

**OSTEOPOROSIS: PREVENTION, EDUCATION,  
AND RESEARCH**

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**HEARING**  
BEFORE A  
SUBCOMMITTEE OF THE  
COMMITTEE ON APPROPRIATIONS  
UNITED STATES SENATE  
ONE HUNDRED FIFTH CONGRESS  
SECOND SESSION  
**SPECIAL HEARING**

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**WEDNESDAY, MAY 20, 1998**

U.S. SENATE,  
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN  
SERVICES, AND EDUCATION, AND RELATED AGENCIES,  
COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 12 p.m., in room SD-138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.  
Present: Senator Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

**STATEMENT OF DR. STEPHEN KATZ, DIRECTOR, NATIONAL INSTITUTE  
OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES**

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. The hearing will proceed. We are on a very tight time schedule. The Senate is considering the tobacco bill. We may have a vote, and it is very hard to reassemble, so I want to ask all the witnesses to come together. We customarily have witnesses up separately, but I want Ms. Black, Ms. Burdick, Mr. DiMaggio, and Dr. Singer to all join us at the witness table at this time, please.

The Subcommittee on Labor, Health, and Human Services has convened a special hearing to discuss osteoporosis and to explore the role the Federal Government can play in increasing research, education, and prevention efforts. Osteoporosis is a major cause of bone fracture in older persons in general and in women in particular. Over 28 million Americans are affected by this disorder, and medical costs reach \$13.8 million a year.

At this time there is no known cure. Recent developments have made it possible to identify those who are at risk so that treatment can begin to prevent bone thinning and reduce the incidence of fractures.

We are delighted to have this very distinguished panel of witnesses. We regret that Mrs. Barbara Sinatra could not be with us today due to the death of Mr. Frank Sinatra over the weekend, and there has been a state of national mourning, which we all know about, but her testimony will be presented by Dr. Fred Singer.

Our time is limited, so we would ask each witness to keep within the 4-minute rule for making their opening statements, and thank you very much, Dr. Katz, for being with us today. Dr. Katz is the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

You have been serving in that capacity since 1995, and we have tried to increase the funding as much as we could. We are going to try again this year, and we look forward to your testimony with particular emphasis on what it will take to find the answer.

Dr. Katz, the floor is yours.

#### SUMMARY STATEMENT OF DR. STEPHEN KATZ

Dr. KATZ. Let me start by thanking you for all of your efforts in past years. It is an honor and privilege to speak with you today as director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and to represent the efforts of the many NIH institutes centers and offices and other Federal agencies that have an interest in and support research on osteoporosis and related disorders.

Osteoporosis is the most prevalent of the bone diseases that affects Americans. It represents a thinning of bone and architectural abnormalities that contribute to bone fragility and increased fracture risk. A fracture is not a benign condition. It is not a benign event.

For example, following hip fracture, 10 to 20 percent of patients die during the next 6 months, 50 percent of people are unable to walk without assistance, and 25 percent require long-term care.

Unfortunately, osteoporosis is common, particularly in women. That means that osteoporosis is a threat to more than 28 million Americans. Although women are far more vulnerable to osteoporosis, men are not immune. They represent 20 percent of the affected population.

I would like to provide a brief glimpse and highlights of how far research has brought us in understanding osteoporosis. It is only in the last 15 years that we have come to understand that the normal development in structure and function of bone depends on a delicate balance between cells that build up bone and cells that break down bone. We know that this delicate balance depends on many factors, including genetic, environmental, exercise, nutritional—for example, like calcium intake and vitamin D—and hormonal factors such as estrogens, parathyroid hormone, calcitonin, and others. When the balance goes awry, that is when we have problems. There is a loss of integrity in bone that results in diseases such as osteoporosis and that makes one more vulnerable to the fractures.

Federal research efforts are multipronged and are directed at a better understanding of the basic biology of bone. Examples include laboratory and animal studies, genetic studies to identify risk factors, clinical and epidemiological research to identify better diagnostic tools and risk factors for osteoporosis and fractures, and education research to better understand how to translate knowledge into behavioral change.

There is a major effort to optimize calcium intake across our Nation, including, and very importantly, in young people. Key calcium

metabolic studies are being supported by the institute in adolescents to identify optimal daily calcium intake. In addition long-term studies in nuns are being conducted to see how hormones and how calcium intake alters bone integrity.

The identification of risk factors to hip fractures is important because preventive measures can be implemented. Prominent and modifiable risk factors were identified in a large cohort of female patients involved in a study of osteoporotic fractures. These risk factors include poor visual acuity, excessive weight loss, lack of exercise, and use of some medications. These are all factors we can actually do something about.

Another important ongoing effort is the development of inexpensive and accessible tools such as quantitative ultrasound for assessing skeletal health, because we know that we have treatments now that really work. These treatments include estrogens, bisphosphonates, calcitonin, as well as the recently introduced SERM's, the selective estrogen receptor modulators.

Prevention of osteoporosis is the goal, and it is key to reducing fracture risk. The window of opportunity to add bone to the skeleton is limited. This means that educational strategies to encourage adequate calcium intake and regular exercise, and to discourage smoking, while extremely important at all ages, are particularly critical in children and in adolescents.

During the past 4 years, we have supported the Osteoporosis and Related Bone Diseases National Resource Center that is currently operated by the National Osteoporosis Foundation in partnership with the Paget Foundation and the Osteogenesis Imperfecta Foundation.

Information on prevention, early detection, treatments, and coping strategies are disseminated widely through various media. We have also collaborated with the Public Health Service Office on Women's Health and the National Osteoporosis Foundation to enhance strategies to promote bone health in women. The first focus of this collaboration will be on adolescent teenage girls.

In closing, I hope that I have increased the committee's awareness of the tremendous progress we have made in research in understanding the fundamentals of bone biology and how to prevent and treat osteoporosis. Our objective over the next decade is to continue to promote research in all aspects of osteoporosis and related bone diseases. The goals are to reduce the burden of disability and enhance the lives of people who suffer from osteoporosis, and to prevent this and other musculoskeletal diseases in others.

#### PREPARED STATEMENT

I would ask that the written testimony of Dr. Wanda Jones on behalf of the Public Health Service, Office on Women's Health, be submitted for the record at this time, and I would be happy to answer any questions you may have.

Senator SPECTER. We will accept her statement for the record, and your full statement will be made a part of the record.

[The statements follow:]

## PREPARED STATEMENT OF DR. STEPHEN I. KATZ

Mr. Chairman and Members of the Subcommittee, I am Dr. Stephen Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the lead institute at the National Institutes of Health (NIH) for research on osteoporosis and related bone disorders. I am pleased to have this opportunity to testify before you today to highlight recent research advances and opportunities that relate to osteoporosis and related bone diseases and to the enhancement of bone health in general. I would like to leave you today with knowledge of how far research has brought us in understanding this disease and in providing us with critical clues about how to prevent this disease from impacting our lives and the lives of our families and friends. Osteoporosis does not need to be a consequence of aging. It is largely a preventable disease, and many research opportunities exist to enhance our knowledge about how to maintain a healthy skeleton throughout our lives.

Osteoporosis is the most prevalent of the bone diseases that affect Americans. It results in low bone mass and architectural abnormalities that contribute to bone fragility and increased fracture risk. Although it is the underlying cause of most fractures in older people, the condition is silent and undetected in most cases until a fracture occurs. A fracture is not a benign event, particularly in older people. The major fracture sites associated with osteoporosis are the hip, the spine, and the wrist. Of all the injury sites, hip fractures have the greatest morbidity and socio-economic impact. Following a hip fracture, there is a 10–20 percent mortality rate during the next 6 months. This means people can and do die as a result of hip fractures. Fifty percent of those people experiencing a hip fracture will be unable to walk without assistance, and 25 percent will require long-term care.

Recently we gained insight into how many Americans are affected by osteoporosis through the National Health and Nutrition Examination Survey (NHANES). Conducted from 1988 to 1994, this survey measured the bone mineral density of a sample population across the United States and indicates that osteoporosis and low bone mass are common. For women, estimates indicate that 13 to 18 percent over the age of 50 have osteoporosis of the hip, and another 37 to 50 percent have low bone mass placing them at increased risk for developing osteoporosis as they age. Conservatively, this means that osteoporosis is a threat to more than 28 million Americans. The percentage of men affected is lower but still adds up to millions of men at risk of fractures. Although white women account for 75 percent of the approximately \$14 billion cost of fractures in the United States, men and minority women are substantially vulnerable. The development of prevention and therapeutic strategies is critical given the impact of this problem in the United States.

Women are particularly vulnerable to getting osteoporosis. In the United States, women are four times as likely to develop osteoporosis as men. This is attributable to two factors: women have approximately a 10 percent lower peak bone mass by maturity, and they experience an accelerated bone loss after menopause. Although African American women have a considerably lower rate of osteoporosis and fractures, the NHANES data indicate that 10 percent of African American women over 50 have osteoporosis and 29 percent have low bone mass. While men are at a lower risk for osteoporosis than women, they are not exempt from this disease.

A great many research studies in osteoporosis and related bone diseases are underway at the NIH. In addition to the NIAMS, 13 other institutes, centers, and offices at the NIH are involved in research on osteoporosis and related bone diseases ranging from very basic studies to early intervention and prevention projects to clinical and translational research. Studies being conducted range from investigations of the causes and consequences of bone loss at cellular and tissue levels to clinical trials testing strategies to maintain and even enhance bone density. Evaluation of skeletal status is of major concern as scientists explore the roles of such factors as hormones, calcium, vitamin D, drugs, and exercise on bone mass. The influence of environmental factors (e.g., cadmium, lead, and boron) is also being examined.

Each NIH institute, center and office comes to the study of osteoporosis and related bone diseases from the vantage point of its individual and different mission. These efforts are both collaborative and complementary. For example, the NIAMS supports research across the spectrum from basic studies that are attempting to understand the normal functions of cells that build up and break down bone to clinical studies of the diagnosis, treatment, prevention, and epidemiology of osteoporosis and related bone diseases. The NIAMS bone biology and bone diseases programs not only provide improved understanding of osteoporosis, but also of other bone diseases such as Paget's disease, osteogenesis imperfecta, cancer metastasis to bone, and multiple myeloma. The National Institute on Aging (NIA) has unique lines of research that are derived from its mission to understand the aging processes and

pathological changes that cause disability and compromise the quality of life in older people. The NIA supports a strong program of clinical studies of age-related bone loss and fracture epidemiology, intervention trials to prevent or reverse bone loss, and basic research studies on bone cell biology and the role of sex steroids, cytokines, and growth factors on bone cell function. NIA, in conjunction with the National Institute of Nursing Research (NINR) and the NIH Office of Research on Women's Health (ORWH) supports a large multi-ethnic longitudinal study of women, aged 42–52 years, at five clinical field sites to evaluate mid-life changes on bone loss and the risk of osteoporosis as women approach and traverse the menopause. The National Institute of Dental Research (NIDR) supports a strong basic bone biology program with a focus on the connection between oral bone loss and osteoporosis. The NIDR also has an intramural program that researches normal bone growth and turnover as well as the pathophysiological mechanisms of brittle bone diseases, including the hereditary disease osteogenesis imperfecta. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) provides support for research on nutrition and endocrinology, including the hormones regulating bone metabolism. The National Institute of Child Health and Human Development (NICHD) supports research to enhance understanding of how to prevent this disease by influencing the behaviors of children in such areas as diet and exercise, and supports studies in reproductive endocrinology and the possible impact of hormones and reproductive history on the etiology of osteoporosis. In addition, through the NICHD intramural program, studies are conducted on the genetics, growth, and rehabilitation of children with heritable disorders of connective tissue such as osteogenesis imperfecta. The National Institute of Environmental Health Sciences (NIEHS) research focuses on metals such as cadmium, lead, and boron found in the environment as risk factors in development of the disease. The NIH Office of Research on Women's Health has made a vital contribution to osteoporosis research through supplemental grants and the Director's leadership role in the Women's Health Initiative (WHI). The WHI project is led by the National Heart, Lung, and Blood Institute and coordinated with the NIAMS, the NIA, and the National Cancer Institute. This project contains the largest test of the effect of hormone replacement therapy and calcium and vitamin D supplementation on osteoporosis.

