## Call to Action to Address the Crisis in the Treatment of Osteoporosis

New evidence is emerging that the 30-year downward trend in hip fractures in the U.S. has hit a plateau in the last few years, indicating that the field as a whole must take action to aggressively reduce fracture risk in our aging population.<sup>1</sup> Many experts are now acknowledging that there is a crisis caused by the declining rate of testing, diagnosis and treatment of high-risk patients. Allowing these patients to go untested and untreated frequently leads to debilitating fractures that cause disability, loss of independence and even death.

In the US, hospitalizations for osteoporotic fractures accounted for 43% of combined hospitalizations for osteoporotic fractures, heart attack, stroke and breast cancer. And over 50% of the osteoporotic fracture hospitalizations were for hip fracture, the most devastating consequence of osteoporosis. <sup>2</sup> This is not only a medical crisis but an economic one too.

Surprisingly, in the U.S. Medicare has reduced reimbursement for office-based bone density tests to an unsustainable level leading to fewer physicians in the U.S. now offering bone density testing. Additionally, new cuts are being proposed to reimbursement for hospital-based bone density testing.<sup>1</sup>

Despite compelling data that bisphosphonates reduce both risk of a second fracture and reduce death in those patients who have had a hip fracture, many clinicians do not have the necessary information or resources available to help their patients make informed decisions to prevent hip fractures.

Moreover, patients are increasingly reluctant to take osteoporosis therapies, citing fears of rare side effects, even though the number of fractures that are prevented with treatment far outweighs the risk of atypical femur fractures and osteonecrosis of the jaw.<sup>3</sup> Treatment of women with osteoporosis for up to five years would result in fewer than one atypical femur fracture caused per 100 osteoporotic fractures prevented.<sup>4</sup>

To address this osteoporosis treatment crisis, the undersigned organizations pledge to intensify their current efforts and collaborate on new opportunities to increase the screening, diagnosis and treatment of high-risk individuals to prevent fractures and to partner with patients to make informed choices about osteoporosis treatment options. This includes supporting regional efforts in those areas of the world that have a need for greater health professional education and public awareness.

They also call for:

- Health professional education programs and continuing medical education programs to expand education for health care professionals to focus on recognizing, diagnosing and treating patients at high risk for fracture, with clear messages to inform patients and clinicians about the real health risks of osteoporosis and fractures (e.g., hip fractures have high rates of death and disability).
- Governmental organizations (health, public health, research, elected groups) to increase focus and support for programs to reach the highest risk patients, to ensure access to testing and to all currently available and future therapies; to develop action plans for research to develop improved treatments and around new evidence on treatment strategies for diagnosing, monitoring and treating, and early identification of high-risk patients.
- Insurers (private and public) to cover the most effective services to improve diagnosis and treatment of those at the highest risk.
- Health systems and medical practices to adopt and use quality measures that incentivize clinicians and health systems to screen for osteoporosis and treat high-risk individuals.

#### Signed,

American Society for Bone and Mineral Research American Academy of Orthopaedic Surgeons American Academy of Physician Assistants American Association of Clinical Endocrinologists American Bone Health American College of Rheumatology American Medical Society for Sports Medicine American Orthopaedic Association American Osteopathic Academy of Orthopedics American Society for Surgery of the Hand Australia New Zealand Bone and Mineral Society Bulgarian Society of Osteoporosis and Osteoarthritis Czech Society for Metabolic Bone Diseases Dutch Society of Cancer and Bone Metabolism **Endocrine Society** European Calcified Tissue Society European Union Geriatric Medicine Society Finnish Osteoporosis Association Georgian Association of Skeletal Metabolism **Diseases Hellenic Osteoporosis Foundation** International Geriatric Fracture Society, Inc. International Osteoporosis Foundation International Society for Clinical Densitometry Michigan Consortium for Osteoporosis National Bone Health Alliance (US) National Osteoporosis Foundation (US) National Osteoporosis Society (UK) Northern California Institute for Bone Health, Inc. Orthopaedic Research and Education Foundation Orthopedic Research Society Orthopedic Trauma Association Osteoporosis Australia Osteoporosis Canada Osteoporosis New Zealand Syrian National Osteoporosis Society University of Rochester Department of Orthopaedics and Rehabilitation U.S. Bone and Joint Initiative 4BoneHealth

