FDA MEDICAL PRODUCT APPROVALS

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL ECONOMIC GROWTH, NATURAL RESOURCES, AND REGULATORY AFFAIRS

OF THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

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FDA MEDICAL PRODUCT APPROVALS

TUESDAY, AUGUST 8, 1995

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL ECONOMIC GROWTH,
NATURAL RESOURCES, AND REGULATORY AFFAIRS,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
Rochester, MN.

The subcommittee met, pursuant to notice, at 1:08 p.m., in the Rochester City Council Chambers, 224 First Avenue, Rochester, MN, Hon. David McIntosh (chairman of the subcommittee) presiding.

Members present: Representatives McIntosh and Gutknecht.

Staff present: Mildred Webber, staff director, Karen Barnes, professional staff member, David White, clerk, and Bruce Gwinn, minority professional staff.

Mr. MCINTOSH. The Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs is called to order. On behalf of the subcommittee, I would like to welcome you to our 10th field hearing.

I'm David McIntosh, a Republican from Indiana. Gil Gutknecht, who is also a member of the subcommittee, is with us today. This is our third field hearing in Minnesota. I would like to let you know that Minnesota has a great deal of influence in the subcommittee because of Gil's leadership. Also, Collin Peterson is the ranking minority member on the subcommittee, also from the State of Minnesota. He was going to be with us here today, but was detained because of weather in St. Cloud and wasn't able to fly his own plane over to be with us, but I'm sure will pay close attention to the record that we build in this subcommittee hearing.

I especially want to point out that the mission of our subcommittee is to look at the burdens of regulation in this country that affect our competitiveness, affect our ability to create jobs, impose costs on consumers and, the area that we're focusing on today, impede our ability to offer the best and highest quality health care services to American citizens.

We will hear from physicians and medical manufacturers who, on a daily basis, must deal with unnecessary and overly burdensome regulations. These regulations, enforced by the Food and Drug Administration, OSHA, HCFA, and other Federal agencies, reduce the quality of patient care and drive up the cost of health care in America.

The Food and Drug Administration plays a critical role in health and safety. It regulates more than $1 trillion worth of products. That's about a quarter of the economy of the United States. The

FDA regulates everything from the food we eat to the drugs we take to new medical devices and the procedures used to implement them in treating people with life-threatening to very common diseases.

Because of FDA's critical role, it is appropriate that the new Congress take a hard look at that agency to ensure that the American people are receiving the best possible medical care, receiving the latest possible treatments, and doing so in the most cost-effective means possible. We have taken that hard look in the subcommittee. We had a field hearing in Norristown, PA, where we examined the Food and Drug Administration's drug approval process. We heard from several individuals with life-threatening diseases, who complained about the agency's lengthy and costly processes for developing new drugs and new devices.

Last week, in Washington, we had a joint hearing with Chris Shays' subcommittee on health issues and specifically looked at the burdens that the FDA has created for women who suffer from breast cancer because of their investigation into silicone breast implants, where, in the process of scaring women throughout the country, they have created incentives for people to avoid detection and treatment of that potentially deadly disease.

Today, thousands of Americans are needlessly suffering and dying because of the FDA and their having prevented them from receiving medicines and medical devices that are both safe and effective and in use in industrial nations around the world, but not available widely to American patients.

The FDA is not only the only culprit. Today we will hear testimony from physicians and medical manufacturers who say that their ability to provide high quality health care to the American people is severely hampered by OSHA, HCFA, and other Federal regulatory bodies. The evidence is overwhelming. American companies are moving overseas to countries like Ireland and the Netherlands to escape the heavy hand of Federal regulatory agencies. We see this particularly in areas where they are trying to do research and develop new products and new techniques.

And I shudder to think what would have happened to the Mayo Clinic, where we are today in Rochester, if we had an FDA at the turn of the century. The ability to innovate and revolutionize the health care system in this country was overwhelming at that time and, thanks to the foresight of the Mayo brothers, we've seen tremendous strides. The sad part is that today, those two brothers would have encountered enormous regulatory hurdles in putting together what they have done here in Rochester.

Doctors are effectively prohibited by the FDA from talking to drug and device manufacturers about breakthrough developments. In a very real sense, our family doctor has been handcuffed by that agency. New drugs now require, on average, between 10 and 12 years, 100,000 pages of paperwork, and $359 million in order to win approval by FDA. This must be changed for the benefit of patients everywhere in this country.

Thank you for coming and participating in the hearing today. Your testimony will add to the record of this subcommittee. We will also refer it to the Commerce Committee and other committees of

jurisdiction in the House of Representatives and refer it on to the Speaker's Advisory Committee for Corrections Day.

Before we begin, I want to apologize that we don't have more time to hear from each witness. We will ask you to confine your testimony to 5 minutes and then a period of question and answer. Any additional remarks will be put into the record and made available as part of the official transcript of these subcommittee hearings.

Now, let me turn to my colleague, Mr. Gutknecht, who has been an outstanding Member of Congress. We're both freshmen and it's been a privilege to be able to serve with him and be able to visit his hometown here in Rochester. Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Chairman McIntosh. I want to welcome you—and I'm sorry that Representative Peterson couldn't make it this afternoon, but I want to welcome the subcommittee and their staff to Rochester, MN.

Earlier this year, when we started talking about putting together some field hearings—and I strongly believe in field hearings because all together too often out in Washington, we hear from the representatives of some of the special interest groups and we also hear from the bureaucracy, but it's seldom that we get out and actually hear from real people who have to deal with the consequences of some of the Federal regulations. So I'm delighted to have you here.

I know when we first talked about perhaps having some field hearings in Minnesota, I told some stories that we had heard from researchers, people in the biotechnology industry, and perhaps one of the scariest stories was a quotation from the founder of one of the original pacemaker companies in the world, who said and was quoted in the paper last year as saying that if he had it to do over again, he would not have—knowing what he knows now, with the regulatory influence that we have in the United States of America today, he would not have started the company here in the United States.

That is an incredible quotation. That's an incredible realization of just how far we have gone in terms of over regulation. You've referred to, to a certain degree, the enormous costs in terms of dollars and paperwork that Federal regulation imposes upon new technologies, new devices, new drugs and so forth in the United States, but I think, too, we have to also understand that there's a huge cost in terms of the human factor for people who cannot get those treatments, who cannot get the new technologies, the new drugs and so forth, which are widely available over in other countries.

I don't want to steal any of the thunder of some of the people that I know are going to testify, but some of the stories that I've heard are just unbelievable. So I'm delighted to have the subcommittee here.

I also want to say that what we've heard so much of in this particular subcommittee are examples of what I call $50 solutions to $5 problems. Most of us have read and I distribute freely a Reader's Digest version of a new book which came out earlier this year, entitled "The Death of Common Sense." We were accused and we've had some protesters at some of our subcommittee hearings talking

about how we want to gut some of the safety regulations and gut the clean water stuff and gut this and destroy that. Nothing could be further from the truth.

I think we all want clean water. I think we want effective safety on the job. I think we want regulations which will protect us from food and drugs and so forth that might be put on the market before they're ready. But I think what we really want as Americans, in the main, is we want reasonable regulations, and I think that's really the chart of this particular subcommittee.

And I want to add one other point that normally you make, Mr. Chairman. That is that the Speaker is strongly in favor of moving rapidly ahead in terms of getting rid of some of the needless and duplicative regulations and, as a result, has implemented what we call Corrections Day. I invite anyone here today, if you have specific ideas of rules or regulations which are either duplicative or just don't seem to make any sense, particularly in view of new information or new technologies, please let us know, because we're trying to collect ideas and we will be offering those as we go forward. At least once a month we will have a Corrections Day. As we get more ideas, we may even actually have them more often than that.

So I want to welcome you to the city of Rochester and I want to thank all the people who have participated in helping to make, hopefully, this a successful hearing. We've had two great hearings here in Minnesota and I'm certain that the information at this one will be every bit as useful.

So thank you, Mr. Chairman, and let's hear from the first witness.

Mr. MCINTOSH. Thank you. Thank you very much. I also extend thanks to your staff here who have helped us set up this hearing and identified the witnesses for us.

If I could call forward the first panel of witnesses. If I understand it correctly, we're going to ask you to sit there, but address us in the front mic. But if you could come forward. Mr. Clinger, who is the chairman of the full committee, has asked that we administer an oath to each of our witnesses. So if I could have the first panel all please stand and raise your right hands.

[Witnesses sworn.]

Mr. MCINTOSH. Thank you. Let the record show that each of the witnesses answered in the affirmative. Our first witness on this panel of medical experts is Dr. Robert Schwartz, who is a cardiologist with the Mayo Clinic. Thank you, Dr. Schwartz, and please give us your testimony.

STATEMENTS OF DR. ROBERT SCHWARTZ, CARDIOLOGIST, THE MAYO CLINIC; DR. RICHARD GEIER, PRESIDENT, OLMSTED MEDICAL GROUP; AND DR. MIKE MURRAY, PRESIDENT-ELECT, MINNESOTA MEDICAL ASSOCIATION

Dr. SCHWARTZ. Thank you, Mr. McIntosh, Mr. Gutknecht, ladies and gentlemen. I sincerely appreciate the opportunity to speak with you today concerning these problems of medical device regulation—their approval and their impact today on patient care in these United States.

My name is Rob Schwartz. I'm an interventional cardiologist here at the Mayo Clinic. Cardiologists in my specialty perform procedures that open the blocked coronary arteries. These arteries give the heart a continuous supply of fresh blood, nutrients, and oxygen. A disease process called atherosclerosis, known in lay terms as hardening of the arteries, frequently causes narrowing or occlusion of these vessels, causing severe chest pain and sometimes heart attacks.

Over the past 15 years, tremendous progress has been made in being able to open these narrowed arteries without the need for bypass surgery. These procedures are known as PTCA, or coronary balloon angioplasty. They are performed with the patient fully awake and in a typical case, the patient can go home within a day or two following the procedures. This is important because it avoids the pain, the time and the expense of an otherwise major open-chest operation.

A wide variety of sophisticated medical devices has been developed to perform these procedures over the past 15 years and the rate of new technology in this arena continues to expand rapidly, markedly enhancing our ability to perform these procedures in a better and more advantageous way.

My research laboratory here at the Mayo Clinic is devoted to designing, evaluating and bringing into clinical practice new angioplasty technologies. Thus, we are intimately involved in the development of these devices at many stages, frequently from their inception all the way up to and including first human use. As a practicing cardiologist, my first and foremost concern is for patient care and patient safety. It is for this very reason that we have built our research laboratory to extensively test and evaluate new angioplasty devices, to guarantee that they are safe, reliable and effective before they are ever brought into human application.

In this perspective, we are indeed concerned about the process of getting these devices approved for patient use. We indeed have a problem regarding the amount of time and effort currently involved due to the regulatory burden of the device approval process. Specifically, the time, the expense and the work required for device approval in these United States has clearly put us at a distinct disadvantage in the world as it relates to bringing this new technology to our patient care and application.

I am certain this is well known to you—patients in Canada, Europe, and Japan now routinely receive the benefits of these new devices many years before they are available to American patients. The irony of the situation is that the vast majority of these new devices are being designed and developed here in the United States. We are thus in the paradoxical situation of testing and perfecting new interventional technologies here in the States, but cannot offer them to our patients until many years after they have been available elsewhere.

When such devices are ready for patient use, we must go outside the United States to perform these first procedures. Obviously, this is unfortunate in terms of being unable to offer our American patients this state-of-the-art care. It's also unfortunate in terms of lost jobs and economic benefits, as the devices are built and used in foreign countries, as well.

You will, no doubt, hear more about this aspect of the problem from other testimony that you will hear today. Again, I emphasize that the greatest care is taken to ensure that these devices are safe and efficacious prior to their human application.

A specific example of our concerns relates to the coronary stent, a small, thin, metallic device that is permanently implanted into coronary arteries of ill patients to hold these vessels open. Only two types of stents are currently available in the United States. Both devices were available to European patients long before they were available in the United States.

