MEDICAL TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY

OF THE

COMMITTEE ON SCIENCE
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

NOVEMBER 2, 1995

[No. 26]

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MEDICAL TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

THURSDAY, NOVEMBER 2, 1995

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE,
SUBCOMMITTEE ON TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:10 a.m., in Room 2318, Rayburn House Office Building, Hon. Constance A. Morella [chairwoman of the subcommittee] presiding.

Present: Representatives Morella, Calvert, Gutknecht, Seastrand, Tanner, Johnson, McCarthy, and Lofgren.

Also present: Representative Walker.

Staff present: Mike Quear, professional staff, and Farrell Corley, professional staff.

Mrs. MORELLA. The hearing of the Subcommittee on Technology will now come to order.

Good morning. This is the second in a series of oversight hearings the Technology Subcommittee has been holding regarding the effect of tax, antitrust legislation, and other legal and governmental policies and their impact on our Nation's high technology companies. The impact of these factors are very important since the successful promotion of technology and competitiveness are significant determinants of our sustainable economic growth, productivity, and competitive standing.

In this hearing we're going to discuss the impact of these factors specifically upon one of our Nation's most important and competitive industries, medical technologies. Research and development of medical technologies is literally a matter of life and death. Advances in medical technologies are crucial, not only for our Nation's biotechnology and medical device companies, but also for the billions of people around the world who wait and hope for cures for major illnesses. Delays in getting new drugs to market are not only economic, but also result in human suffering and potential loss of lives.

Despite this recognized need for the continual advancement of medical development and innovations, I and many of my colleagues keep hearing our Nation's medical technology companies call for major overhaul of regulations and policies which hinder the creation and commercialization of new technologies.

And, in addition, there have been studies which conclude that the steady movement of clinical trials, research and development, and manufacturing overseas represent a potentially large loss of

high quality American jobs and an overall decline in our Nation's leadership in biotechnology and medical technology innovations.

These conclusions are particularly alarming since the United States has always been heralded as the unparalleled leader in this industry. We must do all that we can to foster this vital and emerging field, so that we don't lose our competitive edge in the global marketplace.

And so this hearing seeks to answer questions which relate to the heart of maintaining our United States competitive edge in medical technologies, and these questions are such as: how are medical technologies and products being affected by tax, antitrust, regulatory, product liability, and other government policies? How can Americans gain quicker access to breakthrough medical technologies while maintaining reasonable safety and efficacy standards? Is the competitive position of the United States medical technology industries being eroded by the movement of clinical trials, research and development, and manufacturing overseas?

I'm pleased to welcome our distinguished panelists this morning. We're first going to have one of two of our congressional colleagues appearing before, Congressman George Gekas from Pennsylvania. He's the Co-Chair of the Congressional Biomedical Research Caucus.

Later on, Congressman Bill Baker from California, a member of this committee, plans to join us. Both Members have been leaders in promoting the medical technologies industry. I welcome their participation.

Our colleagues—and Mr. Gekas, indeed—will be followed by representatives of various sectors of the medical technology industry, including biotechnology, biopharmaceutical, and medical devices.

Panel two witnesses will discuss their firsthand experiences of the impact of government policies on medical technology, development, and commercialization.

Our third panel will discuss next generation medical technologies, incorporating telemedicine, virtual reality, microrobotics, smart devices, and 3-D imaging. Panel three witnesses will also provide us with an excellent preview of the type of technologies which will be on display at the 21st Century Medical Technologies Fair that's going to follow this hearing. So we have a pretty exciting morning and early afternoon. The Technology Fair will begin at one o'clock in the Rayburn foyer. Joining me to help kick off the fair will be Speaker Gingrich and Chairman Walker, and I urge all of you to join us this afternoon at the Rayburn foyer for this informative and interesting presentation.

I would now like to recognize the distinguished ranking member of this Subcommittee, Mr. Tanner.

Mr. TANNER. Thank you, Ms. Morella. And I want to thank you for holding the hearing on the impact of government policies on the development and commercialization of medical technology. All too often in this field, legislation for regulating the health care industry has been a knee-jerk reaction to a public crisis.

The enactment of the Pure Food and Drugs Act of 1906 was a result of the scandal associated with the fraudulent claims of patent drugs. Thirty-one years later, the software elixir incident, where more than 100 patients died from consuming what they

thought was simply a reformulated antibiotic, became the catalyst for passing the Federal Food, Drug, and Cosmetic Act of 1938. The the thalidomide tragedy precipitated the enactment of the 1962 Kevaufer-Harris drug amendments. Problems with the Dow ConShield and cardiac pacemakers in the early 1970s resulted in the Medical Device Amendments of 1976 Controversy surrounding shoddy heart valves prompted passage of the Safe Medical Device Act of 1990.

It is rare that Congress has reviewed the impact of these statutes and the resulting regulations on technology development and their effect on access to, and quality of, medical products. From my discussions with medical device manufacturers in our district, it is my impression that many of our existing laws and FDA regulations don't reflect the current state of affairs. We need to fix the situation. Our regulatory framework must be efficient while insuring that drugs and medical devices are safe and effective.

At the same time, we have to realize that the regulatory structure is only one piece of the puzzle affecting medical technology development. The recent Wilkerson Group Report, forces reshaping the performance and contribution of the U.S. medical device industry, described six factors: changes in the health care industry itself, regulation, product liability, government payment for medical technology, reduction in the availability of venture capital, and the diminishing capacity of the clinical infrastructure. This report highlights the profound changes that are affecting the medical device industry.

The vitality of the health care industry is important not only to the well-being of Americans, but to our economy as well. This is a multibillion dollar industry that employs thousands of Americans in high wage, high tech jobs. I hope that in today's hearing we will gain a better understanding of how these changes mesh together and what the government can do to improve the climate for the industry and the public.

Currently, proposals range from abolishing the Food and Drug Administration to doing nothing at all. Neither of these two extremes benefit either the industry or the public. We need regulatory reform as we move through this process. We should be guided by one principle only: that Americans can be assured of having safe and effective medical products delivered to them as quickly as possible.

I want to join the Chair in welcoming today's witnesses and thank you all for appearing today.

Mrs. MORELLA. Thank you, Mr. Tanner.

We've been joined by Mr. Gutknecht. I'd like to ask him if he'd like to make an opening statement.

Mr. GUTKNECHT. Just briefly, Madam Chairwoman, I just want to thank you for holding these hearings. This is a critical issue, particularly back in my home State of Minnesota, where we have an organization called the Medical Alley, who has been very active in pushing for regulatory relief and reform, and I just want to publicly invite the subcommittee perhaps to sometime come to Minnesota and meet with some of the technology firms and people who are working in this area.

I would also like to share a story that, shortly before he retired, one of the Mayo brothers gave a talk to the Rochester Chamber of Commerce, and he talked about medical research and the importance of it. He said, you know, the plain truth is that the average American becomes seriously ill about 11 times during their lifetime, and they recover 10 times. And the reason they recover as many times as they do is because we know as much as we know, and when we know more, they will recover more times.

And one of the things I think this government has to strive is not to be an impediment toward that kind of research, and I think more and more we're hearing evidence that the government is not really helping or guiding in that research; we're actually becoming a serious impediment. And so I think hearings like these can go a long ways toward shaping policy in the future, so that we do protect the public safety and health, but we do not become that kind of an impediment.

So, again, I want to thank you, Madam Chairwoman, for holding these hearings, and I hope we can work together to solving some of these regulatory problems.

Mrs. MORELLA. Thank you. I agree with you, it's a very important hearing, and we have to strike that kind of balance. Your story is most appropriate.

And it's always good to have Members of Congress, colleagues, who are leaders in the area where you're having hearings. And so it's a pleasure to welcome my distinguished colleague, George Gekas, who is the Co-Chair, as I mentioned, of the Congressional Biomedical Research Caucus.

Mr. Gekas, thanks for joining us this morning.

STATEMENT OF THE HON. GEORGE W. GEKAS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. GEKAS. I thank the Chair, and my first duty is to invite anybody up there, staff or member, to come down and join me in my breakfast. There's plenty left.

[Laughter.]

Mrs. MORELLA. I thought you were going to say to join the caucus.

Mr. GEKAS. Yes, well, you can do that, too. Some of you are members of our Biomedical Research Caucus. In that caucus over the last five years, and previously to that through publications, of course, we have become aware of hundreds of new medical devices and advances in technology that save lives 10 times or more, as Congressman Gutknecht has said, and they have become marvels of interest and of lifesaving capacity to so many people, that we ought to be giving incentives for the development of more and not putting hurdles in front of the development of those already on the market, which brings to mind immediately, when I tell you brain-shunt or pacemaker or jaw implant, marvelous advances that have helped people for a long period of time.

We must also, then, look behind it and see that, for instance, in the jaw implant technology a little bit of Teflon is required, a tiny little bit of Teflon. Dupont, a mega-company, of course, has supplied the Teflon for those technicians who provide these wonderful devices. Yet, they have been, Dupont has been drawn into the

sparse number of cases that have arisen out of some malady that might have happened to a beneficiary of one of these implants and has been sued right along with everybody else for daring to supply some Teflon. Now they didn't have anything to do with the design of the implant, nor in any way did the Teflon itself cause an injury, if any injury was caused. Yet, they're sued. They always win, but each time hundreds of thousands of dollars have been expended for naught.

Well, we have brought about in this session of Congress a movement toward settling some of these issues by what we have included in the products liability bill that's moving through the Congress and that's been passed by both Houses in Conference, and I'd like the Committee to be aware of it, to help us when the Conference Report emerges for final consideration, in which we take special steps to protect those suppliers of these supplies that don't have anything to do with the injury sustained, to absolve them early in the process, so that they can have incentive to continue providing these materials, and at the same time save them from the cost and embarrassment and futility of a suit in which they shouldn't be involved in the first place. We're making progress in that. I'd like the Committee to be on the alert when that reaches the floor on the Conference Report. Congressman Gutknecht is a co-sponsor of that piece of legislation, and so I'm going to impose a duty on him to keep all the rest of you informed as to its progress.

Secondly, another anomaly that just is painful. In our own, my own district in Hershey, Pennsylvania, there's a company called American Pharmed, P-H-A-R-M-E-D. They market, it's an over-the-counter analgesic patch, much like a bandaid, but it's an analgesic formation which is a wondrous reliever of pain, et cetera, and so they market it. All of a sudden, what happens, the FDA starts prohibiting or putting hurdles in front of the importation of this patch, which is being distributed by our local—my own district firm. And it's in big wrangles now as to different aspects of import-export and whether it's utilitarian and all that sort of thing, nothing having to do with whether or not it works.

It works and it's good, and people want it, and it has a company in Hershey, Pennsylvania which provides jobs in distributive enterprise that is wondrous to behold. But the FDA, we're working with them; we're trying to untangle this entanglement, but, nevertheless, your Committee would have a grand opportunity in the future, and we'll keep you aware of it, on how these kinds of minute micromanaging on the part of FDA prevents a product from coming to the bedside of a person who is ill.

The other irony here is that the foreign company that was producing these patches wants to come to the United States and institute a new enterprise here based on it, and now it's having second thoughts because its product can't come in to the United States because of something that the FDA is doing that makes no sense at all.

That's the extent of what I wanted to bring to your attention. I want to finish my breakfast, and so I'm going to leave, but I would like the Chair to entertain my written statement, which we've already submitted to the Committee, and to incorporate it into its record.

Mrs. MORELLA. Of course, Mr. Gekas, your entire statement will be included in the record.

[The prepared statement of Mr. Gekas follows:]

TESTIMONY OF THE HON. GEORGE W. GEKAS

COMMITTEE ON SCIENCE
SUBCOMMITTEE ON TECHNOLOGY

Thursday, November 2, 1995

CHAIRWOMAN MORELLA AND MEMBERS OF THE SUBCOMMITTEE:

Thank you for allowing me to present to you my thoughts on the future of medical technology in this country. I want to focus very briefly on two aspects of medical technology with which I have been directly involved, product liability and FDA regulations.

First, let me speak to what I consider a looming public health crisis, the unavailability of life-saving medical devices. Current U.S. product liability law allows suppliers to be held liable for huge damage awards even though suppliers have no direct role in the raw material's ultimate use as a "biomaterial." The suppliers of raw materials and component parts used in manufacturing lifesaving and life-enhancing medical devices implanted within the human body have in many cases ended their sales operations. This is because the litigation costs necessary to defend themselves successfully against suits alleging inadequate design and testing of medical devices, or inadequate warnings related to their use, far exceed their potential sales revenue. As a rule, of course, suppliers have in fact no role in the design, testing, or production of implantable medical devices.

The present situation is leading to shortages and even the outright unavailability of some raw materials and component parts. In turn, this has created a developing crisis in the supply of finished implantable devices to over 7.5 million patients. There is no doubt that this could seriously jeopardize public health in the course of the next few years.

I introduced early in the 104th Congress H.R. 753, the Biomaterials Access Assurance Act (and by Senator Lieberman as S.303 in the Senate) to respond to this impending medical emergency. Simply put, H.R. 753 allows suppliers of the biomaterial used to make medical implants to obtain dismissal, without extensive discovery or other legal costs, in product liability suits in which the plaintiffs allege harm from a finished medical implant.

The act would not affect the ability of plaintiffs to sue manufacturers or sellers of medical implants. It would, however, allow suppliers to be dismissed from the lawsuit if the raw material used in the device (1) met contract requirements or specifications and (2) the supplier cannot be classified as either a manufacturer or seller of the medical implant. Discovery against biomedical suppliers would generally be limited to these issues pending a ruling on a motion to dismiss.

The New York Times reports that major companies such as DuPont and Dow Chemical are discontinuing the medical side of their business because of the high risk of being dragged into lawsuits filed against implant makers

and the small, often nearly infinitesimal volume of business involved.

At last count, DuPont has been named as a defendant in 259 suits brought against a manufacturer of a jaw implant device that uses a nickel's worth of Teflon. It has spent at least $8 million a year for the past 5 or 6 years to defend itself against these suits. It has won 258 out of the 259 cases, and the other one is on appeal.

To cite another example, the makers of the silicone rubber used to coat the wires used in heart pacemakers -- which help keep untold numbers of people alive today -- have begun to withdraw from the market. They will continue to do so, to the point where patients may die prematurely for lack of a pacemaker, unless the Congress enacts the Biomaterials Access Assurance Act and other similar reforms.

Currently, the text of H.R. 753 has been contained within the body of both the House and Senate product liability reform measures, upon which we may soon be going to conference.

The examples above show the need for reform of our nation's product liability laws and how that need severely impacts our most critical and complicated medical technology. I would also like to share an example which illustrates the impact of FDA regulations on a much lower, yet still important, level of medical technology.

American Pharmed is a small company in my congressional district. Through their Hershey, Pennsylvania facilities, they market an over-the-counter analgesic patch, know as "Lidopain." Lidopain contains just one active ingredient, lidocaine, at a level which the FDA has determined to be safe and effective. As this Committee may know, lidocaine is one of the oldest topical analgesics in use today. It has an extremely wide margin of safety. And the patch itself is not a sophisticated time-release dosage form, but a completely conventional gauze bandage.

Unfortunately, the FDA recently raised objection to the patch form. These objections have resulted in the detention of the product at our borders, preventing American Pharmed from importing and marketing the product in the United States. The company's inventory of the product is now depleted, and they are presently unable to supply existing customers and new orders. This situation has caused Pharmed considerable economic hardship, and has put the livelihoods of several dozen of my constituents in jeopardy.

There is an additional irony here. Lidopain is presently manufactured overseas. But company officials had planned, prior to their present regulatory difficulties, to move their manufacturing activities to the U.S. At a time when the FDA is cited as a reason for many companies moving their operations offshore, it's ironic that, in this case, the agency is responsible for obstructing the return of manufacturing jobs to this country.

The company is working with the FDA to try to resolve this matter. I am hopeful that they will be able to do so before this particular regulatory action as permanent economic consequences. And I appreciate the opportunity to bring this incident to this Committee's attention. I think

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it illustrates for all of us that federal regulations can have significant adverse impact for many, many kinds of technologies.

Again, I thank you, Madam Chair, and the Subcommittee on Technology for holding this important hearing and for receiving my statement.

# # #

Mrs. MORELLA. I'm going to see if my colleagues have any questions——

Mr. GEKAS. Yes.

Mrs. MORELLA [continuing]. to direct to you, but I want to thank you again for your leadership of the Biomedical Research Caucus, and let you know that we look forward to continuing to work with that caucus in terms of your recommendations, and we're delighted that Mr. Gutknecht is part of it. I am also part of that caucus, and this is what we're hoping to get at at this hearing, too: why do we create and it goes overseas, and what are the impediments trying to maintain that balance?

I thank you very much.

And, Mr. Tanner, would you like to ask Mr. Gekas any questions or make any—

Mr. TANNER. No, I want to thank him for being here. I know that the gentleman realizes that problem that we are trying to address here, and I, again, thank the Chair for having this in a noncrisis situation, because oftentimes in this area that's what has happened.

There was an article in The New York Times just yesterday where the FDA was criticized for approving a longer-acting calcium channel blocker without adequate evidence of long-term safety. And so what we do is we complain bitterly about the agency doing something that may not make sense, in the case of your group in Hershey—I don't know specifically—but then if anything goes wrong, as we scream and shout for more and more efficiency and speed, and something does go wrong, then we kick the agency to death because somebody got hurt.

