

Congressional record Sept 29, 2010 p. E 1872-1874 Hon Christopher H Smith

E1872 CONGRESSIONAL RECORD — Extensions of Remarks September 29, 2010 honor for me to rise today to recognize the life of northwest Florida's beloved George Ireland. Mr. Ireland is survived by Jacqueline, his wife of 57 years; his three sons, George, Timothy and Bruce; as well as two grandchildren and three great-grandchildren. To his family and friends, I would like to offer my deep and sincere condolences. George Ireland was not only a compassionate man, but also had a sharp wit and an immense love for his community. Northwest Florida has truly suffered a great loss with his passing. Mr. Ireland served his country with honor and distinction in both the Korean and Vietnam Wars and retired after more than 27 years of service in the United States Air Force with the rank of Chief Master Sergeant. Following his retirement, Mr. Ireland moved to Niceville, Florida, where he served his local community as City Clerk for over 32 years and also served as President of the Florida Association of Clerks. Mr. Ireland was described by his colleagues as a "financial whiz"; his remarkable aptitude for managing budgets and records helped the city of Niceville continually run a budget surplus. In 1978, he was the catalyst for the purchase of a cutting-edge computer system Niceville. He convinced the Niceville City Council to approve the purchase of computers to help facilitate a sophisticated internal system that allowed the city to save countless dollars. He was also responsible for founding an institute for the education and training of city clerks in northwest Florida; this service, provided at no cost to the cities of northwest Florida, was especially crucial as it allowed each city to cut the cost of sending their clerks to train in south Florida. Mr. Ireland's excellence in financial management was recognized by the Government Finance Officers Association, which bestowed upon his office more than 20 annual awards for excellence in financial reporting. He was also the recipient of the prestigious Robert N. Clark Award from the Florida Association of City Clerks. Mr. Ireland's dedication to his community was beyond reproach. After his retirement as City Clerk, he continued to give his time, even though he was off the payroll. He was also deeply involved in a myriad of fraternal organizations. Mr. Ireland was a member of the Veterans of Foreign Wars of Florida, where he served as District 1 Commander. He was a Master Mason of the Okaloosa Masonic Lodge 312 in Niceville, and was a 32nd Degree Knights Commander of the Court of Honor for the Hadji Shrine in Pensacola, Florida. He also served multiple times as President of the local Lions Club, but his real love was in serving as secretary and treasurer of the Lions Club—a position he held since the early 1960s. Mr. Ireland's service to his community was recognized in 2005 when he was awarded the Melvin Jones Fellowship Award—the highest award given by Lions Clubs International for humanitarian service. To some George Ireland will be remembered as a courageous member of our armed services where he fought to protect the liberties and freedoms we all hold so dear; to others he will forever be a sharp, intelligent, and exceptionally compassionate public servant. He will long be remembered by his family and friends as a loving husband and father; and we will all remember his wit, energy, motivation and commitment to serving his community. His impact he had on northwest Florida can never be forgotten. Madam Speaker, on behalf of the United States Congress, it gives me great pride to honor the life of George Ireland, and his living legacy. f MONROE JOURNAL EDITORIAL CALLING FOR RENEWAL OF BUSH TAX CUTS HON. JO BONNER OF ALABAMA IN THE HOUSE OF REPRESENTATIVES Wednesday, September 29, 2010 Mr. BONNER. Madam Speaker, I wish to submit for the RECORD an editorial published in the September 16th edition of the Monroe Journal in my congressional district, calling for the renewal of the Bush tax cuts of 2001 and 2003. CONGRESS MUST RENEW BUSH'S TAX BREAKS In this economic environment it would be ludicrous to even consider not renewing the "Bush tax breaks" for everyone, especially so for middle class Americans. President Barack Obama has said he supports renewing the federal income tax breaks for middle class workers, but he does not support renewing the tax breaks for persons making \$250,000 or more annually. Unfortunately, the problem with not renewing the tax breaks for those who make \$250,000 or more is that many of those individuals are small business owners. We all know that the majority of jobs in America are created by small businesses. If the tax breaks are not continued for middle class workers, they would see an average increase of \$1,500 per individual in their annual federal income tax. And, if the tax breaks are not continued for small business owners, many of those middle class workers could find themselves on the unemployment lines in 2011. Why not amend the tax law to continue the tax breaks for everyone, who makes less than \$250,000 annually and for small business owners, who make no more than \$500,000 annually? This would help middle class workers continue to make

ends meet and help small businesses with minimum operating capital stay afloat in this shaky economy that is still in a rebound stage. Madam Speaker, oftentimes the best ideas come from real America, not just those generated here inside the Washington Beltway. I hope my colleagues will take to heart this urgent plea from the editors and publisher of the Monroe Journal.

