THE MEDICAL DEVICE REGULATORY MODERNIZATION ACT OF 1997

HON. ANNA G. ESHOO

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Ms. ESHOO. Mr. Speaker, I'm pleased to join with my colleague from Texas, Mr. BARTON, to introduce the Medical Device Regulatory Modernization Act of 1997.

Since coming to Congress over 4 years ago, I have heard a consistent message from medical device companies in my district—the Food and Drug Administration is not keeping up with innovation. Companies were asking for congressional action to help modernize FDA's regulatory process.

The bipartisan legislation we are introducing today accomplishes that goal.

We've had testimony before the Commerce Committee that the agency lacks the resources to keep up with its workload and as a result reviews were taking too long.

The Barton/Eshoo bill frees up FDA resources by allowing for independent review for class I and class II devices that are not implantable or likely to cause serious harm if they fail. Class I and class II devices are relatively less complex, ranging from surgical gloves and syringes to MRI machines. By increasing the use of third parties for lower risk devices, the agency will be able to focus their attention on higher risk, more complicated products that demand greater resources and time.

We were told that a chasm of communication exists between medical device companies and the FDA.

Under our legislation, FDA will be required to meet with applicants at their request both during the investigational device exemption phase and early on in the product review stage. It is hoped that through this increased communication, there will be a greater understanding on the part of the applicant as to what the agency will require for approval, and a greater understanding by the agency of the technology being employed by the applicant.

We heard that the FDA needs to recognize national and international performance standards to cut down on paperwork and redundant reporting requirements.

The bill allows the FDA to recognize national and international standards and allows companies to self-certify to these standards. There are penalties for the falsification of data and all certification information is available at FDA's request.

Last, companies have raised concerns that in reviewing applications, FDA has, in the past, required information from companies that is outside the scope of the application.

The bill makes clear that it is FDA's job to review applications for substantial equivalence, for lower risk devices, or safety and effectiveness, for higher risk devices. The agency is not charged with reviewing relative effectiveness, which should be determined by the marketplace, or for reviewing items outside the proposed intent of the device; as long as the public health is not at risk.

These are some of the key provisions of the legislation, but they are by no means the only important provisions in this bill. There are 22 sections to the legislation that address issues including cost market surveillance, dispute resolution, humanitarian use of devices, device tracking and regulatory harmonization to name a few. It is a comprehensive approach to modernizing the way the FDA regulates medical devices.

Representative BARTON and I have worked very hard to ensure that this bill moves the agency forward. It's a positive blueprint to strengthen the FDA's oversight of the public health. I believe it will help the agency review products more efficiently and improve communications between FDA and industry, brining new products to market and to the patients that urgently need them.

I urge my colleagues to support it.

IN MEMORY OF HAZEL SCHWEIRKING GRAFFEO

HON. MARCY KAPTUR

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Ms. KAPTUR. Mr. Speaker, I rise today to pay tribute to a remarkable woman from my district. Hazel Schweirking Graffeo of Oregon, OH passed away on Tuesday, April 29, 1997. Mrs. Graffeo fought a very courageous 8 year battle with cancer. Although that battle cost her dearly, she never lost her spirit.

Mrs. Graffeo was devoted to her husband and family, and enjoyed cooking for them. She also loved entertaining for others. She was a fan of big band music and enjoyed dancing. She loved reunions and other family activities.

Mrs. Graffeo's generous heart extended beyond her family and friends. She was an active member in the Alba Club, the Oregon Democratic Club, St. Charles Hospital Auxiliary, VFW Post 9816, and St. John Lutheran Church in Williston, OH. Everywhere, she exuded good cheer, strong values, and made others feel welcome.

Mrs. Graffeo is survived by her husband Joe and daughters Sharon, Janet, Janice, and Carolyn, as well as 12 grandchildren and 12 great-grandchildren. Our sympathies and prayers are with them, but we know that the memory and example set by Hazel Graffeo will give them a measure of comfort. Even as they mourn their loss, may they celebrate her life.

SUPPORT FOR THE DRUG FREE COMMUNITIES ACT OF 1997

HON. BERNARD SANDERS

OF VERMONT

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. SANDERS. Mr. Speaker, I rise today in support of the Drug Free Communities Act of 1997, legislation which supports communities across the Nation in their efforts to reduce rising teenage drug abuse. Studies show that teenage use of marijuana, inhalants, cocaine, methamphetamine, LSD, heroine, and other drugs is on the increase—and it is among children that we are seeing the greatest increase in use. The Drug Free Communities Act of 1997 is an important step toward empowering communities to fight the growing phenomenon of drug abuse among our Nation's youth.