Osteoporosis and related bone diseases are complex, and their study reflects a multiplicity of interests. To provide coordination and to enhance cooperative research and education activities across agencies, the NIAMS launched the Federal Working Group on Bone Diseases (FWGBD) in 1993. As Director of the NIAMS, I chair the FWGBD, whose membership includes not only representation from the NIH institutes, centers and offices, but also other Federal agencies including the Agency for Health Care Policy and Research, the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), and the Public Health Service (PHS) Office on Women's Health. I have attached to my statement a list of all NIH components and Federal agencies represented on the FWGBD. The FWGBD meets regularly throughout the year and provides a structure for information sharing, formulation of collaborative research efforts, and coordination of osteoporosis research across all Federal agencies with an interest in bone diseases and bone health.

Outside of the DHHS, the NASA and the DOD have supported osteoporosis and related bone diseases research over the past several years. The NASA's interests relate to what happens to bone in a reduced-gravity environment. The depletion of bone and muscle while in space is a significant risk to astronauts. Exposure to reduced gravity during space travel profoundly alters the load placed on bone and muscle, and thereby has direct effects on the tissues. The DOD initiated an osteoporosis program in 1995, and this expanded in 1997 with grants solicited in the area of mechanical stimulation of bone growth, focussing on military preparedness in a physically active population. The NIAMS program and review staff helped with the planning of the solicitation of application and with their review.

With this as background on the importance of a broad multipronged approach to targeting osteoporosis and related bone diseases, I would like to focus my remaining testimony on research highlights, advances, and opportunities. Specifically I will address (1) the importance of identifying prevention, early intervention, and assessment/diagnostic tools to reduce the prevalence of osteoporosis; (2) recent breakthroughs in basic research leading to improved understanding of bone formation and the role genetics in predisposing one to osteoporosis, (3) the status of treatments for this disease; and (4) a summary of exciting research opportunities.

## IMPORTANCE OF PREVENTION, EARLY INTERVENTION, AND ASSESSMENT TOOLS

*Prevention of Osteoporosis Through Diet and Physical Exercise*

This is an exciting time for research related to osteoporosis and bone health. There has been a revolution in thinking about osteoporosis over the last decade. The most significant insight comes from the recognition that osteoporosis and fractures are not a natural consequence of aging. NIH support for clinical studies of nutrition and physical activity interventions has provided strong evidence that fractures can be prevented and bone loss reduced even in older individuals. We have learned a great deal about the need to build bone across the life span, beginning at a very young age. Most significantly, we have learned that rapid bone acquisition occurs before, but also at and after puberty, and this period is crucial in skeletal development and critical for the prevention of osteoporosis later in life.

This past August, the Institute of Medicine (IOM) completed a study of calcium and related nutrients. The goal was to provide an update of the dietary information published in 1989 as the Recommended Dietary Allowances (RDA's). This IOM study follows and in many ways parallels the successful 1994 NIH Consensus Development Conference on Optimal Calcium Intake. Key calcium metabolic studies supported by the NIH made it possible for the Consensus Conference and the IOM to approach the issue of optimizing calcium intakes, not only to prevent deficiency diseases, but to build a better skeleton and to preserve it throughout life.

The primary data used for setting adequate intakes for children 9 through 18 years of age are derived from careful and innovative metabolic studies estimating the intakes necessary to achieve maximal calcium retention in the body. The NIH has supported several studies of calcium in young girls. In one such study, young girls have attended "Camp Calcium" where careful calcium balance studies that require several weeks to be completed are carried out on the Purdue University Campus in a sorority house where the girls have fun and see how scientists work.

Understanding the role of calcium absorption and vitamin D intake in pre- and postmenopausal women is also extremely important to maximizing bone health later in life. Critical long-term studies with a major impact on the field of calcium nutritional physiology have been conducted with NIH support that began in the late 1960's. Investigators have followed a cohort of Catholic nuns for more than 30 years from early premenopause up through their early seventies, thus far. Results emanating from the "Nuns' Study" have described the changes in calcium balance with age, hormone status, and vitamin D intake and have also contributed to our understanding of calcium absorption from different food sources (milk vs. vegetables) and from different types of supplements. This study and others indicate that adequate calcium intake may prevent bone loss, decrease the prevalence of osteoporosis, and prevent fractures in the elderly.

While the progress to date has clearly been impressive, the story is not complete. The largest study of osteoporosis and fractures ever conducted is now underway as part of the NIH Women's Health Initiative. Hip fractures are the most devastating consequence of osteoporosis, but testing the effectiveness of calcium and vitamin D in preventing hip fractures requires a large number of women over a long period of time (8 years). This study will determine what can be achieved with calcium and vitamin D supplements and may lead to new public health initiatives to optimize the intake of these nutrients in the U.S. population.

*Identification of Risk Factors for Hip Fractures in Women*

The NIAMS and the NIA cooperatively support the Study of Osteoporotic Fractures (SOF), a study that followed more than 9,000 women for over 10 years in order to determine what risk factors are associated with hip fractures and especially which ones are preventable. Results of this study have shown that one in every six white woman will have a hip fracture in her lifetime; thus identifying preventable risks can make an enormous impact on preventing disability in older women. Some prominent and modifiable risk factors identified in this study that increase the chance of hip fracture are poor visual acuity, especially poor depth perception and contrast sensitivity; weight loss after age 25; more than two cups of coffee a day; no walking for exercise; being on one's feet less than 4 hours a day; and the use of some medications such as long-acting benzodiazepines and anticonvulsant drugs. Clearly an increase in physical activity, an eye checkup and a review of medications can do a lot to prevent hip fractures.

*Identification of Risk Factors for Hip Fractures in Men*

Although 50-year-old white men have about a 13 percent lifetime risk of fractures of the hip, spine, or wrist, the causes of and mechanisms involved in osteoporosis in men have received little research attention to date. Men develop osteoporosis and

osteoporotic fractures about a decade later than women do. This has been attributed to a higher peak bone mass at maturity and a more gradual diminution in sex steroid influence in aging men. At each age, the rate of hip fracture in men is about 50 percent that in women. With the decline in premature cardiovascular mortality in men, fractures later in life are becoming an increasingly important cause of morbidity and mortality in older men. In a recent study, risk factors thought to affect bone density (weight, smoking, physical activity, some drugs) as well as factors identified as risk factors for falls (lower limb dysfunction, psychotropic drugs) appear to be important determinants of the risk of hip fracture in men. Physical activity may be a particularly promising preventive measure for men and can favorably influence other chronic diseases such as heart disease.

#### *Assessment and Diagnostic Tools*

As new treatment strategies become available, it becomes critical to be able to assess skeletal health to identify those in need of intervention as well as to determine the effectiveness of particular treatments. The development of new technology to measure bone mineral density as well as bone quality is an active focus of research. Ultrasound technology is emerging as an alternative to bone densitometry for some clinical applications. It is faster, cheaper, and without the radiation exposure of conventional bone densitometry devices. Studies are also underway to develop blood and urine tests that may one day be used to screen for osteoporosis.

#### *Prevention Through Public Education Campaigns*

As stated many times throughout this testimony, prevention of osteoporosis is the key to reducing the risk of this disease for men and women in later life. Because the window of opportunity to add bone to the skeleton is limited, educational strategies are extremely important, for example, encouraging calcium intake by children and adolescents at the recommended levels and encouraging regular exercise. Likewise, strategies to encourage regular exercise, especially weight-bearing activities, discourage smoking and limit alcohol consumption across the life span are important to maintaining optimal bone health. Equally important are educational strategies designed to inform those most at risk of developing osteoporosis of the modifiable risk factors and available diagnostic tools so that early intervention is possible.

The NIAMS supports the Osteoporosis and Related Bone Diseases—National Resource Center (ORBD–NRC). The Center is currently operated by the National Osteoporosis Foundation (NOF) in partnership with The Paget Foundation and the Osteogenesis Imperfecta Foundation under a grant from the NIAMS. The Center provides patients, health professionals, and the public with resources and information on osteoporosis and related bone disorders. Information on prevention, early detection, treatments, and coping strategies is disseminated widely through publications, online services, professional and patient meetings, and general media outreach. The NIAMS, along with several other NIH institutes including the NIA, the NICHD, the NIDR, the NIEHS, and the Office of Research on Women's Health, has issued a Request for Applications (RFA) inviting applications to continue support for such a center.

The NIAMS has collaborated with the PHS Office on Women's Health, the NOF through the Osteoporosis Resource Center and the Centers for Disease Control and Prevention (CDC) to enhance the strategies to promote bone health for women. The National Osteoporosis Education Campaign will first focus on 9–12 year old girls, just approaching their peak bone building years, but as the campaign develops, it will expand to cover 13–18 year old girls. The goal is to develop strategies for effectively reaching this age range so as to influence life-long healthy bone behaviors.

"Milk Matters" is another public health campaign led by the NICHD. It is designed to increase calcium consumption among children and teens. Studies show that most kids are not getting adequate levels of calcium during this critical period when bones grow and incorporate calcium most rapidly. The "Milk Matters" campaign works to reach children and teens, as well as parents and health care professionals, with the message that increased calcium and weight-bearing exercise during the first two decades of life can be critical to good health as an adult.

### BASIC RESEARCH ADVANCES

#### *Bone Formation and Breakdown*

Treatments for osteoporosis and further information on preventive strategies for osteoporosis and related bone diseases will come from basic studies on understanding the genetics of bone formation and the process of bone loss and remodeling. Bone is constantly being built up and broken down. As evidenced by what has been learned about the role of calcium, we try to build bone up as much as possible with calcium in the early years because this serves as a storage bank for later years. En-

hancement of cells that build bone (osteoblasts) and interference with cells that break down bone (osteoclasts) tend to result in sturdier bones. All of our achievements and future progress in osteoporosis and other bone diseases, such as Paget's disease and osteogenesis imperfecta, are based on understanding the normal functions of bone cells and investigating strategies to manipulate the normal physiology of bone for therapeutic advantage. Likewise, new insights into the control of bone remodeling by bisphosphonates (chemicals that block resorption of bone) have led to approaches to controlling the skeletal complications of malignancy.

