

Statement on Signing the Medical Device User Fee and Modernization Act of 2002

October 26, 2002

Today I have signed into law H.R. 5651, the “Medical Device User Fee and Modernization Act of 2002.” The Act protects patients from inappropriate reuse of medical devices, strengthens the inspection regime for medical device manufacturing facilities, modernizes Food and Drug Administration (FDA) medical device operations, and establishes a program under which the users of the FDA’s medical device review services pay for those services.

Section 201(a) of the Act enacts section 704(g)(10) of the Food Drug and Cosmetic Act, which purports to make the operation of the “accredited persons” inspection provisions for medical device establishments dependent upon certain determinations by the Comptroller General, a legislative agent, of amounts obligated by the Secretary of Health and Human Services for particular purposes. The executive branch

shall construe this provision in accordance with the principles set forth in *Bowsher v. Synar*, 478 U.S. 714 (1986).

Several provisions of the Act require executive branch officials to submit recommendations to the Congress. The executive branch shall construe such provisions in a manner consistent with the President’s constitutional authority to submit for the consideration of the Congress such measures as the President judges necessary and expedient.

GEORGE W. BUSH

The White House,
October 26, 2002.

NOTE: H.R. 5651, approved October 26, was assigned Public Law No. 107–250. This statement was released by the Office of the Press Secretary on October 28.

Remarks in Alamogordo, New Mexico October 28, 2002

The President. Thank you all very much. *Hola.*

Audience members. *Hola.*

The President. *Si.* Thank you all for coming today. It’s a beautiful day here. Of course, every day is a beautiful day in New Mexico. I love to come to a part of the country where the cowboy hat is—the cowboy hat, instead of the tie, is a part of the work uniform. It kind of reminds me of home, right around the corner from here.

They tell me I’m the first President ever to come to Alamogordo. For that, I’m honored. I’m honored, and I’m honored so many of my fellow Americans have come

out to say hello, to listen to what’s on my mind. First of all, what’s on my mind is that in order to be a good American, in my judgment, you’ve got to exercise your right. You’ve got to go to the polls. In order to do your job as an American, you can’t take democracy for granted. You owe it to our society to go vote.

Of course, I’ve got a few suggestions for you when you go to the polls. It doesn’t matter to me whether you’re a Republican, Democrat, or independent. You have an obligation. So I’m here to urge you all to do your duty and to go to your coffee shops and your houses of worship, community centers, and urge your fellow citizens to

do their duty as well. And while you're asking them to do it, remind them, for the good of New Mexico and for the good of the country, Steve Pearce is the right man for the Congress.

And I also want you to remind them that you've got a good man running for Governor, a man who can do the job, a man who represents the best of New Mexico. Tell them John Sanchez is the right man for the Governor of New Mexico.

I'm proud to be here today with a member of my Cabinet. His name is Mel Martinez. I want to tell you about Mel's story right quick. He was a young boy, born in Cuba, but his mother and daddy realized the promise of America. They realized that the land of freedom was the right place to raise their child. And so they sent Mel by himself from the island of Cuba, from the island of Cuba to escape the clutches of Fidel Castro's repressive regime, to America. His mother and daddy decided America was so important and so promising that they made an incredibly difficult choice for a mother and dad, and that is, they said, "Son, we love you. We love you so much that we're sending you by yourself as a young boy to America." And here he is today, in the Cabinet of the President of the United States. He represents the best of America, the promise of America, and the hope of America.

And that's the greatness of this country. And that's what we've all got to work together to achieve, to make sure the greatness of America and the promise of America shines brightly for everybody.

I'm proud to be here today with my friend the Governor of New Mexico and the great first lady of New Mexico, Gary and Dee Johnson. And one thing for certain is, I'm not going to challenge him to a footrace—[laughter]—or a bike race, or a swimming race. [Laughter] I mention the first lady—unfortunately, you drew the short straw today. If you really were smart, Steve would have invited Laura to come instead of me. I just talked to her on the

phone. She's in Crawford. She's fixing to head up to Washington. She's doing great, by the way. I'm really proud of her. She was born and raised in Midland. When I met her, she was—actually, we went to eighth grade together at San Jacinto Junior High. And then we got to know each other again, and when I met her, she was a public school librarian. [Applause] Oh, yeah. There's always one or two in every crowd. [Laughter]

I don't know how you feel about politics, but I can tell you how she felt about politics. She didn't care for them. [Laughter] When I married her, she didn't like politicians. Yeah, I know. [Laughter] But fortunately, she said yes when I asked her to marry me, and she is a great First Lady for America. I think it has a lot to do with the part of the world that we're from, the part of the world she's from—your part of the world, a place where values matter a lot, where family counts first, where faith is important.