38 organizations as of March 28, 2017

# Call to Action to Address the Crisis in the Treatment of Osteoporosis

Here are the alarming facts on what is now being recognized by experts as a crisis in the treatment of osteoporosis:

### Osteoporotic fractures have serious health consequences:

- Around the world, 1 in 2 women and 1 in 5 men age 50 and above will suffer osteoporotic fractures.<sup>6,7,8</sup>
- Worldwide, osteoporosis causes more than 8.9 million fractures annually, resulting in an osteoporotic fracture every 3 seconds.9
- In the US, 8.2 million women and 2.0 million men age 50 and above have osteoporosis and 51.4 million women and 35 million men have low bone mass and are at a higher risk of fracture.<sup>9</sup>
- By 2050, the worldwide incidence of hip fracture is projected to increase by 310% in men and 240% in women, compared to rates in 1990.<sup>10</sup>
- In the US, hospitalizations for osteoporotic fractures accounted for 43% of combined hospitalizations for osteoporotic fractures, heart attack, stroke and breast cancer. Over 50% of the osteoporotic fracture hospitalizations were for hip fracture, the most devastating consequence of osteoporosis.<sup>2</sup>
- In the U.S., the number of hospitalizations for osteoporotic fractures (43%) exceeds those for heart attack (25%), stroke (26%) and breast cancer (6%). And over 50% of the fracture hospitalizations are for hip fractures.<sup>2</sup>
- There were two million fractures in the U.S. caused by osteoporosis in 2005, projected to reach 3 million by 2025.11
- All low trauma fractures are associated with increased mortality risk for 5 to 10 years after the fracture.<sup>12</sup> Mortality following a hip fracture is about 2-fold higher than expected even 10 years after the hip fracture.<sup>13</sup> Black women are more likely to die after their hip fracture than White women.<sup>14</sup>
- The worst consequences of osteoporosis can happen after a hip fracture. Up to 25% of hip fracture patients die within a year of their injury.<sup>11</sup>

### Fewer individuals at high risk for osteoporotic fractures are being treated:

- New evidence is emerging that the 30-year successful downward trend in hip fractures in the U.S. has hit a plateau in the last few years, indicating that fundamental progress in reducing fractures is being reversed.<sup>1</sup>
- In the U.S., Medicare reimbursement for office-based bone density tests was reduced by 70%, leading to 24% fewer physicians offering bone density testing when compared to 8 years ago and resulting in 2.3 million fewer DXA scans being performed on Medicare-age women. Between 2009 and 2014, osteoporosis diagnosis in Medicare women declined by 18%.<sup>1</sup>
- FDA approved treatments for osteoporosis reduce the incidence of spine and hip fracture by 40-70%.<sup>15-21</sup>
- Over the past decade, use of bisphosphonates following hospitalization for hip fracture has substantially decreased from 15% in 2004 to 3% in the last quarter of 2013.<sup>6</sup>
- The rate of patients in the U.S. age 50 and above on osteoporosis drug therapy after a hip fracture declined from 40.2% in 2002 to 20.5% in 2011.<sup>23</sup>
- More than 60% of patients in the U.S. who are prescribed bisphosphonates stop taking them after one year<sup>14</sup> (despite needing three years of continuous use to reduce the incidence of spine and hip fractures by 50 percent in those patients with a prior vertebral fracture or those who have osteoporosis at the hip).<sup>15</sup>
- The number of fractures that are prevented with treatment far outweighs the risk of atypical femur fractures (3.2 to 50 cases/100,000 person years) and osteonecrosis of the jaw (1 in 10,000 and 1/100,000).<sup>3</sup>
- Treatment of women with osteoporosis for up to 5 years would result in fewer than 1 atypical femur fracture caused per 100 osteoporotic fractures prevented.<sup>4</sup>
- In the European Union, the majority of high-risk individuals remain untreated. In 2010, of the 18.4 million women who were at high risk of fracture, 10.6 million were untreated. A conservative estimate finds a treatment gap that varies from 25% (Spain) to 95% (Bulgaria).<sup>25</sup>