And so all of these statements that people throw around—I know the Speaker said the FDA was the biggest job-killer in America. I think that's irresponsible, quite frankly, because I think the American people want an agency that does its job and does not do foolish things to impede perfectly safe products to the market, on the one hand. On the other hand, I think that the American people expect a certain amount of caution to be exercised by someone so that they are not killed by products that have not been tested by their government.

So we'll—I want to work with you; I know the Committee does, but some of these statements I think need to be put in the context of what happens on the other side. And I don't defend the FDA for everything they've done, on the one hand, but on the other, I think there's a necessity for such an agency. I hope you would agree.

Mr. GEKAS. I have no animosity against the work of the FDA, but we have seen countless examples of needless impediments. That's what I'm honing in on.

Mrs. MORELLA. Thank you.

Mr. Gutknecht, did you want to ask Mr. Gekas any questions?

Mr. GUTKNECHT. Well, just briefly, I would like to thank Representative Gekas for his work and leadership in this. I know when he started it was kind of a lonely path. The chorus is growing stronger. I don't think we want to completely dismantle the FDA, but I do think we have to continue to stress that we don't need $50 solutions to $5 problems, and that's what we get altogether too often when it relates to medical research in new technologies.

And so thank you for your leadership. The chorus is growing stronger, and I think we've just about reached critical mass.

Mrs. MORELLA. Thank you.

We've been joined by Congresswoman Seastrand from California. Would you like to make any comment to Mr. Gekas?

Ms. SEASTRAND. No.

Mrs. MORELLA. Thank you. Thank you again very much, Mr. Gekas.

Mr. GEKAS. By all means, thank you very much.

Mrs. MORELLA. And we're going to have the first panel come forward. As the first panel comes forward, Mr. David Holveck, President and Chief Executive Officer of Centocor, Incorporated, in Malvern, Pennsylvania; Peter A. Chevalier, Dr. Chevalier—I think I pronounced that correctly, giving it the French twist—Vice President, Chief Quality and Regulatory Officer of Medtronic, Incorporated, Minneapolis, Minnesota; Mr. Alan Magazine, President of Health Industry Manufacturers Association, Washington, DC.; Mr. J.J. Finkelstein, President and Chief Executive Officer of Cryomedical Sciences, Incorporated, Rockville, Maryland; Dr. Jeffrey A. Brinker, Director of Interventional Cardiology and Professor of Medicine at Johns Hopkins Hospital and University in Baltimore, and Mr. Richard F. Pops, Chief Executive Officer, Alkermes, Incorporated, in Cambridge, Massachusetts.

What we're going to do, gentlemen, we have your testimonies, which will all be included in their entirety in the record. We're going to start off asking questions immediately of you, give you an opportunity at that time to put in any comments that you think are critical to the work that this Committee is seeking.

I did want to point out that I, and I know the members of the Committee, are looking for that balance we spoke of. We're not here to castigate the FDA. As a matter of fact, I represent the Food and Drug Administration in my district. I also represent the National Institutes of Health. I also represent about 60 biomedical firms. So that this is really a partnership, and what we're trying to do is to find out whether there are impediments, what your experiences are, and let you tell us, to see whether or not there should be any action that should follow.

So perhaps I could start off with one question to all of you, and that is: from your experiences, maybe you could just give some examples of how government regulations have affected medical technology development and commercialization in your companies. So kind of a free-flowing question about how has it affected it; do you have any examples that you think are representative of the situation?

Perhaps I might start off with Mr. Holveck, if that's okay. And welcome.

STATEMENTS OF DAVID P. HOLVECK, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CENTOCOR, INCORPORATED, MALVERN, PENNSYLVANIA; ALAN H. MAGAZINE, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.; J.J. FINKELSTEIN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CRYOMEDICAL SCIENCES, INCORPORATED, ROCKVILLE, MARYLAND; RICHARD F. POPS, CHIEF EXECUTIVE OFFICER, ALKERMES, INCORPORATED, CAMBRIDGE, MASSACHUSETTS; JEFFREY A. BRINKER, DIRECTOR OF INTERVENTIONAL CARDIOLOGY AND PROFESSOR OF MEDICINE, JOHNS HOPKINS HOSPITAL AND UNIVERSITY, BALTIMORE, MARYLAND; AND PETER A. CHEVALIER, VICE PRESIDENT, CHIEF QUALITY AND REGULATORY OFFICER, MEDTRONIC, INCORPORATED, MINNEAPOLIS, MINNESOTA

Mr. HOLVECK. Well, welcome, Madam Chairwoman and Mr. Chairman. It's a pleasure to be here at the Committee. I think, again, as indicated in the opening statements, it's an important conference in order to create the dialog on an industry that has tradition in creating jobs and creating welfare for our populace.

I think your question is a good opening one in terms of how we've seen the regulatory, if that is one element of our environment, how that has affected our industry. I think the elements of our regulatory bodies are really one made up of laws and statutes, as well as policy, and I think in many cases when opportunities to correct situations get into the statute area, it becomes a very difficult process in order to move forward.

I think in the opening statement, in terms of having statutes correct situations that occur, does, in fact, tie the hands of industry over time. Of course, many of the statutes were written very early, and, of course, the technology curve, as we've all seen, has grown at an exponential rate over time. So we have some environmental activities; we have some solutions that sometimes run at cross purposes.

Centocor, particularly, has had, I think, a very good experience with the Bureau of Biologics in getting a drug approved in less than a year, and I think that is because of the focus and the skill sets at the Bureau of Biologics. On the other hand, we've had a lot of frustration in the Bureau of Devices because of the fact that in vitro diagnostics, which are blood tests, are incorporated into class III devices, which a class III device would be an implantable heart valve. Now in some cases it's not that there shouldn't be regulatory aspects around blood tests, those tests that are run outside the body, but I do think they do get lost when they get embedded into class III devices.

An example only as to how sometimes classifications are not in keeping with the risk-benefit of technology, and I think that our abilities to point these out in the case of regulatory bodies, the FDA, their ability to take steps to rectify this, is sometimes a long and very bureaucratic process.

Of course, all of this reflects against our industry because we're an industry that does not just work here in the United States; it's a global industry, and I think in the years we've seen a lot of parity in the technology around the world. And, here again, having regu-

latory situations that are drastically different than what we see in Europe or Japan meeting the more modern societies that would incorporate some of this technology leads one to, as a businessman, start to look at those areas as maybe more accessible to the marketplace. And, of course, that just starts the whole cascade of jobs, technology, training, education which follows those elements, and, of course, we tend to suffer, both on the fact of getting application in our populace to get practice of these technologies within their hands, but then, of course, also having the drain of skill sets and development.

So it is a challenging process. I think we're all here to advance both in dialog and, hopefully, advance some solutions. Thank you.

[The prepared statement of Mr. Holveck follows:]

Testimony of David P. Holveck
President and CEO
Centocor, Inc.

Before the Subcommittee on Technology of the House Committee on Science

Regarding Medical Technology and Commercialization

November 2, 1995

Madame Chairwoman, Mr. Chairman and members of the Committee. I am pleased to submit this testimony concerning the United States Government's impact on the commercialization of medical technology products. First, I would like to give you a brief overview of my company and its products. I am the President and CEO of Centocor, one of this nation's leading biotechnology companies. We employ over 300 people in the Philadelphia suburbs, and nearly 500 worldwide. Centocor focuses on the development, manufacturing and marketing of diagnostic and therapeutic products for human healthcare. Centocor is a unique biotechnology company in that we produce drugs and also medical devices.

Our first drug was approved in the U.S. late last year. ReoPro, a cardiovascular drug, is now being used by doctors to help stop the complications resulting from high risk angioplasty operations. In fact, we were very pleased with the approval of ReoPro -- it only took one year from application to final approval by the FDA. We have another biotech drug product, Panorex, which is now approved in Germany to treat colorectal cancer patients.

In addition to drug therapies, Centocor develops diagnostic products -- the routine laboratory blood tests which are used by doctors throughout the world. Centocor's products include tests for recurrence of ovarian, breast, lung, pancreatic and gastric

cancers, as well as a test for syphilis. Unfortunately, for reasons which I will explain shortly, only the ovarian cancer test is widely available in the United States.

Clearly, the medical technology industry is one of this nation's finest sectors. Our industry spends more than any other on research and development. According to a July 1995 Business Week article, all industry sectors in the United States spend an average of $7,651.00 per employee on research and development. Yet the 1996 Ernst and Young report on the biotechnology industry reveals that biotech companies invest more than $71,000.00 per employee on research and development. That is **ten times** the United States industry average. In addition, the biotechnology and medical device industries provide high-skill and high-paying jobs to American workers. This is a young industry, the average Centocor employee is 38, and the work these men and women do on a daily basis has a direct and positive impact on the answers to our most complex healthcare questions.

As you know this is probably one of the most highly regulated industries. This is of course understandable and warranted. However, there is also a danger that overregulation can also put Americans at risk. For example, as I mentioned, of the five cancer laboratory blood tests (or *in vitro* diagnostics) we manufacture, only the ovarian cancer test is available in the United States. So, a clear and real-life example of overregulation is that these laboratory blood tests which test for cancer

are regulated in the highest classification of medical devices by the FDA (Class III). Other Class III devices include heart valves, hip replacements and pacemakers -- clearly blood tests do not hold the same risks as these other products. The result of this classification is that American patients do not have broad access to a technology available throughout the rest of the world.

So, as you can see from this specific example, the result of overregulation can be lack of patient access to the most cutting edge medical technology products. But there are other consequences as well. Companies in this competitive global market are now facing the facts that manufacturing their products overseas is sometimes more realistic than having those facilities and those jobs in the United States. Regulations concerning manufacturing practices, exporting rules, and marketing requirements tie the hands of American companies when the time comes to sell the product overseas. Because of all of these factors, as well as economic development incentives. Centocor produces both of its drug products in The Netherlands. That decision, made in the early 1980s, was also due in part to FDA exporting restrictions. Although the drug exporting regulations have since been modified somewhat, there is still a regulatory barrier for exporting. Exporting a drug or device product which is manufactured in the U.S. still requires a regulatory process which can be formidable in getting a product to an overseas market. It is much easier to manufacture a drug or medical device in an overseas facility and then export it throughout the world from there. I am pleased with the work of

Congressman Fred Upton in his effort to make these exporting regulations more sensible with his legislation (HR 1300), and I would urge Members to support Congressman Upton's bill.

Yet another factor in jobs moving overseas is the length of time it takes to get a drug or device approved in the United States. However, a study commissioned by the Health Industry Manufacturers Association, estimates that there is up to a three-year lag between European approvals and U.S. approvals of medical devices. That same study showed that the rate of growth of U.S. employment in the device industry is slowing as more high quality jobs are created overseas. HIMA's study estimates a loss of 50,000 jobs over the next five years in the medical device industry if no changes are made to the FDA. That is the equivalent of two jumbo jets full of American jobs flying to Europe once a week for the next five years.

There is another very critical point I would like to make about the biotechnology industry. On the whole, the industry is not making money. Many of our companies, though they may be on the verge of finding new healthcare discoveries, are strapped for cash. Ernst and Young estimates that most biotech companies have about two years of capital left. So, just as science is about to make crucial breakthroughs, money is drying up for the companies on the cutting edge of our medical research.

These issues by themselves may not be detrimental to an entire industry. But think about all of these factors piled up against a company under 500 people trying to become commercially successful. It is the combination of all of these governmental pressures that has led many companies to seek facilities overseas.

The question then becomes, how can government **help** the medical device and biotechnology industries? Sensible, yet real reform of the Food and Drug Administration, is key for our industry. In addition, targeted tax incentives for the industry would go a long way to help improve the investor climate for companies looking for capital. Finally, issues like product liability and securities litigation reform also have a direct impact on our industry. Below I have outlined some specific initiatives in these areas:

- **FDA Reform**

It is **critical** that Congress move on FDA reform this year. Centocor has been working very closely with the Biotechnology Industry Organization, the Health Industry Manufacturers Association, and the Medical Device Manufacturers Association in helping them in developing their proposals to reform the FDA. I strongly urge Members to study their FDA reform proposals closely and call upon the House and Senate to vote on this legislation before the end of 1995. Among the areas of FDA reform most important to Centocor are the following:

> **-IVD Reclassification:** One of the issues I believe is often forgotten in the area of FDA reform is *in vitro* diagnostics (IVDs). The agency itself believes that over 1200 companies in the United States have some IVD-related business. For Centocor, the issue is simple: access to the marketplace. The FDA automatically classifies all new IVDs into Class III, thereby putting them into the same approval pile as pacemakers, heart valves, and hip replacements, and making IVDs go through the onerous PMA process. We propose putting all new IVDs automatically into

Class II (allowing for the 510(k) process), unless the agency has an overriding reason to put them into Class III (example: a new genetic testing diagnostic). Centocor is pleased that BIO has incorporated this issue into their FDA reform proposal.

-Eliminate inconsistent regulations associated with regulations under the Public Health Service Act: Under the current approval process, the majority of biologics are reviewed by the Center for Biologic Evaluation and Research (CBER) under the Public Health Service Act. This requires that companies file an Establishment License Application (ELA) subjecting biologic products to a dual track approval process. We support the BIO proposal to eliminate the requirements for the ELA and for associated lot release for products that can be well-characterized. This would streamline the process and make it similar to the regulation of chemically derived drugs.

-Exporting: Current FDA exporting regulations are driving manufacturing jobs and live-saving medical products overseas. Changing these regulations is essential for keeping American medical technology in America. Centocor supports HR 1300, introduced by Congressman Fred Upton, which would eliminate the FDA-approval of exporting products going to GATT nations.

-FDA Marketing and Dissemination of Information: The agency's restrictions on marketing and promotion have gone beyond the bounds of their original intent. We believe that industry's marketing practices must comply with FDA standards, but the current regulations are not working either. Again, we endorse BIO's proposal to curtail items such as exempting press releases involving SEC requirements, and prohibiting prior FDA approval of advertising or sales literature. In addition, we strongly support legislation introduced by Senator Connie Mack which would allow companies to send physicians information on off-label uses of products (S. 1197).

These four areas concentrate on sensible, market-driven ideas to reach some of the problems the agency itself would like to be solved. Wholesale restructuring of the agency is not needed. What is needed is a "business-agency" partnership to reach for common goals.

- **Tax Incentives**

The Senate Finance Committee approved tax bill includes the following three items which is supported by the biotechnology industry:

-Enactment of two-tiered capital gains incentive: We support the efforts of Congressmen Bob Matsui and Phil English to address venture capital incentives in their legislation, HR 1918. In addition, the biotechnology industry supports S. 959, the Hatch-Lieberman capital gains bill, and Section 6301 of HR 1215, the House-passed capital gains bill. A two-tiered capital gains bill, with one tier providing a broad-based capital gains incentive for investments held for at least one year, and a venture capital incentive for direct investments in the stock of small companies held for at least five years, would be a big boost to the biotechnology industry.

-Enactment of permanent R and D and Orphan Drug Tax Credits

-Restructuring of Orphan Credit to provide for carryforwards of credits by firms which have no current tax year liability

- **Product Liability/Securities Litigation**

Small, high growth companies, like Centocor, need product liability and securities reform to help stop frivolous lawsuits which can cripple a growing company. I applaud the House for passing both product liability and securities litigation reform in the Contract With America. I urge quick results from conference committees on both these issues and urge Members to vote in favor of the conference reports. In addition, please support all efforts to include the "FDA Defense" in the product liability legislation, as well as in the current budget reconciliation discussions.

Only through a mutual understanding and sharing of concerns and information can we succeed in providing Americans with greater and quicker access to this nation's health breakthroughs. In my opinion, the key to success is allowing the medical technology industry the ability to focus on what will give American's access to U.S. medical

innovation. I am very pleased with the efforts thus far by the 104th Congress to reform regulatory burdens.

We in the industry will drive ahead to innovate and create products that meet unmet medical needs, such as cancer, arthritis, and heart disease. We need a well-run and market-sensible regulatory process to make that happen. I look forward to the continuing efforts of this Committee and this Congress to address these issues. In addition, I would urge immediate attention to FDA reform efforts. This industry and the American public cannot wait much longer while jobs, scientific research, and medical breakthroughs are exported overseas.

Mrs. MORELLA. Thank you. Thank you, Mr. Holveck. I notice you also in your testimony have come out with some specific suggestions, including the product liability and securities litigation—legislation.

Mr. Magazine, we look forward to your comments. I notice you talk about zero-based mentality of the FDA.

STATEMENT OF ALAN H. MAGAZINE

Mr. MAGAZINE. Thank you, Madam Chairwoman. It's a pleasure to be here.

First, I want to begin by saying that we at the Health Industry Manufacturers Association represent more than 700 manufacturers that manufacture more than 90 percent of all the devices, diagnostics, of health information systems in the United States. And we favor a very—we favor a strong, predictable FDA. We are definitely not in favor of dismantling the agency, but we think that major reform is in order, in order to protect patients.

There are a wide range of regulatory issues that are affecting the industry, and for that reason, we commissioned this study by the Wilkerson Group, which I believe you have copies of—

Mrs. MORELLA. Yes, we do.

Mr. MAGAZINE [continuing]. which chronicles the impact of those varied regulations on the industry. I'd like to take a minute to answer your question and address a couple of those.