f ISSUES REGARDING LYME DISEASE HON. CHRISTOPHER H. SMITH OF NEW JERSEY IN THE HOUSE OF REPRESENTATIVES Wednesday, September 29, 2010 Mr. SMITH of New Jersey. Madam Speaker, as chair of the congressional Lyme Disease Caucus and a person who has been closely involved in Lyme disease issues for over twenty years, I want to bring to your attention extremely troubling issues regarding Lyme disease. Lyme disease is the most common of all vector-borne infections in the U.S., with approximately 290,000 new cases in 2008. With the increase in Lyme cases, problems due to poor diagnostics and ineffective treatments for Lyme disease have become almost overwhelming—affecting larger numbers of people over longer periods of time. Many patients are angry because progress in addressing Lyme disease has been impeded by entrenched bias and a lack of accountability in the science of tick borne diseases. It is critical that we identify biases and impediments that are constraining the science on Lyme and to open up the dialogue to honest and transparent debate. The scientists who have long been marginalized, the treating physicians who have felt intimidated and threatened, and most importantly the sick patients and their families need our help. My main purpose here today is to introduce for inclusion in the CONGRESSIONAL RECORD the following statement “The Patient Perspectives on the Research Gaps in Tick Borne Diseases,” written by three of the Nation’s largest Lyme disease advocacy organizations, who represent tens of thousands of patients. I believe that this statement provides important perspectives that need to be heard and taken to heart.

PATIENT PERSPECTIVES ON THE RESEARCH GAPS IN TICK BORNE DISEASES (Submitted by Time for Lyme, the national Lyme Disease Association, and the California Lyme Disease Association on behalf of our patients across the United States) In December 2009, Labor HHS 2010 appropriations language, signed into law by President Obama, encouraged the National Institutes of Health (NIH) to “sponsor a scientific conference on Lyme and tick-borne diseases . . . the conference should represent the broad spectrum of scientific views . . . and should provide a forum for public participation and input from individuals with Lyme disease.” The language also requires NIH to identify research gaps to understand the “mechanisms of persistent infection.” The passage of this language represents a significant opportunity to summarize and solidify the issues that prevent scientific progress for a disease recognized here for 35 years, if, and only if, this process occurs without bias. Progress can be accomplished if the stewards commit to the elimination of predisposition by key decision makers. It is not clear why the NIH elected to subcontract this issue to the Institute of Medicine (IOM), given that the existing NIH conference structure contains the best process to address the appropriations language requirements. According to the NIH Consensus Development Program, which explains the two relevant types of conferences offered by NIH, “when the available evidence is weak or contradictory, or when a common practice is not supported by high-quality evidence, the State-of-the-Science label is chosen.” This conference format would appropriately address the research gaps that exist for Lyme and tick-borne diseases as it provides a “snapshot in time” of the state of knowledge on the conference rather than a policy statement of the NIH or the Federal Government. In Lyme disease, there are two distinct disease paradigms, each providing science to support its claims. One paradigm views the disease as “hard to catch and easy to cure” and denies the existence of chronic Lyme disease—persistent infection with *Borrelia burgdorferi*, the spirochete that causes the disease. Under this paradigm, the state of the science for patients with chronic Lyme disease is closed. Any treatment is considered too risky because practitioners are unable to determine the cause or extent of patient symptoms, or they view the symptoms

VerDate Mar 15 2010 05:59 Oct 01, 2010 Jkt 089060 PO 00000 Frm 00080 Fmt 0626 Sfmt 0634
E:\CR\FM\A29SE8.276 E29SEPT2 tjames on DSKG8SOYB1PROD with REMARKS September 29, 2010

CONGRESSIONAL RECORD — Extensions of Remarks E1873 as insignificant and write off the patients’ complaints as psychiatric in nature. This leaves seriously ill patients without any viable therapeutic avenues. It also shuts the door on future research necessary to get patients to a state of wellness. The alternative paradigm says that the science is too unsettled to be definitive and there can be one or more causes of persistent symptoms after initial treatment in an individual who has been infected with the agent of Lyme disease. These causes include the possibility of persistent infection, or a postinfectious process, or a combination of both, with the Lyme bacterium itself driving the autoimmune process. This paradigm allows doctors the ability to exercise their

