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.

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

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

health is one of the five priorities of the agency, as articulated by its Director, Dr. David Satcher.

Again, I congratulate the agency and its dedicated scientists, epidemiologists, and public health personnel for their hard work and accomplishments, and wish them continued success in the next 50 years.

MANAGED CARE BILL OF RIGHTS FOR CONSUMERS ACT OF 1996

HON. NYDIA M. VELÁZQUEZ

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Ms. VELÁZQUEZ. Mr. Speaker, I rise before you today to introduce a crucial piece of legislation—the Managed Care Bill of Rights for Consumers Act of 1996. I introduced this legislation in response to a repulsive and dangerous trend taking place in this country. Seven out of ten Americans are now in some form of managed care plan. Although this newest form of health care has been successful in cutting costs, it has done so at the expense of patient care. Working class people are falling victim to a cruel and vicious system that far too often puts profits before people.

Health care companies should make people healthy, not sick, yet enrollees with specific or rare diseases are not provided specialists to treat their illnesses. Even more alarming, HMO patients are routinely denied compensation for emergency room visits and managed care companies often include financial perks in the contracts of doctors who withhold patient services and lab reports in order to save money. So while ultra wealthy HMO's are making billion dollar profits, working class families are paying for those profits with their health and in some cases their lives.

My bill seeks to eliminate these problems and many more by ensuring that there is a wider variety of care providers to choose from and that providers are geographically accessible to patients. Moreover, my bill seeks to prohibit unhealthy HMO policies by allowing out of network options for specialists and emergency room care without prior approval.

I implore my colleagues on both sides of the aisle to join me in sponsoring this essential piece of legislation. Assist me in safeguarding the American citizens' access to quality, affordable health care.

DEFENSE AGAINST WEAPONS OF MASS DESTRUCTION ACT OF 1996

HON. JOHN M. SPRATT, JR.

OF SOUTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. SPRATT. Mr. Speaker, Dhahran is a grim reminder that terrorists today are not only insidious and stealthy but technically sophisticated. It is only a matter of time till they couple their unconventional tactics with unconventional weapons. Terrorists have already released chemical weapons in the Tokyo subways. Biological, and even nuclear weapons, are only a few steps removed, and well within their reach.

For that reason, I am pleased to sponsor in the House a bill that Senator NUNN, Senator LUGAR, and Senator DOMENICI offered in the Senate this morning as an amendment to the Defense authorization bill. Rep. BILL MCCOLLUM, who has a longstanding interest in counter-terrorism, joins me as a cosponsor.

In the Defense Against Weapons of Mass Destruction Act, we set forth a set of policies to respond to a threat that has emerged and grown with the end of the cold war. We can all be relieved that the risk of nuclear attack by Russia has receded. By the end of this year, Ukraine, Byelorussia, and Kazakhstan all should be free of deployed nuclear weapons. But the breakup of the Soviet Union has opened up a storehouse of destructive weapons and components to terrorist groups and nations hostile to the United States. So, ironically, while the risk of nuclear annihilation has become more remote, we find ourselves faced with a growing risk of attacks, albeit limited, by nuclear, biological, or chemical weapons.

We have spent considerable time in the House debating defenses against intercontinental ballistic missiles, and it is a pertinent debate about a serious threat. But our focus on ICBMs may have deflected our attention from a far more likely threat: a terrorist-type bomb, with a nuclear, biological, or chemical warhead. This technology is easier to develop than ICBMs, and as the chemical attack in the Tokyo subway makes clear, terrorist groups can and will use these weapons. In fact, they offer terrorists plausible deniability—they can use such weapons and leave the United States with no clear-cut enemy to retaliate against. Ballistic missiles, on the other hand, leave a return address written in several thousand degrees fahrenheit.

This bill will help shift attention to the everyday threats that proliferation is creating. Moscow has acknowledged that it has 40,000 metric tons of chemical weapons in its stockpile. There are about 80 facilities in the former Soviet Union that store weapons grade nuclear materials, and as the Center for Strategic and International Studies said in a report released this week, these poorly protected storage sites are patrolled by demoralized and underpaid guards. Russian law enforcement officials reported 54 cases of theft of fissile materials in 1993 and 1994, and both German and Czech officials have seized fissile materials originating in the FSU. In Project Sapphire, we airlifted 600 kilograms of highly enriched uranium-enough for a dozen bombs—from a facility in Kazakhstan that was protected by little more than a padlock. We cannot possibly bring all of the nuclear, chemical, and biological weapons and materials of the former Soviet Union here to the United States; we must help these nations secure these materials, and by doing so, help protect ourselves.

It is not just the FSU, of course, that we have to be concerned about. Libya is constructing a chemical weapons facility in Torhuna. North Korea probably possesses enough plutonium to make several nuclear weapons. China is assisting Iran in building a uranium hexafluoride [HEX] facility which converts uranium into a gaseous form so it can be diffused to produce highly enriched uranium. There are allegations that a Russian General helped smuggle binary nerve agents to Syria. All these incidents point to the possibility of a terrorist-type attack by some weapon of mass destruction at some point in the not-too-distant future.

The legislation Representative MCCOLLUM and I are introducing today addresses the problem in three broad ways:

First, stopping the spread of weapons of mass destruction and their components. The FSU offers terrorist groups and nations hostile to the United States their multiple chances to pilfer or acquire on an inchoate black market various weapons of mass destruction [WMD]. This bill will help the FSU tighten up security over these weapons and materials, and monitor and verify their status.

Second, making sure the United States can detect and interdict weapons of mass destruction and their materials. The United States has concentrated very little effort on how to detect weapons of mass destruction or their component materials if smuggled into this country, and we have done too little to learn how to disable these weapons safely, once discovered. This bill will help develop these capabilities.

Third, being prepared should the United States be the victim of a weapon of mass destruction. The United States is not equipped to deal with an attack by a weapon of mass destruction. The World Trade Center and Oklahoma City bombings were devastating, and the bombing in Dhahran shows just how vulnerable Americans are to terrorist attack—but these attacks pale in comparison to a nuclear, biological or chemical weapon attack. This bill will train Federal, State and local officials to act in a coordinated way in response to nuclear, biological, or chemical weapon attacks.

I am pleased to have Representative MCCOLLUM join me in introducing this legislation. He is a leader in the Congress on this and related issues of law enforcement. He was a member of the CSIS steering committee that produced The Nuclear Black Market study published earlier this week, which helped frame this legislation. And as Chairman of the Judiciary Committee's Subcommittee on Crime, Representative MCCOLLUM's support of this legislation will be critical in ensuring its adoption.

Representative WELDON weighed cosponsoring this legislation with Representative MCCOLLUM and me, but decided to take more time to consider specific parts of the bill. I understand that Representative WELDON may introduce a modified form of the bill sometime next month, and I hope to work with him on that. Representative MCCOLLUM and I likewise may modify or add to the bill before us, so this does not purport to be the last word on the subject, but it does represent a solid, bipartisan baseline from which to start. In dealing with threats like these, we do not need to divide along party lines. The bill received an enormous vote of support in the Senate this morning. I hope we can amass the same support in the House and move the bill swiftly to passage or include it in the Defense authorization conference report, so that we can begin implementing it in earnest.

DOROTHY AND DON BERO CELEBRATE 50TH WEDDING ANNIVERSARY

HON. PAUL E. GILLMOR

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 27, 1996

Mr. GILLMOR. Mr. Speaker, I rise today to pay tribute and give congratulations to Don