

educational loans to employees of a particular company must meet a number of criteria to avoid severe Federal tax penalties. Those criteria are designed to assure that such foundations were not set up as tax shelters or to provide nonmonetary compensation or benefits to employees. I agree with the good intentions of the current law, however, one of the requirements stifles the ability of private foundations to design scholarships for particular purposes. I am referring to the "25-percent test."

Under current law, a private foundation—usually established and funded by a single individual or employer—can offer scholarships to only 25 percent of students who apply. That means three out of four applicants must be turned down, not because of lack of merit or lack of funds, but to satisfy Federal rules.

My bill would remove that requirement from Federal law, but keep in place the seven guidelines the IRS has drawn up to meet the law's "objective and nondiscriminatory" standard. That way, private foundations could design more focused programs without weakening the safeguards against using such organizations for tax benefits or as hidden compensation. It also removes current law's discrimination against small communities with a single large employer.

Our laws should not discourage support for higher education. Foundations, reflecting the demonstrated generosity of their financial supporters, should not be told by the Federal Government that they have to deny three out of four of the students who may need their help. Rather, the door should be open for expanding the opportunities available to individuals.

TRIBUTE TO BOB LEE

HON. SCOTT MCINNIS

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. MCINNIS. Mr. Speaker, I rise today to recognize a great community leader in my home State of Colorado, Mr. Bob Lee. Although Bob recently retired from Daniels and Associates, he remains active in and continues to be sought out for advice and guidance by everyone from his neighbors, to Presidents of the United States.

He is a dedicated conservative and has been an active member of the Republican Party. He was first elected Denver County Republican chairman in 1958, and was instrumental in implementing a statewide plan to build a solid organization.

Word of Bob's skills and his conservative convictions traveled rapidly around the country. While he never intended to give up his real state career in Denver, he was called upon to advise and direct numerous campaigns. At the request of Richard Nixon, he agreed to run a successful legislative campaign in New Jersey, resulting in the Republicans controlling both Houses there for the first time in 25 years.

Mr. Speaker, Bob Lee and his wife Bee recently celebrated their 57th wedding anniversary, and I know you will join me in congratulating them on their wonderful marriage. Together they have three children, five grandchildren, and two great-grandchildren. They are respected in their community, which they have given so much back to.

PERSONAL EXPLANATION

HON. WILLIAM F. GOODLING

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. GOODLING. Mr. Speaker, last night I was present for roll vote No. 279, amendment 37 to H.R. 3666, the Veterans Affairs, Housing and Urban Development, and independent agencies appropriations bill. I slipped my voting card into the electronic voter tallying device and voted no. However, due to an electronic error I was recorded as not voting. I regret that my no vote was not recorded. As a result, my vote was paired with the minority leader.

AMERICAN LAND SOVEREIGNTY PROTECTION ACT OF 1996

HON. DON YOUNG

OF ALASKA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. YOUNG of Alaska. Mr. Speaker, today I introduce legislation which will require the specific approval of Congress before any area within the United States is subject to an international land use nomination, classification, or designation. International land use designations such as World Heritage Sites, Biosphere Reserves and some other international land use designations can affect the use and market value of non-Federal lands adjacent to or intermixed with Federal lands. Legislation is needed to require the specific approval of Congress before any area within the United States is made subject to an international land use restriction. The rights of non-Federal landowners need to be protected if these international reserves are created.

This legislation asserts the power of Congress under article IV, section 3 of the U.S. Constitution over management and use of lands belonging to the United States; protects State sovereignty from diminishment as a result of Federal actions creating lands with international designations; ensures that no U.S. citizen suffers any diminishment or loss of individual rights as a result of Federal actions creating lands with international designations; protects private interests in real property from diminishment as a result of Federal actions creating lands with international designations; and provides a process under which the United States may when desirable designate lands for inclusion under certain international agreements.

Many Americans may be surprised by the expanse of our Nation's territory which is subject to various special international restrictions, most of which have evolved over the last 25 years. The most extensive international land use designations are UNESCO Biosphere Reserve Programs and World Heritage Sites. These international land designations have largely been created with minimal, if any, congressional input or oversight or public input. They are usually promoted as a type honorary title which will provide additional publicity resulting in increased tourist visits and a corresponding increase in economic benefits. Promoters at UNESCO Biosphere Reserves and World Heritage Sites say these programs are voluntary and nonbinding.

However, in becoming a party to agreements underlying international land use designations, the host government explicitly promises to undertake certain actions to protect these areas and limit or prohibit certain land uses. Honoring one of these agreements could force the Federal Government to choose between regulating surrounding non-Federal land uses to conform to the designated international use of breaking a pledge to other nations.

Federal regulatory actions could prohibit certain uses of non-Federal lands outside the boundary of the international designation, thereby causing a significant negative impact on the value of non-Federal property and on the local and regional economy. This legislation would compel the Congress to consider the implications of an international designation and protect non-Federal lands before the designation is made.