#### *Genetics of Bone Formation*

In an exciting convergence of efforts by investigators around the world, a gene essential for the formation of bone has been identified. Researchers made two key observations: First, mice in which both copies of the "Cbfa1" gene have been inactivated exhibit a complete lack of bone and bone-forming cells and die at an early age. Thus, the "Cbfa1" protein appears to function as a "master switch" for bone formation. Second, mice in which one of the two "Cbfa1" genes was inactivated exhibited a combination of specific skeletal defects that closely resembled those seen in a heritable human disorder called cleidocranial dysplasia, which is characterized by defective bone formation. Consistent with this evidence from mice, genetic studies in families with cleidocranial dysplasia showed that the disorder is associated with mutations in the human "Cbfa1" gene. Thus, in order for normal skeletal development to occur in both mice and humans, the "Cbfa1" protein must be present in amounts that can be provided only by two active copies of the gene. The discovery of the critical role of "Cbfa1" in bone formation opens a number of exciting new research areas.

Understanding the role of genetics in predisposing one to osteoporosis is a very important area of research. Bone mass at any point in life represents a balance between the amount of bone accumulated during growth and development and the amount of bone lost with aging. Studies using families, particularly twins, indicate that bone mass and osteoporosis may be due to an inherited trait in some families. Resolving the genetic underpinnings of a complex trait in humans is difficult, because human populations are genetically diverse. Thus, current efforts include studies of the genetics of bone mass in animals such as mice, in which selective breeding can reduce the complexity of the problem. Because both bone metabolism and genetic organization exhibit parallels across mammalian species, it is expected that the results of the animal studies will provide important guidance to further efforts in human populations.

Several human candidate genes have been examined for their regulatory effect on bone mass including those for collagen type I, estrogen and vitamin D. A great deal of work has focused on the vitamin D receptor (VDR) gene, and experience with this locus will probably act as a model for many future studies. There is increasing evidence of a complex interaction between this gene and environmental factors in the regulation of bone mass. Moreover, it is clear that bone mass and density are influenced by many genes (mostly unknown) and a complex interaction with environmental factors such as nutrition and physical activity.

#### *Interactions of Bone and the Hematopoietic and Immune Systems as Consequences for Skeletal Health*

Bones are not only a crucial mechanical support for our bodies, they also enclose the bone marrow, the site of the process called hematopoiesis, in which blood cells are produced, including the many different cells of the immune system. Interactions among bone cells, hematopoietic cells, immune cells, and other cells of the marrow environment can have important consequences for skeletal health. In August of 1997, the NIAMS and several other NIH components sponsored a scientific workshop entitled "Bone and the Hematopoietic and Immune Systems" that brought together over 200 bone biologists, hematologists, immunologists, and physicians for 2 days of scientific presentations and discussions. As a result, a number of areas have been identified in which further research seems especially important. Future efforts seem likely to be particularly rewarding if they can either clarify the importance of specific cell types and effect or molecules or identify previously unrecognized cellular and molecular agents that influence bone physiology. Examples of important areas of pursuit include (1) the determination of mechanisms that regulate the differentiation of different bone cell types, including the nature of stem cells and factors that govern their development, and (2) the identification of other bone marrow cell types, such as hematopoietic cells and stages of lymphoid and myeloid differentiation, that may influence bone cells. The development and application of treatments for conditions of bone loss, such as osteoporosis and for rarer conditions of bone formation, depend upon a thorough understanding of the factors that control

the breakdown and formation of bone. It is likely that bone cells do not function in isolation, but instead respond to a complex mixture of influences arising in part from immune, hematopoietic, and stromal cells. Understanding these influences may identify targets for new bone-active agents, and may help to explain the complex effects of agents already in use.

#### TREATMENTS FOR OSTEOPOROSIS

Although there is no cure for osteoporosis, there are now several effective therapies to help stop further bone loss and potentially prevent future fractures. Studies have shown that estrogen can prevent the loss of bone in postmenopausal women; however, many questions remain about the effect of estrogen on other tissues in the body. The questions about estrogen have led to the development of a new class of drugs called Selective Estrogen Receptor Modulators (SERM's). The hope is to produce a drug with all the positive effects of estrogen on bone and lipids and not to stimulate the activity of the breast or the uterus. Tamoxifen is a SERM that has recently been shown to reduce the risk of breast cancer in women at high risk. Another SERM, raloxifene has recently been approved by the Food and Drug Administration (FDA) for the prevention of osteoporosis.

Alendronate, a bisphosphonate, has recently been approved by the FDA for treatment of postmenopausal osteoporosis. This class of drug targets bone specifically, reducing bone breakdown and decreasing fractures in older women. These are very promising avenues of development and will undoubtedly lead to even more choices for postmenopausal women.

NIH-supported studies of the underlying pathophysiologic mechanisms of bone loss and remodeling as well as the development of animal and cellular models, have made new drug approaches possible. These approaches are crucial to determine the underlying mechanisms of action of drugs and to devise alternative therapies. In recent research results investigators have shown that estrogen induces programmed cell death in osteoclasts which are responsible for the degradation of bone. This discovery opens up an exciting new avenue of research opportunities for investigators to explore whether other drugs can also affect the programmed cell death of osteoclasts, making them potentially useful as bone-protecting treatments.

#### RESEARCH OPPORTUNITIES

Numerous research opportunities exist to alter the increasing occurrence of osteoporosis. In the past decade, there has been an explosion of fundamental and clinical research in osteoporosis. Large epidemiological studies have identified risk factors for low bone mass and fractures. Clinical studies have pointed to the efficacy of calcium and vitamin D supplementation in a subset of elderly women, and physical activity has been associated with decreased bone loss and improved musculoskeletal stature and balance. There are many fundamental advances in molecular and cellular biology, immunology, genetics, and bioengineering that have not yet been applied to skeletal biology. Many opportunities exist to build on and expand the current knowledge base.

##### *Basic Research*

Details are beginning to emerge about the complex network of signaling mechanisms that control bone growth and maintain skeletal integrity. Specific probes have made it possible to identify new molecules responsible for the local and systemic regulation of bone cell function, as well as the cell surface molecules and linked signal transduction pathways that mediate their effect. Research opportunities exist to better understand osteoclasts and osteoblasts, cells that are essential for bone remodeling. Furthermore, the complex relationship between the bone microenvironment and the immune system demands attention. Evidence is accumulating to indicate that regulation of the immune system operates on common principles and employs common effectors.

The identification, mapping, and structural analysis of genes with crucial functions in the regulation of bone are increasingly feasible research goals. The use of genetically manipulated animals allows investigators to test the effects of specific gene inactivation or overexpression. The identification of genetic variations in the human population that underlie different vulnerabilities to bone loss is made possible by the increasing knowledge of the human genome and advancing molecular screening technology. While several candidate genes have been identified in osteoporosis, the complete picture will require both human and population genetics and further animal studies. The study of the genetics of osteoporosis is likely to yield insights into the pathophysiology of the disease and clues for targeting interventions.

*Behavior Modification and Education Research*

Translating knowledge to behavior change is extremely difficult. While current evidence indicates that there are effective dietary, exercise, and lifestyle guidelines that one can follow to increase peak bone mass and promote long-term bone health, translating this message into changed behavior is a challenge. Research targeted at identifying promising health education approaches that enhance awareness and knowledge for young and adolescent females is needed. Similarly, education messages targeted to postmenopausal women that identify risk factors, promote regular exercise and physical activity, and discuss intervention and treatment strategies are critical as well.

*Improved Diagnostic and Assessment Tools*

The establishment of new diagnostic procedures that provide insight into the structural defects in diseased bone and allow a means to assess bone strength is an important area of research. Currently, the approaches to the assessment of osteoporosis are largely limited to measurement of bone density, for example, dual energy x-ray absorptiometry (DXA). While these methods are good predictors of future fractures, they do have their limitations in accuracy and precision. One significant limitation is that they do not provide insight to the underlying abnormalities in osteoporotic bone. Bone mass and architecture together determine the resistance of bone to fracture. New technologies are being developed to evaluate the contribution of architecture *in vivo*. These new methods may include variations of micro-computed tomography or magnetic resonance imaging (MRI) techniques.

One alternative diagnostic technique recently approved by the FDA is ultrasound. With ultrasound, different properties of bone can be measured, reflecting mechanical quality, an important determinant of bone strength. Biochemical markers of bone turnover offer yet another technique for assessment of osteoporosis. These measurements may add to the ability to assess the pathophysiological basis for the disorder and the effects of therapy. However, biological variability limits the utility of these measures to population screening, and they are not yet applicable to detailed evaluation of an individual patient.

*New Improved Treatments*

Bisphosphonates that target bone and reduce bone loss and fractures have been approved for osteoporosis treatment and prevention. These new agents may also have promise in reducing the skeletal complications of malignancy. Estrogen replacement therapy has been clearly shown to effectively retard bone loss in postmenopausal women. However, it has effects on multiple organ systems and is not without risk. The new selective estrogen receptor modulators that have been developed appear to lessen bone loss in postmenopausal women without the adverse effects on other organs. Fundamental research on estrogen receptors and their target organs fuel the development of these new agents.

In closing, I hope that I have increased the Committee's awareness of the tremendous progress we have made through research in understanding the fundamentals of bone biology and how to prevent and treat osteoporosis. Our objectives over the next decade are to stimulate new fundamental research, to translate advances in other fields to bone biology, to move basic/fundamental research to clinical application, to enhance the uptake of research knowledge by the public, especially the population most at risk of osteoporosis, and to apply this knowledge to develop effective preventive strategies. Our goal in osteoporosis and other musculoskeletal diseases that are our research focus is to reduce the burden of disability and enhance the lives and contributions of the populations who suffer from these chronic musculoskeletal disorders.

I would be happy to answer any questions that you may have regarding osteoporosis research.

FEDERAL WORKING GROUP ON BONE DISEASES

FEDERAL MEMBER ORGANIZATIONS

*National Institutes of Health*

National Institute of Arthritis and Musculoskeletal and Skin Diseases  
 National Institute of Child Health and Human Development  
 National Institute of Environmental Health Sciences  
 National Institute of Diabetes and Digestive and Kidney Diseases  
 National Cancer Institute  
 National Institute of Dental Research  
 National Institute on Aging  
 National Institute of Nursing Research

National Institute on Alcohol Abuse and Alcoholism  
 National Center for Research Resources  
 Office of Research on Women's Health

*Other Federal Agencies*

Agency for Health Care Policy and Research/Forum for Quality and Effectiveness of Health Care

Health Care Financing Administration/Office of Research and Demonstration

Department of Agriculture/Human Nutrition Research Center

Department of Defense/Army Operational Research Program

Centers for Disease Control and Prevention

—National Center for Chronic Disease Prevention and Health Promotion

—National Center for Health Statistics

Food and Drug Administration/Division of Metabolism and Endocrine Drug Products

Department of Education/National Institute on Disability and Rehabilitation Research

National Aeronautics and Space Administration/Life and Biomedical Sciences Applications Division

*Liaison Organizations/Federal and Non-Federal*

NIH Office of Disease Prevention

NIH Clinical Center Nursing Department

NIH Nutrition Coordinating Committee

Department of Health and Human Services

—Office on Women's Health

—Administration on Aging

Osteoporosis and Related Bone Diseases National Resource Center

National Osteoporosis Foundation

The Paget Foundation

American Society for Bone and Mineral Research

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PREPARED STATEMENT OF DR. WANDA K. JONES, PUBLIC HEALTH SERVICE, OFFICE ON WOMEN'S HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I am delighted to have an opportunity to provide information on the National Osteoporosis Educational Campaign; a public/private informational campaign designed to improve the quality of life and reduce health care costs for America's aging population.