The regulatory process at FDA has been marked by a lack of predictability in the approval process, to the point where, as the Wilkerson Group study shows, companies are either abandoning innovation or going overseas in very large numbers. The worst thing you can say to a company in any industry is that we can't tell you when you can go to market. This is having a profound impact both on large and small companies, and I should add that most of this industry is comprised of small companies, companies with less than 50, fewer than 50 employees. And so, if they have one, two, or three products on the market in a very innovative industry, which ours is, and can't have some sense as to when they're going to be able to go to market, they're in very big trouble, meaning they may go out of business.

The Wilkerson study showed that as many as 20 percent of medical device companies in this country are likely to go out of business within the next five years. Many of those companies are also going overseas, and they're going overseas so that they can get a revenue stream going, so that they can survive, but many can't afford to even go overseas.

So you have a combination of forces in action here. One of the reasons for the lack of predictability at FDA is what we call a drive toward the drug model, which is also related to the issue of what we have somewhat hyperbole called "zero-risk mentality." It's not zero-risk, but it's requiring such a proof of safety and efficacy as to put at risk patients who can't get access to new and advanced devices. There needs to be some reason, some balance, with regard to keeping unsafe products off the market and getting new products onto the market.

The mentality that we've seen at FDA has been the former, to keep unsafe products off the market, which we favor. But this

study shows very clearly that people are dying; the cost of the health care system is increasing; people are suffering as a result of not being able to get new and advanced medical products.

There are a number of other issues. The reimbursement for clinical trials is a major issue. HCFA has basically said to the Congress, "We're not going to reimburse for clinical trials until we get some resolution within the Congress or some definition of what is permissible and what isn't." HCFA has come out with a regulation which takes on—which actually took effect November 1—they're accepting comments until November 20—which divides products between incremental improvements and breakthrough devices. And what they're saying is we will consider reimbursement for the incremental improvements, but not for the breakthrough devices, and FDA will make the cut in telling us which are breakthrough and which are incremental. There is legislation that we support that would give HCFA the direction, or at least the permission, to reimburse for all clinical trials.

The problem with this issue, in part, is that the market for medical devices, or the market for any medical device grouping, of which there are about 3,000, is relatively small. Very few products have a potential market of more than $150 million, as opposed to pharmaceuticals which has a market for many of their products well over a billion dollars. And so as you add costs to doing business, if you can't get reimbursed for clinical trials, if you have a slowdown in the product approval process, if you can't get raw materials for your products, and on and on and on, you face the fact that you may not be in business very long or you abandon those innovations.

One other comment and I'll—I could go on for hours.

[Laughter.]

Venture capital is a major problem in that venture capital in this industry has been drying up. You are seeing less investment in this industry in the last two years than we did before, instead of more. The venture capital is the lifeblood of the most innovative new companies. Venture capital is drying up because of all of this uncertainty. And so, consequently, what we're seeing is that, according to a survey that Wilkerson did, 66 percent of all medical device companies in the United States who were surveyed, who responded to a major survey, said that they were going to be doing clinical trials, R&D, and manufacturing overseas, and they're taking their scientific infrastructure with them. And that's as a result of the coming together of these policies that I've mentioned, plus many more.

[The prepared statement of Mr. Magazine follows:]

STATEMENT FOR THE RECORD

HEARING ON

MEDICAL TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

THE SUBCOMMITTEE ON TECHNOLOGY
OF
THE COMMITTEE ON SCIENCE

SUBMITTED BY

ALAN H. MAGAZINE
PRESIDENT
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

NOVEMBER 2, 1995

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Thank you, Madam Chairwoman and members of the committee, for this opportunity to talk about the impact of federal regulation on the medical technology industry.

I am Alan Magazine, president of the Health Industry Manufacturers Association. HIMA is a Washington, D.C.-based national trade association representing more than 700 manufacturers of medical devices, diagnostic products, and health information systems. HIMA's members manufacture more than 90 percent of the nearly $50 billion of health care technology products purchased annually in the United States.

It is very gratifying to us to see Congress turn its attention to this vital issue. Federal regulation affects not just our industry but also has enormous repercussions for patients and the practice of medicine in this country.

Let me begin by saying that the medical device and diagnostics industry is a powerful reason why American medicine is the best in the world today. The industry develops products that make possible faster, less invasive diagnosis and treatment and facilitates delivery of care in the home and other less expensive settings. During the past 20 years, these medical technologies have revolutionized medicine. Thanks to achievements in such fields as fiberoptics, imaging, biomaterials, electronics, and biotechnolgy, today's medical technology is faster, more efficient, and more productive than ever. But most important, it has substantially improved health care for patients.

Medical devices also help build economic strength. From 1988-93, the number of medical technology jobs grew more than 3 percent annually—well ahead of U.S. industry overall. During the same period, exports increased 16 percent annually, contributing to a trade surplus that last year exceeded $5 billion. The industry, composed principally of smaller companies, invests in research and development at a rate twice the national average.

But while the past has been marked by advances for both patients and the economy, the present is increasingly troublesome and the future by no means assured. U.S. patients are being deprived of the newer, more advanced generations of devices to which European patients have access. Americans are finding that they must go abroad to take advantage of these technologies. And U.S. device firms are themselves moving production and research facilities overseas.

Too often public policies, especially FDA regulations, inhibit the device industry's ability to develop and supply new technologies. The cumulative effects of these policies can chill the climate for innovation and permanently disrupt the U.S. research and development infrastructure. To be sure, FDA does have a vital role in ensuring that medical devices are safe and effective. But FDA often overlooks the fact that getting new and better technologies *onto* the market can be as important to patient health as keeping unsafe technologies off.

FDA delays in reviewing devices means that patients with debilitating illnesses wait months and years to receive beneficial new technologies. In addition, FDA regulation is driving up product development costs and driving innovation, clinicians, and jobs offshore.

The Wilkerson Report: Quantifying Lost Lives, Lost Leadership, Lost Jobs

A recent study quantifies, for the first time, just how dangerous FDA regulatory policies really are and why it is time for Congress to take swift, decisive action to reform FDA. According to the study, conducted by The Wilkerson Group, Inc.—a New York-based independent research firm—unpredictability and uncertainty surrounding product reviews at FDA are forcing U.S. medical technology companies to introduce medical products overseas well before introducing them in the U.S.

The Wilkerson Group developed an illustrative list of 100 types of medical devices that are available to patients in Europe or other countries, but not to Americans (unless, of course, they travel to Europe for treatment). These include soft tissue biopsy needles, diagnostic reagents for prostatic cancer, urine tests for osteoporosis, and microcatheters for neurology procedures. According to the study authors, the list of 100 is just the tip of the iceberg—there may be thousands more.

In the largest survey of its kind of the medical device industry, more than two-thirds of companies told Wilkerson they anticipate delays of up to 3 years before they would introduce new products in the U.S. after they were available elsewhere, notably Europe. Virtually all companies point to complexities, delays, and uncertainties of FDA product review requirements as the reasons for bypassing the U.S.

This, of course, has devastating results for U.S. patients. In a sample of just 10 disease areas and conditions, Wilkerson carefully calculates what an average three-year delay in introducing selected technological advances in the U.S. could mean. They estimate that the U.S. would lose the opportunity to save, at a minimum, 50,000 lives. For example, an implantable pump to deliver insulin would save an estimated 3,000 lives. Tissue adhesives for use in skin grafting and heart surgeries would save an estimated 6,000 lives. Stent grafts to repair aneurysms in the aorta could potentially save 25,000 lives and prevent 3,000 strokes and more than 10,000 heart attacks.

Further, the study finds that the small, start-up company—the true innovator in medical technology—faces a terribly uncertain future because of FDA. Wilkerson found that current FDA policies double the costs of developing a significant technological advance—from almost $19 million to $36 million—and delay positive cash flow for two years. That helps explain why venture capital, their traditional source of financing, is drying up. The study found that device companies are getting fewer dollars and a smaller share of the total funds venture capital firms invest. Wilkerson predicts fewer small companies will form, many will close altogether, and patients will be deprived of many new medical technologies.

More ominous, perhaps, is an even deeper threat to patient care that the study forecasts—one that reaches across generations. More than half of U.S. device manufacturers and 87 percent of development stage companies are increasing clinical trials in Europe, while 46 percent of

manufacturers and 55 percent of development stage companies are increasing R&D in Europe. At the same time, the report found that nearly one-quarter of device manufacturers are reducing R&D employment in the U.S. Until now, it had been axiomatic that companies increased R&D in the U.S. every year.

What this all means is that the U.S. is beginning to lose the innovative firepower needed to launch tomorrow's medical breakthroughs. It also means that the U.S. is losing potential new jobs (50,000 according to the study) and leadership in an industry it has long dominated. It is no more unthinkable that the U.S. could "lose" this industry than it was that the U.S. would lose other industries before it, such as consumer electronics.

Root Causes of Overregulation

FDA's actions seem to be deeply rooted in a "zero-risk mentality"—a view that products should not be approved without absolute proof that no risk exists. But FDA's attitude flies in the face of the realities of science and, for that matter, the law. Even the most rigorous testing of a device cannot yield absolute assurances about risks because science itself rarely, if ever, yields absolute answers. Recognizing this, Congress wrote the law to require a *reasonable* assurance of safety and effectiveness. This standard requires FDA to balance the benefits for patients against any potential risk. Other "root causes of overregulation" include:

- The **law enforcement mentality** in which FDA will issue a warning letter rather than help fix the problem.
- The **drift toward the drug model** which imposes drug review standards on devices.
- The **intrusion into the practice of medicine**—in which FDA is regulating therapies and devices, thereby preventing physicians from providing patients with the medical care that best fits their needs.
- The **blind eye that FDA casts toward U.S. competitiveness** by imposing excessive rules well beyond what other countries require.
- Finally, there is the **institutional arrogance** that reinforces all of these problems.

These very issues lie at the heart of the movement of U.S. jobs, facilities and products to other countries. European countries, for example, clear products in less than one-third the time it takes in the U.S. and with no indication that quicker approval there increases patient risk. In fact, prompt approval may do just the opposite because it permits swift patient access to a broad array of products.

FDA Reform Now

This is where Congress comes in. Left on its own, the agency is not going to make the kind of deep-seated changes in attitude or approach that will have a measurable effect. Ultimately, profound, meaningful change must be enacted into law by Congress, sooner rather than later. Congressional inaction could easily be construed as a silent endorsement of today's FDA, emboldening the agency to stay its course.

HIMA has developed suggested legislation and a blueprint for reforming FDA that we believe will put the agency back on track toward becoming the reasonable and efficient regulatory agency the American people need and expect.

Clarify FDA's Mission for Medical Devices

FDA should be charged with the clear mission of advancing the public health by facilitating innovation, and creating an environment in which citizens can be assured of timely access to new technology.

Make "Premarket" Reviews More Timely, Efficient, and Beneficial to Patients

Medical devices are among the very few products in the economy that require government review before they can be marketed. The law establishes specific time frames for completing these "premarket" reviews—90 days for incremental innovations (cleared under the "510(k)" process) and 180 days for breakthrough technologies (cleared under the "Premarket Approval" or "PMA" process). FDA's recent record, however, makes these time frames almost meaningless. From 1991-94, the review times for 510(k) devices more than doubled while the number of decisions for PMA devices dropped 35 percent and review times exceeded 800 days. Some device applications have been in play for nearly 2,000 days, a "streak" to take pride in only if your name is Ripken.

FDA's premarket review system should be reformed by, among other means:

- Accrediting organizations that, in addition to FDA, would be authorized to conduct premarket reviews and grant marketing clearances for medical devices (following FDA statutory requirements).

- Putting "teeth" into the statutorily mandated time frames for reviews.

- Returning to the law's definition of "effectiveness" so that reviews are based on device performance and proposed labeling, not on pharmaceutical criteria or concepts like "clinical utility" that try to regulate the practice of medicine.

- Clarifying that FDA's authority over communications between manufacturers and physicians does not extend to regulation of the practice of medicine.

- Accelerating activities that will lead to the U.S. and other countries "harmonizing" and mutually recognizing quality systems standards.

Focus FDA Enforcement Programs on Improving Public Health

Recently, enforcement has seemed an end in itself to FDA. The agency has taken an adversarial approach that diverts attention and resources from true issues of public health. FDA enforcement programs should be reformed by:

- Providing clearer rules and encouraging more consistent FDA enforcement practices.

- Targeting enforcement to intentional/repeated violations that threaten public health.

- Accrediting organizations that could conduct inspections and determine compliance with "good manufacturing practice" (GMP) requirements.

- Abolishing the so-called "reference list" that blacklists companies without due process protections, and that illegally ties GMP inspections to product approvals.

- Allowing companies a meaningful opportunity to respond to negative FDA findings before the agency takes enforcement actions or issues "warning letters".

These are just some of the many reforms that would help invigorate FDA and make it more of a partner with industry, rather than an adversary. In essence, what is needed is a renewed regulatory culture at FDA that encourages open communication and investment in innovation. That, in turn, will yield for the United States improved public health and strengthened industry competitiveness.

Without strong action in Congress, Madam Chairwoman, I'm afraid that we will find ourselves back here again in the not-too-distant future, discussing the same problems and concerns.

Again, Madam Chairwoman, I want to commend you and the committee for your leaderhship and your interest in this issue. If you have any questions, I would be glad to answer them. Thank you.

Mrs. MORELLA. Thank you. All right. Thank you very much. I realize that you're all giving us kind of a synopsis and you could talk on and on and on, because this is your lifeblood and you have all the experiences. I appreciate your trying to give us the critical parts of it, and there will be more questions.

I'd like to now ask Mr. Finkelstein—he, of course, is pretty special to me since Cryomedical Sciences is in Rockville, Maryland, but I know he's had a situation that is in his testimony with regard to AccuProbe.

Welcome, Mr. Finkelstein.

STATEMENT OF J. J. FINKELSTEIN

Mr. FINKELSTEIN. Thank you, Madam Chairwoman. I would like to state that, first of all, first and foremost, that I strongly believe in the need for a Food and Drug Administration. As an industry, CEO, and medical product consumer, I want patients to have access to innovative and improved medical products that are safe and effective with as little risk as possible.

As a society, however, we must be prepared to accept some reasonable risk or face the prospect that many medical innovations and advancements will never reach patients in this country. I believe the laws guiding product approval should be updated to reflect state-of-the-art medical developments. Furthermore, FDA must develop and implement sound regulatory policies, and its mission must be redefined to better serve the public's interest and the industry it regulates. To that end, the agency should weigh the dual responsibilities of the protection of public health with the advancement of public health by facilitating ready access to innovative products and medical information.

Now I have experienced two situations with the agency that I'd like to briefly describe and illustrate some of the problems and frustrations that we as CEOs in this industry have, and as well as patients.

First, we spent three years developing a urethral catheter which is used as an accessory to the AccuProbe. It was submitted for 510(k), premarket clearance, in October of 1992, based on a number of predicates that were on the market at that time. We went through a number of iterations with the agency, including at one time the agency saying that it would require a PMA to bring this product to the market. A PMA, of course, is a much more difficult and strenuous regulatory process that's typically reserved for implants and other class III devices, of which this is not.

We discussed this with the FDA, and they agreed that, yes, we could get it under a 510(k), but we went through a number of iterations and several years of development, including second set of clinical trials, all of which we believed were unnecessary to begin with, but, of course, we had no other option.

During that period while the AccuProbe, which was the primary product that was being used for the minimally invasive treatment of prostate cancer by freezing tumors, letting the body absorb the dead tissue—the patients undergoing this procedure did not have accessibility to the urethral warmer that was part of the accessory and which was developed to avoid side effects.

So, in essence, what happened for three years was that patients received this surgery at thousands or hundreds of hospitals, and they received unnecessary side effects because a simple catheter was not on the market. Finally, about a week ago, the FDA, after three years and at least a million dollars of expenditures by our company and legal fees and all the things that are necessary to bring the product to the market, cleared the product. So it took three years and perhaps 2,000, over 2,000, unnecessary procedures that were undertaken with unnecessary side effects attributed solely to the fact that this urethral warmer was not on the market.

The second case that I believe is also indicative of our frustration, mine as a CEO and others in my industry, is the issue of promotion. We've seen and heard a lot about the FDA's promotional policies regarding products. And it is a very inconsistent policy, certainly as it affects my product, which is a generally-cleared device. And to illustrate, let me tell you that we received clearance in 1991 to sell the AccuProbe in the fields of urology and oncology, among others. And, of course, urology is the reproductive tract and urinary tract in men, and oncology is synonymous with cancer.

However, when we went to market the product at sometime after we had received clearance, the FDA said we cannot market this product as a cryosurgical device used in the treatment of prostate cancer. Both of those terms, of course, fall within oncology and urology. And we got into many discussions with the agency about this policy. We believed we had resolved it. We changed our promotional literature to reflect what we had discussed with the agency, and a year later we received a warning letter saying that we were still in violation because now we were implying its use in this area for a specific disease; i.e., prostate cancer.

When we received that warning letter, a number of things happened, which I can go into a little later, including a class action lawsuit. But we were effectively prohibited from promoting this product within its intended use, and FDA, by its own admission, told us and has told the public in a number of areas that its promotional policies are inconsistent, and they do not even have a consensus on how these products should be promoted. Yet, we received a warning letter. We spent hundreds of thousands of dollars in professional fees dealing with the issue, and we were sued by shareholders of my company, which is a public company, because they said we should have known that this was their policy, which, of course, the FDA was unable to articulate by their own admission.

So these are issues that I have experienced firsthand that make me as a CEO, and our industry, very frustrated with the lack of policy direction and focus of the agency in these areas. Thank you.