clinical judgment and provide therapies that are helping their patients. Patients with Lyme disease need a research agenda that reflects outcomes that matter to patients, namely effective diagnostic tools and effective treatments that restore them to health. The reason there are two disease paradigms in Lyme disease is because central pieces of the puzzle are missing or are inadequate. The first area of concern involves testing. There are no reliable biomarkers of the disease.¹ Current diagnostic tests commonly used do not detect the spirochete that causes Lyme disease, rather, they detect only whether the patient has developed antibodies to the pathogen. Antibody production, if it registers on the tests at all, takes weeks to appear, thus rendering the current tests ineffective in the earlier and more easily addressed stage. Additionally, the Lyme antibody has been shown to form a “complex” with the bacterium itself—and tests cannot detect “complex” antibodies. Once triggered, antibody reactions may remain long after an infection has been treated, also clouding the diagnostic and treatment picture. The two-tier testing system endorsed by the Centers for Disease Control and Prevention (CDC) is very specific for Lyme disease (99%), so it gives few false positives. But the tests have a uniformly low sensitivity (56%)—missing 88 of every 200 patients with Lyme disease. By comparison, AIDS tests have a sensitivity of 99.5%—missing only one of every 200 infected patients.² Sensitive AIDS tests were developed less than 10 years into the disease, while archaic Lyme tests remain unreliable 35 years later. There is a critical need for research exploring newer technologies such as polymerase chain reaction (PCR), which is used with many other diseases, and cutting-edge proteomics. Strain variations and co-infections with other organisms, often transmitted by the same tick bite, obscure the diagnostic picture further. A vast number of strains of *Borrelia burgdorferi* have been identified. Variation in strain may cause differing symptoms or severity of symptoms as well as determine the appropriate antibiotics and duration of treatment needed to clear the infection.³ Different strains may also express different proteins. Preliminary research shows that proteins need to be examined to find the ones most often expressed, then using microarray technology, doctors may be able to diagnose patients using a chip which contains the proteins. Research is needed concerning the role of mutation on persistence. Some research indicates that bacteria can exchange genetic material, probably contributing to its ability to invade different systems in the body— some may have a proclivity for the heart muscle, others for the brain, and some for muscles and joints. By exchanging genetic material, bacteria may be able to form a symbiotic relationship to avoid detection by the immune response or to further invade the body. To date, every NIH-funded treatment research study has been designed using the inaccurate diagnostic test results as part of the entry criteria. The entry criterion in these studies excluded the vast majority of Lyme patients and created sample sizes too small (less than 220 patients to date) to detect clinically important treatment effects or generalize to the clinical population. Moreover, Lyme has not attracted industry funding for treatment approaches, which places the disease at a considerable research disadvantage. To detect clinically relevant treatment effects requires much larger treatment trials with sample populations that reflect those seen in clinical practice.⁴ One thing that past research has demonstrated is that patients with Lyme are a heterogeneous population. Hence, the course of illness and responsiveness to treatment may vary depending on the duration of onset of the disease to its diagnosis and treatment, the presence of co-infections, comorbid factors, other genetic characteristics of the patients, and the virulence of the strain(s) with which the patient is infected. Research sample populations must reflect those seen in clinical practice to yield clinically relevant results. As advised by the Appropriations language, research on the pathophysiology of Lyme disease is necessary. Research projects need to be designed which determine the course of the disease from inception, and which utilize treatments that effectively interfere with the mechanisms that allow the infection to persist. Little to no government sponsored science has been dedicated to the effects on persistence of the different forms of the Lyme bacterium (cyst vs. flagellar), the role, if any, of biofilms, sequestration of the organism from the immune system, the exchange and mutation of genetic material of the spirochete, and the role that components of the bacterial genome may play in protecting it from eradication by the immune system or antibiotics. Understanding the pathology of the organism can greatly enhance targeted diagnostics and treatment modalities. Patients also need studies that explore a range of treatment options. The ideal antibiotics, route of administration, and duration of treatment for any stage of Lyme disease are not established. No single antibiotic or combination of antibiotics appears to be capable of completely eradicating the infection in all patients, and treatment failures or relapses are reported with all current regimens, although they are less