At least 25 million Americans are afflicted with osteoporosis, most of them women. Osteoporosis robs bones of their mineral and organic reinforcements, decreasing bone density and increasing susceptibility to fractures. It is a major underlying cause of bone fractures in older women, often taking away their independence at a time they should be enjoying life. Women with bone fractures can even die from surgery-related complications, with a reported mortality rate of 20 percent in the first post-surgery year for women.

We are lucky to live in a time with new medications that can help prevent or treat osteoporosis. Even so, this disease leads to 1.5 million fractures a year, mostly in the hip, spine and wrist, and costs \$10 billion annually.

Much of the pain, suffering and costs associated with osteoporosis could be avoided if women would take preventive measures early in life. Current evidence indicates that young women can increase their peak bone mass, promote long-term bone health, and reduce the risk of disease later in life by following effective dietary, exercise, and lifestyle practices. Yet we have so far not been able to effectively communicate this prevention message to young women. Studies show that less than 25 percent of adolescent females get the required daily allowance of calcium; the prevalence of smoking among female high school seniors now exceeds that for their male counterparts; over 18 percent of all adolescent females in a recent survey had used alcohol in the preceding month; vigorous physical activity was significantly less common among female high school students than among male students; and 95 percent of anorectic and bulimic patients were adolescent females.

In September, 1996, the U.S. Public Health Service's Office on Women's Health (PHS OWH) convened a task force to design a blueprint for a national osteoporosis education campaign. The Task Force recommended that getting osteoporosis prevention messages to the 13 to 18 year old group should be a priority. These are the years appear when girls begin making their own decisions about diet, smoking, exercise and leisure activities, and start shifting away from their parents' advice to their peers and the popular media. These are also the years when girls are on the verge

of accruing 90 percent of peak bone mass. The National Osteoporosis Foundation (NOF) and the Osteoporosis and Related Bone Diseases National Resource Center (ORBD-NRC) subsequently recommended that girls ages 9–12 years also be included in this project and these organizations have joined with the PHS OWH to develop this educational initiative.

Research reveals that selecting effective health education approaches and messages for adolescent females is far from simple. So, prior to developing and implementing health education programs targeted to adolescent females, the PHS OWH, NOF, ORBD-NRC, and the National Institutes of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) felt it was necessary to conduct a study to determine how to reach adolescent females with prevention messages. This study was designed to identify effective health education approaches and apply the lessons of practical experience to meet health education objectives for target populations.

There were several key strategies used to collect data. First of all, an exhaustive search was conducted of the published literature using online databases such as Medline to gather findings on adolescent females' knowledge, attitudes, and practices concerning bone health and the prevention efforts aimed at this population. Secondly, a questionnaire was prepared to use in interviews with representatives of organizations that have developed messages and implemented programs for adolescent females, including the NHLBI Education Programs Information Center, the National Maternal and Child Health Clearinghouse for Alcohol and Drug Information, Girl Scouts of the USA, Future Homemakers of America, Inc., and Girls Clubs of America. Thirdly, baseline data was gathered on adolescent females' knowledge of bone health and its relative importance to them. And finally, adolescent and young women representing diverse population groups ages 9 to 18 were recruited for focus groups to solicit and explore their responses to prepared questions concerning their knowledge of bone health and preferred prevention messages, approaches, and channels.

The principles, patterns, and criteria for developing message content, designing effective approaches, selecting and using channels, and addressing adolescent populations were identified. Apparent gaps in the knowledge base and any conflicting findings were also highlighted.

From the findings of this study, the PHS OWH is collaborating with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the NOF to establish a national education campaign on osteoporosis to increase bone healthy behaviors of women and their understanding of the importance of bone health. Attention will first be placed on 9–12 year old girls, just approaching their peak bone building years, but as the campaign develops, it will expand to cover 13–18 year old girls. An interesting finding of this recent study is that it is important to make efforts to change the behaviors of parents, who are critical role models on these issues for pre-teens. Thus, parents will also be targets of an expanded educational program.

The PHS OWH, NIH, CDC, and NOF would like to see significant strides made to reverse the current trend in teen health so that there is a marked increase in physical activity, a greater consumption of calcium among 9–18 year olds, and adoption of other healthy lifestyle behaviors associated with bone health. We believe a long term national campaign can help effect these changes and are committed to working with our collaborators to ensure that this educational program can continue past the initial year of funding provided by the PHS OWH.

In the past century, we have done much to increase the life expectancy of women. As a result, in the next century we will see a significant increase in the number of older women in our population. We must use visionary, long-term strategies to ensure that these bonus years for women are fruitful, rewarding and comfortable. Only by preparing women in their pre-teen and teen years for a lifetime of good health will we achieve that goal.

## NONDEPARTMENTAL WITNESSES

### STATEMENT OF JUDY BLACK, MEMBER, BOARD OF TRUSTEES, NATIONAL OSTEOPOROSIS FOUNDATION

Senator SPECTER. I will have some questions as we move through, but I would like to turn now to our next distinguished witness, Ms. Judy Black, who currently serves on the board of the National Osteoporosis Foundation, chairperson of that group's event, America Walks For Strong Women.

She is also senior vice president for governmental relations for Ticketmaster, and a very, very able advocate for many causes, including osteoporosis, and the principal exponent of this hearing.

Ms. Black, the floor is yours.

Ms. BLACK. Thank you, Senator, and on behalf of NOF and millions of American women everywhere I want to thank you for holding this important hearing on osteoporosis and other related bone diseases.

In my written testimony I have provided several startling statistics about this disease, including the fact that it affects 28 million Americans, 1 out of every 2 women and 1 out of every 8 men over the age of 50, and it costs this country, as you said, \$13.8 billion annually in medical cost.

This expenditure is projected to grow to \$60 billion by the year 2020 if steps are not taken now to stop this disease, but you know, no dollar amount can be placed on the pain and suffering of millions of our citizens, usually in the twilight of their years.

The face of osteoporosis is the face of a friend of mine who broke several bones in her feet simply walking barefoot in the sand. It is the face of a father who stepped down one step off his porch and snapped both of his collar bones. It is the face of a grandmother's spine breaking vertebra by vertebra over and over, several times, each time bringing agony and finally resulting in the loss of several inches in height and stooped posture, but with your help, we can stop this kind of suffering.

Osteoporosis is a silent disease which can affect people at all ages. Many people do not realize that it can strike young female athletes who have trained to the point where they can no longer menstruate. It often strikes women with breast cancer due to chemotherapy, a cruel reward for surviving breast cancer. It strikes asthmatics who take steroid medication in order to help them breathe.

In fact, I could go on and on, but let me tell you that at my age I was shocked to discover that an exoscan found that my bones were thin. Fortunately, I am one of the lucky ones, because I found out early, and I know how to take action and do for myself what I can to prevent fractures.

All of this is why, Mr. Chairman, I, along with the NOF, call for an all-out effort to combat this invisible enemy on all fronts. We

need a national osteoporosis education prevention campaign along the lines of high blood pressure or stroke. Everybody knows about cholesterol, but not enough people know how to take the steps to prevent this disease.

The Office of Women's Health and the NOF call on this education program to focus first on young people. This is because, if people learn early enough, they can stop the disease before it gets started. Over 90 percent of a person's bone is developed in the teenage years. By building strong bones early, they will avoid fractures later.

We thank you for your leadership in wanting to provide \$3 million increase this year to the Office of Women's Health for the purpose of this campaign. We also need to increase our research efforts, and you have heard about some of those efforts from Dr. Katz.

The National Institute for Arthritis and Musculoskeletal and Skin Diseases, the lead institute for bone research, is one of the smallest at NIH even though this disease affects millions of people. It will remain one of the smallest unless we increase it a great deal.

Another place where research is taking place right now is the Department of Defense. This is a program we think needs to continue. Stress fractures remain one of the most frequent injuries of our military. Over 10 percent of women recruits experience stress fractures during their training. Thus, we need to continue with this program at the Department of Defense.

#### PREPARED STATEMENT

In summary, this Nation needs to pay attention to building peak bone in young people through this national education prevention campaign. We need to focus on additional research to find the answers to osteoporosis and related bone disease. In a country that loves and respects all human beings, we must step in to help millions of Americans stop this horrible disease so that the final years of life are not a slow, painful crumbling of their bodies.

I thank you again, Senator, and look forward to any questions after the panel.

Senator SPECTER. Thank you very much, Ms. Black. We very much appreciate your testimony and your leadership, and I would note for the record the presence of your very distinguished husband, Charles Black, in the hearing room.

[The statement follows:]

#### PREPARED STATEMENT OF JUDY A. BLACK

I am Judy Black, member of the Board of Trustees of the National Osteoporosis Foundation. On behalf of the NOF, I want to thank you Mr. Chairman for holding this important hearing on osteoporosis and related bone diseases. The women of America thank you for helping to bring attention to this serious public health threat which causes 1.5 million fractures annually and costs this country \$13.8 billion in medical costs. Osteoporotic fractures caused one-half million hospitalizations in 1995, along with 2.5 million visits to physicians and about 180,000 nursing home admissions. These expenditures are projected to grow to \$60 billion annually by year 2020 if steps are not taken now.

This disease affects 28 million Americans, 80 percent of whom are women. Ten million have the disease and 18 million more are at risk due to low bone mass. A woman's risk of a hip fracture—the most debilitating of the osteoporotic fractures—

is equal to her combined risk of breast, uterine and ovarian cancer. One out of two women and one out of eight men over age 50 will experience a fracture due to osteoporosis.

Osteoporosis is a silent disease—which can affect people at all ages. Many people do not realize that it can strike young female athletes who have trained to the point where they no longer menstruate; it often strikes women with breast cancer due to chemotherapy—a cruel reward for surviving breast cancer; it strikes asthmatic men and women who take steroids in order to help them breathe; I could go on, but let me just tell you that, a few years ago, I was shocked to discover that I had osteoporosis. Fortunately, I am one of the lucky ones, because I found out early, and I knew how to take action and do for myself what I need to do to prevent fractures.

