reviewed studies have found that up to one-third of late-stage patients never receive arterial testing in the year prior to amputation to evaluate whether or not they may be candidates for limb-saving revascularization.

Racial, ethnic and geographic disparities compound this serious problem. According to the Dartmouth Atlas, amputation risks for African Americans living with diabetes are as much as four times higher than the national average. Data analyses have similarly found that Native Americans are more than twice as likely to be subjected to amputation as Caucasians and that Hispanics are up to seventy-five percent more likely to be amputated than Caucasians.

In this light, we believe there is a need for a comprehensive strategy to achieve a "sprint to zero" non-traumatic amputations. This strategy should include the following components:

- **Increasing PAD Awareness.** Although it is estimated that 18 million Americans live with peripheral artery disease, many are unaware of the potentially significant implication of leg pain and the need for early screening and intervention. In addition, there appears to be significant variation in whether a clinician chooses amputation versus revascularization based on a clinician's given specialty. Nevertheless, there is currently no dedicated PAD awareness effort that parallels the successful Fistula First Breakthrough Initiative that encouraged low-infection fistulas for ESRD patients over high-infection catheters.
- **Increasing PAD Screening for At-Risk Patients.** The U.S. Preventive Services Task Force assigns a grade of I (insufficient evidence) for PAD screening for the general population. However, guidelines issued by the American College of Cardiology and American Heart Association recommend screening of at-risk patients (defined as those who are over age 65, have a history of diabetes, smoking, and/or PAD; or have been diagnosed with other vascular disease).
- **No Amputation Without Arterial Testing.** Currently, there is no intragovernmental Federal health policy to ensure patients are assessed for non-amputation treatment options before they suffer limb loss. Such a policy could include quality measures, guidelines or appropriate payment incentives to increase the number of patients who receive arterial testing prior to a non-traumatic amputation.
- **Multidisciplinary Care.** Centers of excellence across the country have shown that multidisciplinary care has been effective in driving amputation rates down to near zero. Unfortunately, many PAD patients – including a large share of African Americans, Hispanics and Native Americans – do not live near a center of excellence. Since such patients experience higher rates of PAD-related limb loss as a result, they may realize particular benefit from the encouragement of multidisciplinary care through payment reforms under the Medicare Access and CHIP Reauthorization Act and other mechanisms.

We request that you inform Congress on the steps your departments either already have in place or are considering that relate to the aforementioned components. In addition, please advise us regarding (1) existing regulatory authority within your departments relating to the Medicare and Medicaid programs as well as the Veterans Health Administration and the Indian Health Service that could be used to implement these policies, and (2) whether any new statutory authority is needed to reduce the rate of non-traumatic amputations to zero.

We thank you for working with us to make non-traumatic amputations a thing of the past and look forward to your timely response.

Sincerely,



Erik Paulsen
Member of Congress



Donald Payne Jr.
Member of Congress



Alma Adams
Member of Congress



Karen Bass
Member of Congress



Joyce Beatty
Member of Congress



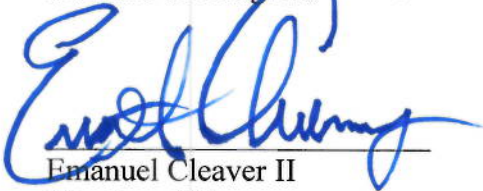
Sanford D. Bishop Jr.
Member of Congress



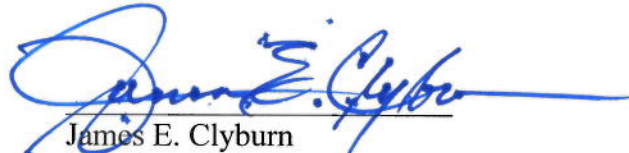
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Andre Carson
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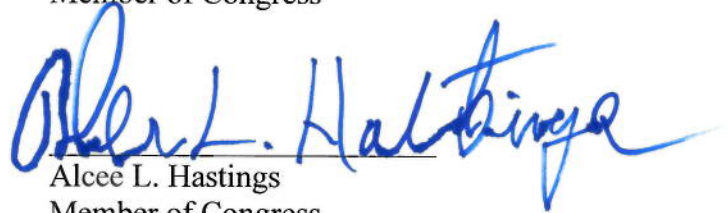
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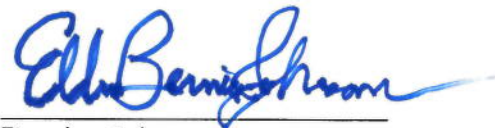
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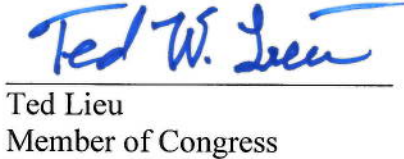
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Barbara Lee
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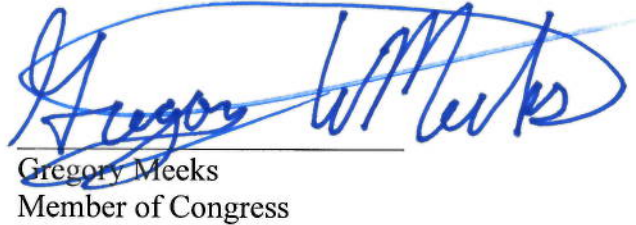
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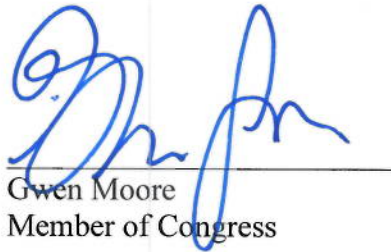
Ted Lieu
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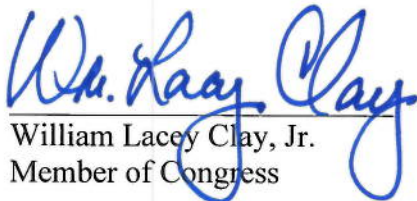
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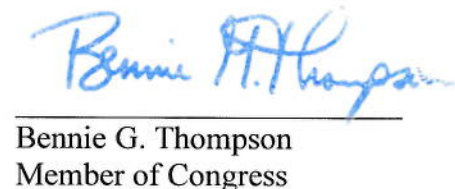
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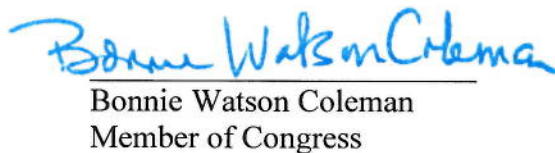
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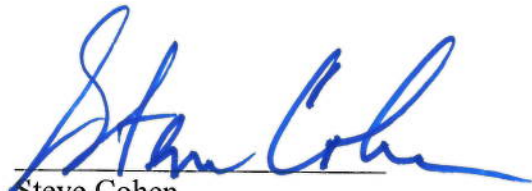
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