A current example of this problem as it now stands relates to a new type of stent that is coated with a drug. In the past, a small fraction of these stents occluded causing potentially serious problems and an innovative solution has been developed by an American company that has pioneered this technology of putting an antiquag, that is a drug, on the stent that prevents it from occluding. These devices are currently being tested across Europe. None of them are available for use or testing in the United States.

These devices will not be available in this country, in fact, for many years; yet, there has been not one single record of any of these devices occluding in Europe.

The situation is of great concern to us for obvious reasons, thus. First and foremost, American patients do not have access to these life-saving devices, not proven quite efficacious and safe. Second, the problems in the application of this new technology have important downstream consequences. For example, as technology leaves the country, the excellence of our research, both in a clinical and basic context, suffers.

American researchers in medical devices are becoming followers rather than leaders as it relates to new device research. Jobs, expertise and leadership are thus continuing to leave this country.

In summary, this problem is insidious and very difficult to quantify since patients who do not benefit from the best technology cannot be vocal. Indeed, they are frequently unaware that better solutions are available for their problem and are being widely used at places outside the United States.

We are willing and able to work with you or any government agency to correct this problem as an academic and interventional community. Our goal, once again, is the most safe and efficacious patient care available in the world. Again, I thank you for your time and allowing me to speak.

I have included for you an editorial comment that recently appeared by a colleague of mine, Dr. Bill O'Neill, in Michigan, outlining this same problem and, once again, this has appeared in a medical journal, if you'd like. It's summarized there, as well.

[The prepared statement of Dr. Schwartz follows:]

Ladies and gentlemen of the Committee, I sincerely appreciate the opportunity to speak with you today concerning the problems of medical device regulation, their approval and the impact on patient care in the United States.

My name is Robert Schwartz. I am an Interventional Cardiologist here at the Mayo Clinic. Cardiologists in this specialty perform the procedures that open blocked coronary arteries. These coronary arteries give the heart a continuous supply of fresh blood, nutrients, and oxygen. A disease process called atherosclerosis, or hardening of the arteries, causes narrowing or occlusion of these important blood vessels, causing severe chest pain and heart attacks.

Over the past 15 years, tremendous progress has been made in being able to open narrowed coronary arteries without the need for coronary bypass surgery. These procedures are known as PTCA, or coronary balloon angioplasty. They are performed with the patient fully awake, and in a typical case the patient can go home within a day or two following the procedure, thus avoiding the pain, time, and expense of a major operation. These procedures are very technology intensive. A wide array of sophisticated devices has been developed to perform these procedures over the past 15 years, and the rate of new technology in this arena continues to expand rapidly.

My research laboratory at Mayo Clinic is devoted to designing, evaluating, and bringing into clinical practice new angioplasty technologies. Thus, we are intimately involved in the development of these devices at many stages, frequently from their inception all the way to first human use. As a practicing physician, my first and foremost concern is for patient care and safety. It is for this very reason that we have built our research laboratory, to extensively test and evaluate new angioplasty devices to guarantee that they are safe, reliable, and effective before they are ever brought to human application.

In this perspective, we are concerned about the process of approving devices for patient use. We indeed have a problem regarding the amount of time and effort currently involved due to the regulatory burden of the device approval process. Specifically, the time, expense, and work required for device approval in the United States has clearly put us at a distinct disadvantage in using new technology for patient care. I am certain this is well known to you; patients in Canada, Europe, and Japan now routinely receive the benefits new devices <u>years</u> before American patients. The irony of this situation is that the vast majority of these new devices are being designed and developed here in the United States. We thus are in the paradoxical situation of testing and perfecting new interventional technologies in our laboratory, but cannot offer them to our patients until years later.

When such devices are ready for patients use, we must go outside the United States to perform the first procedures. Obviously, this is an unfortunate situation in terms of being unable to offer American patients state-of-the-art care. It is also unfortunate in terms of lost jobs and economic benefits as the devices are built and used in foreign countries. You will, no doubt, hear more about this aspect of the problem from other testimony today. Again, I emphasize that the greatest care is taken to insure that these devices are safe and efficacious prior to first human use.

One specific example of our concerns relates to the coronary stent, a metallic device that is permanently implanted into the coronary artery to hold it open. Only two types of stents currently available in the United States. Both devices were available to European patients long before they were available here, although both were invented in the United States. A current example of the problem concerns a new type of coronary stent that is drug coated. In the past, a small fraction of stents occluded, creating a potentially serious problem. An innovative solution has been to coat the stent with a drug that prevents blood clotting. An American company has pioneered this technology, but has had to test it in patients overseas first. None of these new stents have occluded in the European experience. Yet these devices will likely not be available in this country for years. The problem is exemplified further by the observation that the two most important scientific meetings this year on coronary stenting are being held

in Europe.

This situation is of great concern to us for obvious reasons. First and foremost, American patients DO NOT HAVE ACCESS TO THESE LIFE-SAVING DEVICES, now proven quite efficacious and safe. Second, the problems in new technology application have important downstream consequences. For example, as technology leaves the country, the excellence of our research (clinical and basic) suffers. American medical researchers are becoming followers rather than leaders in technology. Jobs, expertise, and leadership continue to leave this country.

What are the solutions to this problem? Clearly there is no single cause for the current situation. I strongly believe that regulation is important in maintaining safety and accountability for new technologies. A number of my colleagues believe that we in the academic medical community could lend expertise to the Federal Government in this regard. This might take the form of advisory committees that would review proposals rapidly, and assist in the decision making process. We can discuss more of this later, if there is interest on your part.

In summary, this problem is insidious, and very difficult to quantify since patients who do not benefit from the best technology are not vocal. Indeed, they are frequently unaware that better solutions are available and being widely used outside the United States. We are willing and able to work with you or any

agency to rectify this problem, since the important goal of the best patient care possible is being compromised by our current situation.

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EDITORIAL COMMENT

THE AMERICAN AUTOWORKER AND THE AMERICAN CORONARY INVESTIGATOR: TWO ENDANGERED SPECIES

William W. O'Neill, M.D., F.A.C.C.
Director, Division of Cardiology
William Beaumont Hospital

Tuesday, February 18, 1992, was a tragic day in Southeastern, Michigan. Thirteen thousand families had their lives shattered by the news of the General Motors auto plant closing in the area. Early that morning, I drove through Detroit en route to the airport. I was flying to Madrid for an interventional cardiology demonstration course. On that gray, bitter-cold winter morning, Detroit was a barren, broken ghost town. A mere shadow of its glorious past as the "Arsenal of Democracy". The city stood as a monument to bureaucratic mismanagement, hostile regulatory environment, and predatory Japanese industrial policy.

I arrived in Madrid to find the streets alive and bustling. As hard as I tried, I could not see a Japanese car in sight! When I arrived at the hospital, medical advances surprised me. Intracoronary stents were routinely available, angioscopy was done routinely, excimer laser, PDA occluders and mitral valvuloplasty balloons were all routinely used. I was struck by the irony that our "advanced" medical system has not yet provided these advances to the American public. In my discussions with device manufacturers, it is apparent these trends will continue. Not only will America lag in routine use of new devices, but new device investigation will be largely done outside the United States.

The American coronary investigator is just like the American autoworker, *an endangered species!* Most major advances in coronary intervention were initiated in the U.S. over the last decade. Because of impossible bureaucratic regulations, this golden era of U.S. investigation is closing. American investigators will be relegated to the status of sideline cheerleaders for our foreign colleagues. It would be easy to put the entire blame for the loss of the American medical device industry on the FDA. I believe that much of the delay and over-regulation is prompted by congressional criticism of the FDA's performance. Congress is demanding that only completely safe, infallible devices be approved. An infallible device has never been designed or manufactured! Since Congress is pressuring the FDA to only approve infallible devices, it is in the best interest of this bureaucracy not to approve any devices. After all, if a device is not approved then no one can criticize a safety problem with it.

Who loses by this cautious, extremely conservative approach to device approval? First of all, thousands of patients who can benefit from new devices lose. What if Mother Teresa had a PTCA in a center without availability of a bail-out stent? The second losers are the device companies who must spend over five years and twenty million dollars before FDA approval is feasible. Small start-up companies with ingenious devices will be locked out of this business. Finally, American cardiology is losing since most devices will be tested elsewhere. The vascular plugs and the aortic aneurysm stents were American ideas being investigated in Europe and South America.

Can these two endangered species be saved? Solutions do exist. Since we will never impose a 2% market share on a Japanese car like the Spanish do, purchase of American assembled cars must be voluntary. The auto industry remains the foundation of American industrial might and is the mainstay of our standard of living. For this reason, it is in our vital national interest to support this industry. In order to preserve the American coronary investigator and American medical device industry, political activism will be required. An excellent model for this is the AIDS movement. AIDS activists force the FDA to modify rules and expedite approval of new drugs that have the potential for the treatment of AIDS. We must pressure Congress to provide adequate funding and staff for the FDA. The device companies and drug companies could be assessed a tax to fund the agency. They would gladly do this as delays related to poor staffing are so costly to them now. At the same time, the FDA must be forced to abide by simple published guidelines for device approval. As an example, coronary artery angioplasty devices should be tested on 200 patients and shown to be associated with a mortality of less than 0.5%, an emergency bypass rate of less than 3% and a myocardial infarction rate of less than 5%. This will provide safety comparable to currently approved devices. It will also allow for detailed planning in trial design by the device manufacturers without the worry of the rules being changed in midstream. It is totally foolish to subject devices to randomized clinical trials. Randomized trials will never have the power to assure safety of a device. Tens of thousands of patients would be required to demonstrate a difference in event rates (such as prosthetic valve strut fracture) that occurs in a frequency < 0.05%. Only rigid post release reporting can assure

safety. Demonstrating superior efficacy should be left to investigators or third party payors and not the FDA. As long as devices are reasonably safe, the welfare of society is protected. Decisions for use of a new device thus becomes an economic one and should not be the purview of the FDA. Although most coronary investigators are not politically active, it is imperative that we become so. Our patients' care and our pre-eminence in health care is at stake.

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Mr. MCINTOSH. Thank you. I appreciate that and I would ask unanimous consent that we include that extra material in the record of the hearing. Thank you very much, Dr. Schwartz.

Let me mention that we've had several witnesses in these other hearings who have been somewhat reluctant to come forward and I appreciate your courage, and I mean courage in bringing forward this issue to us, because these other witnesses or potential witnesses have indicated they fear that FDA might seek reprisal and prohibit their research from going forward.

So let it be known that if that should occur or if you detect anything happening of that nature, bring it to our attention and we will fully investigate it. I have told Dr. Kessler and his deputies that if we notice anything along those lines, they will receive the most severe possible repercussions from this subcommittee. I think it's unconscionable that an agency might discourage people from coming forward to Congress in an effort to work together to improve these very, very serious problems in our regulatory system, and I appreciate your coming forward today.

We'll let all of the panelists testify and then we'll have questions for any one of them who may be there. Our second witness on this panel is Dr. Richard Geier, who is president of the Olmsted Medical Group, a multipractice group here in the county. Welcome, Doctor. Appreciate you coming and share with us your testimony.

Dr. GEIER. Thank you, Mr. Chairman, a fellow Hoosier.

Mr. MCINTOSH. Thank you. It's always good to see a fellow Hoosier.

Dr. GEIER. From the 8th District, originally. Mr. Gutknecht, ladies and gentlemen, I'm Dr. Richard Geier, president of the Olmsted Medical Group, a 75-doctor, not-for-profit, multispecialty group, with our main office here in Rochester and with eight, soon to be nine branch offices in communities within a 30-mile radius of Rochester.

In the time allotted, I can barely scratch the surface of the effects of Federal regulation on medical practice, but I would like to spend a few minutes on the Clinical Laboratories Improvement Act of 1988, which regulates the physician office laboratories.

CLIA arose because a woman had allegedly had a PAP smear misdiagnosed by a reference laboratory; that is, a large laboratory to which physicians send specimens for tests that they don't do in their own offices. In the process of looking at this problem, someone discovered that physician office laboratories were not regulated by the Federal Government, a situation which Representative Dingell clearly could not allow to continue, although it had caused no known problems.