I would like to add that I very much appreciate that the original cosponsors of this bill, Mr. PORTMAN, Subcommittee Chairman HASTERT, Mr. LEVIN, and Mr. RANGEL, as well as the subcommittee ranking member, Mr. BARRETT, were very willing to work with me to mold this legislation so that rural communities, as well as urban communities, are given the same chance to benefit from this Federal program. Because of our discussions, this bill now provides that antidrug coalitions in rural communities, communities under 30,000 people, will be given the opportunity to receive up to $100,000 in Federal matching funds. This puts rural communities at the same level as urban communities for receiving Federal matching funds.

Mr. Speaker, let me emphasize that drug abuse is not only an urban problem, but is also a problem in the rural communities of this country. Drug pushers find a market for their drugs, not only in the schools of urban areas, but also in the schools of our rural areas. We are beginning to see gang activity in our rural communities and these gangs are largely centered around drug use. Presently, it is our rural areas which are ill-equipped to handle an influx of drugs because rural areas do not have access to the local resources which urban areas enjoy. Because of bipartisan cooperation which has taken place, rural antidrug coalitions will be better able to deal with drug abuse problems.

Again, I thank the gentlemen for their cooperation and willingness to accept my input on this bill, and I urge passage of this important legislation.

SMALL BUSINESS REMEDIATION ACT

HON. JOE BARTON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. BARTON of Texas. Mr. Speaker, I rise today to introduce a bill which will help improve the environment while protecting small businesses. This bill, the Small Business Remediation Act, will enable the Nation's 30,000 dry cleaners, their employees, neighbors, and customers to improve the local environment while preserving the dry cleaners' ability to preserve businesses and remain vital contributors to their communities. The bill has bipartisan support in Congress and tremendous nationwide support from the dry cleaning industry, and I urge the House to pass the legislation.

For the last few years dry cleaners, one of the largest groups of small businesspeople in America, have faced substantial potential liability associated with the remediation of soil surrounding some dry cleaning businesses. This potential liability has resulted in the small business owners in the industry having trouble obtaining or renewing leases and borrowing money, or even risk bankruptcy.

This potential liability is being greatly compounded by the misapplication of the Federal drinking water standard to soil remediation projects. This makes no sense, of course, but this standard is being used by States which are overseeing the remediation of some dry cleaning sites mostly because there is no other standard readily available.

The Federal drinking water standard for the relevant compound—perchlorethylene or

perc—is set at 5 parts per billion. Unfortunately, while that level might be appropriate for drinking water, it can hardly be considered necessary for protection from perchlorethylene in dirt.

As a result of the arbitrary, illogical situation of applying the drinking water standard in other cases, dry cleaners increasingly face clean-ups requiring staggering sums of money. In many cases, the dry cleaner may simply be forced to declare bankruptcy and walk away penniless. In such cases, the soil is not remediated, the environment is not improved, and the community is weakened.

Last fall, the House Commerce Committee, Subcommittee on Oversight and Investigations, which I chair, held hearings on this issue. We heard witnesses who testified that they had lost businesses built over a lifetime, suffered terrible emotional distress, spent millions of dollars chasing illusory risks, and been prevented from expanding their businesses because of this mismatched regulatory approach. Most disturbing, we repeatedly heard that many dry cleaners fear to pass their business along to their children, all because of the possibility of being caught in this bureaucratic web. This is not healthy for our communities or our environment.

To remedy this problem, the Small Business Remediation Act would like the soil remediation standard for perc to the Occupational Safety and Health Administration standard, which is currently set at 100 parts per million. This is the standard which OSHA has found to be protective of workers who are exposed to perc in the workplace everyday for their entire working lives.

The bill I am introducing today would set the remediation standard 10 times stricter than the OSHA standard. If OSHA strengthened its standard in the future, the soil remediation standard would be strengthened automatically. Therefore, it does not freeze science, and allows changes in new evidence dictates.

The bill does not change the Federal drinking water standard and does not prevent States or EPA from cleaning up dry cleaning sites.

Our approach will provide certainty to dry cleaners, their neighbors, surrounding businesses, banks, and the entire community. At the same time, by setting an achievable goal, the Small Business Remediation Act will lead to more efficient and timely improvements of the environment. By providing certainty, it will help focus resources on clean-ups, not lawyers.

Mr. Speaker, I encourage all Members to join us in this commonsense approach to a problem that affects all American communities. By supporting the Small Business Remediation Act, Members can help improve the environment, strengthen small business, and promote the prosperity of our neighborhoods and towns.

THE MANAGED CARE PLAN ACCOUNTABILITY ACT OF 1997

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. STARK. Mr. Speaker, together with Mr. KILDEE, Mrs. LOWEY, Mr. MILLER of California, Mr. FRANK of Massachusetts, Ms. PELOSI, Mr. SANDERS, Mr. TIERNEY, Mr. FROST, Mr. DELLUMS, Ms. CHRISTIAN-GREEN, Mr. LEWIS of Georgia, Mr. DEFAZIO, Mr. WAXMAN, Mr. RANGEL, Mr. KLECZKA, Mr. BERMAN, Mr. KENNEDY of Rhode Island, Ms. RIVERS, Mr. MCGOVERN, Mr. KUCINICH, and Ms. TAUSCHER, I am proud to introduce the Managed Care Plan Accountability Act of 1997, a bill which amends ERISA to provide equality and fairness to the millions of Americans whose health benefits are regulated by the Federal Government.