[The prepared statement of Mr. Finkelstein follows:]

TESTIMONY OF J.J. FINKELSTEIN, PRESIDENT AND CEO OF CRYOMEDICAL SCIENCES, INC., BEFORE THE SUBCOMMITTEE OF TECHNOLOGY OF THE HOUSE COMMITTEE ON SCIENCE NOVEMBER 2, 1995

My name is J.J. Finkelstein and I am the President and CEO of Cryomedical Sciences, Inc. (CMS), located in Rockville, Maryland. I have been a senior executive and CEO in the biotechnology and biomedical industries for over thirteen years and have had considerable experience with matters concerning the Food and Drug Administration (FDA) during that time. I am a member of both the Biotechnology Industry Organization (BIO) and the Health Industry Manufacturer's Association (HIMA). I come before you today, at your invitation, to speak of two recent experiences with FDA pertaining to medical products developed at my company and serious problems related to their regulation. I hope that Cryomedical's experiences with the FDA will illustrate the need for enactment of FDA reform legislation as soon as possible.

Let me state, however, that I strongly believe in the need for a Food and Drug Administration. As an industry CEO and medical product consumer, I want patients to have access to innovative and improved medical products that are safe and effective, with as little risk as possible. But as a society, we must be prepared to accept reasonable risk or face the prospect that many medical innovations and advancements will never reach patients in this country. I believe the laws guiding product approval should be updated to reflect state-of-the-art medical developments. Furthermore, FDA must develop and implement sound regulatory policies and its mission must be redefined to better serve the public's interest and the industry it regulates. To that end, the agency should weigh the dual responsibilities of the protection of public health with the advancement of public health by facilitating ready access to innovative products and medical information.

INEFFECTIVE PRODUCT REGULATION

Cryomedical Sciences is a biomedical company specializing in the development, manufacture, and marketing of minimally invasive cryosurgical instrumentation, most notably, the CMS AccuProbe. Cryosurgery is a form of surgery that uses extremely cold temperatures (approximately -190° Celsius) to freeze and destroy tissues and tumors in the body and facilitates the use of minimally invasive surgical techniques. The destroyed tissue is left in place and slowly absorbed by the body, eliminating the need for surgical removal. The cost of cryosurgery, when used in the treatment of

prostate cancer, is approximately 40% less than traditional surgery and radiation therapy and requires shorter hospitalization than surgery. In general, it has fewer side effects than traditional surgery and patients have a shorter convalescence.

Cryosurgery has been practiced in the U.S. since the 1960s and most people are aware of it through the dermatological practice of freezing warts and skin lesions or its use in certain gynecological procedures. The company has been developing, manufacturing, and marketing cryosurgical products since 1989 and, prior to certain FDA actions, employed nearly 100 employees. Today, after undergoing a series of cost reductions resulting from FDA-related activities, CMS employs approximately 65 people. Presently, there are over 120 hospitals and medical centers in the U.S. using the AccuProbe for the cryosurgical treatment of prostate cancer, liver cancer, breast cancer and gynecological conditions. These include such institutions as M.D. Anderson Cancer Center, the Universities of California in Los Angeles, San Diego and San Francisco, Memorial Sloan-Kettering, Crawford Long Hospital at Emory University, The New England Medical Center, Yale University Medical Center, Pennsylvania Hospital, and many others. Over the past four years, nearly 6,000 patients have been cryosurgically treated for prostate cancer and approximately 500 for liver cancer.

In 1991, CMS received 510(k) clearance from FDA to market the CMS AccuProbe, for use by physicians to destroy unwanted or diseased tissue in numerous medical fields including: urology, oncology, gynecology and general surgery, among others[1]. In 1992, the CMS AccuProbe was launched in the urology and oncology fields after having been studied for several years at Allegheny General Hospital in Pittsburgh, Pennsylvania, a prominent and well established medical center. Several important medical papers had been published describing the use of ultrasound and cryosurgery and the improved, minimally invasive technique for the cryodestruction of prostate cancer. The data from

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[1] The CMS AccuProbe is regulated as a medical device. A 510(k) marketing clearance for medical devices is based on the doctrine of "substantial equivalence" whereby devices substantially equivalent to predicate devices on the market prior to the 1976 Safe Medical Devices Act may be legally marketed. Over 90% of all medical devices currently marketed in the U.S. are done so pursuant to 510(k) clearance.

those papers suggested, and more recent data further justified, the use of cryosurgery in certain patients with prostate cancer. Based on this growing body of information and numerous presentations at medical society meetings, many hospitals purchased the instrumentation necessary to perform this procedure.

It quickly became apparent that there existed a significant medical need for this technology, as the "gold standards" of radical prostatectomy and radiation therapy were most useful only in certain groups of patients suffering from prostate cancer and the extent of their use was being questioned by many members of the medical community. Physicians wanted and continue to want the ability to have additional options beyond a scalpel and radiation, should their patients not be good candidates for either radical prostatectomy or radiation therapy.

During the period of initial development of the CMS AccuProbe, physicians determined that urethral "sloughing", a side effect historically associated with cryosurgery for prostate cancer, might often be prevented[2]. While this problem is not life-threatening, it can be uncomfortable for the patient. It appeared that it could be greatly eliminated by simply circulating warm water through the urethra during cryosurgery using a common catheter, similar to catheters used every day in the urologic field. The doctors suggested that CMS develop this accessory product so that it would be available to urologists using cryosurgical procedures.

CMS finished commercial design of the catheter accessory and submitted a 510(k) application to FDA in October of 1992. Four months later, in January of 1993, FDA requested additional information on the use and design of this warming catheter. In August 1993, CMS submitted clinical data on over 100 patients and FDA indicated that this additional information would be treated as an amendment to the original 510(k) application and would be promptly be reviewed.

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[2] "Sloughing" is the process whereby destroyed tissue in the prostate or the urethra sometimes becomes lodged in the urethral tract and may require removal by a physician. The urethra is the small tube through which urine passes from the bladder through the penis.

After another six months passed, in January 1994, FDA wrote to CMS stating that the device would not be cleared under a 510(k) and the warmer would have to go through the Premarket Approval (PMA) process, a lengthy and expensive regulatory process akin to a new drug application in cost and complexity and typically reserved for Class III devices (e.g. cardiac pacemakers and implants), of which the warmer clearly is not. No medical or regulatory authority whom I contacted ever recalled the rejection of a simple application such as this nor did anyone agree with FDA's position, especially since the AccuProbe itself had not required a PMA.

After a meeting with FDA, the agency reversed itself and concluded that CMS could resubmit a 510(k) application, but only after a second clinical study was conducted on the warmer accessory. In the Summer of 1994, CMS initiated the clinical trial at four sites, although with some reluctance by physicians because they felt that the clinical trial required by FDA was not warranted.

During this interim period and due to the lack of availability of the CMS urethral warmer, physicians performing cryosurgical procedures decided to use "makeshift" warmers rather than do without. The design of "make-shift" warmers took on various configurations, but physicians felt that it was the best way to perform cryosurgery on patients who were not candidates for other procedures. Unfortunately, these systems were not optimal and could cause unnecessary side effects for patients. In fact, after a year of experience without the CMS urethral warmer, reports began emanating from the field and medical society meetings indicating that urethral "sloughing" with prostate cryosurgery had increased due to use of "makeshift" warmers[3].

Upon hearing this information, I immediately wrote a letter to the Food and Drug Administration indicating that I had heard these reports from the field, seen the urologist's survey, and believed it

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[3] A urologist having no affiliation with CMS, conducted a survey among his peers at 18 hospitals involving 2287 cases, and reported that without the CMS urethral warmer, complications from prostate cryosurgery increased at 88.8% of the sites surveyed, that excess health care dollars were being spent to deal with these complications, and the lack of the CMS warmer was causing unnecessary patient suffering.

was in the interest of public health to meet with FDA to discuss a means to immediately rectify the situation. To FDA's credit, they quickly called me after receiving my letter and we arranged for a meeting in April of 1995 between the agency, representatives from my company, and two urologists who were utilizing cryosurgery and familiar with the clinical issues.

The meeting with FDA seemed to achieve the desired results, i.e. CMS was to rapidly submit to FDA all pertinent clinical data for quick evaluation in order to receive 510(k) clearance. CMS compiled a second 510(k) application which included clinical data from the ongoing clinical trial and submitted it to the agency in June of 1995. Interestingly, the company received word that three of the four FDA staffers attending the meeting in April had recently left the agency and, in September of 1995, the agency sent a letter to CMS asking for additional information, albeit somewhat less in scope than previous requests. Within two weeks CMS submitted another 510(k) amendment addressing all questions asked by FDA.

On October 25, just a few days ago and in the midst of preparing this testimony, the company received FDA 510(k) marketing clearance. While we are obviously pleased to be able to market this device and appreciate the agency's decision, it remains important to understand the substantial effort and resources required to provide this simple accessory to the medical community. It is unfortunate for everyone, especially those patients for whom the product was not available, that it took over three years to receive regulatory clearance.

Let me summarize the effect of FDA's actions:

- *over 2,000 men have been treated for prostate cancer using minimally invasive cryosurgery without the CMS urethral warmer accessory;*
- *the incidence of side effects associated with this procedure substantially increased without the CMS urethral warmer;*
- *CMS spent over three years obtaining 510(k) clearance for this simple accessory;*

- *CMS has spent hundreds of thousands of dollars in professional fees, and much more in corporate resources, dealing with an issue that should have been no more than a routine 510(k) medical device clearance;*
- *the lack of availability of the CMS urethral warmer has been a factor causing the use of cryosurgery in the field of urology to drop over the past 18 months; corporate revenues have similarly declined;*
- *CMS has been forced to lay off employees to deal with the reduction of product revenue, and most importantly;*
- *patients have unnecessarily received sub-optimal care due to FDA's regulatory actions.*

IRRATIONAL PRODUCT PROMOTIONAL POLICY

A second situation between FDA and CMS developed during the same time as the interest in prostate cancer cryosurgery expanded and the company began experiencing urethral warmer regulatory problems. As previously described, In October of 1990, CMS submitted a 510(k) application to FDA and received marketing clearance for the AccuProbe in April of 1991, the entire process taking approximately six months. The 510(k) application discussed the use of the AccuProbe for prostate cancer and FDA was aware that at least one use would be for the minimally invasive treatment of this disease. The company provided FDA with dozens of medical journal citations from the National Library of Medicine in order to support the product's specific use in the fields of urology and oncology, as well as an early manuscript describing the latest procedure[4]. In fact, one of the predicate devices on which the AccuProbe relied, had promotional literature using the words prostate, oncology and tumors throughout.

Notwithstanding these facts, in late 1992, the company received correspondence from FDA informing it that it may not promote the AccuProbe for use in the treatment of prostate cancer. This

[4] Oncology is the study of cancer. Urology is the branch of medicine which concerns itself with the urinary tract in males and females and the genital organs of males.

letter took the company by surprise as our FDA counsel, on whom we relied for such matters, indicated that all of our promotional literature and activities were within the statutory language pursuant to such activities.

Upon receiving the correspondence from FDA, our counsel made several phone calls to the agency to discuss its apparent new and unstated policy. During the telephonic meeting, a senior FDA official stated that the word "treatment" is what bothered the agency, but that he had no problem with use of the word "prostate". Although we did not agree that the word "treatment" necessarily implied efficacy, we nonetheless removed it from all promotional material. The FDA official also agreed with our position that the word "oncology" (cleared by FDA with respect to this device) was synonymous with "cancer". In a follow-up meeting with FDA's compliance department (again requested by CMS) one senior staff member simply stated that, "We have no regulatory concerns with CMS." Another staffer stated that we should "chill" with respect to our unnecessary concern about running afoul of FDA's policies.

After receiving assurances that FDA had no problem with CMS or the promotion of our FDA-cleared device, we were shocked to receive a "warning" letter a year later in 1994, stating that CMS was illegally promoting the product by "implying" its use for the treatment of prostate cancer, a rather curious approach to such regulation. Obviously, this action contradicted previous meetings with the agency and, in my opinion, is indicative of FDA's inability to develop and implement sound policy.

Consider the following: medical devices cleared for use in specific fields of medicine necessarily are always used to treat specific diseases; however, under FDA's current policy, every time a physician uses a medical product such as the AccuProbe for a specific disease within its 510(k) clearance, he or she is using it beyond its approved labeling ("off-label"). Therefore, according to FDA's policy, it is impossible to use this product "on-label". This is irrational, fundamentally unfair to industry and, most importantly, not in the patient's best interest.

A key policy-maker at FDA publicly stated in September of 1994 (after CMS received the warning letter) that the agency is looking at, "how to articulate the way in which the broad indications may be advertised and the way in which specific indications may be advertised. We [FDA] have not come up with a consensus policy that I'm ready to articulate yet. We recognize that there is an inconsistency and we recognize that people feel that they're vulnerable to compliance actions on the basis of how they advertise, so that we need to articulate our policy."[5] One has to ask the question: If FDA has no policy consensus on this issue and is unable to clearly articulate its policy, why would it issue a warning letter related to the matter? It is this type of agency conduct that creates mistrust and frustration among members of the medical industry.

To make matters more frustrating, the agency has determined that I, as CEO of a biomedical company, may not speak at financial and medical industry meetings to discuss the future of our particular area of expertise if it entails discussing specific diseases or specific anatomical sites. In other words, FDA has stated that despite the clearance for promotion of the AccuProbe in the fields of urology and oncology, I may not describe its use in the treatment of prostate or liver cancer nor may I use the words prostate, cancer, or tumor. Similarly, even though neurosurgery is a cleared field of use under our 510(k), I may not use the words brain, brain tissue or brain surgery. I am, therefore, effectively precluded from participating at any meeting which would require direct and honest discussion of the current and future use of cryosurgery or I will be considered to be promoting the "off-label" use of the CMS AccuProbe and subject to FDA action. According to FDA's policy, I am even at risk in providing this testimony to members of Congress or to report material information required by the SEC since both include factual and specific information pertaining to the clinical use of cryosurgery for the treatment of specific diseases. This position would seem to be a violation of the First Amendment and prevents effective and necessary communication between manufacturers, physicians, patients and stockholders.

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[5] The Gray Sheet, *Medical Device Labeling Claims: Broad versus Specific Indications*, September 26, 1994, pages 20-21.

Summarizing the effect of FDA's actions with respect to promotion of the CMS AccuProbe:

- *CMS may not promote its product for use in the treatment of specific diseases, even though it is cleared for use in specific medical fields;*
- *CMS may not use any specific anatomical terms when describing a cleared medical use of the AccuProbe;*
- *CMS personnel may not speak at financial, medical, or stockholder meetings or any other public forums, if such presentations require the mention of specific diseases or anatomical sites in the presentation;*
- *CMS is at risk by reporting material information to the Securities and Exchange Commission as it requires the discussion of specific medical procedures and anatomical nomenclature;*
- *FDA's policy prohibits medical device manufacturers from their right and obligation to honestly present the facts surrounding the use of a medical device;*
- *physicians using such devices may be uninformed as to important aspects of their use; and*
- *the patient is at unnecessary risk due to FDA's promotional policy.*

TWO ADDITIONAL RAMIFICATIONS OF FDA'S ACTIONS

As a result of the agency's actions in both of the above-described situations, Cryomedical Sciences has suffered substantial and unnecessary damage which it is currently trying to overcome. In April of 1994 after receiving the FDA warning letter for its promotional activities and after having been informed that 510(k) clearance for the urethral warmer would not be forthcoming, the company was subjected to a shareholder class action suit filed within days of the public announcement of FDA's warning letter. While the judge presiding over the case dismissed a substantial majority of the suit, the company was forced to spend over $150,000 dollars in legal fees and countless hours of corporate time and resources just to engage in its defense pursuant to the original complaint.

Only after a year of such activities and after the sixth or seventh settlement offer by plaintiff's counsel, did CMS agree to settle the action at substantially less cost than would have been the case simply to continue with its defense. The case has since been settled, costing CMS $100,000 in cash

and $350,000 in stock, plus the original $150,000 used for its own legal expenses, not to mention a tremendous amount of wasted time and energy. As further indication of this abuse of the legal system, plaintiff's counsel has requested, and will likely receive, 33% of the settlement proceeds, after reimbursement of nearly $100,000 in out-of-pocket expenses, leaving the entire class of several thousand stockholders with little more than $200,000, or a few cents for every share sold during the class period. While such abusive legal tactics are becoming ever more common, the problem would never have occurred were it not for FDA's actions.

We have seen another consequence of FDA regulatory actions in the reimbursement area. While Medicare reimbursement is a complicated issue affected by many factors, FDA's promotional policy regarding cryosurgery is one of the factors that has resulted in inconsistent insurance coverage of this procedure, including the lack of a national coverage determination from Medicare.

As this Committee is aware, reimbursement is a crucial factor in the current health care climate. Without adequate assurance of reimbursement, doctors and patients face a difficult dilemma in considering treatment options: whether to undertake a procedure which could leave them liable for thousands of dollars of medical expenses, even if -- like cryosurgery -- it is less costly than other, covered treatments. This results in de facto restrictions on technology dissemination, and in discriminatory access. Wealthier patients, who can afford to pay out of pocket, or younger patients, who rely on private insurance rather than Medicare, may choose a procedure like cryosurgery while older or less affluent patients will not have that choice.