Because of this law, about 10,000 physicians have simply stopped doing laboratory tests in their offices and many thousands more have had to limit what tests they can do. All these tests that cannot be done in their offices are, of course, sent to reference laboratories, which were the source of the original problem.

Last month, the Inspector General of HHS released a report stating that CLIA had had no adverse affects on accessibility to tests; that is, everyone who needed a test could get it done. What he did not mention, however, is that test results which were available in less than an hour now take at least a day and often several days

to be reported. In many cases, the patient has to travel some distance to a laboratory to have the specimens collected.

Prior to the enactment of CLIA, the Olmsted Medical Group's main office laboratory was already accredited by the College of American Pathologists and has not been directly affected to a major extent. Our branch office laboratories were involved in quality control programs and while they have been greatly affected by the legislation, they have not been improved by it.

For the Olmsted Medical Group, the dollar cost of this law has been significant. When our ninth branch office opens this fall, we will have spent almost $200,000 on additional laboratory equipment and personnel training which results in some marginal increase in accuracy of results, but not enough to be of any clinical significance. In addition, the maintenance agreements for the equipment cost nearly $20,000 a year and the direct costs of registration, inspection and proficiency testing are about $9,000 a year.

Increasing the educational requirements for personnel creates a shortage and increases personnel costs. The costs of recordkeeping required to show compliance are difficult to measure. Some tests that were done in the branch offices now have to be sent to Rochester, which exacts costs in time, effort and psychological stress on patients and may adversely affect care. All of this has resulted in minimal, if any improvement of our clinical laboratories.

The main thing I notice when I visit our branch office laboratories is the psychological pressure this has placed on the technicians. They feel harassed by the paperwork and threatened by the testing and unannounced inspections. The Government regulatory approach is exactly the opposite of modern management techniques based on Deming's Total Quality Management or Juran's Continuous Quality Improvement. CLIA's approach is two strikes and you're out. The proficiency testing used is an artificial situation. One supervisor has seen errors caused by a nervous tech incorrectly reconstituting a sample, something that isn't even done in real life. Our own quality management process is one of continuous monitoring, looking for problems and correcting any that are found, without threatening our people in the process.

I would like to just briefly mention a few other areas of regulation. First is the disposal of infectious waste, which costs us about $25,000 per year to get rid of items that are about as dangerous as a dirty Kleenex and used Band-Aids that we all throw in our trash at home. One good thing about the attention to this area is that we do a much better job of safely disposing of needles and knife blades, but the special processing of nondangerous trash is really overkill.

Everyone's favorite agency, OSHA, is another problem. Complying with the Employee Right-to-Know regulations takes a third of a nurse for no benefit that anyone has ever been able to detect. Regulations concerning blood-borne and air-borne pathogens are also excessive. We recently spent several hundred dollars to buy special $7 masks that are issued to personnel who must keep them in a drawer someplace collecting dust. I have not needed one of these in 21 years and I doubt that I will need one for the rest of my career. If I do, having a few in boxes in a central location would

be more useful than having to remember where my personal dust-covered allergenic mask might be.

Incidentally, if we had all sworn that we had asthma, we could have purchased a different mask for 73 cents. Presumably, this mask is also effective unless asthmatics are simply being sacrificed.

There are two major problems with government regulation in general, as I see it. First is that it is too adversarial rather than being educational, consultative, or otherwise helpful. The regulators seem to believe that all citizens are either crooks or idiots. The second is that the laws and regulations are often created by people who are unfamiliar with the systems they are regulating, which sometimes leads to ridiculous rules, like the outhouse in the farmer's fields, frequently to unnecessary ones and usually to rules that make compliance difficult and expensive.

While the dollar cost of regulations and the hassle factors are not negligible, perhaps the greatest cost of misregulation is the loss of respect for the government which it engenders. This is certainly not healthy for democracy. Thank you.

Mr. MCINTOSH. Thank you very much, Dr. Geier. Appreciate it. Our third witness on this panel is Dr. Michael Murray, who is president-elect of the Minnesota Medical Association. Dr. Murray is also a physician at the Mayo Clinic. Welcome and thank you for participating today.

Dr. MURRAY. Thank you, Mr. Chairman, Mr. Gutknecht, ladies and gentlemen. Thank you for the opportunity to testify before this committee today.

As stated, I'm a physician here in Rochester at the Mayo Clinic, and, like Dr. Schwartz, I, too, am a principal investigator on a number of studies that require FDA approval, both of drugs and devices. But I am here today as president-elect of the medical association. With 9,000 members, we represent approximately 90 percent of the physicians, residents in training and medical students in the State of Minnesota.

When reflecting on the focus of this subcommittee, many of my colleagues immediately agreed that reform is indeed necessary. In fact, many people propose a simple solution—abolish all Federal regulation, because, after all, the regulations are no more than bureaucratic red tape that add to the cost of doing business and do little to improve patient care.

I know that this thought is not uncommon in the health-care field, and yet the simple solution is not always the right solution. I am not here today to tell you that all government regulation needs to be eliminated. Numerous health-care regulations do indeed have benefit to patient care.

I assume, perhaps naively so, that most Federal health care regulations adopted into law began with the legislature's intent to improve the health care of the public, to ensure high quality of care, and to protect the public from harm. Problems arise, however, when the regulators lose sight of these goals and create problems larger than the problems the regulations were designed to address.

What I hope to do today is to provide you with a few examples of some specific regulations that have been adopted to address a problem, but because of the broad nature of the regulations, have resulted in unintended negative consequences. I suspect from the

previous hearings that you've heard from other physicians complaining about similar problems, but my first example is Minnesota-specific.

In 1988, the Minnesota Medical Association, along with the Minnesota Hospital Association and the Senior Federation of Minnesota, developed a program to address the health-care needs of low income Medicare recipients. In its desire to waive medical costs not covered by Medicare, this program ran afoul of Federal regulations. I have attached background information for you, attachment A, that explains the reasons why we were forced to discontinue this program.

The Federal regulations that caused the demise of this worthwhile program were related to the antikickback prohibitions in Medicare. The intent of the antikickback regulations is indeed good—to prohibit inappropriate rebates or payments based on volume of Medicare recipients. The regulation was drawn so broadly, however, that our program, which waived the copays and deductibles for indigent senior citizens, violated the law and had to be discontinued. I cannot imagine that in writing these regulations that this was HCFA's intent, but that's exactly what happened. And the irony is that it was the physician community that took the brunt of the adverse publicity.

Dr. Geier has already commented upon CLIA. I would share with you only one anecdote. A colleague told me, in anticipation of my coming to this meeting, of a diabetic patient she was managing with an insulin infusion. The patient seized. The doctor wanted to have a glucose drawn by the nurse. The nurse couldn't do it in the hospital. The CLIA regulation stated that they had to have someone come from the laboratory. Several minutes later, they finally got a glucose. If the patient's spouse was in the room, he or she could have drawn the glucose, but the health-care worker at the bedside could not. Someone had to come from the lab.

The comment has already been made about these HEPA masks. Now, the masks do indeed run $7 and I think we would all agree that if it could decrease the incidence of tuberculosis, that perhaps it would be worthwhile. But in one hospital, $18 million would have to be spent over 44 years before one single case of tuberculosis, acquired by a health care worker, would be prevented.

My final example concerns Medicare patients and the documentation that physicians must record in the patient's record in order to comply with HCFA regulations. In particular, the documentation requirements relating to evaluation and management (EM) services are excessively restrictive and cumbersome. EM services include everything we do in the outpatient and inpatient environment.

Again, I have included copies of documentation score sheets that have been recently adopted by HCFA and used by our medical directors for our local Medicare carrier to evaluate physician documentation. It has not contributed anything to patient care. The time I would normally spend with a patient is now spent documenting things in the chart.

In conclusion, I hope that by sharing these examples with you, I can caution not to overreact to a problem by assuming that if a little control is good, a lot is better. While patient protections are

needed, I implore you to move slowly, obtain input from those parties that are affected by these regulations, the patients and the physician community. An entity that needs regulation, by the way, is not necessarily a regulator's enemy.

The Minnesota Medical Association shares with you your concern about improving quality of care that American citizens receive from physicians, but we need to do so in a cost-effective manner that's not over-regulatory. Thank you so very much for your time.

[The prepared statement of Dr. Murray follows:]

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Testimony to the House Subcommittee on National Economic Growth, Natural Resources and Regulatory Affairs
Tuesday, August 8, 1995

Opening

Mr. Chair and members, thank you for the opportunity to testify before you today. My name is Michael Murray. I am a physician at the Mayo Clinic here in Rochester, and I am currently the president-elect of the Minnesota Medical Association (MMA). The MMA represents over 9,000 physicians, residents in training, and medical students throughout Minnesota.

When reflecting on the focus of your subcommittee, many of my colleagues immediately agree that regulatory reform is indeed necessary. In fact, many people propose a "simple solution"—repeal all government regulations because these regulations are, after all, nothing more than bureaucratic red tape that adds cost to doing business without adding benefit. I know that this thought is not uncommon in the healthcare field, but I also know that the "simple solution" is not always the right solution.

I am not here today to tell you that government regulation is bad and should be eliminated. Numerous healthcare regulations are absolutely crucial. I assume, and maybe naively so, that most federal healthcare regulations adopted into law begin with the lawmakers intending to protect the public, ensure high-quality care, or improve the overall health of U.S. citizens. Problems arise when the regulators lose sight of these goals and create problems larger than the problems that the regulations were intended to address.

What I hope to do today is to provide you with examples of some specific regulations that have been adopted to address a problem but, because of the broad nature of the regulation, have resulted in unintended negative consequences. I am sure that other physicians, perhaps even physicians in your own communities, have already told you about some of these problems. My first example is, however, specific to Minnesota.

Senior Partners Care Program

In 1988, the Minnesota Medical Association, the Minnesota Senior Federation, and the Minnesota Hospital Association banded together to address the healthcare needs of low-income Medicare recipients. In its desire to waive medical costs not covered by Medicare, this program ran afoul of federal regulations.

I have attached background information on this and another program, entitled Physicians Serving Seniors, and have shown you the reasons why we were forced to discontinue these programs (See attachment A). The federal regulations that caused the demise of these worthwhile programs were related to the antikickback prohibitions in the Medicare program. The intent of the antikickback regulations is good—to prohibit inappropriate rebates or payments based on volume of Medicare recipients. The regulation was drawn so broadly, however, that our program, which waived the copayments and deductible costs and helped to ensure the availability of care for *indigent* senior citizens, violated the law. I cannot imagine that in writing these regulations, the Health Care Financing Administration (HCFA) intended to obstruct access to care for our impoverished elders.

Clinical Laboratory Improvement Act of 1988

I am sure that each of you has heard innumerable complaints about the Clinical Laboratory Improvement Act of 1988, otherwise known as CLIA. Exemplifying a regulation that intended to protect the public and improve quality (but has instead had the almost opposite effect), CLIA resulted from identified concerns regarding the quality of certain laboratories performing Pap smears. Instead of developing regulations to address this narrow problem, HCFA established CLIA, a ruling that has affected every laboratory and *every physician office* that performs *any* clinical laboratory tests.

When CLIA first took effect in 1992, more than 4,000 physicians informed HCFA that they were dropping their in-office laboratories. A recent study by the Health and Human Services Inspector General's Office noted a decrease of 12,500 physician office laboratories run by solo practitioners from 1988 to 1994. Of the 232 practices interviewed for the study, 18 had

closed their laboratories, and most of those (14) indicated that government regulations were at least a partial reason for closing (*American Medical News*, July 24, 1995).

The important result to consider with this regulation is the impact on the patient. Because of CLIA's extremely broad powers over any physician doing laboratory tests, thousands of physicians' offices have closed their laboratories or discontinued providing many tests that they had previously performed. Enactment of this regulation has unintentionally resulted in increased costs and delayed care. By forcing patients to travel to independent or hospital laboratories for tests, this regulation now imposes the burden of additional visits to perform the tests and to receive the results.

