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June 22, 2015

The Honorable Orrin Hatch
Chair, Committee on Finance
United States Senate
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member, Committee on Finance
United States Senate
Washington, D.C. 20510

The Honorable Johnny Isakson
Co-Chair, Working Group
United States Senate
Washington, D.C. 20510

The Honorable Mark Warner
Co-Chair, Working Group
United States Senate
Washington, D.C. 20510

Dear Chairman Hatch, Ranking Member Wyden, Co-Chairs Isakson and Warner, and Members of the Working Group:

On behalf of Samumed, LLC, I write to share with the Committee's working group on chronic care some important facts regarding the impact of the chronic condition osteoarthritis (OA) on patients and the health care system as a whole, and to raise the need for further analysis of the correlation between OA and other chronic conditions. Samumed is an independent, management-controlled company leading medical research in regeneration of numerous tissue types, including cartilage, dermal, and neural tissue. In the coming years, we hope to bring to market several breakthrough therapies to treat a range of degenerative diseases, including OA.

Reports by the U.S. Department of Health and Human Services (HHS), among others, identify arthritis as one of the most impactful chronic conditions facing our nation.[1] Arthritis is the number one cause of disability in the U.S. Although there are numerous types of arthritic conditions, the most common by far is OA. OA affects greater than ten percent of the U.S. adult population, and more than one-third of those aged 65 and over.[2] Unlike rheumatoid and other autoimmune forms of arthritis, OA is a degenerative disease defined by the deterioration of the protective cartilage in joints, which causes swelling and inflammation, bone spurs, misshapen joints, reduced range of motion, decreased function, and chronic pain. In essence, it is caused by the wear and tear in a joint over time. While OA may affect any joint, OA most commonly afflicts the lower extremity joints, such as knees and hips. Because the condition inevitably worsens over time, it often affects more than one of these joints, severely limiting mobility. These mobility limitations often lead to or worsen other comorbid conditions, such as obesity, diabetes, and heart disease.

[1] *E.g.*, U.S. Dep't. Health & Human Servs., Initiative on Multiple Chronic Conditions (2014).

[2] Ctrs. for Disease Control & Prevention, *Osteoarthritis: Prevalence*, http://www.cdc.gov/arthritis/basics/osteoarthritis.htm (May 2014); Reva C. Lawrence et al., *Estimates of the Prevalence of Arthritis and Other Rheumatic Conditions in the United States, Part II*, 58 Arthritis & Rheumatology 26, 26–35 (Jan. 2008).

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Despite the high prevalence of OA in the population, there is presently no cure for the disease, and the existing treatment regimens are merely palliative, seeking to reduce the pain for as long as possible, until pain and loss of functionality renders joint replacement surgery unavoidable. The existing drug therapies are ineffective,[3] treating only the disease's symptoms, and many of these therapies—including opioids, nonsteroidal anti-inflammatory agents like naproxen, and corticosteroids—have well-known negative effects on organ health when used long-term. Thus, the treatments themselves add further health risks to those afflicted with the disease and impose significant additional cost burdens on the health care system.

To highlight some of these costs, it is estimated that the annual per patient direct cost of the disease—not including joint replacement surgery and the associated costs—is approximately $10,000 to $20,000.[4] Moreover, OA is the diagnosis associated with the highest number of hospital stays for individuals aged 45 to 64.[5] Furthermore, commentators have identified major joint replacement surgeries as the most common inpatient discharge paid for by Medicare.[6] In 2009, the number of U.S. hospital discharges associated with knee and hip replacements was 620,192 and 284,708, respectively, with corresponding hospital expenditures of $28.5 billion and $13.7 billion.[7] Unlike the other leading causes of hospitalization, total joint replacement has steadily risen over time; projections indicate that the volume of knee and hip replacements is expected to increase by 673 and 174 percent, respectively, between 2005 and 2030.[8]

Hospital stays represent only a fraction of the direct health care costs associated with OA. Other direct expenditures include emergency department visits, outpatient and physician care, diagnostic imaging services, and high prescription drug utilization.

OA is also associated with considerable indirect costs, such as lost earnings, lost work days and productivity, disability payments, and other economic losses. Despite the obviously substantial burden of OA, there are very limited studies that have measured the economic impact of the disease, or the interrelated nature of the burden of related comorbidities. We feel it is important

[3] *E.g.*, Arthritis Foundation, *Comment Letter on 21st Century Cures Discussion Draft* (Feb. 13, 2015).

[4] *See, e.g.*, Ariel Berger et al., *Patterns of Pharmacotherapy and Health Care Utilization and Costs Prior to Total Hip or Total Knee Replacement in Patients with Osteoarthritis*, 63(8) Arthritis & Rheumatology 2258, 2272 (2011) (reporting total costs of $19,466 during two years preceding hip or knee replacement surgery); Alan White et al., *Direct and Indirect Costs of Pain Therapy for Osteoarthritis in an Insured Population in the United States*, 50(9) J. Occupational & Envtl. Med. 998, 998–1005 (2008) (finding that the annual direct cost associated with OA diagnoses was $11,542 in a privately insured sample of patients); T. Kim Le et al., *Healthcare Costs Associated with Osteoarthritis in US Patients*, 12(8) Pain Practice 633, 633–640 (2012) (comparing annual Medicare costs for newly diagnosed OA patients at $19,391 with previously diagnosed OA patients at $18,728).

[5] Agency for Healthcare Research & Quality, Healthcare Cost and Utilization Project (HCUP), Exhibits 2.2a & 2.4 (2009).

[6] *See, e.g.*, Bob Herman, *Medicare Sheds New Light on Hospital, Physician Pay*, Modern Healthcare (Jun. 1, 2015), http://www.modernhealthcare.com/article/20150601/NEWS/150609999.

[7] Louise Murphy, PhD & Charles G. Helmick, MD, *The Impact of Osteoarthritis in the United States: A Population-Health Perspective*, 112:3 Am. J. Nursing S13, S16 (2012) (analyzing 2009 HCUP data).

[8] Steven Kurtz et al., *Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030*, 89(4) J. Bone Joint Surg. Am. 780, 780–85 (2007).

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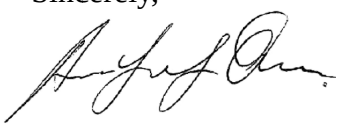
that chronic care policy properly prioritize research, innovation, and effective care strategies for the affected population.

Samumed appreciates the work the Committee is undertaking on the important issue of chronic diseases. We respectfully submit these comments, and welcome future opportunities to serve as a resource to the working group.

Sincerely,



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