Although I have addressed our FDA experiences in great detail, I have done so in the interest of patients, physicians, and the industries which serve them. I believe there is much to reform at FDA and recognize the need to do so in an effective and timely manner. I hope that our experience will encourage those members of Congress interested in FDA reform to take the steps necessary to achieve their goal. I encourage Congress to strongly consider FDA reform proposals put forth by industry associations such as BIO and HIMA, in order to accomplish this formidable task. Thank you for allowing me this opportunity to appear before you

Mr. GUTKNECHT. [presiding] Mr. Finkelstein, could you—just on that point, approximately any idea of what that total cost was to you then, as a result of that, with the shareholders' problem and the legal problems, and all that entailed?

Mr. FINKELSTEIN. The total cost for the three issues that I discussed, including the legal problem, was well over a million dollars. There's both the hard costs and the soft costs, the soft costs being lost profits from the inability to sell our product, which certainly is in the millions. But the actual out-of-pocket costs with the lawsuit, dealing with the FDA on two different occasions over three years on these issues, was easily a million dollars.

Mr. GUTKNECHT. Thank you.

Mr. Pops?

STATEMENT OF RICHARD F. POPS

Mr. POPS. Good morning. I'll focus my remarks really just in response to the question, which was: how does the government affect what we do? And maybe I can give it the perspective of a smaller biotechnology company on its way, hopefully, to becoming a bigger biotechnology company.

Everything we do is based on capital formation and FDA interaction in the case of companies like mine which are developing new therapeutic products, in our case for the treatment of brain cancer, is our first product in the clinic. So anything that affects our ability to raise money, and lots of it, and our ability to get our drugs on a timely basis through the FDA are critical to us.

And we saw this last year and the year before with the specter of massive health care reform and price controls on innovative new products. We saw how the public capital markets closed to biotechnology companies.

And to put some numbers onto it, our company was financed with about $10 million of venture capital, and Mr. Magazine's book about the dearth of venture capital in that uncertain environment—but venture capital is only the first step. We reckon that it will cost us on the order of $250 to $400 million of investors' money before we ever turn a profit. So the first ten came from venture, but the balance of it is coming from the public equity markets. We went public in 1991, and we raised, following the initial $10 million, we've now raised about $140 million from trips to the public capital markets.

To the extent that FDA reform, positive or negative, or anything that affects capital formation positive or negative, is enacted, it has a very immediate impact on our ability to grow these companies.

So I'll stop there.

[The prepared statement of Mr. Pops follows:]

TESTIMONY OF RICHARD POPS
CHIEF EXECUTIVE OFFICER OF
ALKERMES, INC.

BEFORE THE
SUBCOMMITTEE ON TECHNOLOGY
OF THE
HOUSE COMMITTEE ON SCIENCE

REGARDING MEDICAL TECHNOLOGY
DEVELOPMENT AND COMMERCIALIZATION

November 2,
~~OCTOBER 26~~, 1995

TESTIMONY OF RICHARD POPS
CHIEF EXECUTIVE OFFICER OF ALKERMES, INC.
TESTIFYING BEFORE THE
SUBCOMMITTEE ON TECHNOLOGY OF THE
HOUSE SCIENCE COMMITTEE
OCTOBER 26, 1995

Good afternoon. My name is Richard F. Pops and I am Chief Executive Officer of Alkermes, Inc., a biotechnology company located in Cambridge, Massachusetts developing products based on sophisticated drug delivery technologies.

The Bottom-Line

As all entrepreneurs must do, let me start with the bottom line: the biotechnology industry is a unique national asset, admired around the world. The industry is based on the superb scientific capability of this nation and it has the potential to provide life-saving and life-enhancing technologies to improve the standard of living in the United States and around the world.

It is, therefore, in everyone's interest for our government to support a variety of tax, regulatory, and patent reforms which will enhance research by the biotechnology industry. My company, our industry, and I personally also support government funding for basic research and effective technology transfer policies to ensure that this technology is available to biotechnology companies for development.

Among the reforms which we support are the following:

* Enactment of a meaningful and substantive reform of the drug approval process at the Food and Drug Administration;

* Enactment of both broad-based and venture capital gains incentives to encourage investors to fund research by our industry;

* Enactment of permanent R and D and Orphan Drug Tax Credits and restructuring of the Orphan Credit to provide for carryforwards of credits by firms which have no current year tax liability;

* Enactment of amendments to the GATT 20 year patent term to ensure that diligent patent applicants do not lose patent term for reasons which are beyond their control;

* Enactment of amendments to the Hatch-Waxman Patent Term Restoration Act to ensure that biotechnology and pharmaceutical companies do not lose patent term when the FDA delays approval of a product for which a patent has been granted;

* Enactment of securities litigation and product liability reform legislation will protect the biotechnology industry against strike suits and excessive damage awards and increase capital available for research.

* Finally, full funding of research for the intramural and extramural research programs of the National Institutes of Health and other Federal biomedical research programs and vigorous programs to facilitate the transfer of this technology to biotechnology companies for development which will continue to energize our industry.

My testimony will outline **my and our industry's three top priorities: enactment of a two-tiered capital gains incentive, FDA reform legislation, and protections to ensure that the patent term for our inventions is not eroded by government regulatory delays.**

Alkermes, Inc.

Alkermes, Inc. is an emerging biopharmaceutical company focused on the development of products based on sophisticated drug delivery technologies. These include RMP-7, a product designed to facilitate drug delivery to the central nervous system, and products based on the company's ProLease technology, which enables complex, fragile biopharmaceuticals to be delivered in sustained release formulations. We are developing technologies which enable improved drug delivery to the brain by altering the chemical selectivity of the blood-brain barrier. RMP-7 is currently being tested in three multi-center Phase II clinical trials in combination with the chemotherapeutic agent carboplatin in patients with primary brain tumor. In the last 12 months Alkermes has entered into or expanded collaborative agreements for ProLease product candidates with Boehringer Mannheim GmbH, Genentech, Inc., and Schering-Plough.

My own background is that I was Vice President of PaineWebber Development Corporation, a wholly-owned subsidiary of PaineWebber Incorporated, providing product development financing for advanced technology companies. During my time at PaineWebber I was fortunate to be involved in the early product development efforts of the country's leading biotechnology companies, including Amgen and Genentech. In 1991 I joined Alkermes, a biotech start-up of 25 people, mostly scientists from the Boston area. Today, Alkermes employs approximately 120 people in the United States and Europe, has raised over $150 million in capital and is a publicly traded company. I also serve on the Governing Body of the Emerging Company Section of the Biotechnology Industry Organization (BIO), the Board of the Massachusetts Biotechnology Council (MBC), the Brain Tumor Society, and

Link-Up (a foundation supporting AIDS research). I earned my B.A. from Stanford University.

Capital Formation to Fund Research

There is one simple fact about the biotechnology industry that distinguishes it from other technology-based industries; most of our firms fund long-term research on deadly and disabling diseases from investor capital, not revenue, for a period of many years. Without investors willing to take the risk of investing in our companies, our vital research would end. You can understand why our industry cares so much about capital gains incentives and about incentives for venture capital in particular.

Almost without exception our industry cannot borrow capital. Our principal source of capital is equity capital.

The biotechnology industry is one of the most research intensive industry in the civilian manufacturing sector. The average biotechnology company spends $71,000 per employee on research, over nine times the U.S. corporate average of $7,650. In a 1995 survey by *Business Week*, the top five firms in the U.S. in terms of research expenditures per employee were biotechnology companies: Biogen ($210,724), Genetics Institute ($114,943), Genentech ($112,030), Immunex ($102,719), and Amgen ($91,266). Ernst & Young[1] reports that biotechnology companies spent $7.7 billion on research and development in 1995, up eight percent over 1994.

[1]A fiscal year for Ernst & Young is from July 1 through June 30. Therefore, 1995 indicates July 1, 1994 through June 30, 1995.

Bringing a biotech drug product to the market today is both a lengthy and expensive process. From the initial testing of the drug to final approval from the Food and Drug Administration (FDA) can take 7-12 years, and this process can cost anywhere from $150 to $359 million. Both the length and cost of this process are a tremendous impediment for small biotechnology companies attempting to bring a product to the market.

The biotechnology industry consists of more than 1,300 companies, of which 260 are publicly traded. Approximately 525 of these are biotherapeutic companies and 344 are diagnostic biotech companies. Ninety-nine percent of the companies in this industry have 500 or fewer employees and less than one percent are profitable. The industry currently employs over 108,000 people in high-skill, high-wage jobs.

There are currently 33 biotechnology therapeutics and vaccines approved by the FDA. Ernst & Young reports that there are 270 in human clinical development, and over 2,000 in early research stages.

As products move into clinical trails, expenses increase. This means that the need for capital for biotechnology companies to fund research is increasing right at the time when it is difficult for the majority of biotechnology companies to obtain sufficient capital. The biotechnology industry experienced a net loss of $4.6 billion in 1994, and has lost over $12 billion in the last three years.

A September 1995 Ernst & Young report finds that biotech companies, on average, have 19 months of capital left at their current burn rates (the rate at which capital is being

expended).[2] According to a March 1994 report by Dr. Robert Goldberg of the Gordon Public Policy Center at Brandeis University, 75 percent of biotechnology companies have two or fewer years of capital left.[3] Ernst & Young estimates that there are 1,308 companies. If 75 percent have two or fewer years of capital left at their current burn rates, a staggering 981 companies would need to return to the market for more capital.

My agenda and our industry's legislative agenda reflects this fundamental economic reality.

* FDA reform will reduce our cost of doing business and enhance our ability to raise the equity capital we need to fund research.

* Capital gains tax incentives, particularly incentives which focus specifically on direct equity investments in stock, will help us to raise capital from investors without which we would not exist.

* The R and D and Orphan Drug Tax Credits are valuable as incentives for research but it is critical that we be permitted to carry forward both credits as the majority of biotechnology companies do not have current year tax liability with respect to which to claim the credit.

* Strong intellectual property protection is indispensable to reassure our investors biotechnology inventions will not be pirated by our competitors.

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[2] "Biotech 96: Pursuing Sustainability," Tenth Anniversary Edition, Ernst and Young (September 1995).

[3] "Price Controls and the Future of Biotechnology: The Results of a Survey," Dr. Robert Goldberg, Senior Research Fellow, Gordon Public Policy Center, Brandeis University (March 1994).

* Abuse of the tort system to hold biotechnology companies hostage in shareholder and product liability lawsuits raises our cost of doing business and reduces the funds we can devote to research.

* Finally, government funded basic research and the effective transfer of this technology to biotechnology companies is what led to the creation of the biotechnology industry and it is a model for the public-private partnerships which will maintain the preeminence of the U.S. biomedical research establishment.

International Competitiveness and Foreign Competition

The United States currently has the dominant biotechnology industry when compared with any other country in the world. Precisely because the U.S. is preeminent in the field of biotechnology, it has become a target of other country's industrial policies. In 1991, the Office of Technology Assessment (OTA) found that Australia, Brazil, Denmark, France, South Korea and Taiwan (Republic of China) all had targeted biotechnology as an enabling technology. Furthermore, in 1984, the OTA identified Japan as the major potential competitor to the United States in biotechnology commercialization.[4]

The OTA also identified the manner in which Japan had targeted biotechnology. The report stated, "In 1981, the Ministry of International Trade and Industry (MITI) designated biotechnology to be a strategic area of science research, marking the first official pronouncement encouraging the industrial development of biotechnology in Japan. Over the

[4] U.S. Congress, Office of Technology Assessment, Biotechnology in a Global Economy 243 (October 1991).

next few years, several ministries undertook programs to fund and support biotechnology." One of the Japanese ministries, the Ministry of Health and Welfare (MHW), instituted a policy whereby existing drugs would have their prices lowered, while allowing premium prices for innovative or important new drugs, thus forcing companies to be innovative and to seek larger markets.[5]

It is widely recognized that the biotechnology industry can make a substantial contribution to U.S. economic growth and improved quality of life. For example:

- The National Critical Technologies Panel, established in 1989 within the White House Office of Science and Technology Policy by an Act of Congress,[6] calls biotechnology a "national critical technology" that is "essential for the United States to develop to further the long-term national security and economic prosperity of the United States."[7]

- The private sector Council on Competitiveness also calls biotechnology one of several "critical technologies" that will drive U.S. productivity, economic growth, and competitiveness over the next ten years and perhaps over the next century.[8]

- The United States Congress' Office of Technology Assessment calls biotechnology "a strategic industry with great potential for heightening U.S. international economic competitiveness." OTA also observed that "the wide-reaching potential applications of biotechnology lie close to the center of many of the world's major problems -- malnutrition, disease, energy availability and cost, and pollution. Biotechnology can change both the way we live and the industrial community of the 21st century."[9]

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[5] U.S. Congress, Office of Technology Assessment, Biotechnology in a Global Economy 244-245 (October 1991).

[6] National Competitiveness Technology Transfer Act, Pub. L. No. 101-189, 103 Stat. 1352 (42 U.S.C. §6681 et seq.).

[7] White House Office of Science and Techno ,y Policy, Report of the National Critical Technologies Panel 7 (1991).

[8] Council on Competitiveness, Gaining N / Ground: Technology Priorities for America's Future 6 (1991).

[9] U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: U.S. Investment in Biotechnology-Special Report 27 (July 1988).

o The National Academy of Engineering characterizes genetic engineering as one of the ten outstanding engineering achievements in the past quarter century.[10]

The competitiveness of the U.S. biotechnology industry means that U.S. patients with rare deadly and disabling diseases have hope. It means that they can look to American biotech companies to develop the therapies and cures which will ease their suffering.

Let me now focus on the three highest priorities for our industry -- enactment of a two-tiered capital gains incentive, FDA reform and the patent term issues. The remaining issues are discussed in an appendix to my testimony.

Two-Tiered Capital Gains Incentive

The biotechnology industry strongly endorses a two-tiered capital gains incentive modeled on the Senate Finance Committee bill. We support pairing the House-passed, broad-based capital gains incentive with the venture capital incentive introduced by Congressmen Bob Matsui and Phil English, H.R. 1918.

The Finance Committee bill provides a 50% capital gains exclusion for all investments in any "capital asset" held for one or more years. It also provides a 75% exclusion for new, direct, investments in the stock of a small company held for five or more years.

The House-passed capital gains incentive, Section 6301 of H.R. 1215, also provides a 50% capital gains exclusion for all investments in any "capital asset" held for one or more years. The Matsui-English bill, H.R. 1918, provides a 75% exclusion for new, direct, investments in the stock of a small company held for five or more years. I support pairing

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[10] National Academy of Engineering, Engineering and the Advancement of Human Welfare: 10 Outstanding Achievements 1964-1989 2 (1989).

section 6301 with H.R. 1918.

I believe that these two capital gains incentives are complementary and that at two-tiered capital gains incentive will ensure that venture capital is formed for America's entrepreneurs and emerging companies.

A second-tier, venture capital incentive recognizes that not all investments in capital assets are the same. Venture capital investments typically involve more risk, and potentially provide greater economic and social benefits, than other types of investments. The greater risk arises because venture capital investors are more likely to lose some or all of their principle and the holding period tends to be quite long. At the same time these investments can be the most productive, economically and socially, creating whole new industries and revolutionizing our standard of living. This is why the bill provides a special, more powerful second-tier incentive for venture capital investments.

The second-tier incentive is justified because of the dynamic ability of high technology entrepreneurs to create jobs and capture markets. The electronics, biotechnology, and other high technology industries have changed our economy and changed our lives. The venture capital incentive in the Finance Committee bill and H.R. 1918 is not sector-specific, it applies to any type of business which raises capital with a stock offering, but it is most likely to be utilized by high technology firms which are capital and research intensive and have no other source of capital available.

The venture capital provision focuses on the most dynamic sector of our economy. According to the latest State of Small Business Report, "The greatest gains in employment come from sectors of the economy where small firms dominate. Overall industries

dominated by small firms posted a net gain of 1.6 million jobs in 1993, while industries dominated by large firms lost more than 200,000 jobs." The report also cites reports that small firms are responsible for 55 percent of manufacturing product innovations and they produce more than twice as many inventions per employee as larger firms. They also produce twice as many significant innovations per employee.

The most recent survey of the National Venture Capital Association found that between 1989 and 1993 young, venture capital backed firms generated an average of 152 U.S. jobs per company. For the first five years of a venture-backed company's life, it grows its workforce by nearly 90%. These venture backed companies invest an average of $8.7 million per company and the research investment grows by 70% during the company's first five years. The companies generated the average company generated $4 million in export sales. And these are only the companies backed by the professional venture capital industry. It does not include the many more companies which are backed by founders, initial employees, angel investors, the informal venture capital financiers, and the public capital markets. Taking just one example of job growth, the American electronics industry now employs one million more workers today than it did in 1974.

The entrepreneurial sector is classically American. America has great universities, a great education system, and an entrepreneurial tradition. When we combine this with equity capital, we see often spectacular results. Of course, the risk is considerable as well. Many small entrepreneurial firms die. This is an inevitable, even desirable, part of this process of "creative destruction," American economist Joseph Schumpeter's descriptive phrase, which is at the heart of a free enterprise economy.

Entrepreneurial firms are the ones which can dramatically change our whole health care system, clean up our environment, link us in international telecommunication networks, and increase our capacity to understand our world. The firms are founded by dreamers, adventurers, risk-takers who embody the best we have to offer in our free-enterprise economy.

In terms of the venture capital incentive it is important to focus these capital gains incentives in part on investments in corporate stock as America's entrepreneurs rely on equity investments to fund research and development. Most of them have no sales and, therefore, no ability to borrow funds. To raise capital they must issue stock, to angels, to venture capitalists, or to investors in public offerings. Capital raised from equity offerings is the most usable type as it does not involve any carrying costs. It tends to be patient capital, precisely what struggling entrepreneurs need. This is exactly what the type of capital formation covered by this incentive.