Today I'm sorry that one of the really finest United States Senators amongst the 100 is not with us. He's on his way to mourn the loss of a fellow Senator, Paul Wellstone. We all send our prayers and thoughts to his family. Pete Domenici is one of the fine ones. He's a really, really great American. He's a solid, solid citizen. And I hope, if all goes right next Tuesday, all around the country we're going to start calling him Mr. Chairman again, because we're going to change the United States Senate.

No, I'm working hard to make sure that Denny Hastert remains the Speaker. That's why I want you to send this good man, Steve Pearce, to the Congress. I want to urge you to make sure that Pete Domenici goes back to the Senate. We're working hard so that we can say with certainty that in Washington we're working together to make America a better place.

I appreciate so very much the fact that Joe Skeen has served New Mexico with distinction. Joe's a good man. I've known

him for a long time. Of course, he's struggling right now with physical affliction, but his faith is strong; his spirit is high. And we all owe him a debt of gratitude for serving this great part of the world with class.

I want to thank the mayor of Alamogordo for coming here. I appreciate, Mr. Mayor, your good work for this important community. I want to thank all of you all who are involved with grassroots politics—Republican grassroots politics, those of you who man the phones and put the signs in the yards and lick the envelopes. It's an essential part of democracy. It's an essential part of how people win. I want to thank you for what you have done. I want to thank you for what you're going to do, which is do everything you can to turn out a big vote for these good candidates.

And there's a reason—not just because they look pretty. [*Laughter*] Well—[*laughter*—because they've got ideas on how to make New Mexico a better place and how to make the country a stronger place. John Sanchez understands that education is the most important priority for any State. That's what he knows. He knows what I know, that in order to be effective, in order to make sure people can learn, you've got to set high standards. You've got to believe every child can learn. You've got to challenge what I call the soft bigotry of low expectations.

If you lower the bar, you're going to get lousy results. If the system believes that certain children can't learn, you know what's going to happen? People are going to get left behind. You've got to have the highest of high standards. You've got to believe every child can learn, especially those children whose parents may not speak English as a first language. You've got to have a Governor in whose heart of hearts understands that high expectations is one of the keys to success. And then you've got to have a Governor who doesn't get captured by the special interests of any State capital or National Capital but a Gov-

ernor who trusts the local people to chart the path to excellence for every child. Local control of schools is an incredibly important part of educational excellence.

No, education is important. And if you believe every child can learn, then you want to have an accountability system which will show us whether every child is learning. See, if you believe every child can learn, then you better have yourself a Governor who's willing to ask that fundamental question, can our children read and write and add and subtract? Can we teach them early enough, before it's too late? You want to have a measuring system so that you're able to praise the teachers for their good work. And for all of you who are teachers, thank you from the bottom of our heart.

But in order to make sure every child can learn, if you believe every child can learn, then you want to know. In order to make sure, you better have an accountability system that tells us whether or not our children are trapped in schools which will not teach and will not change. And then you have a better—Governor who's got the courage and the willingness, for the sake of the children, to demand change. No child should be left behind in the State of New Mexico when John Sanchez is your Governor.

If one of the concerns is jobs in New Mexico, then it seems like to me you better get you a Governor who knows how to create jobs. See, he's done that. He's an entrepreneur. He understands the role of small business in our society. Small businesses create 70 percent of the new jobs in America. So get you a Governor who knows that, and get you a Governor who also understands the role of Government is not to create wealth; the role of Government is to create opportunity, opportunity for our small businesses to grow to be big businesses, opportunities for our farmers and ranchers to be able to make a living.

John Sanchez is the right man for Governor. When you turn out the vote, make sure you back this good man. He's going

to make you one you can be proud of. And I need Steve up in the United States Congress. I don't need to be worried about a vote from this part of New Mexico. I need somebody who's going to work with me on a solid way, somebody we can count on. And the reason I know I can count on him is because we share the same philosophy about life. We understand the role of Government, and we understand and are optimistic that we can accomplish anything put in this country's path.

And we've got some big hurdles to cross. We've got some big steps to climb. There's no question in my mind we can do that. After all, this is the finest nation on the face of the Earth.

One big hurdle we've got to cross is to make sure this economy keeps growing, make sure people can find work. Anytime one American who wants to work can't find a job, says to me we've got a problem. And therefore, in Washington, we've got to be promoting pro-growth policies, pro-growth in the sectors necessary to increase employment.