- 1 Lewiecki EM 2016 Hip Fractures and Declining DXA Testing: At a Breaking Point? J Bone Miner Res 31 (Suppl 1).
- 2 Singer AJ, et al. Mayo Clinic Proceedings 2015. 90; 53-62.
- 3 Shane E, et al. Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Second Report of a Task Force of the American Society for Bone and Mineral Research. J Bone Miner Res, 2014 Jan;29(1):1–23.
- 4 Black DM, Rosen CJ. Postmenopausal Osteoporosis. N Engl J Med 2016; 374:254-262.
- 5 Kim SC, Kim DH, Mogun H, Eddings W, Polinski JM, Franklin JM, Solomon DH. Impact of the US Food and Drug Administration's Safety-Related Announcements on the Use of Bisphosphonates after Hip Fracture. J Bone Miner Res. 2016 31(8):1536-1540.
- 6 United States Public Health Service. Office of the Surgeon General. Bone health and osteoporosis : A report of the Surgeon General. Rockville, MD.: U.S. Dept. of Health and Human Services Public Health Service Office of the Surgeon General; 2004.
- 7 Kanis JA, Johnell O, Oden A, et al. (2000) Long-term risk of osteoporotic fracture in Malmo. Osteoporos Int 11:669.
- 8 Johnell O and Kanis JA (2006) An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporos Int 17:1726.
- 9 Wright NC, Looker AC, Saag KG, et al. The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. J Bone Miner Res. 2014;29(11):2520-6.
- 10 Gullberg B, Johnell O, Kanis JA (1997) World-wide projections for hip fracture. Osteoporos Int 7:407.
- 11 Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A Tosteson A. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025. J Bone Miner Res 2007. 22(3): 465-475.
- 12 Bliuc D, Nguyen ND, Milch VE, Nguyen TV, Eisman JA, Center JR. Mortality risk associated with low-trauma osteoporotic fracture and subsequent fracture in men and women. JAMA, 2009;301(5):513-21.
- 13 Abrahamsen B, van Staa T, Ariely R, Olson M, Cooper C. Excess mortality following hip fracture: a systematic epidemiological review. Osteoporos Int. 2009;20(10):1633-50.
- 14 Jacobsen SJ, Goldberg J, Miles TP, Brody JA, Stiers W, Rimm AA. Race and sex differences in mortality following fracture of the hip. Am J Public Health. 1992;82(8):1147-50.
- 15 Black DM, Cummings SR, Karpf DB, et al. Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures. Fracture Intervention Trial Research Group. Lancet. 1996;348(9041):1535-41.
- 16 Cummings SR, Black DM, Thompson DE, et al. Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial. JAMA. 1998;280(24):2077-82.
- 18 Harris ST, Watts NB, Genant HK, et al. Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. Vertebral Efficacy With Risedronate Therapy (VERT) Study Group. Jama. 1999;282(14):1344-52.
- 19 McClung MR, Geusens P, Miller PD, et al. Effect of risedronate on the risk of hip fracture in elderly women. Hip Intervention Program Study Group. N Engl J Med. 2001;344(5):333-40.
- 20 Black DM, Delmas PD, Eastell R, et al. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. N Engl J Med. 2007;356(18):1809-22.
- 21 Cummings SR, Black DM, Thompson DE, et al. Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial. JAMA. 1998;280(24):2077-82.
- 22 Melton LJ, 3rd, Atkinson EJ, O'Connor MK, et al. (1998) Bone density and fracture risk in men. J Bone Miner Res 13:1915.
- 23 Solomon DH, Johnston SS, Boytsov NN, McMorrow D, Lane JM, Krohn KD. Osteoporosis Medication Use After Hip Fracture in U.S. Patients Between 2002 and 2011. J Bone Miner Res. 29(9): 1929-1937.
- 24 Modi A, Siris ES, Tang J, Sen S 2015 Cost and consequences of noncompliance with osteoporosis treatment among women initiating therapy. Curr Med Res Opin 31:757-765.
- 25 Kanis JA, Borgstrom, Compston J, Drienhofer K, Nolte E, Jonsson L, Lems WF, McCloskey EV, Rizzoli R, Stenmark J. SCOPE: A Scorecard for Osteoporosis in Europe.