common with early aggressive treatment.⁵ Treatment failure rates suggest the need to re-examine the effectiveness of the currently recommended monotherapy as a treatment approach. Studies need to explore combination treatments and longer term treatment regimens, which have been critical to the successful treatment of AIDS and tuberculosis. Patients need the type of outcomes research advocated by the IOM to examine how well treatments are working in actual clinical practice.⁶ While not all patients with chronic Lyme disease have returned to a state of wellness, many have, and we need to find out how and why. This information can then be applied to other patients and used to establish a research agenda for treatment that has a likelihood of success, rather than abandoning patients based on limited treatment trials. The IOM process does not allow these research ideas to be heard in an unbiased and transparent fashion with balanced divergent viewpoints. While the NIH process precludes bias on the part of panel members, the IOM does not. Four of the six members of the IOM panel that have been selected belong to IDSA, a medical society that has a known bias against chronic Lyme disease diagnosis and treatment. Rather than providing curative treatments that restore health, the IDSA would provide costly and long term palliative treatments, presumably for life. While the NIH requires participation by major stakeholders (including patients and treating physicians), the IOM does not. The summary of the IOM proceedings will reflect this pervasive lack of objectivity, undermining its integrity and credibility. Additionally, much IOM deliberation is done behind closed doors and an anonymous panel will be permitted to comment on the written record. Because of such flaws in the IOM proceedings, the three largest patient interest groups who were offered a brief opportunity to speak (TFL) at the IOM October 2010 meeting and an opportunity to provide a commissioned paper—CALDA, the LDA and TFL—pulled out of the conference in protest. From a research perspective, strongly held paradigms can create a closed loop, and experiments may be designed, implemented and interpreted to support a particular viewpoint.⁷ The antidote to bias is to balance scientific perspectives and to ensure that all scientific viewpoints are being heard and explored. Given the extraordinary stream of federal funding granted to researchers who support the closed paradigm which was created and is supported by the Infectious Diseases Society of America (IDSA) and their vested interest in maintaining the status quo, it is not reasonable to expect this group of researchers to serve as neutral arbiters of scientific debates over competing scientific paradigms. For example, Lyme related panels dominated by IDSA have time and time again excluded opposing viewpoints from participating or controlled the review process to ensure outcomes that reinforce the IDSA paradigm. If past is prologue, it is obvious what the future holds for panels dominated by one group. Worse, the small treatment trials that have been conducted have been given an undue amount of weight by IDSA researchers and in its guidelines and used to apply a degree of certainty on the science that far exceeds the limitations of the small sample sizes of the studies. Further, they claim that the state of the science is sufficient to determine with certainty that chronic Lyme disease does not exist, is not treatable with antibiotics, and that no further research on this topic is needed. Sample size affects the strength of the conclusions that may be drawn from them: “Providing definitive answers in the face of low event rates and small-to-moderate treatment effects necessitates sample sizes in the thousands or tens of thousands. . . . Funding for such megatrials is very limited, and is often restricted to industry sources.”⁸ For that reason, the Connecticut Attorney General antitrust investigation into the development process of IDSA Lyme guidelines found exclusionary practices and suppression of divergent viewpoints on the part of IDSA panels that crafted IDSA 2000 and the 2006 Lyme disease guidelines. Although IDSA settled the investigation with the Attorney General by agreeing to review its guidelines with a panel without conflicts of interest, the control of the process was in the hands of IDSA, which again selected a panel consisting almost exclusively of IDSA members and excluding treating physicians who held divergent viewpoints. It was patients who pressed for the language in the Appropriations bill that called for a review of the state of the science of Lyme disease. However, patients need that process to occur in a transparent manner, without bias, and with the participation of all stakeholders. Albert Einstein defined insanity as “doing the same thing over and over again and expecting different results.”

VerDate Mar 15 2010 05:59 Oct 01, 2010 Jkt 089060 PO 00000 Frm 00081 Fmt 0626 Sfmt 0634
E:\CR\FM\A29SE8.278 E29SEPT2 tjames on DSKG8SOYB1PROD with REMARKS E1874 CONGRESSIONAL RECORD
— Extensions of Remarks September 29, 2010 This process is a perfect example of that insanity. Patients want research which will restore their health. Their voice and the voice of the clinicians must be given the necessary weight to legitimize the research agenda and the research process. Truth in science can be achieved through

open debate in an independent process free from bias and conflicts of interest. The scientific process fails when one side of a debate controls the arena and sets the rules to ensure that its viewpoint prevails. Lorraine Johnson, JD, MBA, Chief Executive Officer, California Lyme Disease Association. Patricia V. Smith, President, Lyme Disease Association, Inc. Diane Blanchard/Deb Siciliano, Co-Presidents, Time for Lyme, Inc. ENDNOTES 1 Steiner I. Treating post Lyme disease: trying to solve one equation with too many unknowns. *Neurology* 2003; 60:1888–9. 2 Stricker RB, Johnson L. Lyme wars: let's tackle the testing. *BMJ* 2007; 335:1008. 3 Weintraub P. What we don't know about Lyme. *Experience Life Magazine* June 2009. 4 Guyatt GH, Mills EJ, Elbourne D. In the era of systematic reviews, does the size of an individual trial still matter. *PLoS Med*, 2008; 5:e4. 5 Hunfeld KP, Ruzic-Sabljić E, Norris DE, Kraiczky P, Strle F. In vitro susceptibility testing of *Borrelia burgdorferi sensu lato* isolates cultured from patients with erythema migrans before and after antimicrobial chemotherapy. *Antimicrobial agents and chemotherapy* 2005; 49:1294–301. 6 Institute of Medicine (Committee on Quality of Health Care in America). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press, 2001. 7 Ernst E, Canter PH. Investigator bias and false positive findings in medical research. *Trends Pharmacol. Sci.* 24(5), 219–221 (2003). 8 Guyatt GH, Mills EJ, Elbourne D. In the era of systematic reviews, does the size of an individual trial still matter. *PLoS Med*, 2008; 5:e4.

<https://www.congress.gov/crec/2010/09/29/CREC-2010-09-29-pt2-PgE1872-2.pdf>