OSHA-Mandated Use of HEPA Masks for Tuberculosis Control

My next example relates to a current Occupational Safety and Health Administration (OSHA) requirement that certain healthcare personnel wear high-efficiency particulate air (HEPA)-filter masks to protect against the spread of tuberculosis. We all know that tuberculosis is extremely contagious and appropriate protections are needed. HEPA-filter masks are, however, a radically expensive preventive measure. A report in *The New England Journal of Medicine* (July 21, 1994) estimates that the hospital under scrutiny would have to spend $18.5 million, and wait 41 years, before a HEPA-filter mask would prevent one case of occupation-acquired tuberculosis. Nevertheless, OSHA mandates the use of these masks and allows no alternatives. This regulation again adds cost to providing care without necessarily adding benefit.

The Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health have recently begun to address these problems by reviewing the types of respiratory-filter masks that could be used. While we welcome potential changes, this very frustrating issue has persisted for two years.

Documentation and Coding Requirements for Patient Care

My final example concerns Medicare patients and the documentation that physicians must record in the patients' medical records in order to comply with HCFA regulations. In

particular, the documentation and coding requirements relating to Evaluation and Management Services (E/M) are excessively restrictive and cumbersome. E/M services include clinic office visits, hospital visits, and consults provided by physicians.

I have attached copies of the E/M documentation "score sheets" recently endorsed by HCFA and used by medical directors of our local Medicare carrier to evaluate physician documentation (Attachment B). The sheer size, breadth, and complexity of these documents are reflective of the significant efforts that physicians and allied health staff must put forth in complying with HCFA's requirements.

These efforts have not improved patient care, if anything, patient care has deteriorated because the time that physicians would normally spend with their patients must now be spent on documentation to satisfy bureaucratic requirements.

Conclusion

I have elaborated upon only a few of the well-intended regulations that were developed to address specific problems. Yet, when broadly adopted, without taking into consideration all of the aspects of an issue, these regulations resulted in unplanned consequences that either reduced access or quality or added cost.

I hope that by sharing these examples I can caution you to not overreact to a problem by assuming that if a little control over a situation is good, then a lot of control will be even better. While patient protections are needed, I implore you to move slowly. And finally, obtaining input from affected parties is critical; please include patients and physicians in your deliberations. An entity that needs regulation is not necessarily the regulator's enemy. I can assure you that the MMA shares your goals of protecting the public, ensuring high-quality healthcare services, and improving the health U.S. citizens.

Thank you very much for this opportunity to testify before you. I would be happy to answer any of your questions.

Mr. MCINTOSH. Thank you, Dr. Murray. Let me also say I would like to forward your example about the Medicare program to the Health Care Task Force that the Speaker has set up that's looking at various reforms for Medicare.

I am told by the staff member, Karen Barnes, that in order to have your question and answer session picked up by television, we need to ask you all to go to the podium. So if I could ask you to do that.

Dr. MURRAY. The shortest or the tallest?

Mr. MCINTOSH. Any way you like. Let me thank you, Dr. Schwartz, for mentioning the stent and angioplasty. There's a company in Indiana, Cook Industries, that makes that and has done a lot of work in it.

When I was at the Hudson Institute, they presented testimony to us that indicated the number of lives that they estimated statistically had been lost because of delay in FDA approving that device. I was wondering if it was your experience that there are other devices out there with that type of serious consequence due to the failure of rapid turnaround at the agency.

Dr. SCHWARTZ. Indeed there are. In fact, recently, it's been discovered, interestingly, in Europe that if one uses, after deploying one of these stents, a short balloon—that is just a standard angioplasty balloon, except just half the size, half the length—that one can markedly reduce even the occlusion rate of these stents.

We have been unable to access any of these short balloons because, again, of the regulatory environment here. It was only roughly 6 months ago. The Europeans, again, had had these particular devices for roughly 3 years before we were able to utilize these short balloons.

I had a patient that I was working on here who I could have used one on. I didn't. His stent, in fact, occluded a week later. Fortunately, no major complication or no serious problem. But indeed it would have saved him a trip back to the catheterization laboratory, a potential heart attack, so on and so forth had this auxiliary technology been available, as was discovered in Europe, and would have been available in the States.

Mr. MCINTOSH. Could I enlist your help, as an ongoing matter, but if you have any available right away, we can include it in the record for this hearing in the next few days, if there are statistical analyses or evidence that might be available to help give us some idea of the magnitude there.

I have discovered that people are shocked when you, in the case of the stent that Cook company made, pointed out that there were probably over a thousand people statistically who died from heart attacks that were needless deaths, because had the device been available earlier, that's how many people they estimate are benefited each year as a result of that device being available.

So if you have available or come across any data like that, if you could make that available to us.

Dr. SCHWARTZ. I would be happy to forward that to you, specifically as it relates to, in one case of the stent, as you probably know, avoiding bypass surgery and the angioplasty procedure. Those numbers are very hard and fixed and will be available.

Mr. MCINTOSH. Thank you. I appreciate that.

Dr. SCHWARTZ. Thank you.

Mr. MCINTOSH. Let me ask each of the members of this panel really two general questions. They're ideas that I'm looking into. One of them, Representative Gutknecht and I are examining the possibility that when we look at FDA reform, maybe what we ought to do is create a new entity to focus in on life-threatening diseases and treatments, either devices or drugs, that need approval for those.

We can keep the old FDA both for that purpose and the general activities that they engage in, but rather than trying to reform an agency that for many years now has been responding admittedly to terrible incentives coming out of Congress, where they only get blamed for things that go wrong and don't get any of the credit when they do something right.

But that culture has arisen out there and it's very hard to get that turned around. It has occurred to me that maybe we need to just create a new one and have a couple possibilities that people can go to when they have a new idea in those areas. I wanted to just see if you had any reaction, informally or firsthand, to that notion.

The other one is the idea that a doctor in my district has told me about, which he wanted to take through the Indiana State Medical Association, of taking care of a lot of indigent care by giving doctors a tax credit for the fees that they were charged, and then not having to reduce the amount of reimbursement for Medicare; in fact, don't give them any reimbursement in those cases, but simply do it as a tax credit, and whether you think that would have sufficient incentives to take care of people who do need that type of care.

I'll let anybody who wants to tackle either of those, we'd welcome your insight on that.

Dr. MURRAY. Well, let's take the first question first about the FDA, a new FDA. I guess I would be opposed because then I would have two sets of regulations with which to deal. I can't believe that the second set would be any less onerous than the first.

Mr. MCINTOSH. My thought was that you wouldn't have to go to both. You could choose one or the other.

Dr. MURRAY. But some of my studies of drugs might be under the old FDA and some of the new ones, life-saving investigations involving the study of patients with severe lung injury, have looked at artificial lungs and looked at new ways to ventilate those patients. All I'm saying is I might have two sets of regulations that I'd have to comply with, one for a non-life-threatening and one for a life-threatening illness.

I guess my simple approach would be to work with the FDA to make it more user-friendly and in those situations where it is a life-threatening illness, HIV infection or coronary artery disease or lung injury, that there would be some way to facilitate the process to make it less burdensome.

With respect to the tax credit, without actually looking at it specifically, and speaking on behalf of the medical association, I had better not say a word.

Mr. MCINTOSH. Thank you. Either of the other of you.

Dr. GEIER. I guess I'm skeptical on both issues. Like I say, the first problem, the first issue is going to be to define what's life-threatening and you could argue for years on that. I agree with Mike. I'd rather see the FDA change. I'm sure there are some legislative issues dealing with it.

On the tax credit issue, I think that's just a whole new can of worms. It could make it more complicated.

Dr. SCHWARTZ. Just in reference to your first question, I would agree with the other two participants here. It seems to me that the FDA is not the entire problem; that, in fact, part of the problems in the past may have been originating in Congress, intense scrutiny that the FDA was put under and the tremendous pain that was inflicted for saying yes, perhaps. It is much easier to have said no to a particular device since, once again, the patients who suffered did not receive a particular device or technologies were unaware of that. Yet, there was a very visible mistake if something was approved that indeed had had a problem with it.

So FDA is not entirely to blame here. I think in my earlier comments, speaking with colleagues, we would love to be able to work with you, work with the Federal Government, work with the FDA perhaps to design a better system and work with industry, as well, to get us all together and to make a system that is efficient and still maintains the goal of patient safety and good patient care.

I think we can perhaps do that within the structure that already exists, with some help from people like yourself.

Mr. MCINTOSH. Thank you. I'll turn to Mr. Gutknecht. Let me just mention one interesting thing that happened in the last election is that three of our classmates are physicians and they bring a very different perspective to a lot of these issues, one that I think is very helpful to Congress, and I have enjoyed working with all three of them on various issues related to improving our health care. The medical community can definitely feel that there will be better receptivity to these issues as a result.

Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman. First, Dr. Schwartz, a couple of stories—I want you to relate them, because I—if you can. I don't tell them as well as you do. The first, you were telling me about liquid injectable aspirin and I wonder if you could tell the subcommittee, on the record, a little bit about that.

The second—well, start with that one and then I'll get to the second one.

Dr. SCHWARTZ. I have spoken with Mr. Gutknecht in the past about specifically it has been discovered recently that aspirin is a very good agent in some of these procedures that I mentioned earlier. Frequently, a patient will come from an emergency room or come into a setting where they can take nothing by mouth and the availability of having an aspirin compound that is injectable would be quite useful.

Liquid aspirin, injectable aspirin is readily available currently in many European countries. It is used frequently for some of these procedures, to great substantial patient benefit. It is not available in the United States, the reason for that being the companies that make the aspirin have told us essentially that the costs in terms of time, expense, getting through the regulatory process just would

make it unprofitable for the amount of money that they could actually sell it for.

So we do have an agent. It's available in Europe, as simple as intravenous injectable aspirin, aspirin, of course, being a drug that has a very well known, very highly proven safety record, been around for many, many years, and is not available to us in an injectable form.

Mr. GUTKNECHT. I think the example here—I mean, if it's injectable aspirin, imagine how many other drug companies are saying it's just not worth our time and our trouble and the expense and so forth of getting FDA approval.

The other story is one that you related to me. You were in town for a—you were in Washington for a medical convention and perhaps you can share that you went down to look at technology that was widely available around the rest of the country, and I thought it was an interesting observation.

Dr. SCHWARTZ. Thank you for reminding me. There is a large meeting each year in Washington, DC, typically in the late February or early March timeframe, where all these interventional technologies are showcased in a large teaching forum. Roughly 2,000 to 3,000 people attend this meeting who specialize in these procedures.

It's very common—in fact, each year, two separate countries are routinely highlighted as far as the technology, the techniques, and what is being used in those countries. This year, Israel was one of those countries. The organizations at this meeting leased satellite time. There are live large-screen procedures that are beamed into this meeting in terms of teaching.

During one of these procedures, it was jokingly, half-jokingly, in fact sad, commented by the moderator sitting here in Washington, DC, regarding the procedure that was being done in Israel, that not a single device that was being used on this particular patient in Israel was available in this country. So we have all these American cardiologists trying to learn the latest and the newest and the best techniques to do this, yet all the devices that have been used on this specific teaching case, none of which were available in the States.

Mr. GUTKNECHT. The second question, and probably more to Dr. Geier and Dr. Murray. Probably the mother of all Federal regulations as it relates to the operation of health care right now is the Health Care Finance Agency, HCFA. Can you talk a little bit about that and just, in general, do you think it's more—has it achieved what it was supposed to? Can you talk a little bit about HCFA?

Because one of the ideas we're kicking around, some of us more radicals, is that maybe it's time to just get rid of HCFA all together.

Dr. GEIER. Well, somebody has to administer the Federal programs. So if you eliminate HCFA, then you have to create something else to do the same thing, which, if it operates in the same environment, we'll end up having another HCFA. So I think that probably——

Mr. GUTKNECHT. So we need a HCFA.

Dr. GEIER. We need some kind of HCFA, yes. And like some of the coating problems, there are a lot of problems of that nature.