I thought because I was an active young woman with a healthy lifestyle, that osteoporosis was something I did not need to worry about. How wrong I was. Everyone needs to worry about their bone health. This is why, Mr. Chairman, I with NOF, call for an all out effort to combat this invisible enemy.

First, as you know, we need a National Osteoporosis Education Prevention Campaign along the lines of the High Blood Pressure Program or the National Cholesterol Education Program. Despite the availability of effective prevention, detection, and treatment for osteoporosis, most women at menopause are not taking—or being advised to take—appropriate steps to prevent, detect or treat this disease. A 1997 Roper Starch survey indicated that women 50 and older lack critical understanding of how to maintain their bone health after menopause. Furthermore, while one in two women 50 and over will suffer an osteoporotic fracture, only one-third (34 percent) of women are very concerned about the disease. During the five–seven years post menopause, women can lose up to 20 percent of their bone—about one-fifth of the bone they will lose in their lifetime, yet only 39 percent of postmenopausal women cited menopause as a risk factor for osteoporosis. Finally, nearly three-fourths (73 percent) of the respondents believe good posture, a characteristic not at all related to developing osteoporosis, can prevent and treat the disease.

However, in the first phase of such a prevention campaign, the focus should be on young girls to avoid the prospect of today's youth becoming tomorrow's generation of osteoporotics. Such a recommendation was made by a task force convened jointly by the Public Health Service's, Office of Women's Health and the National Osteoporosis Foundation. By building strong bones in the early years, they will avoid fractures in the older years. Ninety-seven percent of a young girl's bone is laid down before the age of 18. We thank you for your leadership in wanting to provide a \$3 million increase to the Office of Women's Health for the purpose of a National Osteoporosis Prevention Education Campaign, and we look forward to continuing to work with you on this issue.

Second, we need to increase our research efforts. We will hear from Dr. Katz about some of the important progress that has been made in osteoporosis and related bone research—and there is no question that there have been important discoveries in the detection and treatment of the disease. We now know how to stop bone loss in many people, but we still do not know how to trigger new bone growth.

The first and foremost priority is an overarching recommendation to increase clinical research. We have major gaps in our patient-oriented research. We are simply not making the necessary translation from basic research to benefits available to patients. Figuring out the mechanisms of disease is very important, but once we solve the puzzle, we need to transmit the findings to help the patient. These are some examples of needed patient-oriented research:

We need human intervention studies to resolve unanswered clinical questions regarding vitamin D. Our vitamin D research has been remarkable, however, it has stopped short of translation into improved public health. The unanswered questions regarding vitamin D are as follows. What is the optimum vitamin D status? Will optimizing vitamin D status reduce the fracture burden? How much vitamin D do typical adults normally produce in their own skin every day—summer and winter? What is the interaction between dietary calcium and vitamin D status? Finally, we need an inexpensive, reliable, and effective vitamin D preparation. Physicians cannot practice nutritional medicine without this kind of information.

How Fluoride acts on bone is another example of our lack of knowledge. There is good reason to believe that, in an appropriate dosage form and regimen, and with appropriate co-therapy, it could be extremely useful, both in the management of patients who already have osteoporosis and in the rebuilding of bone mass of individuals who are osteopenic but have not yet fractured. But as one scientist noted, fluoride has three drawbacks: it is old, it is cheap and it is non-patentable. Because of the private enterprise system in the U.S., non-patentable preparations will never elicit the necessary investment by the pharmaceutical industry. We do not know what the right dosage is; we do not know the right dosage form; we do not know

how to monitor therapy in terms of blood levels; and we do not know what blood levels have to be achieved in order to be effective. Thus, a potentially promising agent languishes.

We need human research on the incremental effectiveness and safety of combination therapies. These combinations include simultaneous administration of calcium, vitamin D, male and female hormones, and bisphosphonates or other pharmaceutical agents.

We need psychosocial and quality of life studies. Osteoporosis among older adults often involves vertebral fractures which are responsible for substantial pain, deformity, compromised function, and multiple social and psychological impairments. Deformity can wreck havoc with self-esteem and mastery, but it can also cause pragmatic problems such as finding clothes. Depression appears to be a major problem in women with this disease. We need a better understanding the social and psychological variables of these different quality of life factors.

We need research on behavioral issues surrounding the widespread lack of compliance with well-known preventive measures in osteoporosis.

We need research on methods of rehabilitation in the frail elderly who have suffered fractures. There has been little research on how to engage patients in physical activity when they are suffering painful fractures, muscle weakness, and reduced endurance.

Studies should be conducted in minorities to determine the extent of vitamin D deficiency and osteoporosis. It has been assumed, based on genetics, that African American women are not as susceptible to osteoporosis. Although it may be true that young adults have a higher bone density on averaged compared to Caucasians, it is not certain that the same could be said for women and men over the age of 50. Indeed, one researcher's experience is that African Americans are prone to develop osteoporosis as a result of low life-time intake of calcium and vitamin D.

Exercise for the prevention of osteoporosis is an area that needs further exploration. For example, what are the specific exercise needs at each life stage to maintain optimal bone health? We lack good controlled clinical trials which evaluate the benefits of exercise on osteoporotic fracture outcome.

Factors that affect attainment of peak bone mass in young women need to be looked at.

Eating disorders and exercise induced amenorrhea in young women needs additional attention as well.

On the basic research front there is still much important research to be done and I will just give a few example of a much larger list of research needs:

The number one priority should be to investigate the biology of bone adaptation to mechanical loading. The most important research to be done in this area is on the set point mechanism which senses loading and responds appropriately to control the skeletal adaptive response.

Genetic studies are, of course, needed in osteoporosis. Between 50 and 90 percent of variation of peak bone mass is inherited. Thus, we need to discover the genes associated with regulation of peak bone mass and to determine their function so that their function might be mimicked by pharmaceutical interventions. We also need studies of the genetic linkage to rates of bone loss.

Research is needed to understand the recently discovered relationships between important diseases of postmenopausal women: osteoporosis and breast cancer, depression, rheumatoid arthritis, stroke and coronary heart disease. Do these associations provide clues to etiology and preventive medicine?

In summary, because osteoporosis is such a young disease in terms of research focus and public attention, the research needs are great on multiple fronts. The National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS) the lead institute for osteoporosis and related bone diseases research is doing a important job, but it is one of the smallest institutes at NIH. It will remain one of the smallest institutes as long as its annual increase is based only on a percent of its current funding. For a disease that affects millions of Americans and costs us so much in money and suffering, NIAMS should take a jump up to a bigger institute.

Bone disease research is also taking place at the Department of Defense and that program must be continued. Young people, often with sedentary lifestyles, enter the military where they as fighting men and women are asked to perform physically. As a consequence, they develop injuries. Stress fractures remain the one of most frequent injuries that take men and women in the military off duty. According to the Army, the minimum time away from significant duty for a male or female soldier who develops a stress fracture is 6–8 weeks.

Up to 10 percent of women recruits experience stress fractures during the 8 weeks of basic training. With the increasing number of women in the military, the bone health of female recruits becomes a concern of growing proportions if they are to

serve at maximum capacity. One research project among 22,000 recruits in the U.S. Marine Corp, in San Diego, showed that as much as \$4.5 million annually could be saved by reducing stress fractures. More research is needed to understand how to do just that.

In conclusion, this nation needs an all out effect to combat this invisible enemy. Public education and research are the battlegrounds. We must pay attention to building peak bone mass in young people through a National Osteoporosis Education Prevention Campaign and we must intensify our research effort on osteoporosis and related bone diseases. Through these endeavors, I believe, Mr. Chairman, that we can get our arms around this disease and eliminate it in the first part of the 21st Century. If we fail to do so, this disease will not only bankrupt our health care system, but also the lives of millions of women and men.

Mr. Chairman, I thank you for the opportunity to testify and would happy to answer any questions.

**STATEMENT OF SUSAN BURDICK, ON BEHALF OF THE NATIONAL OSTEOPOROSIS FOUNDATION**

Senator SPECTER. We now turn to Ms. Susan Burdick, educator, civic activist, and mother, who has campaigned to promote osteoporosis prevention. She became involved with the National Osteoporosis Foundation after being diagnosed after an automobile accident.

Thank you for joining us. Ms. Burdick, the floor is yours.

Ms. BURDICK. Thank you. When I heard the word osteoporosis, 7 years ago, I thought of someone much older and inactive and stooped over, not someone like me. I was, after all, young, physically active, and doing the right things to take care of myself.

Then in October of that same year I broke my left leg, at the same time fracturing all of the bones in my right foot. I underwent surgeries and required a long hospital stay. Casts were placed on both legs. I needed skin grafts, and screws were placed in my leg. Through hours of physical therapy and hard work I learned how to walk again.

I fell and broke my right ankle 3 years later. Permanent plates and screws were put in the ankle at this time, once again requiring hospitalization and physical therapy.

During each of these times I used wheelchairs and eventually walkers and canes to assist me in my daily living, making it very difficult to care for my family.

In February of this year I broke my sternum.

I have certainly learned first-hand that osteoporosis is a disease that can affect the young as well as the old. Dealing with the constant physical pain and its consequences is very difficult for both myself and my family. The pain is immense. On many days my feet and legs simply do not want to work properly, and I must crawl through my house on my hands and knees.

Often, I cannot exercise or function normally because of the pain. The unpredictability of this can be frustrating. I have little way of knowing when I will have a good day or a bad day from a physical standpoint. I often have sleepless nights due to pain. I try to pace myself in everything I do. I must sit and rest my feet because my feet and legs swell so badly. Sometimes I walk with a visible limp, and there are simply some things that I can no longer do, or I must modify.

I now have to be careful in everything I do, asking myself, is this safe? Will it help me or hurt me? I must be constantly aware of falling or lifting incorrectly. Often, I have to ask others for assist-

ance with even the simplest of things. I find I must be a spectator instead of a participant in some activities now. This is hard.

I must take several medications on a daily basis. I miss things like being able to wear a pretty shoe, or dancing on my feet all night long. Skiing down a powdery slope is no longer feasible, and running fast is just a memory.

PREPARED STATEMENT

I am only 39. What is my future? Mr. Chairman, please do what you can to help educate young women about this disabling disease and through research to find a way for me to get back the bone that I have lost so once again I can be strong and physically active.

Thank you. I would be happy to answer any questions.

Senator SPECTER. Thank you very much, Ms. Burdick.

[The statement follows:]

PREPARED STATEMENT OF SUSAN BURDICK

Seven years ago when I heard the word osteoporosis, I thought of someone much older, inactive and stooped over, not someone like me. I was, after all, young, physically active and doing the "right" things to take care of myself.

Then, in October of that same year, I broke my left leg at the same time fracturing all of the bones in my right foot. I underwent surgeries and required a long hospital stay. Casts were placed on both legs. I needed skin grafts and screws were placed in my leg. Through hours of physical therapy and hard work I learned how to walk again. Three years later, I fell and broke my right ankle. Permanent plates and screws were put in the ankle at this time, once again requiring hospitalization and physical therapy.

During each of these times I used wheelchairs and eventually walkers and canes to assist me in my daily living—making it very difficult to care for my three children.