One of the things I took on was the Tax Code. I told the people of New Mexico and the country that if you elected me as President, I was going to do everything I can to reduce the tax burden on the American people. And fortunately, it came at the right time.

See, here's what I believe—here's what Steve knows—that if you let a man or a woman keep more of their own money, they're more than likely to demand an additional good or a service. And when somebody demands a good or a service in our society, in our marketplace, somebody is likely to produce the good or a service. And when somebody produces that good or a service, it means somebody is more likely to be able to find a job.

The best thing we have done in Washington for our economy is to let the people of New Mexico and America keep more of your own money. And now we need to have us a Congressman who will join

me in making sure that the tax relief is permanent, that it exists for the next decade, so you know you've got that money in your pocket, so you know no one is going to come and take that money back away from you. See, that's an important issue. It's an important issue.

There's a fundamental difference among some of us in Washington. One of the things Steve and I understand is, when we're talking about the money up there, it's not the Government's money; it's the people's money.

We're working hard in Washington to make sure the country is a better place. And that means fulfilling some of our commitments that we made. One such commitment, of course, is Medicare. Medicine has changed; Medicare hasn't. Medicine is becoming more and more modern with the new technologies and the new medicines; Medicare is stuck in the past. For the sake of a better America, for the sake of an America fulfilling its promise, we need to modernize Medicare, including a prescription drug plan for our seniors.

Steve understands that. Steve understands that. I look forward to working with him on issues important, whether it be education or Medicare or taxes or making sure Congress doesn't overspend. These are key issues we need to work on. But there's no more important issue than to make sure our homeland is secure. The most important obligation we have at all levels of government is to do everything we can to secure the homeland, is to protect innocent life, is to prevent an enemy which hates America from hurting any American.

And that's an important job, because—and it's an ongoing job, because you've just got to understand that an enemy lurks out there. They're dangerous. They're determined. They're based upon—they base their sentiments upon hatred. They don't value innocent life. See, that stands in stark contrast to America and Americans. We value life. We say everybody is precious; everybody counts.

That's not how the enemy thinks. They've hijacked a great religion, and they murder in the name of that religion. They don't value life. They hate America because of what we love. We love freedom. We love the idea of people being able to worship an almighty God any way you see fit. We love our free society. We love the idea that people can come to America and realize their dreams. Freedom stands at the heart and soul of America, and we're not changing. And so long as we love freedom, they're going to hate us.

The other thing that's important for our citizens to realize is that the stakes have changed. After September the 11th, we learned a hard lesson and a cold lesson, and that is, oceans no longer protect us from the hatred of our enemies. When a lot of us were coming up, we used to, could sit back and say, "Oceans protect us. Therefore, we have the luxury of picking or choosing what threat we deal with. We can take our time." If we chose not to be involved, we could just let a threat materialize, and we don't have to worry about it.

We've got to be clear-eyed about the new dangers we face. We've got to be realistic. If we're going to protect America, it's very important for all of us, particularly those of us in Washington, to not hope for the best but to see clearly the threats. And there is a real threat, in my judgment, a real and dangerous threat to America in Iraq, in the form of Saddam Hussein. I want to—this is a man who told the world that he wouldn't have weapons of mass destruction. He's got weapons of mass destruction. This is a man who has used weapons of mass destruction. He's used them against his neighbors. He's used them against his own people. This is a person who can't stand America. This is a person who has had contacts with Al Qaida. This is a person who has defied international bodies time and time again. This is a person who has made the United Nations look foolish.

I went to the United Nations. I said to them as clearly as I could, in Western language—[laughter]—I said, "You can be an effective body to help us keep the peace. You can be an effective U.N., or you can be the League of Nations. That's your choice to make. You have the choice as to whether or not you will allow this dictator to continue to defy the United Nations and therefore weaken you. Or you can join with the United States and disarm him like he said he would do."

I've also sent a message to Mr. Saddam Hussein: After 11 years, you have defied the U.N. You have not done what you said you would do. And now it is the time for you to disarm.

The United States Congress, both Republicans and Democrats, have debated this issue, and they spoke with one clear voice. And here is what the administration and now your elected Representatives are saying to the world: Either the United Nations will do its duty to disarm Saddam Hussein, or Saddam Hussein will disarm himself. In either case, if they refuse to act, in the name of peace, in the name of a secure tomorrow, in the name of freedom, the United States will lead a coalition and disarm Saddam Hussein.

Audience members. U.S.A.! U.S.A.! U.S.A.!