FDA APPROPRIATIONS

HON. JOE BARTON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. BARTON of Texas. Mr. Speaker, I again note that the Appropriations Committee is recommending increased funding for the Food and Drug Administration. As chairman of the Oversight and Investigations Subcommittee of the Committee on Commerce, I commend the Committee on Appropriations for its strong support of the Food and Drug Administration, which plays an important role in protecting public health. In addition, I commend my colleagues on the Committee on Appropriations for their oversight activities regarding the Food and Drug Administration.

The Subcommittee on Oversight and Investigations has worked diligently in this Congress to identify shortcomings in FDA's performance of its important duties and work with the agency to correct those shortcomings. No problem in agency performance is as vexing as the systematic failure of FDA to meet its statutory duties to timely review various applications and petitions about food, drugs, and medical devices. Indeed, not only does the agency fail to meet its statutory duty for timely reviews, the agency refuses to acknowledge it. In testimony before the Committee on Appropriations, as well as the Committee on Commerce, Commissioner Kessler has boasted of meeting the goals of the Prescription Drug User Fee Act, alluding to objectives he identified and included in letters sent to Congress that were then made part of the legislative history of the Prescription Drug User Fee Act. However, Commissioner Kessler's testimony has consistently ignored the plain language of the Federal Food, Drug, and Cosmetic Act specifying review periods. Given Commissioner Kessler's legal training, one would expect that his testimony might be more mindful of the plain language of FDA's authorizing statute.

Timely review of applications and petitions is a matter of very real consequence. Witnesses who have come before the Oversight and Investigations Subcommittee have repeatedly told heart-wrenching stories of their inability to obtain in the United States safe and effective treatments that are available elsewhere. These patients, often fighting life-

threatening diseases, are the very personal side of the grim statistics regarding the adverse effect on public health caused by excessive delay in approval of safe and effective drugs and medical devices. There are also economic consequences. Hearing records explain clearly that as approval of medical devices is excessively delayed in the United States, the developers of those devices, principally U.S. firms, are forced by economic realities to begin manufacture of those devices overseas where more timely approvals have been obtained. It is dark humor that a joke told at an international medical device conference observed that if a medical device is approved in the United States, it must be obsolete. These delays not only deny American patients the most safe and effective therapies, but also result in the loss of U.S. jobs.

Regrettably, these are not small shortcomings. I urge my colleagues to review a table that lists the statutory deadline for review of certain applications and petitions, as well as the average time that FDA takes to conduct these reviews, according to the latest published FDA reports.

I trust my colleagues will share my concerns that agency performance is woefully off the mark. The Committee on Appropriations is to be commended for directing FDA to meet its statutory duties for timely review. I ask unanimous consent that this statement be printed following my remarks.

Food Additive Petitions.—Within 180 days (6 months) after filing of a petition, FDA is required to publish a regulation authorizing the use of the food additive or deny the petition. 21 U.S.C. §348(c). Current "average time to approval"—48 months. "Agriculture, Rural Development, Food and Drug Administration, and Related Appropriations for 1996," Hearings Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations, House of Representative, Part 6, 104th Cong., 1st Sess., p. 664 (Mar. 28, 1995) (hereafter "FY 96 House Agriculture Appropriations Hearings").

Health and Nutrient Content Claim Petitions.—Within 190 days (6.25 months) after filing of a petition, FDA is required to propose regulations authorizing the use of the health or nutrient content claim or deny the petition. 21 U.S.C. §343(r)(4). Current average review time from filing to issuance of a proposed rule—10 months. 62 Fed. Reg. 296 (Jan. 4, 1996); 60 Fed. Reg. 37,507 (July 20, 1995).

Nutrient Content Claim Synonym Petition.—Within 90 days (3 months) after submission of a petition, FDA is required to approve the use of the synonym for nutrient content claims or deny the petition. 21 U.S.C. §343(r)(4). Current average review time from submission to approval—19.5 months.¹ FDA Docket No. 94P-0216 (Letter from F. Edward Scarborough, Ph.D., Director, Office of Food Labeling to Douglas C. Marshall, Darigold, Inc. (Oct. 30, 1995)).

New Human Drug Applications (NDAs).—Within 180 days (6 months) after filing of an application, FDA is required to approve the human drug or give the application notice of an opportunity for a hearing before FDA on the question of whether the application is approvable. 21 U.S.C. §355(c)(1). Current average time for "first action"—twelve months. Statement by David A. Kessler, M.D., Commissioner of Food and Drugs, Department of Health and Human Resources Before the

Subcommittee on Health and Environment, Committee on Commerce, U.S. House of Representatives, p. 4 (May 1, 1996) (hereafter, "Health and Environment Subcommittee Hearing").