Most of the problems with HCFA, though, I think are statutory almost more than regulatory. The big thing, in fact, in Minnesota, of course, is the unequal reimbursement for Medicare, particularly when you get into HMO's. HMO's in Philadelphia are reimbursed five times what they are in one area of Nebraska and Minnesota is real close to Nebraska in reimbursement level.

Dr. MURRAY. I just want to make one comment about HCFA. HCFA gets a lot of publicity. Dr. Geier touched on the fact that we need someone to administer Medicare and Medicaid, the reimbursement part of it, but that—their administrative overhead is so low compared to other insurance plans or HMO's or whatever. But that is a very false figure because all the administrative burden falls back on physicians and their clinics.

We have someone round with us in our intensive care unit on a daily basis to help us with the documentation we require. And it's not for patient care, it's only for documentation for reimbursement. It doesn't improve patient care, as I've said, but we have to, point-by-point, satisfy these different requirements. I didn't go to medical school to learn about documentation requirements. I realize that that's important, but should not be the reason I write something in the medical chart.

Mr. GUTKNECHT. We've had various professional providers, insurance companies, HMO's, so forth who have been in talking to us and they tell us that when we're talking about Medicare, that if they didn't have to deal with so many regulations, they could probably do what they're doing for less cost because, in fact, exactly what you say, a lot of the administrative burden comes back on the providers. So when they say your overhead is only 60 percent, that's not really accurate. Thank you very much.

Mr. MCINTOSH. Thank you all for coming today. I appreciate the input that you had. We may call you from time to time for additional information and advice as we go forward in this area. Thank you, gentlemen.

Let's turn now to our second panel. If I could call both witnesses forward. They are Paul Citron, vice president of science and technology with Medtronic and Mike Gozola, president of Rochester Prosthetic Laboratories. If I could ask each of you to please stand and raise your right hands.

[Witnesses sworn.]

Mr. MCINTOSH. Thank you. Let the record show that both witnesses answered in the affirmative. Let's have first Mr. Citron of Medtronic, if you could come forward to the podium for us. Welcome and thank you for participating in our field hearing today.

STATEMENTS OF PAUL CITRON, VICE PRESIDENT OF SCIENCE AND TECHNOLOGY, MEDTRONIC; AND MIKE GOZOLA, PRESIDENT, ROCHESTER PROSTHETIC LABORATORIES

Mr. CITRON. Mr. Chairman and members of the committee, it is indeed my pleasure to appear before you here today. My name is Paul Citron and I'm vice president of science and technology of Medtronic, Inc.

I want to commend the members of the committee, especially Congressman Gutknecht, for the seriousness of your efforts to

eliminate outdated regulations that have not kept pace with today's technological needs.

Medtronic is the world's leading producer of therapeutic medical devices. To remain competitive, Medtronic and other medical device manufacturers must conduct product development and manufacturing activities in an environment that fosters innovation. As a Nation, we must redesign the environment of innovation in this country, recognizing that laws and regulations created in the 1970's are impediments to innovation in the 1990's.

I know the committee is familiar with the recently published Wilkerson report, a study of the forces affecting the competitiveness of the U.S. medical device industry. The trends are clear. More and more innovation is moving overseas. When we look for the reasons behind these trends, we can point to four major barriers to the development of new medical technologies in the United States. First, unpredictable, overly burdensome U.S. regulatory practices; second, controls on the export of unapproved medical devices; third, restrictive Medicare reimbursement policies; and, fourth, the onerous effects of widespread product liability lawsuits.

I know that in Congress there are efforts underway to reform and address all of these barriers. I would like to focus on one today, in part because we are in Rochester, the home of one of the world's premier medical innovators, the Mayo Clinic. As I address this issue, we should consider one question—what is the ultimate cost of the movement of advanced medical research out of the United States to overseas locations?

The critical ability to do clinical research on new medical technologies in this country is being seriously threatened by recent changes in the interpretation of Medicare coverage policies by the Federal Government. Health care providers are no longer reimbursed when they participate in an FDA-approved clinical trial. But coverage for next generation clinical devices providing therapy already covered by a reimbursement code is a legitimate and necessary coverage policy.

Mr. Chairman, the current HCFA policy is a clear example of an agency regulating without oversight or due process and creating much hardship. The reinterpretation of the Medicare statute that resulted in the policy, a complete reversal of the longstanding interpretation, was undertaken without the opportunity for those affected by the decision, medical providers, device manufacturers, and, most importantly, senior citizens, to comment and was out of consideration of whether the costs are justified by the means, and the costs of this policy are indeed severe.

First of all, not reimbursing providers when they participate in an FDA-approved clinical trial has profound implications for the health of our senior citizens. Let me give you an example. Suppose you are diagnosed with a life-threatening heart rhythm disorder and require an implanted defibrillator. The existing FDA-approved devices have proven themselves to be highly effective and HCFA will reimburse for this therapy. However, a new iteration of this technology, one that delivers the same basic therapy, but has significant next generational improvements, your physician believes to be important to your treatment, is undergoing an FDA-approved medical trial.

Furthermore, because of a much simpler surgery, the device reduces hospital costs to a mean of $13,000 from $21,000 as compared to earlier systems. But under current HCFA guidelines, Medicare will not pay for the procedure if this device is used. Instead, you will receive a device that is obsolete in Europe and will soon be obsolete here.

But the lack of access for senior citizens to important medical advances is not the only disturbing result of this policy. It is also having a chilling effect on medical research in this country.

According to the Wilkerson report, due to the confusion that has resulted from this sudden policy change and the potential severe financial implications, many leading medical research institutions have completely stopped their clinical trials. And just as the policy creates disincentives for hospitals to continue clinical trials, paradoxically, it creates incentives for manufacturers to move those trials overseas.

This is because the FDA allows manufacturers to use clinical data from Europe and elsewhere. What is happening and what I suspect will happen at an even greater pace if this issue is not addressed soon is that companies will be doing all their clinical studies outside the United States in locations where reimbursement is not an issue.

A large coalition of researchers, innovators and providers in the medical community has been successful in getting legislation introduced in the House and Senate to address this problem. The chairman of the House Subcommittee on Ways and Means, Representative Bill Thomas from California, is the prime sponsor of the Advanced Medical Devices Access Assurance Act and is committed to seeing it enacted.

The purpose of this measure is fourfold. It fulfills the original intent of Medicare that the beneficiaries get access to the latest technology. Second, it promotes innovation and research of new medical technologies. Third, it is budget-neutral and imposes no new costs for the Medicare Program. And, fourth, it does not comprise patient safety.

Mr. Chairman, let me conclude my remarks with a word about comprehensive FDA reform. As of this date, there is no major comprehensive FDA reform bill pending before the Congress. We know many are working on proposals and there is hope that somehow we will find the time to get to this issue. I do want to make it clear we believe in the need for a strong FDA, one that effectively protects the public health. Protecting the public health and keeping pace with medical technology development are not incongruous. But in our case, overly burdensome regulations have resulted in a substantial portion of the development of Medtronic's last 15 new products being done in Europe and our Ventures Group, responsible for steering the development of breakthrough technology, is now headquartered in the Netherlands.

There is a real cost to the United States when our regulatory system is outdated and unable to keep pace with innovation. The cost is felt by loss of high quality jobs, by patients not getting the benefit of approved therapeutic outcomes, and by our research community having to cease doing their work in the United States.

I know this issue has been a concern of this committee and I urge you to keep this issue on your agenda. We cannot act too soon. Thank you very much.

[The prepared statement of Mr. Citron follows:]

Paul Citron
Vice President, Science and Technology
Medtronic, Inc.

Mr. Chairman and members of the Committee, it is my pleasure to appear before you today. My name is Paul Citron and I am Vice President of Science and Technology for Medtronic Inc., headquartered in Minneapolis. I want to commend the members of the Committee, especially our own Congressman Gutknecht, for the seriousness of your efforts to eliminate those outdated regulations that have not kept pace with today's technological needs.

Medtronic is the world's leading producer of therapeutic medical devices, focusing on the development and production of advanced cardiac and neurological devices. Our products include many technologically advanced therapies that save and enhance human life, including pacemakers, implantable cardiac defibrillators, heart valves, and implantable drug delivery systems. We operate in 120 countries with approximately 10,000 employees. In addition, Medtronic is part of the larger U.S. medical device industry, one of the strongest export-oriented manufacturing sectors, which accounts for nearly half of the world market for medical devices and creates a favorable world trade balance of nearly $5 billion.

The key to the global leadership of Medtronic and the U.S. medical device industry in general can be summarized in one word--innovation. Our strength lies in our ability to develop innovative therapies that meet patient needs, and to deliver those therapies to the market. Today, medical technology advancements are happening at increased speed compared with the pace just five or ten years ago. And this innovation is occurring throughout the world. To remain competitive, Medtronic and other manufacturers must conduct product development and manufacturing activities in an environment that fosters innovation. If such an environment cannot be found in the United States, we have no choice but to look elsewhere.

As a nation, we must redesign the environment for innovation in this country, creating a system that is synchronized to the technology development process of the Twenty-First Century, a system that recognizes that laws and regulations created in the '70s are impediments to innovation in the '90s. It would be tragic if the medical device industry becomes yet another example of an industry where the United States yields its leadership position due to an overly cumbersome system of regulation and governance. I know the Committee is familiar with the recently published Wilkerson Report, a

study of the forces affecting the competitiveness of the U.S. medical device industry, which details many statistics documenting this problem. The trends are clear. More and more innovation is moving overseas.

When we look for the reasons behind these trends, we can point to four major barriers to the development of new medical technologies in the United States: 1) unpredictable and overly burdensome U.S. regulatory practices; 2) controls on the export of unapproved devices; 3) restrictive Medicare reimbursement policies; and 4) the onerous effects of widespread product liability lawsuits. All four of these barriers need to be addressed if we are to keep medical innovation in the U.S. and if we aspire to give our patients health care as good as that available elsewhere.

I know that in Congress there are efforts underway to reform and address all of these barriers. I would like to focus on one today, in part because we are in Rochester, the home of one of the world's premier medical innovators -- the Mayo Clinic. As I address this issue, we should consider one question: What is the ultimate cost of the movement of advanced medical research out of the United States to overseas locations?

The critical ability to do clinical research on new medical technologies in this country is being seriously threatened by recent changes in the interpretation of Medicare coverage polices by the federal government. Health care providers are no longer reimbursed when they participate in an FDA approved clinical trial. There can be thoughtful debate regarding the timing of reimbursement for pioneering technologies that are, as yet, unproven. But coverage for next generation clinical devices providing therapy already covered by a reimbursement code is a legitimate and necessary coverage policy.

Mr. Chairman, you have called this hearing in order to examine how the exercise of regulatory authority by some government agencies has resulted in unforeseen and unnecessary hardship for patients and those committed to advancing medical research. This current HCFA policy is a clear

example of an agency regulating without oversight or due process and creating such hardship. The reinterpretation of the Medicare statute that resulted in the policy, a complete reversal of the long-standing interpretation, was undertaken without the opportunity for those affected by the decision--Medicare providers, device manufacturers and, most importantly, senior citizens--to comment and without a consideration of whether the costs are justified by the means. And the costs of this policy are severe.

First of all, not reimbursing providers when they participate in an FDA approved clinical trial has profound implications for the health of our senior citizens. Let me give you a recent example. Suppose you are diagnosed with a life-threatening heart-rhythm disorder and require an implanted defibrillator. The existing FDA approved devices have proven themselves to be highly effective for your disorder and HCFA will reimburse for this therapy. A new iteration of this technology is undergoing an FDA approved clinical trial. This new model delivers the same therapy but has next-generational improvements that your physician and you believe to be important to your treatment. Its considerably smaller size allows it to be implanted in the upper chest area with a single incision rather than in the abdominal region, where a thoracotomy may be needed. Its simplified surgery markedly reduces morbidity and allows the procedure to be done in a catheter lab rather than in an operating room environment, significantly reducing surgical costs and the length of the hospital stay. Hospital costs are reduced to a mean of $13,000 from $21,000 for earlier systems. Its batteries are expected to last considerably longer than its predecessors and it provides the physician with advanced diagnostic capabilities to provide better overall therapy. But, under current HCFA guidelines, this device will not be reimbursed prior to full FDA market approval if you are a Medicare patient. You will receive a device that is obsolete in Europe and will soon be obsolete here. This doesn't serve patients well, nor does it support medical innovation and leadership.