The President. No, we've got to be clear-eyed and realistic about the threats we face. History has called us into action. This country loves peace, and we love freedom, and we must lead the world to a more peaceful world and a freer world.

It's also important to be realistic about what could happen here at home. These people are lurking around. And so everybody—you've got to know that we're working hard at all levels of government to run down any lead, to chase down any hint, to deter and defy and deny an enemy who still hates America. There's a lot of people working hard on your behalf. But I believe we can do a better job, and that's why I asked Congress to make sure that we

bring all these agencies involved with protecting America under one Cabinet office, so that we can set a clear priority, and if need be, change cultures to make sure we're doing everything in our power to protect America.

Let me give you some examples of what we need to have happen. On the border, it's important to know who's coming into the country, what they're bringing into the country, and whether or not they're leaving when they say they're going to leave. On our borders, we can be respectful to people and our neighbors and, at the same time, be tough on terror. But there's three Federal agencies full of good, decent people who are working hard on border. There's INS and Border Patrol and Customs, three really fine agencies, full of good people, but sometimes they don't share the same strategy. They've got different uniforms. Sometimes they don't work as closely as they should, because of rules, bureaucratic rules.

And so I've asked the Congress, give me the power to, in the name of national security, to be able to effect those work rules, so that we can better say to the American people, "We're doing everything we can to protect you." The House heard the call. The Senate hasn't. The Senate hasn't moved—another reason we need to change the leadership in the Senate so we can get a—so we can have a Homeland Security Department where this President and future Presidents are able to put the right people at the right place with the right equipment at the right time, to protect the American people.

I don't have to worry about old Steve Pearce's vote on that issue or Pete Domenici's. I want you to know that no matter how hard we work here at home—and we'll work hard; however long it takes, we'll work hard—the most effective way to protect the homeland is to hunt these killers down, one at a time, and bring them to justice. That's the most effective thing, and

we're doing it. Slowly but surely, we're hunting them down.

Now, it's hard to tell progress sometimes because this is a different kind of war. I'm sure we've got some vets out there who remember the wars where, "Yes, we're making progress because we destroyed some tanks," or, "We're making progress because we shot some airplanes out of the sky." That's not the type of enemy we face now. These people are ones who hide in caves, kind of lurk in the dark corners of some of the cities in the world. Then they send youngsters to their suicidal deaths. It's a new kind of war, a different kind of army. But that doesn't mean we can't win. As a matter of fact, I'm confident we will win. And I know we're making progress.

And part of my confidence rests in the fact that we've got the finest United States military in the world. And I just signed a new defense bill. It's the largest increase in defense spending since Ronald Reagan was the President. The message—there's two messages in that bill; it's important to hear. One, anytime this country puts our troops into harm's way, we owe it to the troops, and we owe it to the loved ones of the troops, to make sure they've got the best training, the best equipment, and the best possible pay.

And the second message is that—and this is a message to our friends and to our foes alike—that we're in this deal for the long haul. It don't matter how long it takes. When it comes to the defense of our freedom, when it comes to the—defending the American people, it doesn't matter how long it takes. There is not a calendar in the Oval Office which says, on this day, Mr. President, you haul them home. That just doesn't exist in my way of thinking. It doesn't exist in the way of thinking of most Americans. They understand what is at stake. They understand we have an obligation. They understand no matter how long it takes, no matter what the cost, we're going to do our duty, and that is to defend freedom and to defeat the enemy of terror,

to defeat that enemy that loves terror as a weapon.

We've hauled in a couple of thousand of them so far. I say "we"—the doctrine still stands which says, "Either you're with us, or you're with the others." That doctrine still exists, and there is still a coalition of people working together. The other day we got a guy named bin al-Shibh. He thought he was going to be the 20th hijacker. That's what he wanted to be. He popped his head up. He is no longer a problem to America.

A couple of thousand of them have been hauled in by America and our friends, and we're still making progress, one at a time. We're putting that spotlight into caves, and we're hauling them out of there. We're finding them in the dark corners. A like number hasn't been so lucky, by the way. And they're not a problem, either. Slowly but surely—it doesn't matter how long it takes.

You know, I don't know what was going through the mind of the enemy. They probably took a look at America and said, you know, "These folks are shallow. They've got one religion called materialism. They're self-absorbed." After they hit us, we'd probably take a step back and maybe file a lawsuit or two. [*Laughter*] No, they made a big, big mistake. They don't understand the character of the country.