Abbreviated New Drug Applications (ANDAs).—Within 180 days (6 months) after initial receipt of an application, FDA is required to approve the drug or give the applicant notice of an opportunity for a hearing before FDA on the question of whether the applicant is approvable. 21 U.S.C. §355(j)(4)(A). Current average review time from receipt to approval—34.2 months. Department of Health and Human Services Fiscal Year 1997 Justification of Estimates for Appropriations Committees for the Food and Drug Administration, p. 65 (hereafter "FY 97 FDA Justification of Estimates for Appropriations Committees").

Medical Device Premarket Approval Applications (PMAs).—Within 180 days (6 months) after receipt of an application, FDA is required to approve the medical device or deny the application. 21 U.S.C. §360e(d)(1)(A). "Current average review time"—20 months. Health and Environment Subcommittee Hearing, pp. 9-10.

New Animal Drug Applications (NADAs).—Within 180 days (6 months) after filing of an application, FDA is required to approve the animal drug or give the applicant notice of an opportunity for a hearing before FDA on the question of whether the application is approvable. 21 U.S.C. §360b(c)(1). Current average review time from receipt to approval—39 months. FY 97 FDA Justification of Estimates for Appropriations Committees, p. 83.

Abbreviated New Animal Drug Applications (ANADAs).—Within 180 days (6 months) after initial receipt of an application, FDA is required to approve the generic animal drug or give the applicant notice of an opportunity for a hearing before FDA on the question of whether the application is approvable. 21 U.S.C. §360b(c)(2)(C). Current average review time from receipt to approval—31 months. FY 97 FDA Justification of Estimates for Appropriations Committees, p. 84.

CONGRATULATIONS EAST ORANGE WELFARE DEPARTMENT

HON. DONALD M. PAYNE

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. PAYNE of New Jersey. Mr. Speaker, I urge my colleagues to join me in recognizing the outstanding work that is being done on behalf of women by the East Orange Welfare Department, in my district in New Jersey. For the past 10 years, the East Orange Welfare Department has dispel some of the negative stigmas associated with women and welfare and to recognize and applaud the achievements of women in the community.

Too often, women are the subject of the cruel realities of gender discrimination, sexism, sexual harassment, and the like in this historically male-biased society. The East Orange Welfare Department has taken on the responsibility of speaking out on behalf of the accomplishments of women, and glorifying rather than stigmatizing them. We must join the East Orange Welfare Department as they recognize the invaluable impact that women have had on every facet of our modern communities.

The East Orange Welfare Department has served to support its citizens by the coordination of fiscal, medical, and social services in

the community and has been instrumental in providing an environment intent on fostering financial independence and self-sufficiency. Its recent call to honor women is simply another example of the department's firm commitment to not only help those in need, but to lend a voice to those too frequently unheard.

Mr. Speaker, please join me in commending the dedicated employees at the East Orange Welfare Department for their outstanding work in advancing the progress of women.

50TH ANNIVERSARY OF CDC

HON. CONSTANCE A. MORELLA

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mrs. MORELLA. Mr. Speaker, the Nation's prevention agency, the Centers for Disease Control and Prevention [CDC], will turn 50 on July 1. As co-chair of the Congressional Caucus for Women's Issues and a strong supporter of this agency's prevention mission, I would like to acknowledge the 50th anniversary milestone with a few examples of how CDC has effectively promoted women's health.

The CDC National Breast and Cervical Cancer Early Detection Program provides mammography screening and Pap smear services to low-income and underserved women. This program has been critical to the early detection of breast and cervical cancer in poor, elderly, and minority women.

CDC has been working toward the implementation of a national STD-related infertility prevention plan, and has awarded grants to university/health department consortia for chlamydia research. A chlamydia prevention program in region X between 1988 and 1994 has provided chlamydia screening in nearly every title X family planning clinic; the resulting rate of chlamydia has decreased from about 10 percent to below 5 percent. The CDC is currently working to implement this program throughout the country.

CDC has issued guidelines promoting voluntary HIV counseling and testing of pregnant women, recognizing that a voluntary approach is the most effective way of preventing perinatal transmission of HIV. The CDC guidelines will provide access to early interventions that will actually prevent perinatal transmission, and link them to HIV care and services. Preserving a patient-provider relationship of trust is essential to keeping women in the health care system.

CDC has implemented a long-term, comprehensive national strategy for reducing smoking among women. Cardiovascular disease is the No. 1 killer of American women, and smoking prevention must be a primary part of any strategy to address this women's health threat. CDC has awarded a number of grants to State health departments to implement effective tobacco prevention and control programs targeted to women.

CDC has also funded community demonstration projects to prevent violence against women, another priority of the Women's Caucus.

I am particularly pleased to note the establishment, in 1994, of an Office on Women's Health at CDC, which has worked to ensure that women's health needs are adequately addressed in CDC's research projects and prevention programs. Indeed, promoting women's

¹To date, FDA has received only one synonym petition.