It is also important to recognize that an incentive focused on direct purchases of stock provides an incentive for founders and company employees who acquire stock through the exercise of stock options. Founders and their employees take a major risk when they leave established firms to found start-ups. They often take a major cut in pay with the hope that the value of their stock will justify their decision. We must provide an incentive for outside investors, but it may be even more important to provide an incentive for founders and their employees. No one is more valuable to our economy than our entrepreneurs.

Finally, there is a powerful rationale for, and I support, the broad-based capital gains incentive as well as the venture capital incentive. The broad-based incentive applies to

currently held assets sold after the effective date of the legislation, so it is vital to unlocking the current ownership of capital assets. Reducing the penalty for sale of these assets will free up capital to be invested in more worthwhile investments. In addition, many other sectors of the economy do not rely on direct equity investments and there is a powerful rationale for providing a capital gains incentive for these investments. Finally, there will be cases where an investor makes a qualified venture capital investment but is forced to sell it before the mandatory five year holding period. That investor should qualify for the regular, broad-based capital gains incentive.

Because the 1993 venture capital incentive has already been scored as losing $752 million over five years, fixing this incentive is relatively inexpensive. The Joint Tax Committee has found that the venture capital provision of S. 959, the Hatch-Lieberman bill, which forms the basis for the Senate Finance Committee bill, including the rollover provision, would reduce government revenues by $200 million over five years, $400 million over seven years, and $700 million over ten years. By way of contrast the broad-based capital gains incentive included in the Finance Committee bill is scored as losing $41 billion over seven years.

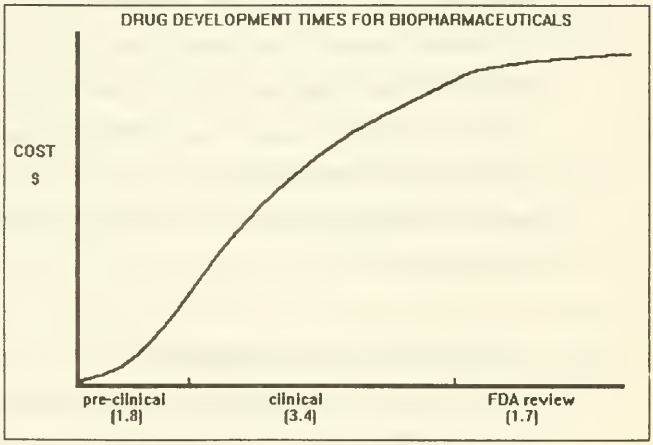
Reform of the Food and Drug Administration

I urge the Congress to enact substantive FDA reform measures that will focus the agency mission on the promotion of public health by the prompt approval of new, safe and efficacious drugs and biologics. The agency's efficiency must be improved along with a commitment to change the present regulatory paradigm. It is critical that the clinical

development of life saving therapies be optimized both to speed new products to needy patients as well as managing risks for sponsors.

The Problem

The clinical develop-ment process for new life-saving therapeutics is both lengthy and expensive. The extent of this problem is highlighted in the figure. Data represented are for approved biopharmaceuticals. The average time from invention to development is seven years. The cost is in relative dollars and shows how it will accelerate during the developmental process.



The critical portion is the clinical investigation phase. FDA has made a commitment through the implementation of the Prescription Drug User Fee Act to review and act upon new NDAs and PLAs in six months. Thus, we can expect the latter stage of the process to shorten in

time. It is unlikely that the pre-clinical phase can be shortened much more than shown. Efforts to improve the access to new therapies must be centered on the middle phase of development. This is especially important for emerging biotechnology companies that do not have product revenues that fund R&D activities.

The principal manner by which the development time can be shortened is to have an extremely interactive IND process between drug sponsors and the FDA. Companies expend the majority of the total cost of drug development prior to submission of data to FDA. FDA must be prepared to make a similar strong commitment to putting its resources to bear during this period.

The Solution

Our industry has examined current FDA practices. The drug approval process must be improved so that FDA does not begin by recalculating the raw data. Further savings can occur by simply expediting an approval of a product that has already been approved by a recognized regulatory bodies such as the United Kingdom's Medicines Control Agency or the European Medicines Evaluation Agency. Why should FDA have to repeat the thorough work that another organization has already done? Refocusing FDA efforts and eliminating areas of oversight that are no longer justified would free up review personnel and make the clinical development process more interactive. To this end, we recommend that the following broad areas be addressed:

- **Streamline the New Drug Application.** Applications should contain tabulations and analyses of the relevant data and not primary data tabulations or case report forms. This would shift the analysis to a "top-down" model as opposed to a

"bottom-up" approach. The size of the submission would be reduced to that essential to support product approval. FDA would retain the right to request the primary data under certain circumstances.

- **Expedite the Approval of New Drugs.** Applications that have already been approved by sophisticated regulatory bodies such as the U.K. Medicines Control Agency or the European Medicines Evaluation Agency shall be eligible for expedited approval. The review would be expedited and such products would be deemed approved unless FDA finds that the drug is unsafe or ineffective.
- **Eliminate outdated and inconsistent regulations associated with the Public Health Service Act.** Legislation enacted in 1912 provides the authority under which FDA regulates many of our industry's products. One of the anachronistic requirements, not imposed on traditional drugs, is the separate approval of the manufacturing process. Emerging biotechnology companies should have the ability to enter into manufacturing agreements at all stages of clinical development so that scarce resources can be focused on product development, not diverted to manufacturing facility construction.
- **Utilize non-governmental experts to review activities that are not central to the clinical review process.** FDA would have more resources to focus on clinical reviews and approvals by relying on outside experts, for example, in the areas of toxicology, assay validation, and environmental reviews, and utilizing academic medical center institutional review boards to review Phase I clinical trials.
- **Modify FDA's regulations over the dissemination of scientific literature on new**

biotechnology products. Physicians can better serve their patients if they have full access to current scientific and technical publications regarding new tests and therapies.

- **Modify export laws so that U.S. companies are no longer faced with having to build manufacturing facilities abroad.** The biotechnology industry developed from scientific advances made in this country. Permitting the exportation of innovative products to patients in other countries will retain the fruits of this investment.

These reforms will improve patient access to new biotechnology-derived therapies. The industry will be better able to compete in international markets by retaining a strong domestic manufacturing capability.

Patent Term Issues

I have mentioned the importance of intellectual property protection. Intellectual property protection is critical to the ability of the biotechnology industry to secure funding for research because it assures investors in the technology that they will have the first opportunity to profit from their investment. Without adequate protection for biotechnology inventions, investors will not provide capital to fund research. There is substantial risk and expense associated with biotechnology research and investors need to know that the inventions of our companies cannot be pirated by our competitors. Therefore, less patent protection means lees biomedical research on deadly and costly diseases because there will be less time to recoup the investment and make a profit.

A June 1994 report by Dr. David H. Austin of Resources for the Future[11] specifically documents the vital economic importance of intellectual property protection and its relationship to research expenditures, including the value of patents, and their effect on competing companies and on the biotechnology industry in particular.

The results of Dr. Austin's study indicate that there is a significant reaction in the stock market when certain broad types of patents issue. When a patent is listed in the Wall Street Journal, it positively affects the value of the stock for the company receiving the patent, and negatively affects the stock price of competitors to that company. Dr. Austin defines a "significant" increase in valuation as $1.7 million on a company capitalized at an average of $400 million. The report found that there is a positive correlation between stock price, when a patent is filed and issued, and research and development expenditures. In addition, the report indicates that the granting of an important patent appears to raise the net value of the entire industry. These findings are consistent with the March 20 Washington Post article entitled "A Biotech Company is Granted Broad Patent and Stock Jumps."[12]

Our industry has taken a consistent position on the patent term issue since the debate began in the middle of last year. We have always pressed for protections to ensure that diligent patent applicants are not penalized for delays which are beyond their control. While we have said that a guaranteed 17 year term from grant would be desirable, we have always proposed ways for patent applicants to achieve a similar result without insisting that there be

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[11] "Estimating Patent Value and Rivalry Effects: An Event Study of Biotechnology Patents," Dr. David H. Austin, Fellow at Resources for the Future (RFF)(Washington, D.C.). Discussion Paper 94-36 (June 1994).

[12] The patent was granted to Genetic Therapy Inc. of Gaithersburg, Maryland for ex vivo gene therapy. GTI's stock jumped 17% the day after the patent was granted.

a minimum 17 year patent term from grant. We are consistent in our support of amendments to the Hatch-Waxman Act to ensure that applicants do not lose patent term due to delay sin the approval of a drug at the FDA.

There are almost always at least two ways to achieve a given result. One of them may be more complicated and indirect than the other, but the more complicated and indirect approach may be the better option given all of the circumstances. Sometimes simplicity is not the greater imperative. This is the case with the GATT patent term issue; the biotechnology industry can live within a 20 year system measured from the date of application if it includes safeguards which protect the legitimate interests of diligent patent applicants.

In March our industry proposed a series of additional amendments to the GATT implementing law to strengthen the safeguards which had been included at our request in the September bill and December law. We are delighted that some of these proposed safeguards are incorporated in the bill introduced by the Chairman of the House Intellectual Property Subcommittee, Carlos Moorhead, H.R. 1733. We believe that our amendments to the Chairman's bill will achieve the result we all desire, a resolution to the patent term debate through the adoption of a package of safeguards sufficient to protect diligent patent applicants from the loss of patent term.

We believe that the Moorhead proposals in H.R. 1733 to provide additional protections for diligent patent applicants vindicate the approach we have been taking since last year. We have always thought that it is possible to avoid erosion of patent term within a 20 year patent term measured from the date of an application by providing safeguards. We have never

thought that the only way to achieve this result was to set a 17 year minimum term from grant. We believe that the only way to save the 20 year patent term is to provide additional safeguards. The safeguards included when the GATT implementing legislation became law are drastically better than those included in the initial drafts, but they do not provide complete protection. There is nothing inconsistent between the 20 year term and a regime of safeguards, and nothing in the safeguards which we propose which would enable patent applicants to intentionally delay the issue of a patent to surprise the marketplace.

We recognize that the issue of "submarine" patents is central to this debate. There are applicants who will intentionally delay the issuance of a patent, amend their claims very late in the prosecution process, and surprise the marketplace with exorbitant demands for royalties. We do not believe that this is a pervasive problem, but there are some notorious examples which can be cited. We do have to guard against "bad facts" making for "bad law."

The proposals in H.R. 1733 and by our industry do not provide refuge for those who would seek to secure submarine patents. We take this as an essential limitation on any amendments to the GATT implementing law. We have taken great care to "game" our own proposals to ensure that they do not open up opportunities for abuse and we do not believe that they lend themselves to abuse. We remain open to any modifications of our own proposals which will clarify their application to individual cases.

The Moorhead bill would safeguards applicants from delays which last longer than five years by raising the cap on extensions from five years to ten years. For biotechnology inventions five years was grossly inadequate to compensate applicants for typical delays

occurring in the processing of biotechnology inventions. Although we appreciate the increase in the cap to ten years this is still inadequate in some instances.

Second, it safeguards against delays within the Patent and Trademark Office by providing for extensions that are necessitated by administrative delays within the Patent and Trademark Office. This is important to this industry because biotechnology inventions are typically more complex than other inventions and consequentially the typical time it takes to process an application through the Patent Office is longer than for other inventions.

Finally, it safeguards the public from a dilatory patent applicant by denying that patent applicant an extension if the applicant fails to make reasonable efforts to secure a patent. The bill does this by requiring the Patent and Trademark Office Commissioner to prescribe regulations establishing what activities constitutes failing to engage in reasonable efforts to secure a patent.

Our industry's proposals build directly on the Chairman's proposals. They do not introduce wholly new issues. We believe our proposals are administratively less complex and provide greater certainty than the Chairman's proposals that diligent patent applicants will not, in fact, lose patent term for delays while the application is beyond their control. This proposal is largely consistent with the intent and terms of the Chairman's bill.

our industry has proposed amendment to section 8 of H.R. 1733

* The proposed amendment eliminates the five year cap that was included in P.L. 103-465 and the ten year a cap that is contained in the Chairman's proposal, H.R. 1733, as a cap of any number of years is an arbitrary cap which is unfair to those who should have a patent term extension greater than that cap.

* The proposed amendment like P.L. 103-465 and H.R. 1733 provides extensions for successful appeals, interferences, and secrecy orders.

* The proposed amendment provides a cumulative time limit for actions on the part of the PTO and thereby initiates a chess clock like mechanism to provide applicant an objective criteria to analyze all administrative delays that would be covered by H.R. 1733's catch-all extensions for "unusual administrative delay".

* The proposed amendment clarifies the starting and ending points for the calculation of delays where extensions are available for secrecy orders, interferences, and appeals.

* The proposed amendment provides for rolling over extensions into a subsequently filed applications where the same invention is prosecuted in both applications.

* The proposed amendment limits extensions so that they can not extend a patent term to longer than 17 years.

Finally, we propose pairing the amendment of H.R. 1733 with an amendment to Hatch-Waxman Patent Term Restoration Act.

We believe that our proposals provide an equitable, fair, and substantive response to the patent term controversy.

Conclusion

In conclusion, my company, our industry, and I personally support a variety of incentives to ensure that the life-saving and life-enhancing research of our industry can be developed in to products. Our industry can improve our standard of living and create high-wage jobs in America. This is a promise that can be realized with the support of the

Congress and the Administration.

Thank you very much. I am pleased to answer your questions.

Mr. GUTKNECHT. Dr. Brinker?

STATEMENT OF JEFFREY A. BRINKER

Dr. BRINKER. Thank you.

Well, unlike the other members of this panel, I am not a representative of industry; I'm a physician who is also an academician, who also does research on medical devices and drugs. I work at the Johns Hopkins University where I'm a professor of medicine and radiology. I've had the opportunity to serve on an advisory committee to the FDA on new circulatory devices and have been the chairman of that committee for two years. So my perspective to this question comes from, as Paul Harvey would say, "the rest of the story." And I don't think that's been quite brought out here.

I think the FDA has a very difficult job; Mr. Tanner has addressed that already, and it's not perfect. There are many problems with the review process, many problems with arbitrariness, delay, and most of the bureaucracy that affects every other governmental agency. But the FDA does have the responsibility to protect the public and it does have the responsibility to insure that devices and drugs are safe and effective and have clinical utility. And, remarkably, the Wilkerson report thinks that the demonstration of efficacy and clinical utility are onerous tasks for new device approval. I don't think that is correct. I think that a lot, or at least a good portion, of the problems that industry has with the FDA, at least from my experience, has been based on industry shortcomings as well: inappropriately designed studies, lack of communication, tunnel vision as to the nature of their product and its ultimate success, all of which are problematic when the device reaches the various stages of review.

On our committee we've had a great deal of difficulty discerning any kind of scientifically valid evidence for most of the products that we see. I think there are a lot of reasons for——

Mr. GUTKNECHT. Dr. Brinker, could you put—without—I don't want you to get too specific and get somebody in trouble here, but could you give us a couple of specific examples of what you're alluding to?

Dr. BRINKER. Sure. As far as poorly designed studies, the Johnson & Johnson original stent application for intercoronary stenting was not a study. It was a series of anecdotes or of registering, and, as people like to say, the plural anecdote is not data; it's just a registry. And it was totally impossible for the committee, made up of physicians, to advise the FDA to initially approve the device on the basis of the company-oriented study. It just so happened that, fortunately, investigators had done two randomized studies, done appropriately, one in the United States and one in Europe, that were done as late amendments to the company's initial application that was later, on a second course and at great expense to Johnson & Johnson, seen to validate the nature and the safety and efficacy the stent, and the device was approved. That's one example.

Another example is laser. Laser angioplasty for the coronary arteries was approved despite almost no information that it was a valid device in terms of safety and efficacy, and this was done in part by the argument that the company made to us and the FDA that they needed to get on the market or this potentially important

kind of technology would fail. Well, they got on the market; the device hasn't been proven to be very effective, and to a great degree the market has left laser angioplasty in its approved state for good, at great cost to everybody concerned.

So I think these are just two instances where poor studies, no real good information, delayed the process, and there are many others also. But I'd like to also just mention that devices do fail, do have problems. There's a need for restrictive clinical trials to determine whether a device offers a risk, so that the risk is limited to patients that are undergoing these trials. This country is perhaps somewhat unique in that we undertake—companies can actually market or sell their product during an investigation. Under an IDE, they have the ability to sell pacemakers, lasers, stents, whatever, in a limited way, and we pay for these devices. We pay for the research necessary to validate and prove that these devices are safe and effective.

How do we pay? In some cases, we pay through the private insurance companies; in some "me, too" devices that are generational changes, Medicare and Medicaid pick up the tab. And when these aren't done, in some cases the hospitals, including the physicians themselves, will assume the cost or pass it on to the patient, to prove whether a device is safe and effective. And if it's not effective and it's not safe, the patients remain unprotected and they don't get their money back.

[The prepared statement of Dr. Brinker follows:]

TESTIMONY OF JEFFREY A BRINKER M.D.