See, this country is strong; it's steady. This country is determined. And so long as we remain strong and determined, so long as we remember that freedom is not created by America, freedom is God-given for everybody around the world, so long as we hold our values dear, we can bring peace. I want you to tell your kids that amongst all the talk about war, there's a burning and deep desire to make the world peaceful, to make America peaceful—not only to make America peaceful because we value each life, everybody counts, peace in other parts of the world, as well.

I truly believe that out of the evil done to America can come some incredible

good—some incredible good. And that good is going to be a peaceful world. I also know here at home that we can be a better America. I've talked about ways for Government to help, but you've got to know that Government, even though it can hand out money, it can never put hope in people's hearts or a sense of purpose in people's lives. The best healing there is in America, the best way to eliminate pockets of despair and hopelessness which exist in this land, the best way to make sure that the American experience is for everybody, is for our fellow citizens to put their arm around somebody who hurts and say, "I love you. I love you."

If you want—I used to tell people right after September the 11th, if you want to join the war on terror, if you want to fight evil, do some good. Do some good. Do some good right here in Alamogordo, New Mexico. Help feed the hungry. Help—mentor a child. If you really want to do some good, teach a child how to read. See, our society is going to change, one heart, one soul, one conscience at a time.

The enemy hit us. They didn't know who they were hitting us. They didn't realize they were hitting not only a strong nation, a tough nation, but a compassionate nation as well. The great strength of America lies not in our halls of Government; the great strength of our country lay in the hearts and souls of our fellow citizens.

You know, one of the things that's happened after September the 11th is that a lot of Americans took a step back and said, "How best to live my life—what can I do? How best to realize the American experience?" I think a lot of it had to do with what took place on Flight 93 that day, when our fellow citizens were flying across the country. They learned that the airplane they were on was going to be used as a weapon to destroy life. On their cell phones they told their loved ones goodbye. They told their loved ones they loved them. They said a prayer; they prayed for guidance and strength. A guy said, "Let's roll." They took

the plane into the ground to serve something greater than themselves in life.

The aftermath of the evil done to America has caused a lot of Americans to understand that a full life, a decent life, a complete life is to serve something greater than yourself in life. If you're a mom or a dad, remember your most important job will be to love your child with all your heart and all your soul. If you care about your community here in New Mexico, get involved with your schools. Help people in need. If you're running corporate America, you remember you have a responsibility to tell the truth and not lie and cheat employees and shareholders.

No, the enemy hit us, but they hit a great nation, a nation which will work to keep the peace, and a nation which will respond in a way here at home, where that great hope of America, the great promise of our country, the spirit that caused Mel's mother and daddy to send him here to America, applies to everybody.

There's no question in my mind, fellow citizens, that we've got hurdles ahead of us. No question in my mind we're going to leap those hurdles, because this is the finest nation, full of the most decent people on the face of the Earth.

Thanks for coming. God bless you all. And God bless America.

NOTE: The President spoke at 9 a.m. at the Riner Steinhoff Soccer Complex. In his remarks, he referred to Steve Pearce, candidate for New Mexico's Second Congressional District; gubernatorial candidate John Sanchez; Mayor Donald E. Carroll of Alamogordo; President Saddam Hussein of Iraq; and Ramzi bin al-Shibh, an Al Qaida operative suspected of helping to plan the September 11, 2001, terrorist attacks, who was captured in Karachi, Pakistan. The President also referred to Senator Paul Wellstone of Minnesota, who died in the October 25 plane crash in Eveleth, MN.

Remarks in Denver, Colorado October 28, 2002

The President. Thanks for coming. Thanks for such a warm welcome. It's nice to be in a part of the world where the cowboy hats outnumber the ties. I'm honored so many of you all came. Please be seated, unless you don't have a seat. [Laughter] I'm honored so many came out today.

I've got some things on my mind that I'd like to share with you. One thing that's on my mind is that we have a duty to our country to participate in the political process. See, if you believe in freedom, you have a duty to exercise your right to vote to begin with. One of the reasons I'm coming to this big State is to encourage people to do their duty, to go to the polls. I want all people, no matter what their political

party is or whether they even like a political party, to exercise their obligation to vote.

Now, I've got some suggestions when you go—[laughter]—I've got some suggestions. For the sake of Colorado and for the sake of the country, Wayne Allard needs to be sent back to the United States Senate.

Audience members. Six more years! Six more years! Six more years!

The President. Whether he wins or not is going to depend upon many of you here. See, grassroots politics makes a big difference—turning out that vote, getting on the telephones and putting up the signs, going to your coffee shops or your houses of worship or your community centers to put out the word that, when you've got