In February of this year I broke my sternum. I have certainly learned first hand that the disease can affect the young as well as the old.

Dealing with the constant physical pain and its consequences is very difficult for both myself and my family. The pain is immense. On many days my feet and legs simply do not want to work properly and I must crawl through my house on my hands and knees. Often, I cannot exercise or function normally because of the pain. The unpredictability of this can be frustrating. I have little way of knowing when I will have a good or bad day from a physical standpoint.

I often have sleepless nights due to pain. I try to pace myself in everything I do. I must sit and rest my feet because my feet and legs swell so badly. Sometimes I walk with a visible limp and there are simply some things I can no longer do or I must modify. I now have to be careful in everything I do, asking myself, "is this safe?" Will it help or hurt me?" I must be constantly aware of falling or lifting incorrectly. Often I have to ask others for assistance with even the simplest of things.

I find I must be a spectator instead of a participant in some activities now. This is hard. I must take several medications on a daily basis. I miss things like being able to wear a pretty shoe, or dancing on my feet all night long. Skiing down a powdery slope is no longer feasible and running fast is just a memory.

I am only 39—what's my future? Mr. Chairman, please do what you can to help educate young women about this disabling disease, and through research to find a way for me to get back the bone I have lost so I once again can be strong and physically active.

Thank you. I will be happy to answer any questions.

**STATEMENT OF HON. CONSTANCE MORELLA, U.S. REPRESENTATIVE FROM MARYLAND**

Senator SPECTER. We have been joined by the distinguished Congresswoman, Constance Morella. First elected to the House of Representatives in 1986, she serves on the Science Committee and chairs the Technology Subcommittee. She also serves on the Basic Research Subcommittee.

Since taking office, she has focused on issues on scientific research and development, the Federal work force, the environment, and equity for women.

We welcome you here. We know you have a vote and we look forward to your statement.

Ms. MORELLA. Thank you very much, Senator Specter. Thank you for letting me join you up here for this very important hearing.

I really do not believe in what you said to me when you invited me here. You said, I do not want to degrade you, but I will let you sit here with me. [Laughter.]

That was not a demotion. I thank you very much for holding the hearing.

Senator SPECTER. We always try to be very polite to the Representatives of the people's House. They consistently exercise seniority. [Laughter.]

Ms. MORELLA. Senator, I thank you for providing me the opportunity to testify at this important hearing on osteoporosis. I want to congratulate you on your leadership in scheduling the hearing, and I know that I speak for the Congressional Caucus for Women's Issues when I express my appreciation for the attention that you are devoting to this critical women's health issue.

I realize the severe budgetary constraints under which you must make your decisions again this year, and I know you will develop a bill that is fair and manages to fund critical programs despite limited funds.

I was very moved to hear Ms. Burdick's testimony, and we know that osteoporosis is a major public health threat for 28 million Americans who either have or are at risk for the disease. Over age 50, 1 in 2 women, and 1 in 8 men will have an osteoporosis-related fracture.

A woman's risk of hip fractures is equal to her combined risk of breast, uterine, and ovarian cancer, and often a hip fracture marks the end of independent living. Many enter nursing homes, a large percentage die within 1 year following the fracture, and the cost incurred due to the 1.5 million annual fractures are staggering, at \$13.8 billion, or \$38 million a day. Osteoporotic fractures cost the Medicare program 3 percent of its overall cost.

While much remains to be learned about osteoporosis, there are several primary and secondary preventive health strategies that can reduce that risk of future fractures. Research and public education, basic and clinical research have made important strides leading to accurate methods to measure bone loss and biochemical markers to detect rates of bone loss.

It has further led to new drugs. We read about them every day—new drugs to help stabilize bone loss, and even increase bone mass. However, further clinical research is needed to accurately identify high-risk women before irreversible damage occurs. Basic research is needed to determine the potential for restoring skeletal architecture to its normal state, and thereby to reverse osteoporosis. I urge you, in your capacity as chairman, to provide increased funding for this critical research in the fiscal year 1999 appropriations bill.

Another key priority is the expansion of osteoporosis prevention and public education. The Public Health Service Office on Women's Health hopes to launch, if given adequate resources, a national

osteoporosis prevention education campaign. Currently, this office has an unfunded mandate to carry out such a campaign, and while Americans of all ages must receive messages about osteoporosis relevant to their stage in life in order to prevent costly and devastating fractures suffered annually due to osteoporosis, a public-private task force determined that the first target group should be young girls.

Of particular concern is the fact that only 14 percent of teenage girls age 12 to 19 obtain the calcium on an average daily basis needed to reach their peak bone mass. Ninety-seven percent of bone mass is reached by age 19. Greater bone mass early in life means fewer fractures later in life.

To help the public obtain accurate information about osteoporosis, Congress established an osteoporosis resource center in the 1993 NIH Revitalization Act. The Osteoporosis and Related Bone Diseases National Resource Center, funded by NIH and housed at the National Osteoporosis Foundation, has been highly successful in educating the public on a very limited budget, \$500,000 annually for 4 years. Unfortunately, due to lack of funding, it is not able to carry out key projects to inform the public.

Finally, while I know this issue is not within your jurisdiction, I do want to mention the issue of insurance coverage for bone density testing for the diagnosis and testing of osteoporosis. Osteoporosis is largely preventable. Thousands of fractures could be avoided if low-bone mass was detected early and treated.

Identification of risk factors alone cannot predict how much bone a person has, or how strong bone is. Experts estimate that without bone density tests up to 40 percent of women with low-bone mass could be missed.

Last year, Senator Olympia Snowe and I were successful in obtaining coverage under Medicare for bone mass measurement tests as part of the Balanced Budget Act of 1997. That coverage will be effective this July 1. Since then, Senator Snowe and I have introduced legislation to extend that same coverage to Federal employees and retirees through the Federal Employee Health Benefits Program. Instead of a comprehensive national coverage policy, FEHBP, the Federal Employee Health Benefits Program, leaves it to each of the over 400 participating plans to decide who is eligible to receive a bone mass measurement and what constitutes medical necessity.

A survey of the 19 top plans participating in FEHBP indicated that many plans have no specific rules to guide reimbursement and cover the test. They cover it on a case-by-case basis. Several plans refuse to provide consumers information indicating whether the plan covers the test and when it does not. Some plans cover it only for people who already have osteoporosis.

I urge the members of this subcommittee to cosponsor Senator Snowe's bill on this side and join us in working to expand the availability of this important diagnostic test. Indeed, as a personal note, had I not had the opportunity to be tested at an osteoporosis event which I cochaired last year, I would not have discovered that I have osteoporosis, and so I am now taking Fosamax, a drug that can prevent further bone loss.

So it is critical that we have improved coverage for testing to ensure early detection and treatment.

PREPARED STATEMENT

Finally, I want to thank you again, Senator Specter, for this hearing, and I also want to commend you on your choice of panelists to testify. I know my husband will be thrilled to know that Dom DiMaggio is here, Dr. Katz, and Dr. Singer, and good friend Judy Black, and Susan Burdick, who has just given such great personal testimony.

So I thank you and look forward to working with you.

Senator SPECTER. Thank you very much, Congresswoman Morella, for your testimony. I want to make an addendum to the record. I did not invite you here with a comment of degrade. I invited you with a comment of demote. [Laughter.]

[The statement follows:]

PREPARED STATEMENT OF HON. CONNIE MORELLA

Mr. Chairman, thank you for providing me with the opportunity to testify at this important hearing on osteoporosis. I congratulate you on your leadership in scheduling this hearing, and I know that I speak for the Congressional Caucus for Women's Issues when I express my appreciation for the attention which you are devoting to this critical women's health issue. I recognize the severe budgetary constraints under which you must make your decisions again this year, and I know that you will develop a bill that is fair and manages to fund critical programs, despite limited funds.

Osteoporosis is a major public health threat for 28 million Americans who either have, or are at risk for, the disease. One in two women and one in eight men over age 50 will have an osteoporosis-related fracture. A woman's risk of hip fracture is equal to her combined risk of breast, uterine, and ovarian cancer. Often a hip fracture marks the end of independent living. Many enter nursing homes and a large percentage die within one year following the fracture. The costs incurred due to the 1.5 million annual fractures are staggering at \$13.8 billion—or \$38 million each day. Osteoporotic fractures cost the Medicare program three percent of its overall costs.

While much remains to be learned about osteoporosis, there are several primary and secondary preventive health strategies that can reduce the risk of future fractures—research and public education. Basic and clinical research have made important strides leading to accurate methods to measure bone loss and biochemical markers to detect rates of bone loss. It has also led to new drugs to help stabilize bone loss and even increase bone mass. However, further clinical research is needed to accurately identify high-risk women before irreversible damage occurs. Basic research is needed to determine the potential for restoring skeletal architecture to its normal state and thereby to reverse osteoporosis. I urge you to provide increased funding for this critical research in the fiscal year 1999 appropriations bill.

Another key priority is the expansion of osteoporosis prevention and public education. The Public Health Service Office on Women's Health hopes to launch, if given adequate resources, a National Osteoporosis Prevention Education Campaign. Currently, this office has an unfunded mandate to carry out such a campaign. While Americans of all ages must receive messages about osteoporosis relevant to their stage in life in order to prevent costly and devastating fractures suffered annually due to osteoporosis, a public-private task force determined that the first target group should be young girls. Of particular concern is the fact that only 14 percent of teenage girls, ages 12–19, obtain the calcium on an average daily basis needed to reach their peak bone mass. Ninety-seven percent of bone mass is reached by age 19; greater bone mass early in life means fewer fractures later in life.

To help the public obtain accurate information about osteoporosis, Congress established an osteoporosis resource center in the 1993 NIH Revitalization Act. The Osteoporosis and Related Bone Diseases National Resource Center, funded by NIH and housed at the National Osteoporosis Foundation, has been highly successful in educating the public on a very limited budget, \$500,000 annually for four years. Unfortunately, due to lack of funding, it is not able to carry out key projects to inform the public.

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Last year, Senator Olympia Snowe and I were successful in obtaining coverage under Medicare for bone mass measurement tests as part of the Balanced Budget Act of 1997. That coverage will be effective on July 1. Since then, Senator Snowe and I have introduced legislation to extend the same coverage to federal employees and retirees through the Federal Employee Health Benefits Program (H.R. 2699, S. 1335).

Instead of a comprehensive national coverage policy, FEHBP leaves it to each of the over 400 participating plans to decide who is eligible to receive a bone mass measurement and what constitutes medical necessity. A survey of the 19 top plans participating in FEHBP indicated that many plans have no specific rules to guide reimbursement and cover the tests on a case-by-case basis. Several plans refuse to provide consumers information indicating when the plan covers the test and when it does not. Some plans cover the test only for people who already have osteoporosis. I urge the members of this subcommittee to cosponsor Senator Snowe's bill and join us in working to expand the availability of this important diagnostic test. Indeed, had I not taken the opportunity to be tested at an osteoporosis event last year, I would not have discovered that I have osteoporosis! I am now taking Fosamax, a drug that can prevent further bone loss. It is critical that we have improved coverage for testing to ensure early detection and treatment.