But the lack of access for senior citizens to important medical advancements is not the only disturbing result of the policy. It is also having a chilling effect on medical research in this country, virtually shutting down the device related research at leading academic medical centers. Susan

Waltman, Senior Vice President and General Counsel of the Greater New York Hospital Association, echoes the concerns of medical institutions across the country when she states:

> Even when HCFA's policy as to what is reimbursable and what is not is explained to hospitals and physicians, most find HCFA's distinctions between reimbursable admissions illogical and difficult to sort out. As a result of this confusion, and in response to the potential severe financial implications of the issues, many of our members have completely stopped their clinical trials, not just with respect to cardiac devices and not just with respect to Medicare beneficiaries, but with respect to all trials for all patients. These actions have been taken with considerable consternation and regret as to their implications for the future of clinical advancements in this country.

And just as the policy creates disincentives for hospitals to continue clinical trials, it creates incentives for manufacturers to move those trials overseas. This is because the FDA allows manufacturers to use clinical data from Europe and elsewhere. What is happening, and what I suspect will happen at an even greater pace if this issue is not addressed soon, is that companies will do all their clinical studies outside the U.S., in locations where reimbursement is not an issue.

The Wilkerson Report provides a clear example involving a development stage company conducting a clinical trial on a new interventional coronary technology. For a trial consisting of 1250 patients, with ninety percent of the eligible patient population comprised of Medicare beneficiaries, the current policy would add $22.5 million to the base cost of the trial. However, moving the trial to Europe would add only $1 million to the base cost. Obviously, faced with these numbers, any manufacturer with the capability to do so would choose to conduct the necessary research overseas.

This problem, with its broad implications, has come to the attention of a large coalition of researchers, innovators, and providers in the medical community. I am pleased to report that they have been successful in getting legislation introduced in the House and Senate to address this

problem. The Chairman of the Health Subcommittee on Ways and Means, Representative Bill Thomas of California, is the prime sponsor of the Advanced Medical Devices Access Assurance Act, and is committed to seeing it enacted.

The purpose of this measure is four fold: 1) it fulfills the original intent of Medicare that beneficiaries get access to the latest technology; 2) it promotes innovation and research in new medical technologies; 3) it is budget neutral and imposes no new costs for the Medicare program; and 4) it does not compromise patient safety.

Fulfills Original Intention of Medicare

The Medicare Act was intended to cover the reasonable costs of services including "new services and techniques as they are adopted in the future." This bill ensures that beneficiaries will have the opportunity to get state-of-the-art medicine. The current blanket exclusion of coverage for all costs associated with the use of investigational devices deprives seniors of the benefits of the newest technologies.

Promotes Medical Research in Academic Settings

HCFA's refusal to pay any of the hospital or medical costs under an IDE is seriously damaging the research function of academic medical centers and major hospitals. Clinical trials are the life-blood of information on the benefits of new technologies. Trials should include patients who are intended to benefit from them, including patients over 65 years of age.

Is Budget Neutral

This bill does not add to the costs of the Medicare program. If a procedure involving an investigational device is used, no payment will be made unless there would have been payment if an FDA-approved device had been used or an alternative procedure performed. In addition, any

payment that is made will not exceed the amount that would have been paid using an FDA-approved device, an alternative procedure, or a lesser amount if the Secretary determines it is necessary to assure budget neutrality.

Does Not Compromise Safety

Devices used in IDEs are subject to extensive FDA control. Manufacturers must submit a detailed application which includes a comprehensive description of the device and the investigational study, a complete report of all prior investigations, a description of the methods, facilities and controls used for manufacturing, processing, and storage, and copies of all materials distributed to Institutional Review Boards (IRBs) that approve the trials and to patients to obtain informed consent.

FDA will not grant an IDE if it determines the risks to patients are outweighed by the anticipated benefits. It limits the use to specific sites and specific numbers of patients. Trials can be terminated at any time. During this investigational phase, the manufacturer is prohibited from promoting or commercializing the device or charging a price that exceeds the amount necessary to recover its costs.

I realize that the Congressional agenda is full, and I know only so many issues can be addressed this year, but I am hopeful that this legislation will receive the priority and attention it deserves. We are here at the home of the Mayo Clinic, a world renowned research center, a place where people come from all over the world to get treatment. Yet, ironically, the medical innovation first conceived here, will not be able to be practiced here because of this policy.

Mr. Chairman, let me conclude my remarks with a word about comprehensive FDA reform. As of this date there is no major comprehensive FDA reform bill pending before the Congress. We know many are working on proposals and there is hope that somehow we will find the time to get to this issue.

I want to make it clear: we believe in the need for a strong FDA, one that effectively protects the public health. Protecting the public health and keeping pace with medical technology development are not incongruous. But overly burdensome regulations have resulted in a substantial portion of the development of Medtronic's last 15 new products being done in Europe, and our Ventures Group, responsible for steering the development of breakthrough technologies, is now headquartered in The Netherlands. There is a real cost to the US. when our regulatory system is outdated and unable to keep pace with innovation. That cost is felt in the loss of high quality jobs. by patients not getting the benefit of improved therapeutic outcomes, and by our research community having to cease doing their work in the U.S.

I know this issue has been a concern of this Committee and I urge you to keep this issue on your agenda. We cannot act too soon.

Thank you and I would be pleased to take any questions you might have.

Mr. MCINTOSH. Thank you very much, Mr. Citron. Let us call now the second witness in the panel, Mr. Mike Gozola, who is president of Rochester Prosthetic Laboratories. Thank you for coming and I appreciate your participating today in the field hearing.

Mr. GOZOLA. My name is Mike Gozola. And maybe the thing that I'm going to bring to this is a little insight from a much less lofty perch. I have a one-sentence prepared remark and that's it. The rest is going to come from the hip.

I'm the president of a very small company that does work in the medical field. We make artificial limbs and braces, prosthetic and orthotic devices, and we employ about 25 to 30 people at any one time. I'm your typical small businessman that's affected by a lot of the things that you're talking about.

My prepared statement is: Focus of regulation should be compliance with the intent of the law. From my point, instead, detection and punishment seems to be the No. 1 job of field personnel, and my example is OSHA. We have a safe place to work. My company is about 11 years old. I think if you were to look back at our history with worker's compensation, our use of the system is very, very minimal and, yet, over the past couple of years, I've had to purchase the services of a company that specializes in interpreting the rules and regulations so that—because I'm not an attorney, I will be kept out of the jaws of the regulators and the people that are coming in to enforce things.

This is one-fourth the paperwork that this project has generated. I was going to bring it all just for something to do, but I didn't. We have spent just over 1 year trying to get our company in compliance with OSHA—and I have to say right now I think we are in compliance. The thing is I don't think we needed it. I have a safe place to work for my employees. We have trained professionals, both on a technical level and dealing with patients, who don't want to get hurt. I don't want my people to get hurt on the job. And, yet, here's some of the things I have to deal with.

I have to pay to get what looks like a library catalog here. Section 1.09. I have to be told that floors are to be kept clean, sanitary and dry to prevent slip and fall exposure hazards. That's just plain common sense. I don't need to have somebody come in and tell me that this is what I need to do.

And, yet, I'm not saying that we don't want to have a safe workplace. To me, OSHA ought to be some place that I can use as a resource. I want to protect my workers. It's not my area of expertise and perhaps I could call them in to go over the things that might be missing in our safety program. And, yet, my No. 1 motivation for all of this paperwork you see here is that I don't want to get fined when somebody comes into my place of business to see what we're up to.

Personally, I'm aware of a couple of OSHA inspections that kind of went that way and the first thing that happened was a hefty fine. That's what kind of made me a little reluctant to come up here and talk about it, because—for the same thing you talked about at the beginning of the hearing. It's just a symptom of the disease is all I really want to bring up here and that it just takes on a life of its own and I think that's hurting American business.

This pile of papers here costs. It doesn't produce anything for anybody. That's all I have to say.

Mr. McINTOSH. Thank you. I appreciate that. I imagine for every minute that you spend focusing on that pile of papers is a minute you can't be thinking about other improved products, offering better product innovations to help people in this particular area. I appreciate you coming.

If I could ask both witnesses to come back to the microphone for a minute. Mr. Citron, I had a question. From what I've been hearing you say, it sounded like the regulations and HCFA, by not reimbursing people who are involved in clinical trials, set a double standard for the elderly in this country, because all of them are required to get their health care through Medicare. It's not legal for insurance companies to offer coverage to people in that program. They can choose whether or not to be in part B, but part A is mandatory.

It strikes me that that double standard is one that is putting them in inferior care. One of the things we're trying to do is reforming that system. We're going to get attacked for cutting Medicare and we can get into a long debate in proving to everybody that we're actually increasing the spending. But one of the things we're trying to do is create a system that actually gives people better health care at less cost by getting rid of some of these Government regulations.

So I wanted to ask you if we eliminated that rule and said we're not going to treat people differently for purposes of Medicare reimbursement, whether or not they're in a clinical trial or receiving some other procedure. Do you think that would—well, certainly, as to Medicare, do you think it would increase the cost or save cost or would it be about neutral in that area?

Mr. CITRON. First of all, I think your observation is a very fair one. Many of the technologies that we are developing in the medical device industry focus on individuals that are in their 40's, 50's, 60's and beyond. And, quite candidly, many of these technologies return patients to essentially the full essentially normal existence after they receive the therapy. So they are very, very, very important.

What I can tell you is that when you follow—first of all, when you have to do a clinical trial, a validation trial on a next generational product, we know that the benefit of fundamental therapy. So when HCFA refuses to reimburse a procedure for a patient who merely happens to be above, let's say, age 65, that's a rather arbitrary decision. This patient definitely needs the therapy. We know the patient will benefit and the patient should not be compelled to get what will soon be an obsolete therapy and likely is, as I mentioned earlier, obsolete in Europe. So that's one aspect.

The other aspect of it is that since many of these devices go into older Americans, the FDA actually requires us to do the clinical study on those patients just to make sure that there isn't some characteristic that needs to be uncovered about how this device acts in an older person. And, yet, this older person will not get the reimbursement currently or the hospital will not get the reimbursement for implanting this device in an older American, which is one of the reasons why we are compelled through this paradox to do

more and more and more of our clinical studies outside the United States. That data will be accepted by the FDA, by the way.

So we are literally moving that clinical experience offshore. So physicians, like physicians at the Mayo Clinic, lose that knowledge on how these devices interact with older Americans.

To get to the last part of your question, if I recall it correctly, and that deals with the economics of the new therapies, I can tell you that based on the trends and following the technology over the years, each generation of device typically offers incremental and sometimes major economic value. Let me just show you some examples in my tenure at Medtronic over the last twenty-some years.

When I joined the company, this was a state-of-the-art pacemaker. It was merely a metronome. It was a very, very simplistic device, but it kept the patient alive. This device is today's pacemaker. This has a microcomputer inside of it. This device reacts to patient's physical activity, changes its rate, turns itself off if it's not necessary. This old device, when it lasted for 2 years, we had a party. This new device will last 7 to 10 or 12 years, depending on how often it has to operate and it shuts itself off.

The pacemaker, as an example, has been determined to be one of the most, if not the most effective medical therapeutic intervention available. So these advances do clearly, I believe, contribute not only to improved quality of life, but does so in a very, very cost-effective manner.

Mr. MCINTOSH. Let me ask you one quick question about pacemakers. We had heard some testimony earlier today or perhaps it was yesterday about silicone and the fact that FDA has not unequivocally stated that it is a safe substance for use inside the body, making it difficult for manufacturers of the end product to be assured that there will be a steady supply of surgical grade silicone. Have you discovered that with that or any other material? Sort of a combination of the failure of the FDA to act and the enormous liability due to lawsuits.