TO

THE SUBCOMMITTEE ON TECHNOLOGY

THE COMMITTEE ON SCIENCE

NOVEMBER 2, 1995

I would like to thank Chairwoman Morella and the Subcommittee on Technology for the invitation to address the issue of "Medical Technology Development and Commercialization". I am a practicing physician, Director of Interventional Cardiology at the Johns Hopkins Hospital, and Professor of Medicine and Radiology at the Johns Hopkins University. I have been actively involved in medical research, including that directed at the evaluation of new medical devices and drugs, for almost twenty years. For the last 6 years I have served on the Circulatory Device Advisory Panel to the FDA including 2 years as its Chairman. In addition, I have assisted the FDA as a mediator between it and industry on a number of occasions. I am Chairman of 2 physician advisory groups to industry concerning the management of patients with recalled implantable devices. I am an active member of a number of professional societies including the American College of Cardiology, the American College of Chest Physicians, the North American Society of Pacing and Electrophysiology, and the Society For Cardiac Angiography and Intervention. I have no financial interest in industry nor do I have a vested interest in the FDA. I did not actively seek the opportunity to speak at this hearing but accepted the invitation to do so because I believe in this process and thus the responsibility to participate. I come here entirely at my own expense.

I think that we can all agree that society is best served when access to safe and effective new medical technology is provided in the most expeditious fashion. It is a measure of the quality of our scientific effort and economic system that the U.S. medical technology industry is a world leader. Our society has nurtured basic and clinical medical research with public as well as private funding. Furthermore the value we place on human life and well-being has been reflected in the increasingly greater contribution of our National Health Expenditure to the Gross Domestic Product. America provides the highest level of medical technology to the greatest number of its population. We are the medical technology industry's biggest customer. In order for American medicine to maintain its preeminent position it is necessary that we continue to invest generously in the research that leads to remarkable new advances. We should recognize the importance of entrepreneurism in medical device development and facilitate this whenever possible.

I acknowledge that there are many challenges to the development of new devices and their introduction into the market. The report of the Wilkerson group lists several obstacles to the commercialization of new medical devices which, in general, reflect the profitability of the industry per se. While these are real problems, they are not unique to the medical device industry. Regulatory agencies, liability concerns, shrinking market, domestic and international competition, availability of capital, and the degree of participation of the academic community complicate the conduct of many businesses.

Much criticism has been directed by industry towards the regulatory process. The Wilkerson report reflects this attitude and focuses upon it as the keystone of the medical device industry's troubles. The FDA is singled out as being a major reason for: the delay in availability of medical technology in this country, forcing industry to leave the country taking jobs and capital with it, and for a reduction in the vitality of medical innovation in general. Furthermore the regulatory process has been implicated as a direct cause of death of thousands of Americans due to the non-availability of life preserving new technology. These claims must be examined in the proper perspective.

There has long been a confrontational relationship between the medical device industry and the FDA. Much blame has been directed at the agency for being slow, uncompromising, excessively bureaucratic, and arbitrary in its actions. Many physician investigators feel that the agency is intrusive and unyielding in protocol design, it is seen to be an interference in the physician's ability to practice medicine as he or she feels fit and a hinderance to the acquisition of new technology. The FDA on the other hand views many in the device industry as being motivated by profit and the "competitive edge" rather than the societal welfare whose priority they claim. The sponsor and their physician consultants and investigators often have a prejudicial opinion of their product which may hamper objective assessment of technology. Much of the delay in the processing of PMAs result from industry shortcomings. Clinical trials used to justify safety and efficacy are often poorly designed and complied with. Physician investigators may be more interested in marketing the availability of new technology in a restricted environment than in truly proving its worth. Industry subtly, but occasionally overtly, encourages the off-label use of devices to circumvent the regulatory process. Physicians all too often are willing to forego the scientific method and fall back on a concept of medical infallibility to decide whether a device should be used. This may be even more problematic when the physician has a vested financial and/or intellectual interest in the product.

While it is true that our regulatory process is deliberate and suffers from many of the shortcomings exemplified by other agencies of our bureaucracy, it serves a most important function. The FDA has been given by you, the Congress, the responsibility of ensuring that drugs and medical devices which are marketed in this country are safe and effective. Recently you strengthened the agency's role in the surveillance of the safety of market approved medical devices. These acts were directed at real and perceived dangers to the public.

It would seem a reasonable requirement that a company be able to demonstrate, by valid evidence, that their product, in fact, does what they claim. Remarkably this has been a difficult task for many devices. Further it would seem the company's responsibility to track and monitor the safety of marketed devices. The mechanism to accomplish this has been woefully inadequate. The GAO has documented that few, perhaps less than 5%, of the adverse events associated with medical devices are reported to the sponsor or to the FDA. In addition there are, albeit rare, instances of negligent and unlawful activity on the part of medical device companies which have placed patients at undue risk of harm.

I feel that most responsible physicians would support the continued need for device regulation. This is so for life sustaining and implantable devices certainly, but it is also so for "low risk" devices. For the former the potential for device related patient injury and death is considerable and may exceed that of many drugs. In addition to the risk posed by these devices, there is substantial financial burden to the patient, private insurers, and the Government in treating device related injuries and failures. Further, there is the cost to society of devices which are low risk but ineffective or of no clinical utility.

While our present regulatory system has engendered a great deal of discontent it is basically sound. I believe that effective regulation that is not unduly obtrusive may be accomplished without major changes in law. Over the last 6 years I have noted significant improvements in the way the CDRH does business. This has included: the development of an expedited approval pathway for innovative technology which addresses definite clinical needs; initiation of an interactive process between the sponsor, physician investigators, advisory panel consultants, and the FDA to address issues of concern at the various stages of the IDE and PMA process; increased reliance on postmarket surveillance to supply safety data; early establishment of performance standards which would simplify the approval process of devices similar to those being marketed; the convening of workshops designed to facilitate communication between the FDA, industry, and the medical community; and circumvention of the advisory panel process in certain situations (including reclassification of some devices) in which approval can be granted on the basis of established standards. These developments have accompanied a change in leadership at the CDRH and a responsiveness to criticism of the regulatory process.

A fundamental obstacle in the relationship between the FDA and the medical device industry is philosophic; I believe that it should be the responsibility of the FDA to FACILITATE the approval of safe and effective medical technology. I have previously suggested mechanism by which this may be accomplished. This does not obviate the necessity for the sponsor to clearly demonstrate safety and efficacy of the device by valid scientific means but it would facilitate and shorten the process. The traditional adversarial relationship between industry and the agency has thwarted the type of communication which is necessary to accomplish this goal. This can and must be changed.

I do not believe that are current state of medical device innovation is in a "crisis". From personal experience I find it rare that a concept offering the potential for substantive clinical benefit can not find venture capital for its exploration. The likelihood of industry taking on the development of a new technology is heavily influenced by the state of competitive devices, the market potential, and profit margin. Clearly the state of the economy in general and that portion directed at health care expenditures specifically, has great impact on the viability of the medical device industry. In a global economy it makes sense for American industry to manufacture and market devices off shore. This would continue to a degree even if there were no regulatory concerns in this country. From an investigator's point of view I am discouraged that initial clinical research of some American innovations is being conducted outside of this country. I would hope that industry might reconsider this and would support FDA policy to facilitate initial study here. Since the U.S. is the largest market for medical

technology, devices thought to be beneficial (and hence profitable) will have to comply with the regulatory process here sooner or later. It would seem to be in sponsor's best interest to initiate that process as soon as possible.

I would urge the Subcommittee to keep an open mind with regard to claims, such as those alluded to in the Hudson and Wilkerson reports, that American lives are being lost because of delays in accessibility of new technology. The conclusions drawn are not scientifically valid and do not take into consideration a number of factors such as the lack of randomized controlled studies and the paucity of data showing statistically significant differences in mortality. Laymen and physicians must be aware that "NEW" cannot be equated with "BETTER". New devices, drugs, and other modes of therapy which seem to be intuitively better than alternatives may later be found inferior. There are certain technologies that do offer the potential for significant advantage in terms of saving or prolonging life. In many instances these technologies offer the most formidable challenges to the regulatory system because they have the greatest potential for adverse (including life-threatening) events. Implantable defibrillators and intra-coronary stents are examples. The former initially had its most vocal opposition from leading members of the medical community. The first intra coronary stent was devised, manufactured, and tested in Europe. While initial reports were favorable, a subsequent study revealed that the long term course of the implantable device was associated with a high incidence of vessel occlusion and no apparent benefit (Serruys PW et al. New England Journal of Medicine 1991;324:13). Even after approval of the Cook and the Johnson & Johnson stents in this country medical opinion has been divided (Hearn JA et al. Circulation 1993;88:2086, Serruys PW and Kean D. Circulation 1993;88:2455, Topal EJ. New England Journal of Medicine 1994;331:539). Clearly we learn more about the use of devices in properly performed clinical trials; our knowledge of coronary stenting including mechanisms of deployment and adjunctive medical therapy continues to grow. The FDA has taken a leadership role in this area by encouraging proper studies to be performed to allow devices to be used in an optimal fashion. The current trail evaluating adjuvant medical therapy for stenting is a good example.

Careful regulation provides a mechanism for clinical trials allowing for the identification of problems and the limitation of their sequelae. Such was the situation with a pacemaker which had a defective connected block that was subject to unpredictable failure. This was noted just prior to market release in this country and allowed for a correction to be made. A relatively small number of patients exposed to the device during the clinical trial had to undergo repeat surgery. If this device had been released without clinical trial thousands of patients may have been at risk of repeat surgery or sudden death due to device failure.

No regulatory system is perfect however agencies throughout the world respect the work and standards of the FDA. The European Community has strengthened its regulatory requirements in recent years rather than relaxed them. The high standards for device manufacture and design set by the FDA encourage industry to conform even if they go off-shore with the device initially. Still some devices which seemingly pass the standards will eventually be found to be flawed. A series of implantable pacemaker leads have been found to have a wire which may protrude and perforate the heart resulting in death or serious injury. There are some 60,000 of these leads implanted in patients all over the world with

about 30,000 in the U.S., A heart valve was found to have a fatal defect, and we all are aware of the silicone breast implant. Considering the number of approved devices being used today the overall record of safety is quite good. I believe that much of the credit for this belongs to the FDA.

Any regulatory process must straddle the boundary line of being too restrictive or not demanding enough. It is imperative that an impartial publically accountable body be given the responsibility for these decisions. This entity must have the resources and authority to do this job effectively and efficiently. Congress first empowered the FDA to regulate devices on a limited basis in the FFD&C Act of 1938. These responsibilities have been clarified and expanded in the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Device Amendments of 1992. The rationale for this evolution of law was the perception that devices needed closer regulation not less.

It is my opinion that the quality of medical care in the United States is the finest in the world. We apply the most advanced technology to the greatest proportion of our population in the most expeditious manner. I encourage continued device and drug innovation and would support those efforts to achieve this end which do not unduly endanger the public. There is much that is right about the way this country regulates drugs and devices. We can all agree that every governmental agency can improve. Attention should be directed towards optimizing the system. The medical device industry in this country should also have a responsibility to work to improve the relationship with regulators. They to might address some of their shortcomings and seriously consider their need to go out of country, if in fact, the healthcare of our population is a major concern to them.

Mr. GUTKNECHT. Thank you.

Dr. Chevalier? I'm sorry, I'll say that wrong. "Chevalier," would you say it, please, Doctor?

STATEMENT OF PETER A. CHEVALIER

Mr. CHEVALIER. "Chevalier," sir.

Mr. GUTKNECHT. Good. Thank you.

Mr. CHEVALIER. Thank you very much.

Perhaps I could bring a little different perspective to the original question, both being an executive from a medical device company—in this case, Medtronic, but also that as a patient. I suffer from a condition known as heart block, which is a common condition which is diagnosed in over 160,000 new patients in the U.S. alone each year. And without proper treatment, usually provided by an implantable pacemaker, it severely limits the physical activity of those who suffer from it; it decreases the quality of life, and often leads to early death.

Ironically, although I work as a vice president for Medtronic, the largest manufacturer of cardiac pacemakers, I am unable to get the best therapy for this condition. It's available to patients in Europe and other industrialized nations, but not to patients like myself in the U.S.

Let me illustrate. In March of 1990, I received my first pacemaker for the condition of heart block. At that time, Medtronic had developed a pacemaker that had significantly increased diagnostic and therapeutic options over earlier models which would produce important clinical benefits to me, both in the quality of the therapy, but also in terms of cost effectiveness.

But although this model was available to patients in Europe, it was not yet cleared for approval in the U.S. So American patients such as myself have a choice of either going to Europe to get the state-of-the-art device or to stay in the United States, as I did, and receive a device which is one or two generations behind that which is available to patients outside of the U.S.

In the five years since my first implant, Medtronic has made significant advances in pacemaker technology. Earlier this year, I received a new pacemaker that incorporates important new therapeutic benefits, but, again, this model is a generation behind that available to patients in Europe. Europeans are receiving a device containing an advanced battery that lasts 30 percent longer than the one in my pacemaker. So had I been able to receive that model, I would be able to put off replacement of my current device from seven, eight, or nine years out to ten, eleven, twelve years, with a significant improvement in cost effectiveness, as well as even peace of mind.

I want to stress that the cause of this dilemma is not the use of more stringent standards in the United States or an increased concern for patient safety. We use, as a company, the same set of data in seeking both European and U.S. approval. The delay comes from the process by which the data are reviewed.

The U.S. system was designed in 1976, when most of today's advanced medical devices were beyond the imagination of providers and researchers. And let me illustrate. This was the state-of-the-art device in 1976 when the device regs were promulgated. You can

see the size of the device. It would last about two and a half years, and it took five years to develop. Twenty years later, 1995, this is the state of the art. This device will last 10 to 12 years. It contains computerized technology in it that wasn't even available back in 1976, when this device was made. It will last 10 to 12 years, and it took 18 months to develop from start to commercialization in Europe.

That gives you a clear indication of which the speed of technology innovation is occurring, not only in the U.S., but outside of the U.S. Can you imagine taking your computerized car of today to your auto mechanic and expecting him or her to take a 1970s manual off the shelf to fine tune your car? And I submit that's the situation that we're faced with today.

It's simply time for us to re-engineer and update our regulatory approval process. Every other nation in the world has done it, and we need to do it to insure that the rapid pace of state-of-the-art technology innovation can occur in this country. Right now I submit it is moving offshore at a rapid pace.

The Europeans rejected our system of review in favor of a regulatory structure that I believe to be as rigorous as any in the world, but which is better able to keep pace with a rapid development of medical technology. The United States must do the same. What hangs in the balance is the health of patients like myself and you, if need be, and our leadership in developing innovative, high technology medical therapies has to occur in an environment, a regulatory environment, which fosters, rather than inhibits or hinders, innovation.

Thank you.

[The prepared statement of Mr. Chevalier follows:]

Peter A. Chevalier, Ph.D
Vice President and Chief Quality and Regulatory Officer
Medtronic, Inc.

Written Remarks

United States House of Representatives
Committee on Science
Subcommittee on Technology

Hearing on

"Medical Technology Development and Commercialization"

November 2, 1995

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Madam Chair and Members of the Committee, my name is Dr. Peter Chevalier and I am the Vice President and Chief Quality and Regulatory Officer for Medtronic, Inc. My company is the world leader in producing high technology implantable medical devices that improve the health of patients. We operate in over 120 countries, under almost every type of regulatory and health care system imaginable.

I am testifying here today not only in my capacity with Medtronic, but also as a patient. I suffer from heart block, a common condition diagnosed in over 160,000 new patients in the United States every year. Without proper treatment, usually provided by an implantable pacemaker, it severely limits the physical activity of those who suffer from it, decreasing the quality of life and often leading to early death. Ironically, although I am a Vice President of the world's leading pacemaker manufacturer, I am unable to get the best therapy for this condition. It is available to patients in Europe and other industrialized nations, but not to patients in the United States.

In March of 1990, I received my first pacemaker. At that time, Medtronic had developed a pacemaker that had significantly increased diagnostic and therapeutic options over earlier models, producing important benefits in both the quality of therapy and cost-effectiveness. But although this model was available to patients in Europe, it was not yet cleared for release in the United States. Therefore, American patients such as myself received pacemakers that were two full generations behind. In short, we did not receive the best medical treatment available.

In the five years since my first implant, Medtronic has made significant advances in pacemaker technology. Earlier this year, I received a new pacemaker that incorporates important new therapeutic benefits. But again, this new model is a generation behind that available to European patients. Europeans are receiving a device containing an advanced battery that lasts 30 percent longer than the one in my pacemaker. Had I been able to receive the same model, I would be able to put off replacement for 9 rather than 7 years, a substantial benefit in terms of cost and peace of mind.

I want to stress that the cause of this dilemma is not the use of more stringent standards in the United States or an increased concern for patient safety. We use the same set of data in seeking both European and U.S. approval. The delay comes from the process by which that data is reviewed.

The U.S. system was designed in 1976, when most of today's advanced medical devices were beyond the imagination of providers and researchers. Can you imagine using a mechanics manual from the 1970s to tune today's high performance, computerized cars? I believe we are experiencing such a situation in the medical device industry. It is simply time to update our system.

When some people think of FDA reform, they often will say that if only the FDA had a better attitude, or if only there was different leadership, or if only there were more resources, we

would have a better and more efficient agency. I am here to tell you that these areas don't tell the whole story of why the FDA is not keeping up with its responsibility.

Madam Chair, the Europeans rejected our system of review in favor of a regulatory structure I believe to be as rigorous as any in the world, but which is better able to keep pace with the rapid development of medical technology. The United States must do the same. What hangs in the balance is the health of patients in the U.S. and our leadership in developing innovative, high technology medical therapies.