Mr. Chairman, I thank you for this opportunity to testify today and I again congratulate you for holding this timely hearing. You have a number of excellent witnesses who will be sharing their expertise with you today. I look forward to working with you and the other members of your subcommittee to improve our response to this serious public health problem affecting so many women and men.

**STATEMENT OF DOMINIC DiMAGGIO, MEMBER, BOARD OF DIRECTORS, THE PAGET FOUNDATION**

Senator SPECTER. Now I want to turn to Mr. Dominic DiMaggio, spokesperson for the Paget Foundation.

Since being diagnosed with Paget's Disease, Mr. DiMaggio has recorded radio and television public service announcements to alert men and women with Paget's Disease. Also one of baseball's greats, having spent 10 seasons and over 13 years with the Boston Red Sox, he still holds the all-time Red Sox record for hitting in 34 consecutive games.

I chatted with Mr. DiMaggio beforehand and commented to him that I grew up in Kansas, where the principal activity was reading the box scores in the days before television. I know about his career on the Fenway Park Green, and I was not aware of the introductory statistics which had been prepared for me earlier, and my first question to you, Mr. DiMaggio, is, who holds the hitting streak for most consecutive games? [Laughter.]

Mr. DiMAGGIO. That is my brother Joe.

Senator SPECTER. And what is that record?

Mr. DiMAGGIO. 56.

Senator SPECTER. 57. [Laughter.]

Mr. DiMAGGIO. No; if it had been 57 he would have gotten a contract from Heinz, 57 varieties. [Laughter.]

Senator SPECTER. And how many consecutive games did he hit in following the day he missed?

Mr. DiMAGGIO. I think it was either 17 or 27. I know there is a 7 behind it.

Senator SPECTER. Well, I think it was 14. [Laughter.]

But we can agree on most things.

Mr. DiMaggio, we welcome you here and look forward to your testimony.

Mr. DiMAGGIO. Senator Specter, I, too, thank you for holding this hearing, for your great support of all medical research, for your interest in osteoporosis, Paget's Disease of bone and other bone disorders, and for inviting me to be here today.

I am here to talk about Paget's Disease of bone, the second most prevalent bone disease after osteoporosis. Paget's Disease is a chronic condition which may affect between 1 and 2 percent of people over 60, or up to 1 million people in the United States alone.

When Paget's is severe, it can cause deformity such as bowing of the legs, fractures, hearing loss, and osteoarthritis, and can not only be very painful but can cause serious problems.

In my particular case, over 20 years ago, after discovering among other things that Paget's had caused bowing of my legs, which deprived me of much needed height, which, believe me, I could ill afford to lose, I went to Dr. Stephen Krane at the Massachusetts General Hospital in Boston for treatment. Almost 10 years later, he prescribed the then up-to-date treatment of self-injecting myself three times weekly with calcitonin, to which I rebelled.

Dr. Krane then advised me that my only alternative was to enter the University Hospital at Leiden in the Netherlands for treatment with a drug called pamidronate, which had not been approved in the United States, and so I went.

The result of that treatment has been an arresting of further deterioration of Paget's Disease. It did not cure me, for there is no cure, but it has been arrested. I am pleased to report that this and other effective drugs are now available in the United States.

Since agreeing to be the spokesman for the Paget's Disease Foundation about 10 years ago, I am pleased to say that this organization, which is the only one in the United States that helps patients and supports and encourages research, has done an outstanding service in those areas.

The most important need now is for increased Federal funding for research on Paget's Disease so that researchers can come to understand why Paget's occurs. I will briefly discuss three important research areas.

1. Genetics. We know that there are genetic factors in Paget's Disease, and researchers are working on identifying one or more genes which predispose people to Paget's Disease, but we need to conduct wider studies.

For example, being originally from San Francisco and having spent most of my life in the Boston-Providence-Rhode Island area, all areas which have large Italian populations, we know that many people of Italian descent are afflicted with Paget's Disease, but we do not know why this is so.

2. Viruses. For many years, scientists, including Dr. Fred Singer, who is here today, have been looking for a virus or viruses which are thought to be a factor in Paget's Disease. Important research funded by the National Institutes of Health is very promising, but more studies are needed to identify the virus or viruses and to learn about a possible connection between viruses and genetic factors.

3. Cancer and Paget's Disease. Though fortunately less than 1 percent of people with Paget's Disease develop a form of cancer called osteosarcoma, research in this area also funded by the National Institutes of Health must be continued to learn why some people develop this cancer and how this may be connected to the genetic and viral factors in Paget's Disease.

That, Senator Specter and other members of the committee, just about concludes the valuable time which you have given me. Thank you for allowing me to speak today on behalf of all of the Paget's Disease sufferers in the United States and the rest of the world.

PREPARED STATEMENT

This committee's support of increased research for Paget's Disease, osteoporosis, and all bone disorders will bring a more hopeful future for the millions who are afflicted by these serious disorders.

Senator SPECTER. Thank you very much, Mr. DiMaggio. We appreciate you being here, and appreciate hearing about your personal experiences.

[The statement follows:]

PREPARED STATEMENT OF DOMINIC DiMAGGIO

Senator Specter, I want to thank you for holding this hearing, for your great support of all medical research, for your interest in osteoporosis, Paget's disease of bone and other bone disorders, and for inviting me to be here today.

I am here to talk about Paget's disease of bone, the second most prevalent bone disease after osteoporosis. Paget's disease is a chronic condition which may affect between 1 and 2 percent of people over 60 or up to 1,000,000 people in the U.S. When Paget's is severe, it can cause pain, deformity such as bowing of the legs, fractures, hearing loss and osteoarthritis.

I have known that I had Paget's disease for more than 20 years. About 12 years ago, I went to Dr. Stephen Krane at the Massachusetts General Hospital for treatment. He suggested calcitonin which I would have had to self-inject 3 times each week. I rebelled and Dr. Krane suggested that I go to the Netherlands to be treated with a drug which was not then approved for treatment in the U.S. I was treated with that drug, pamidronate, which, by the way, was approved in the U.S. in 1994. Though I am not cured, since there is no cure yet, I have been in remission since being treated in the Netherlands. I am glad to report that other effective drugs are now approved in the U.S. and other countries.

The most severe problems I have experienced with Paget's disease are bowing of my legs and a regrettable loss of height. However, I consider myself one of the luckier people with Paget's disease since many others suffer great pain and have serious and sometimes deforming complications.

Ten years ago I became a member of the Board and a spokesperson for The Paget Foundation, the only organization in the U.S. which assists Paget's disease sufferers, provides medical education and supports and encourages increased research.

Now I want to talk about the need for increased federal funding for Paget's disease research so that the cause or causes of this disease can be discovered. There are three important research areas which I will discuss briefly.

1. *Genetics*.—We know that there are genetic factors in Paget's disease, and researchers are working on identifying one or more genes which predispose people to Paget's disease, but more studies are needed. One aspect of the genetics of Paget's disease is particularly interesting to me. I am originally from San Francisco and have spent most of my life in the Boston/Providence, RI area—all areas which have large Italian populations. We know that many people of Italian descent have Paget's disease but we don't know why this is so.

2. *Viruses*.—For many years scientists, including Dr. Fred Singer who is here today, have been looking for a virus or viruses which are thought to be a factor in Paget's disease. Important research, funded by the National Institutes of Health (NIH), is very promising, but more studies are needed to identify the virus or viruses and to learn about the possible connection between viruses and genetic factors.

3. *Cancer and Paget's disease.*—Though it is fortunate that less than 1 percent of people with Paget's disease develop a form of cancer called osteosarcoma, research in this area, also funded by NIH, must be continued to learn why some people develop this cancer and how this may be connected to the genetic and viral factors in Paget's disease.

This concludes the valuable time you have given me. Again, Senator Specter and other members of the committee, thank you for allowing me to speak today on behalf of Paget's disease sufferers everywhere.

**STATEMENT OF DR. FRED SINGER, REPRESENTING BARBARA SINATRA**

Senator SPECTER. We now turn to Dr. Fred Singer, director of the endocrine bone disease program at the John Wayne Cancer Institute. He is chairman of the board of directors of the Paget Foundation and past president of the American Society for Bone and Mineral Research.

We appreciate your being here, and we are told you are going to present the testimony which Mrs. Frank Sinatra would have presented. Thank you for joining us. The floor is yours.

Dr. SINGER. Thank you, Senator Specter.

Mrs. Frank Sinatra was very much looking forward to appearing before you and the subcommittee today to encourage support for medical research directed toward the major problem of osteoporosis. Sadly, she could not appear here today and, therefore, asked me to convey her message to you.

In 1996, Barbara fell and fractured a vertebra. After the considerable pain subsided, a bone density test was done for the first time and revealed that she had severe osteoporosis, a previously absolutely unappreciated condition. Subsequently, she has also experienced a stress fracture of a toe. Fortunately, at present her fractures are healed, she feels fine, and she has been taking medications to help strengthen her bones.

In considering why she had developed osteoporosis she related that her intake of dairy products, i.e. calcium, was always rather limited, particularly when she was a model and greatly restricted her food intake. Thus, it appeared that a low intake of calcium may have been a factor in producing her low-bone density.

In addition, both of her parents probably experienced fractures related to osteoporosis. Barbara has come to appreciate that she is one of 10 million Americans with osteoporosis, 80 percent of whom are women, and that another 18 million have low bone density and are at risk for future problems because of osteoporosis.

She now realizes that in many individuals osteoporosis is actually a pediatric disease with a geriatric consequence. Growing children often do not deposit sufficient bone into their bone bank to get them through the many bone-losing years after age 35. This no doubt contributes to the 1½ million fractures which occur annually in the United States.

Barbara now believes that there is a great need to focus on the children and adolescent girls who are not getting sufficient calcium to build up their bones to their full potential. Surveys have shown, as already stated, that about 14 percent of young girls receive enough calcium to build strong bones. The National Osteoporosis Foundation has already completed research on ways to reach these youngsters which hopefully will be translated into better bones for future generations.

Barbara and her husband dedicated an enormous amount of time and energy to help abused children by building and supporting the Barbara Sinatra Children's Health Center at the Eisenhower Medical Center in Rancho Mirage, CA. Because of Mrs. Sinatra's personal experience with osteoporosis she can clearly see the need to prevent abuse of the developing bones and would like the subcommittee to help support a national effort to teach young people about bone health and how to prevent osteoporosis.

PREPARED STATEMENT

In addition, the millions of Americans and people of other countries who already suffer from the complications of osteoporosis would benefit from an increased emphasis on medical research to find solutions to this troubling disease, which promises to become an epidemic unless we take action now.

I thank you for allowing me to represent her views.  
[The statement follows:]

PREPARED STATEMENT OF BARBARA SINATRA

Senator Specter, Mrs. Frank Sinatra was very much looking forward to appearing before you and your subcommittee to encourage support for medical research directed toward the major public health problem of osteoporosis. Sadly, she could not appear here today and therefore asked me to convey her message to you and the subcommittee.