Mr. CITRON. Let me preface my remarks by saying that the body is an exquisite organism and it attempts to remove, destroy, eat, or eliminate foreign bodies. So any material that is in the body has an enormous challenge in order to correctly do its job.

Silicone rubber happens to be one of the most widely used materials that have proven themselves, or various forms of it, to be biostable and reasonably inert in the body. I can tell you that I have spent an enormous amount of my time over the last 2 years working with raw material suppliers around the world who have been frightened from this industry. They are deeply concerned about the possibility of being drawn into product liability actions.

So it has involved the silicone rubber manufacturers and producers. It has involved the producers of various polymers, like polyurethane, PTFE, commonly known as Teflon, polyester, commonly known as Dacron. The suppliers of these raw materials that are vitally necessary for us to be able to put together, be it a pacemaker or a defibrillator or a heart valve, are exiting the industry and that is having an enormous effect on innovation, particularly for the smaller company who can't even begin to purchase the raw materials that they need.

I can tell you that as recently as yesterday, I received a copy of a letter where a study that was going to be done here at the Mayo Clinic, using some revolutionary microelectronic capabilities present at the Mayo Clinic, that needed to work with a major computer manufacturer who has some core technology that is necessary to build these microcomputers, that major computer company has told the Mayo Clinic that it will not, under any circumstances, provide any circuits to the Mayo Clinic, even for animal work. They want nothing to do with the medical implant area or the medical area at all.

So an idea that is still in its infancy will never be seen. We're seeing that in example after example after example.

Mr. MCINTOSH. And if that becomes widespread that people don't want to supply the materials that you need for these devices, is it possible that even existing technology will no longer be available?

Mr. CITRON. There is a distinct risk of that. I can share with you an experience where we had a supplier that we had been working with for 18 years without any issues. About 6 months ago, we were notified that as of December of this year, they will cease selling us a critical component. We then scoured the world and found only two other possible sources for that critical component.

I think we are OK for the moment, but I can tell you that there were some moments when we didn't know whether we would find a backup material. But you have to remember, Mr. Chairman, that we have the resources perhaps that other companies don't have in order to scour the world for these materials.

So the question I would raise is how many of these stories are existing elsewhere that we never hear about.

Mr. MCINTOSH. Thank you very much. Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman. First for Mr. Citron. Your firm does business all over the world. Specifically, could you enlighten us on why is it that it takes so long to do so much of this here in the United States compared to other parts of the world and why is it you're moving research to Europe? Specifically, what would you recommend that we do to climb into the 21st century?

Mr. CITRON. I think the key difference between how we operate domestically versus internationally is that the expectations are much more clearly stated overseas. The timelines are much more contracted. And another difference that exists overseas is that the process is very, very predictable. So you know, as a supplier, as a manufacturer, what you have to do and if you do those things, you will get timely approval.

There's also a different mindset between how regulators regulate in Europe versus here. There is a presumption, maybe not stated, but a presumption in Europe that the supplier and the physician are competent and do have the best of intentions and that it's not in their interest to perform medical procedures that do not serve the patient well or produce devices that don't perform well.

And so they tend to look to see whether have you done those things that produce a reliable product. They place great emphasis on the manufacturer and the physician working together to make sure that that technology does perform appropriately and do the right things.

Whereas the presumption here is, I think, reversed. The people tend to look for where there might be shortcuts that have been taken. I can assure you that nobody builds into their marketing plan a recall. That is not something that they want to have and that's not something that they say, well, we'll have that recall and we'll put up with it. They're disastrous.

So implicitly the industry wants to produce good products, but it's that difference of mindset. So relative to the agency, I think the key issue that needs to be addressed, in my opinion, is a mindset that operates in a timely fashion, but, most importantly, creates predictability so that you know what you have to do, when you will get an answer, and when, if things perform well, you can get to the marketplace.

And I want to underscore an aspect of that, and I realize I'm a little longwinded in this response. These devices are extremely sophisticated and it's not merely a matter of putting them into commerce and walking away and taking orders. These technologies require enormous education of our field people, of the physicians, of the medical support staff and information and education of the patient. We have to know when the approval will be granted in order to have all of those points of education taken care of when the product becomes available so that the performance of these products is supported by the knowledge base of the community.

So we need to know when to do those things in anticipation of an approval. If you don't know whether the approval will happen in 6 months, 1½ years, 3 years, or even longer, you can't do those preparatory things. That also hurts the ultimate effectiveness of the therapies.

Mr. GUTKNECHT. Are you suggesting more benchmarks? And I think you hit the nail on the head. I think it really is about—and I hate using the word paradigm, but there is a different mindset. Here in the United States, it's like the answer is no unless you can prove completely that the answer is yes, where there they say the answer is yes, unless there is some evidence that it should be no. I don't know if I've said that right.

But we had Dr. Kessler in front of this subcommittee and another subcommittee and Chairman McIntosh referred to this earlier, principally talking about breast implants. And it was interesting—and most of the lieutenants from the FDA were there, as well. Even then, they were asked really specific questions on virtually every question they equivocated. Even on the question—Dr. Kessler was asked would he recommend the silicone breast implants for his mother or his wife. Even on that question, he equivocated. Well, he said it would depend on the circumstance, it would depend on the situation.

It was almost like that was symbolic of the whole problem we have with this, that you can't get a yes or a no. Frankly, some of the researchers we've talked to have said they would prefer having a no. I mean, they'd rather know today that it's not going to be approved than to spend 5 years and another $300,000 or 5 years and $3 million, whatever the number happens to be, or $300 million, they'd rather know today than 5 years from now, and that's the kind of problem we're dealing with.

And it also relates—and I do want to get to Mr. Gozola. I appreciate your coming, because we do need the perspective of some of the smaller businesses, too. We do hear from some of the larger businesses who do business internationally, particularly as it relates to OSHA. We have heard so many examples and sort of along the same line. That is that Federal regulators tend to play the game of "gotcha."

Now, we've been told by both the folks at FDA and even more so by Mr. Deer at OSHA that those days are past. Now we're moving into a new era of cooperation with employers, and we're hopeful that that is the case, although many of us remain somewhat skeptical and most of the people who have testified remain skeptical.

Perhaps you can expand on that "gotcha." Has it happened to you? And maybe some specific examples and, most importantly, some specific recommendations of what we can do to begin to change this mindset or paradigm, whatever term you want to use.

Mr. GOZOLA. I've had just since Friday to prepare for this. I didn't know what I was going to get into here and obviously I don't have big prepared statements like the rest of the gentlemen do. But I thought my perspective would be interesting; just from the guy who was trying to meet payroll every week. We're trying to do all the things that small businesses have to do without the large resources and background of much larger companies.

But in answer to your question, not to me personally. One of the reasons I decided I'd do this is because I don't fear any reprisal. They could come in today and I think I could give them a nice tour of my office and say, "We're not only complying with the intent, but to the letter, and also, hopefully to your satisfaction."

But I have a colleague up in the Twin Cities. Typically how it goes is a disgruntled employee, is dismissed, quits or whatever and it's time to get back at the employer. They blow a whistle. It triggers an investigation and they can always find something. It's just like a tax audit. You can always find something, but it resulted in a fine. The guy paid a big fine. It wasn't that they came in because they wanted to look into the situation and try to correct it. It was a complaint and it was a fine, and it happened up in Minneapolis to a colleague of mine in the same business. That's what really prompted me to come here and just tell my story.

Mr. MCINTOSH. Mr. Gutknecht, if you'll just spare me a couple minutes. You would be interested in something we heard earlier today in St. Paul from a gentleman who had a list of the top hundred citations here in Minnesota by OSHA. Just 4 years ago, in 1991, the top five all were ones that he, as a construction manager, would say were serious safety issues.

But as recently as 1994, those had all changed and they were all paperwork violations and they were easier to demonstrate, to go out and get a fine for, but they had very little to do with actually improving the safety of people on the work site. It shows a real systematic problem that we've got with that agency in failing to accomplish its mission.

Thank you both for coming and participating today. I really appreciate that. Your testimony will be very helpful to us as we move forward.

I would like to, at this point, ask unanimous consent that the testimony of Susan Santaswasso be included in the record for this field hearing.

[The prepared statement of Ms. Santaswasso follows:]

My name is Sue Santosuosso and I'm here today on behalf of Barlow Foods to share some examples of how the FDA's labeling regulations have been a burden to us.

To start, I'd like to present a little background about Barlow Foods. We're a large independent grocery store located in Rochester, Minnesota. Barlows is owned and operated by Mr. Stephen R. Barlow and has been the leading supermarket in Rochester since 1969, when it first opened. Barlow's is open 24 hours and currently employs approximately 400 people; many of which are high school and college students. Barlow's also provides work for professionals not traditionally employed by a supermarket such as a registered dietitian, a personnel administrator, a computer technician, a chef and a daycare provider, along with other professional managers.

The company's mission is to provide an efficient, profitable retailing system on a regional basis with a total commitment to customer satisfaction in convenience, pleasant surroundings, quality, variety, service and the lowest possible price.

Before I begin to demonstrate examples of our experience with the new food labeling law, I'd like to emphasize that we are, in a technical sense, exempt from nutritional labeling for two reasons, (1) our size - we are small relative to our big chain competitors, and, (2) we prepare our bakery and deli items from scratch on-site. However, we do not perceive ourselves as exempt from a competitive point of view and we are not exempt from ingredient labeling.

I will start with ingredient labeling. We have always been required to disclose the ingredients used to make our products and we have. For example, our potato salad label has always read: potatoes, eggs, ground vegetables (celery, radish, onion), salad dressing, mustard, sugar and pepper. Today, however, we must disclose more detailed information, specifically about each prepared ingredient. For instance, to list mayonnaise, marshmallows, food coloring, ham or salad dressing is not enough. We must now indicate the ingredients used to make each of these respective ingredients. Today, the label for our same potato salad recipe reads: potatoes, eggs, ground vegetables (celery, radish, onion), salad dressing (soybean oil, corn syrup, vinegar, modified food starch, egg yolks, salad, spice, onion powder, calcium disodium EDTA, natural flavoring), mustard, sugar and pepper. To do this, we had to purchase specific computer hardware and a new label printer.

This is just one example of one label. Multiplied by nearly 100 deli salads and sandwiches and over 200 bakery products, you can understand the burden this has posed on our store in terms of time, labor, and consequently, company expense.

We question the benefit of our efforts. Are our customers looking at these lengthy ingredient lists? To whom are they an advantage? From a nutritional point of view, I'd respond by saying possibly customers with food sensitivities to specific ingredients. However, the percentage of the population having this problem is small. Therefore, it can be speculated that the extent to which we

devoted time to this effort has benefitted very few.

As I stated previously, we are exempt from nutrition labeling. However, since the Nutrition Facts panel has begun to appear on our competitor's bakery and deli items more and more of our customers have come to expect the same information on our products. Being the consumer-responsive company that we are, we have recently equipped our store with expensive computer hardware, software and labeling machines in order to give our customers what they now want. In addition, we will employ an additional dietitian to analyze these products. This process will be long and costly. We can only hope that our resources prove to be well spent for the majority of our customers.

Aside from ingredient and nutrient labeling, we have been subject to other forms of labeling regulations. For instance, in the previous two years we have had to post signs indicating the origin of wax used on produce. We have also had to "voluntarily" post nutritional information about the top 20 fruits and vegetables consumed by Americans, as declared by the F.D.A. And, as mandated by the U.S.D.A. we have had to adhere a safe food handling label to all of the perishable meats we sell.

I would like to emphasize that we are not opposed to the use of labels if we believe they are, in fact, providing the customer with information they actually want. If we had perceived a demand for the disclosure of nutrient values or ingredient detail, we would have responded to this by now. In fact, our commitment to quality and freshness underscores our consumer-responsiveness. To assure

our customers that the food we sell is fresh, we voluntarily employ a microbiological testing lab to test random samples of our perishable foods for wholesomeness. And, we attach a freshness label to each of our perishable products indicating the time of day the product was prepared. In fact, in working with consumers on a daily basis for 6 years, I have found that the concern and lack of knowledge about proper food handling and food safety surpasses interest in nutrition information. Yet, our efforts to address this are being diverted to extensive ingredient listings and nutritional values.

