

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.