In 1996 Barbara fell and fractured a vertebra. After the considerable pain subsided a bone density test was done and revealed she had severe osteoporosis, a previously unappreciated condition. Subsequently, she also experienced a stress fracture of a toe. At present her fractures are healed and she has been taking medications to strengthen her bones. In considering why she had developed osteoporosis she related that her intake of dairy products was always rather limited, particularly when she was a model and greatly restricted her food intake. Thus it appeared that a low intake of calcium may have been a factor in producing a low bone density. In addition, both of her parents probably experienced fractures related to osteoporosis.

Barbara has come to appreciate that she is one of 10 million Americans with osteoporosis, 80 percent of whom are women, and that another 18 million have low bone density and are at risk for future problems because of osteoporosis. She now realizes that in many individuals osteoporosis is a pediatric disease with a geriatric consequence. Growing children often do not deposit sufficient bone into their "bone bank" to get them through the many bone-losing years after age 35. This no doubt contributes to the 1.5 million fractures which occur annually in the United States. Barbara believes that there is a great need to focus on the children and adolescent girls who are not getting sufficient calcium to build up their bone mass to its full potential. Surveys have shown that only 13 percent of young girls receive enough calcium to build strong bones. The National Osteoporosis Foundation has already completed research on ways to reach these youngsters which hopefully will be translated into better bones for future generations.

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CURE FOR OSTEOPOROSIS

Senator SPECTER. Thank you very much, Dr. Singer, for joining us.

Let me begin with you, Dr. Katz. The question of funding is very much on my mind and the mind of this subcommittee. Last year, the Senate passed a resolution to double NIH funding over 5 years. That would be about \$2.7 billion a year. When the time came for funding, the health account was cut by \$100 million.

Senator Harkin and I joined together in a bipartisan effort offering an amendment for \$1.1 billion, because we had targeted a more modest but we thought a more attainable 7½-percent increase, which was \$952 million. Our amendment was defeated 63 to 27. We were able to find funding by consolidating or eliminating a number of programs.

This year, the subcommittee has funded at a level line and again we, Senator Harkin and I, offered an amendment to add \$2 billion, and that again was defeated 57 to 41.

Now, I say these things because this room is filled with advocates for this ailment, but there has to be a concerted effort to target those 57 Senators and their counterparts in the House on a grassroots campaign. Tell them what you are telling us here today.

Now, the critical question I have for you, Dr. Katz, is what would it take to find the cure for osteoporosis, to be able to instruct people on how to prevent it, on whatever course of action they should take?

Dr. KATZ. We appreciate your support, and have always appreciated the support of this committee, the tremendous support of this committee for the NIH research effort.

With regard to osteoporosis, we, as well as other institutes and offices at the NIH, have taken a multipronged approach to the research effort. These efforts are broadbased and include not only prevention, but also basic and clinical research.

#### OSTEOPOROSIS GENE

Senator SPECTER. Is there an osteoporosis gene?

Dr. KATZ. That is a very good question. Is there a single gene? Probably not. The consensus is that there is not. There have been many candidate genes looked at.

Senator SPECTER. Statistically, only 27 percent of the grant applications are awarded. That means that there are 73 doors unopened. I would like you to focus, Dr. Katz, on what you think it would take on a time line to find the answers to osteoporosis. That is really the critical question.

I know you cannot necessarily answer on the spur of the moment, but I would like you to focus on that.

Let me turn to you, Ms. Black, with a question about education. You identify yourself as one of the lucky ones. We have very substantial funding in the educational line. The amount of \$75,000 was spent to create a focus group last year to make decisions on what age groups to target, and it was young girls 9 to 19, with an additional \$850,000 now being spent to develop a message, to get that message out to the public.

I am told that approximately \$3 million will be needed in fiscal year 1999 to launch the public awareness campaign. I would be interested in your view, and also your view, Ms. Burdick, and not necessarily at this moment—we could start now—as to what you

think it would really take to launch that kind of a public awareness campaign.

Ms. BLACK. It sounds like they are trying to build bone right under us. [Laughter.]

Senator SPECTER. We have the resources, in my opinion, to do this. We have a budget of \$1,700 billion. It is a matter of priorities, and I do not think any priority is higher than health. I put health and education at the top of the list, and what I would like to find the answer to is what it will take, because I think with a sufficiently aggressive grassroots campaign we can do it.

Ms. BLACK. I do, too. I think you are exactly on target, and it is refreshing to hear you say that and push for it, and we will help you try to continue that effort.

This is only a start, the \$3 million, because as you know, with 50 States dividing it up per citizen, it is not a lot of money. On the other hand, we have to start crawling before we can walk and before we can run, and so we have to start working with Governors and the legislatures and the public awareness program throughout the country.

So we agree with you, and we have done research on what exactly, what reaches teenagers, because you know, they are a different breed, and so it takes talking to them a little bit differently, but NOF has done research, and we believe that a lot of it is going to have to be through a mass media campaign, and we appreciate the time lines we have today, but we will continue working with you and with the Office of Women's Health to accomplish that.

Senator SPECTER. Well, let us know as specifically as you can what you think it would take, and also some ideas as to how to proselytize. You are not inexperienced, nor is Charlie Black, on how to carry the message forward.

I do not like the word lobbyist, but public persuasion.

Congresswoman Morella has other duties on the other side of the Hill, but I wanted to give her an opportunity to make a concluding comment.

Ms. MORELLA. I do. I am just so appreciative of Chairman Specter's devotion to health. I do represent the National Institutes of Health, and I am just so pleased with what is being done there and at the National Osteoporosis Foundation.

And so panelists, I want to thank you on behalf of all of the citizens of the United States, and I want to thank you, Chairman Specter. I am excited that we have been making strides. This issue is no longer under the carpet. We know that people need to be measured. We know we can educate young people to prevent it. We know that research is being done, too, and so I thank you.

Senator SPECTER. Thank you very much, Congresswoman Morella.

Ms. Burdick, would you care to make a comment about how we carry out this public awareness campaign?

Dr. Katz has to provide the research and has to answer the question as to what he needs for prevention and cure, and we would like those of you like Ms. Black and Ms. Burdick to focus on what the public education campaign should be.

Ms. BURDICK. I would just like to say that before you can solve a problem you have to be aware that there is a problem, and I feel

that we need to make our best effort to educate people about this and bring an awareness to the public of this dreaded disease.

Senator SPECTER. OK. Thank you very much.

Mr. DiMaggio is a well-known spokesman. I have his literature, both fielding and batting. Do they still call you the Little Professor, Mr. DiMaggio?

Mr. DiMAGGIO. Yes.

Senator SPECTER. Would you care to make a comment on what you think it would take to have this public relations campaign?

Mr. DiMAGGIO. The Little Professor name came about, I guess, because of my small stature with glasses. I looked more like a high school student than I did a professional athlete. That is where the Little Professor name came from.

With all due respect, Senator, I do not believe there is enough money. I know there are so many good causes, and what I believe is absolutely necessary, there are an awful lot of people in this country who do not know about Paget's Disease. They do not know it exists. I think if we could just make more people aware of the fact that it does exist, it would be a great benefit. Beyond that, any further help that my foundation would care to submit I am all in favor of.

Senator SPECTER. Thank you very much.

Dr. Singer, would you care to make a closing comment?

Dr. SINGER. Well, I think it is very important to remember that osteoporosis is a giant problem which needs to be dealt with with considerable funds, and that we should not forget some of the other disorders such as Mr. DiMaggio has experienced, because, in fact, what we have learned from the understanding of the unusual conditions, it actually helps us understand normal bone and osteoporosis.

I think I would like to take a global approach, of course, emphasizing osteoporosis.

Senator SPECTER. Well, thank you all very much. I think today's hearing will focus more attention, and we have the outstanding questions, what resources do you need to find the cause and cure, and what will it take to promote the public relations campaign?

PREPARED STATEMENT OF SENATOR OLYMPIA SNOWE

Senator SPECTER. Thank you very much. We have received a prepared statement from Senator Olympia Snowe, it will be inserted into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF SENATOR OLYMPIA SNOWE

Mr. Chairman, I want to thank you for holding today's hearing to bring attention to the silent killer, osteoporosis.

When I introduced the first bill on Osteoporosis back in 1985, it was a little known disease. It was simply a silent killer that was spreading pain and suffering among millions of older women, while it was hiding itself in their daughters and granddaughters, waiting until they too reached old age to strike. And it wasn't selective about who it attacked. One out of every two women have a lifetime risk of bone fractures due to osteoporosis, and it affects half of all women over the age of 50 and an astounding 90 percent of women over 75.

It is the most prolific and unforgiving bone disease. Twenty eight million Americans are afflicted with osteoporosis and each year 50,000 deaths result from this disease.

While there is no way to measure the cost of the pain and suffering of those afflicted by this disease and their families, we do know that osteoporosis is also a costly disease in strict monetary terms. It costs up to \$1 billion in direct medical costs for osteoporosis fracture patients—an astounding \$27 million every single day. And this cost is projected to reach \$60 billion by the year 2020 and \$240 billion by the year 2040 if medical research has not discovered an effective treatment. In fact, in a report issued by the University of California, it is stated that Osteoporosis, along with Alzheimer's disease are potential "Federal Budget busters" if interventions are not begun immediately.

We have begun work, Mr. Chairman. We have the National Osteoporosis Clearing House, based on legislation I authored, with an 800 number that provides thousands more women with easy access to the most up-to-date information available on the disease itself, the ongoing research, where to get help and what to do to avoid becoming another statistic of this disease.

And last year, with my former House colleague and good friend, Congresswoman Connie Morella, we passed legislation I started introducing almost a decade ago—the Medicare Bone Mass Measurement Coverage Standardization Act—which will allow Medicare beneficiaries at risk of osteoporosis to have their diagnostic tests covered under the program as of July 1, 1998. In an effort to move toward better access to this important test, I have introduced similar legislation to provide coverage under the Federal Employees Health Benefit Program and have cosponsored legislation with Senator Robert Torricelli to provide this coverage under private insurance.

We have come a long way from 1985 when hardly anyone knew what I was talking about when I asked them to work with me to bring this silent killer out into the open and find a way to detect it, stop its progress and find a cure.

Mr. Chairman you have long been a champion of federal research funding and we need your help, again, to continue our fight against osteoporosis. The advancements being made in research—and the recent FDA approval of raloxifene for osteoporosis—are great news. But we need to do more. We have made progress in terms of getting more federal funding for research so that we can find the answers to the many questions we still have about this disease, such as how do we build back lost bone mass and what factors dictate a young person's reaching peak bone mass.

I join the National Osteoporosis Foundation today in asking you and your committee to provide a 15 percent increase in the National Institutes of Health budget for fiscal year 1999 in order to ensure that advances in research on ways to stop this silent killer continue. We need to fight to find the cure and to protect our daughters and granddaughters from this terrible disease. We need to make sure that the only knowledge they have of osteoporosis is in the history books. I look forward to working with you and my colleagues on the Appropriations Committee to provide increased funding.

#### CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 12:50 p.m., Wednesday, May 20, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]