In closing, we at Barlow Foods feel that federal labeling regulatory standards are creating an unnessary burden on small business operators who are trying to excel in an extremely competitive environment. We would like to see less mandates and a greater trust in the "good faith efforts" already put forth by Barlow Foods.

Mr. MCINTOSH. We're now going to open up the microphone. If there is anybody in the audience who would like to testify or add additional comments, please step forward and we'll make your testimony part of the record at this point. What I would ask you to do is state your name for the record and then I'll administer the oath.

Dr. VETTER. Thank you. My name is Richard Vetter, head of Occupational Safety at Mayo Clinic.

Mr. MCINTOSH. Is it doctor?

Dr. VETTER. Dr. Vetter.

[Witness sworn.]

Mr. MCINTOSH. Please let the record show that the witness answered in the affirmative. Thank you for coming.

STATEMENT OF RICHARD VETTER, OCCUPATIONAL SAFETY, MAYO CLINIC

Dr. VETTER. Thank you, Mr. Chairman, Mr. Gutknecht. Thank you for the opportunity to speak to you for a few minutes about the subject of regulatory relief. As I said, my name is Richard Vetter. I'm the head of the section of Occupational Safety at Mayo Clinic, a position that requires regulatory interaction with the Environmental Protection Agency, the Nuclear Regulatory Commission, and OSHA. I am also president-elect of the National Health Physics Society, a professional organization that develops scientific knowledge and practical means for radiation protection.

I just wanted to mention that the Health Physics Society has an office in Washington and is eager to assist you and your staff in any radiation issues.

The purpose of my appearance here today is to provide you with one example of regulation enforcement that goes beyond the bounds of common sense. I have provided a brief description of this example and a suggested solution in a one-page summary that I will leave with you.

This example involves an EPA regulation of clean-burning organic solvents, a waste product from medical laboratories, in a boiler used to generate steam and electricity for Mayo Clinic. The organic solvents consist of alcohol, xylene and acetone. When injected into the boiler, they burn much cleaner than the No. 6 fuel used to fire the boiler. The regulations that govern the injection of these clean-burning waste solvents are onerous and burdensome and we are faced with the decision of whether to continue this method of disposal or whether to process the solvents and ship them to an authorized disposal facility.

Processing these solvents will increase our costs and the costs of health care and shipment over the highways poses much greater risks to the public than burning the solvents in the boiler. The regulatory issue is the 1991 EPA Boiler and Industrial Furnace Rules that treats Mayo's waste and the waste of other medical laboratories the same as hazardous waste from industry that is shipped to commercial boilers that are specifically licensed to burn hazardous wastes.

From an overall safety standpoint, there is no risk to the public from burning these clean-burning solvents in the Mayo boiler, but there is a real risk associated with shipping them down the high-

way. These are large trucks that ship these wastes to commercial disposal facilities. We had an example last night in Minneapolis where a large semi was involved in a collision and two people were killed. Shipping these wastes down the highway are a finite risk that we often realize.

So we find ourselves caught in a counter-productive maze of regulation and enforcement and seek your assistance in advancing a regulatory or legislative solution with the EPA to keep the environment clean and to return some common sense to these regulations.

I will leave a copy of this summary with you for your information. Thank you very much for your assistance.

Mr. MCINTOSH. Thank you, Dr. Vetter. I appreciate that. Mr. Gutknecht.

Mr. GUTKNECHT. Well, we were just visiting you. This sounds like an excellent candidate for a Corrections Day correction.

Dr. VETTER. I was pleased to hear that suggestion and we would like to participate in that.

Mr. GUTKNECHT. We will pursue that with staff and see if there isn't a way we could maybe get that brought up on one of the next Corrections Days.

Dr. VETTER. Thank you very much.

Mr. MCINTOSH. Dr. Vetter, while I've got you here, let me ask you a question in a different area that may be outside your expertise, in which case, just let me know. We've been hearing, both yesterday and today earlier, about safety issues and regulations dealing with meat processors in particular. One of the things that I read in the literature that offered tremendous potential benefits was something called cold pasteurization or often referred to as irradiation, but that people are fearful of using the process because the public may misunderstand what is actually happening there.

I've tried to use the analogy it's like x raying the food, which then kills the microbial organisms and makes it much safer than the current inspection system. Are you familiar with that and is it something that is technologically feasible in a cost-effective way that we could look at in that area?

Dr. VETTER. I'm familiar with the process, with the risks associated with irradiation of food. Basically, it's a process where food is exposed to very high doses of either gamma radiation or x rays and these doses are high enough to sterilize the food; that is, kill the spores. It's primarily spores that are in the food that need to be killed.

It is very efficacious on those foods that have been tested. It extends shelf life. It provides some immediate protection in the event that the food was exposed to a hazardous agent or an infectious—a biological agent. So it does have some very positive benefits.

It's my understanding that the reason it hasn't gone very far is simply because of the public fear of the word radiation. And if they find that the food has been irradiated, those who propose this method of food sterilization—by sterilization, I mean simply killing the microbes. Those who propose this fear a little bit that the public won't buy the food if they find out it's been irradiated. So that relates to the whole subject that the public has a fear of radiation.

But in reality, it's a very safe process. It does not cause the food to become radioactive. There is no way that can physically happen. So it does have very positive benefits.

Mr. MCINTOSH. So it could be something, as we move forward, if we overcome that fear factor, that might offer potentially great benefits. We heard testimony earlier today that as many as 9,000 people die from complications arising out of food poisoning, probably about 2,500 of them dealing with meats and poultry.

Dr. VETTER. It's interesting that most of our medical products are sterilized by radiation.

Mr. MCINTOSH. Oh, really. That are then used in contact with the human body?

Dr. VETTER. 3M, for example, has a large plant in Brookings, SD. They used to sterilize that with a gas called ethylene oxide, which then has to be emitted to the atmosphere. So they eliminated that source of pollution and they now irradiate those medical products.

Mr. MCINTOSH. So the technology is available on an industrial scale.

Dr. VETTER. Yes.

Mr. MCINTOSH. That was another roadblock that people had mentioned to me, that the technology is just not available. My answer to them is that if there's a marketplace for it, people will build it. Sort of like the field of dreams. Build it and they will come. Thank you very much. I appreciate your insight into that area. I have no further questions.

Mr. GUTKNECHT. Mr. Chairman, I would just add, though, not necessarily relating to Dr. Vetter's testimony, but you mentioned about food-borne illnesses. So that the record is clear, we also heard that 97 percent of those food-borne illnesses are as a result of something the consumer did after it left the store. So let's not—we don't want to leave the impression that it's food processors.

Mr. MCINTOSH. Right. And, in fact, this technology is the only thing I've seen that really addresses that problem, because the way they do it is they package it and seal it off so that even a careless consumer is protected, unless they really do something egregious. Very good point. Thank you. Any other citizens? Yes. If you could state your name.

Mr. MURPHY. My name is Michael Murphy. I'm with a company called Comfortex here in Minnesota.

Mr. MCINTOSH. Michael, if you could raise your right hand.

[Witness sworn.]

Mr. MCINTOSH. Thank you. Let the record show that the witness answered in the affirmative. Thank you for coming.

STATEMENT OF MICHAEL MURPHY, COMFORTEX

Mr. MURPHY. Thank you for being here. Comfortex is a company that was founded about 10 years ago. I used to be a health care practitioner and designed a special mattress to take the place of existing hospital mattress, put something in place that would protect patients from bedsores.

We built a business around that and we have been very fortunate. We've grown into an international company and market in Europe and Canada and now in Asia. One of the toughest markets for us to get into, though, is that of the extended care market in

this country. As hospitals are downsizing at a rapid pace, they are discharging patients quicker. They are accelerating discharging the patient into an extended-care facility. The aging population is growing dramatically and the extended-care facilities are being kind of overwhelmed with what's coming.

The acuity level of the patients that they're caring for are much higher than they once were. They're not retirement homes anymore. They're becoming very, very acute care settings. And we do a significant amount of business with hospitals. We're fortunate to have contracts with the Veterans' Administration and provide them with services, with university hospitals.

But to look at where we could really do a lot of good in the extended care side of the business, we are often faced with many, many hurdles. Those facilities will look at a product like ours that can provide better care at a lower cost and they're not incentivized to buy that. They're not allowed to buy that. They'll use special beds that may cost $150 a day to treat a problem when we can do something for 30 cents a day.

In a facility that may have three or four of those very expensive products for treatment, they wait for the patient to get to the point where they're so bad off that they need something and then the Government will pay for the treatments, when it could have been prevented across-the-board for a fraction of what they're paying for it for just a few. And nursing homes, talking about regulations, paperwork, and trying to justify what's being done, from what I understand, nursing homes, that's probably why there aren't any directors of nursing from nursing homes here today. They're at their offices doing paperwork.

They're the second most regulated industry next to the nuclear power plants and for them to try to bring something in that's going to improve the quality of care and reduce their operating costs, it's very difficult because of the regulations that they have to go through to try to make a difference for the people they care for.

If there's anything that can be done to incentivize facilities to bring in products or technologies that will, in fact, enhance the quality of life, reduce the cost of care, this is something that would serve our elderly population and serve us some time in the future.

Mr. McINTOSH. Thank you very much, Mr. Murphy. Do I understand that the problem is in the reimbursement structure and that if we didn't micromanage what things were and weren't reimbursed for, but created a—used a profit motive and simply reimbursed for the overall service, that those products would be more likely to be used?

Mr. MURPHY. If the facility was rewarded for providing quality care or if you could set some standards of what excellence was and more dollars went to those facilities that achieved those benchmarks of quality and excellence, perhaps then we would see a turnaround in what's perceived in this country as a place where we don't want to go.

Those facilities are caring for people now at what you and I would pay for a discount hotel. That's what they get to care for our mothers, grandmothers, and grandfathers. The problem occurs when they'll look at a product that they think is going to have merit, something like ours that can touch a lot of lives in a very

positive way on a day-in-day-out basis, for pennies a day, and they're not allowed to buy it. Their incentive is to wait until one of their residents, one of their patients gets to the point of breakdown and they suffer long enough so that their condition is so bad, then they can get a product to come in that costs $100 or $150 a day. They get that for about 100 days and then it's up to them to pull that patient off of that service or take money from the other patients that they're getting revenue from and support that, which is going to then lead to more problems down the road.

Mr. MCINTOSH. You're very articulate. I can't resist asking. Have you ever considered your product a second generation Murphy bed?

Mr. MURPHY. It's been suggested by my mother and lots of other people.

Mr. MCINTOSH. Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, I don't really have any questions. I think Mr. Murphy has illustrated the problem we have, particularly as it relates to Medicare, and that is that there are sort of perverse incentives. We pay to get people well once they're very sick, but we won't reimburse at a level to keep people from falling into difficult circumstances.

The best example is we've heard an awful lot about diabetes, where people pay to hospitalize somebody to stabilize them. But apparently, as I understand it, right now, we don't reimburse for the injectable drug, insulin. So I think that's one of the things we have to look at as we begin to look at all of our health care reform.

But I would ask. As I understand, Mr. Murphy, you did not require FDA approval to begin marketing the beds.

Mr. MURPHY. No. We were fortunate.

Mr. GUTKNECHT. Thank you.

Mr. MCINTOSH. Thank you very much. Are there any other individuals who would like to testify today?

[No response.]

Mr. MCINTOSH. Well, let me say thank you to everyone who did participate in this hearing. It's been tremendously helpful to us. Thank you, Mr. Gutknecht, for setting it up. Thank your staff for facilitating this hearing. We will take this information back and share it with our colleagues and it will become part of the record, several good ideas of things to correct as a result of today's hearings.

I will now adjourn the subcommittee, until we meet again in Washington. Thank you.

[Whereupon, at 2:40 p.m., the subcommittee was adjourned.]

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