ERISA was enacted in 1974 to uniformly govern employee benefit plans. To this end, ERISA includes a wide-ranging preemption provision that supersedes any and all State laws insofar as they relate to an employee benefit plan, including health insurance.

Under current law, ERISA managed care plans are often completely exempt from liability for any medical decision made as a result of plan policy. If a patient is injured as a direct result of a plan's cost-containment policy, for example, the patient is entitled to sue only for the value of the denied treatment. Patients in ERISA plans are not entitled to other compensation, such as lost wages or pain and suffering, as is currently available to patients in non-ERISA plans.

For example, Newsweek magazine recently reported a case in which a managed care plan denied a heart attack victim's request for surgery because the only hospital qualified to perform the needed procedure was located outside of the plan's service area. By the time the patient appealed the decision and received the necessary approval, it was too late. The patient's heart was damaged beyond repair, and he died shortly thereafter while awaiting a heart transplant. In this case, the patient's health insurance was part of an employer-sponsored benefits package and therefore, regulated by ERISA.

Under current law, the family was entitled only to the cost of the denied procedure. In other words, the most damaging thing that could happen to the HMO responsible for the loss of their loved one is the cost of the procedure that could have saved the person's life.

While a price tag should never be put on a human life, there should be some reasonable compensation paid to patients and their families who are victims of medical malpractice. This is especially true when victims suffer life-altering, if not fatal injuries due directly to the negligence of a plan executive attempting to save money.

Imagine if your child died of leukemia because your HMO would not authorize an early blood test. The twisted irony is that you could recover no more than approximately $130—the cost of the test. A child's life is surely worth more than $130. This is a travesty.

This bill would create a new cause of action under ERISA which would allow consumers to seek additional damages from employer-sponsored health plans. The new cause of action would have concurrent jurisdiction, allowing the action to be brought either in Federal or State court. Additionally, this legislation would protect physicians from unfair lawsuits by making the health plan responsible for constraints they place on providers.

Our legislation is fair and long overdue. Plans that actively manage the care of their enrollees must be held accountable for their decisions. Employees of ERISA-regulated health plans deserve the same rights and protections as people in non-ERISA plans.

HONORING DEWITT CLINTON HIGH SCHOOL

HON. ELIOT L. ENGEL

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. ENGEL. Mr. Speaker, DeWitt Clinton High School, in my congressional district, opened its doors for the first time in 1897 with about 500 boys and 21 faculty assembled to hear from the principal. Since that time the school has moved several times and its enrollment has grown to 3,850.

The school has also grown in stature and this year it was named one of the five most improved high schools in the United States. DeWitt Clinton was also praised because of its outstanding peer mediation and negotiation program.

The school meets or exceeds all of the chancellor's standards. Its college admission rate was 91.1 percent last June while its drop-out rate was only 2.8 percent. Its attendance rate is 90.8 percent. The students have also shown consistent improvement in the State regents exams over the past 4 years. Perhaps most significantly, it is one of only 11 New York City high schools, out of 136, given the highest 5-star rating by the New York Times.

A measure of a school's success is a list of its graduates and DeWitt Clinton's is most impressive with such alumni as James Baldwin, Burt Lancaster, Richard Rodgers, Neil Simon, A.M. Rosenthal, Paddy Chayefsky, Daniel Schorr, Arthur Gelb, Fats Waller, Jan Peerce, Nate Archibald, Bernard Kalb, and Stan Lee. These are people who have given to the country and to the world. The students at DeWitt Clinton have a strong tradition to uphold and show every indication of doing it.

I join my colleagues in congratulating the school, its faculty, its students, and their parents as representatives of a century of higher education.

TRIBUTE TO AARON HENRY

HON. SANDER M. LEVIN

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 22, 1997

Mr. LEVIN. Mr. Speaker, on, May 19 a wonderful human being and a truly great American passed away in Clarksdale, MS—Aaron Henry.

I mention first his human qualities because of the unusual warmth of his personality and capacity for friendship. Had he only been a friend, as he was for so many of us from many walks of life, he would remain indelibly etched in our thoughts and memories. Of course, his life went far beyond private relationships and friendships. He dedicated so much of his time to the public arena, pursuing the American Dream of equal opportunity for all Americans.

He started in this pursuit, in the Army during World War II where he fought for integration and next as he obtained a degree in pharmacy under the GI bill. He then set up shop on Fourth Street in Clarksdale, which became his source of livelihood and a major hub for those working with him to bring equal opportunity and justice to Mississippi. I first saw