Because other areas of the world, like the European Union, have reinvented their regulatory systems to foster innovation, the U.S. is suffering a steady depletion of its medical technology base that has for so long dominated the world market. This trend is evident in the movement of research, development and manufacturing to overseas locations. A recent survey conducted by the Gallup Organization revealed that forty percent of the medical electronics manufacturers surveyed had reduced employment in the U.S. and twenty-two percent had moved U.S. jobs overseas.

Medtronic is among those companies shifting R&D and manufacturing offshore. Fifteen of our last fifteen major new product lines or ventures have been produced and clinically tested first outside the United States. All fifteen of them will be available to patients overseas well before their introduction in this country. It is not uncommon for the gap between commercial availability of new therapies in Europe and the U.S. to exceed 3 years.

We simply cannot afford to continue to hinder technological advancement in this country or usher it overseas. The "brain drain" of medical technology R&D from the U.S. economy threatens to diminish the global leadership of the U.S. medical device industry, and its effects will be felt far down the road. High quality jobs are being lost. What's more, the intellectual infrastructure at U.S. academic medical centers has been weakened as leading edge clinical research is moved overseas. Finally, the availability U.S. venture capital for start-up innovations has been reduced and, as a consequence, the number of new submissions of high technology products to the FDA is declining. Stated simply, the environment in the United States is no longer conducive to technological innovation in the medical device field.

However, make no mistake about our philosophy: Medtronic and the medical device industry want and need an effective approval process and a well-run FDA. The greatest risk to our company would be the sale of an unsafe product, by us or our competitors. But a number of important changes must be made in the regulatory system that oversees medical device development and commercialization. These include moving the FDA away from the evaluation of medical outcomes, which is properly the role of the medical community, and keeping it focused on device safety and effectiveness; utilizing government-certified third parties for the performance of some FDA functions; adopting internationally recognized standards to provide clear criteria for evaluation;

imposing process management mechanisms to the timeliness of review; and redefining clinical testing requirements to reflect the nature of device evolution.

Over the years, the FDA's prescribed product approval process has been broadened from evaluation of the safety and efficacy of the device to the evaluation of the efficacy of the therapy. This broadened scope of studying medical outcomes was not a part of the original legislation, nor was it part of the legislative intent, and it has played a significant part in lengthening FDA review times and increasing product development costs. The Europeans recognize that evaluating the effectiveness of therapies is best left to physicians and payers. Our own academic medical community can and should fulfill this role, not the FDA.

In addition to limiting pre-market review of relative therapeutic outcomes, the European system uses private experts certified by the government, known as notified bodies, to grant efficient and comprehensive approvals for new devices. As a result, total approval time is a fraction of the time required here. The notified bodies are subject to strict competency requirements that are established by the European Union and administered by regulatory officials of the individual nations. The decisions of the notified bodies are reached through the application of well defined standards, designed by experts to be as stringent as any in the world. Through these competency requirements and standards, all interested parties--manufacturers, regulators and patients--have clear criteria by which to hold the notified bodies accountable. Additional assurances of safety are provided through a program of vigorous postmarket surveillance. European and other international regulators pride themselves on their efficiency and believe that patients receive a very high level of safety from their system.

While the establishment of a product approval system similar to Europe's may be an eventual solution to the current problems at the FDA, we must not allow our current system to grind to a halt while we move in that direction. To do so would have immediate devastating effects upon the domestic medical device industry that would be felt through many generations of products. That is why Medtronic, along with other manufacturers of advanced, life sustaining devices and the Health Industry Manufacturers Association, has developed a blueprint containing improvements that can and should be implemented this year to update the current FDA system.

First, we recommend that the evaluation criteria used by the FDA be made more transparent by recognizing international standards for manufacturing and design. Currently, the FDA has few well-defined standards. Manufacturers have little guidance to know in advance the criteria the agency will use, and patients, manufacturers and Congress have no clear measure by which to hold the agency accountable. International standards, already in existence and assembled by world-class bodies of medical and regulatory experts, can provide that guidance.

Second, our proposal would define guide-posts that the FDA must meet throughout the statutorily-mandated 180-day approval process. A key reason that venture capital is so scarce in the U.S. medical device industry is the total inability to forecast the amount of time that the FDA

will take to evaluate any individual product. By identifying set dates when the FDA must sit down with the manufacturer to work through approval issues, we believe our proposal will add certainty and inject a cooperative attitude that has unfortunately been lacking in the process.

Finally, we recommend that clarity and efficiency considerations be brought to the clinical design process, so that we are not unnecessarily involving patients in unwarranted clinical review. Currently, clinical trials for medical devices are predicated on the so-called "drug model," with strict randomization requirements. But this model does not consider the nature of medical devices, which develop incrementally through the introduction of small innovations to existing, well-established technologies. To ensure that patients are not needlessly harmed by being forced to wait through years of unwarranted clinical studies, the proposal would direct the FDA to accept retrospective clinical data on the safety and effectiveness of such next-generation products and use advisory panels of medical experts to determine when randomized trials are truly warranted.

In closing, I would like to mention three related reforms that are currently before the Congress. The first is the self-imposed trade barrier known as Section 801(e), which requires a domestic device manufacturer to secure FDA approval before a device not approved for use in the United States may be exported to a foreign country. No other nation subjects its industry to such a requirement. In a sophisticated world where advanced countries have their own public health regulatory bodies, this type of trade barrier forces companies like Medtronic, and the jobs they create, offshore. This is happening almost every day. I urge all Members of Congress to support legislation introduced by Representative Fred Upton and Senators Orrin Hatch and Judd Gregg to address this serious issue.

The second issue involves recent changes in the interpretation of Medicare coverage policies to deny reimbursement when health care providers participate in an FDA approved clinical trial, which is seriously threatening research on new medical technologies and the health of senior citizens in this country. This decision by Medicare denies seniors access to the most advanced medical technology and has virtually shutting down the clinical research at our leading academic medical centers. Fortunately, HCFA and the FDA have recently moved to reverse this ill-conceived policy, and legislation to codify the administrative proposal, introduced by Representative Bill Thomas, has been added to the reconciliation bill in the House. A bipartisan group of Senators, led by Senator Hatch, have introduced a companion measure.

Finally, the U.S. medical device industry is still facing a critical shortage of biomaterials necessary for the production of life-enhancing medical therapies. In its 1995 study of the competitiveness of the U.S. medical device industry, the Wilkerson Group found that 86 percent of implantable device manufacturers are currently having difficulty obtaining raw materials or expect to have difficulty within 2 years. In some cases, the ultimate result may be the removal of life saving devices from the market and an uncertain future for patients who rely on them. The biomaterials crisis is precisely the type of problem created by our litigation system that the

liability reform bills passed by the House and Senate were designed to address. I hope that Congress will take the final steps necessary to pass real product liability reform this year. In the alternative, it is vital that the Biomaterials Access Assurance provisions, developed and supported by a bipartisan group in both Houses, be separated and passed on their own. Continued delay in enacting legislation that makes vital materials and components available seriously threatens patient health and the innovation process that further improves medical technology. As patients and potential patients we all have a stake in this matter. Our lives may depend on it.

Developing effective and timely solutions for each of these problems will move us significantly toward reversing the decline of American leadership in medical technology. Our long term objective must be to establish an environment for innovation recognized around the world as the best place to develop new technology, and to provide life-saving devices to American patients on a timely basis. We must act promptly if we are to ensure the future of medical device development and the benefits that advancement will bring to patients.

Mr. GUTKNECHT. Thank you, Dr. Chevalier.

I'm going to go to the panel. Mr. Tanner, do you have some questions?

Mr. TANNER. Thank you, Mr. Chairman.

I want to thank this panel. I thought many of your comments were very constructive to this process, and I think, in large measure, put the issue in focus for not only this Committee, but for the House.

I'm told that one of the reasons, to talk about something Mr. Magazine said, one of the reasons that some of our manufacturers have moved overseas, among other things, they may have a financial incentive offered by one country or another, whether it be the Netherlands or some other place, but there was a law passed by Congress in the mid-eighties which made it very difficult to export products that had not received FDA approval. That law is in the process of being repealed; we think that's a step in the right direction, and hope that will give some relieve to the infrastructure of the law as it is today.

On the process question that our last witness talked about, to use a very poor analogy, but one that we all understand, I guess, the IRS, the—as I understand it, in Europe the regulatory agency would accept a summary of one's individual checks—in other words, a bank statement—as proof of what the study has consisted of, whereas is in this country, in most of our processes, we want each individual check to be reviewed. Is that a fair statement about the process, a fair analogy? To anybody?

Mr. CHEVALIER. No, I would disagree with that.

Mr. TANNER. Well, tell me—I'm asking; I need to know.

Mr. CHEVALIER. All right, so let me talk a little bit about the European system and contrast it to the system in the U.S. The system in Europe was established by the European Union. It is designed and administered by the ministries of health of each individual country, and Europeans set down strict standards of competencies for a notified body or a third party reviewer in order to qualify as a third party reviewer. This notified body itself is audited by the ministry of health in that country annually to make sure that it continues to meet those strict standards of competency and performance. There's no auditing going on in the U.S.

Now the notified bodies then utilize well-established international standards that have been designed by physicians, manufacturers, scientists, and so forth, to make sure that the proper questions are being asked when you look at either a system, a product, a design, whatever the case may be. The advantage is that they are very clear, but they are stringent. So, as a manufacturer, we know what's to be expected of us, and the regulatory body knows what to expect from the manufacturer.

Those standards are as stringent, and in many cases more stringent, than what we're faced with in the U.S. So this notion that we get by with a regulatory submission in Europe is just simply a myth. It's not true. The same data gets submitted to Europe that we submit to the FDA in the U.S., but we have to meet the strict standards that are in place and are recognized everywhere in the world. And if you look at these international standards, ISO 9000 for total quality, for example, they are all recognized by over 80

countries throughout the world. And so our products, whether they're being reviewed for safety or effectiveness, meet standards which are as stringent, in some cases more stringent, than what they are in the U.S.

Now there is one difference, and one important difference, and that is in Europe the notified body, driven by the European Commission, has said, "We will evaluate the safety and effectiveness of the device, but we will specifically exclude consideration of the outcomes of that therapy. That is best left to the medical community, the payor community, and the patients, frankly."

So the notified bodies in Europe, operating under the strict standards, say, "We're going to look to see, does this device do what the manufacturer says it does? Does it meet all of the international standards that are in place? And is it safe and is it effective?" The decision as to whether that product is the right product for me as a patient is best left to the doctor and me to decide what we need to do, and the payor, but not to the notified body; whereas, in the U.S., consideration of the medical benefit and the outcome has voluntarily been pulled within the purview of the FDA.

Now beyond that, remember that in Europe the European system also requires very strict post-market surveillance. They call it "vigilance" in Europe. So once a product is introduced into the marketplace, the manufacturers and users of the product must report any issues or problems they have with that product, and that system is in place. And so if there are problems, we know right away if there are problems associated with it.

But the difference is, frankly, that this product, if I said today, "This product is ready for release, if Medtronic is comfortable with releasing this product, I could take it to Europe and to the FDA, and in roughly three months have a notified body which consists of multiple experts in all the technologies relevant to evaluating this device in-house, that review process would be completed within three months. And if there is a need for additional data or information, it's done in an interactive and a cooperative manner. If I take this to the FDA, using FDA's numbers today, it could be up to three years before this same product is approved and released in the U.S.

Is the safety of this device any greater because of that additional review? The answer is clearly no, because the standards that we use in Europe, or that the Europeans use, are as strict, if not stricter than what we see in the U.S.

Mr. TANNER. Does anybody else have a comment on—Dr. Brinker?

Dr. BRINKER. I'd just make a few comments. First of all, the European methodology has evolved recently, evolved from a more chaotic, laissez faire attitude to a stricter attitude, as described by Dr. Chevalier. It's still not as strict as our attitude, but it's much stricter than what it had been, No. 1.

No. 2, there is a fine and important difference between what might be considered effective. I would view that if a device—for instance, a pacemaker can be shown to work for two days or five days or a month, and shown to be effective, and that it delivers an electrical stimulus to the heart, that might be a definition of effec-

tiveness, but if it stopped at six months or at eight months, that would be a noneffective device.

And if I have another device which cleans out the coronary arteries, and if you take a picture of the coronary arteries, it shows a tight blockage; you use this device; it cleans it out. That would be an effective device. But if every one of those patients developed a reocclusion of the artery within three weeks, the clinical benefit of this device would be essentially zero. And that's some of the concerns that the FDA has. Outcomes are important in this society.

I think that we have—we have experience with a pacemaker not made by Medtronic which was undergoing clinical trials in the United States. At the end of the clinical trial, only at the end, just before it was ready for approval, we found that there was a problem with the connector block of the pacemaker, which shorted out and led to unpredictable failure of the device. In the United States this problem was limited to those people receiving the device in a controlled investigational study, whereas around the rest of the world many pacemakers were put in in a relatively unregulated fashion, and more people were at risk of reoperation or the potential of sudden death.

I think we have to have concerns about devices. Again, I think there's reason to think that the process can be improved, and one improvement is better communication. I would also like to tell the Committee that, in my experience, the CDRH has moved to increase communication, to change from an onerous regulator to, hopefully, one of a facilitator, allowing good, effective devices that are relatively safe in regard to what they attempt to accomplish to be approved with as little opposition as possible. They are greasing the skids, I think, and this has been demonstrated, but they also have a policy of trying to identify true impact technology, technology that really makes a difference as opposed to "me, too" technology, competitive devices. And to put this new, innovative technology on a fast track, I think all of that speaks for the likelihood, and hopefully the eventuality, of evolution within the agency itself.

Mr. CHEVALIER. Could I just respond to one thing? I'd like to disagree with my esteemed colleague here on two minor points, and not so minor.

One is the example of the connector block thing is a reflection of a zero-risk mentality. Now, clearly, that problem should have been caught within the manufacturer's scheme, but you could test a device from now until kingdom come to convince yourself that that product is going to be safe and never going to fail, and you may accomplish that objective, but the question is, how many patients like myself in the meantime have been denied the opportunity to have that therapy? That's a concern.

Another concern is the outcomes issue that Dr. Brinker talks about. I think you could pick your examples here, but to highlight the example that I think is important is, if you look at a device—and I'll just use a pacemaker again for an example—this device senses my physical activity. This happens to be the device I have. This senses my physical activity. So if I get up and exercise, it looks at my heart and says, "Is your heart rate increasing fast enough in proportion to your level of activity," and if it doesn't, it

increases my heart rate, which is what all of yours do when you're exercising.

Now we have a second device that's in clinical right now that has two sensors, which measures the oxygen content of my blood as well as my activity level. I'm getting a little closer to what God intended for my heart here, but we're not all the way there yet. But we could bring that to the FDA, but the FDA then asks, how can you demonstrate to us that long term that device is better for patients than this device which only has one sensor. And I submit that if you can demonstrate that that device is safe and does result in appropriate increase in heart rate, that the physician should be able to look at the patient and decide what's best for that patient, and that the long-term experience of the physician and patient should determine that. That should not be an issue that needs to be resolved with long-term, randomized clinical trials before that device reaches the marketplace, because I can assure you it will be in the marketplace outside the U.S. years before it will be available inside the U.S.

Mr. TANNER. Well, this is interesting. I know the chairman might call me on my time here.

I think what we, as the Congress are trying to do is have a balanced public policy, and in some of these individual and specific devices it will necessarily be a matter of give-and-take among people who know what they're talking about, the physicians and technical people who can judge that. What we're trying to get at, I think, is how we make the FDA responsive in a balanced manner, both to the safety and soundness and efficiency of the product that's offered to the American people, on the one hand, but also to use whatever efficiencies there are in the agency itself to not hinder, inhibit, or in any way, by process alone, hold up what otherwise what ought to be available to people. And you're trying to strike that balance, and we're asking for your help in how you all think we ought to do that.

Mr. HOLVECK. I think you bring a good opportunity maybe to take this conversation a little bit on a broader sense. I think that it would be incorrect, if you would, to have it, FDA, judged on the merits of the heart pacemaker or any interventional in cardiology alone, because I think our industry is made up of many companies large and small and many different types of devices large and small. I think the elements in terms of regulatory that frustrates our industry is, as was mentioned, inconsistency or the time it takes to get decisions. Ours is a regulated industry. We have to register when we start a trial. We have to register when we file a product. We have to register when we make a change in our manufacturing. We have to register when we make a change in our product. We have to register when we want to export it. All of those are elements in the process. So it's not just taking technology and science; it's having to go back and forth within a regulated agency in order to move forward.

Now you say, is that an impediment to our business? Time is money; we all know that. We also know that if there is an opportunity to move forward in these processes, if it's a one-step-by-one-step or if it's a regulated agency in Europe where you're allowed to go forward and do a check at the end, it allows you to move in

a more fast fashion. I don't know that it's any better if at the end you're checking all the elements.

So I think our process in terms of this ongoing back and forth in the time—it's not time specific. We put filings in; we may get them back in 30 days; we may get them back in three months. What do we do in the meantime? There's a very strict example of where our regulated elements could be enhanced.

The adherence to a time clock, I just want to——

Mr. TANNER. This is across the board?

Mr. HOLVECK. Pardon me?

Mr. TANNER. This is across the board, this——

Mr. GUTKNECHT. Mr. Pops——

Mr. TANNER. This is probably on my time.

Mr. GUTKNECHT. Well, we're going to be real generous with the time. This is a very important panel and these are great questions, but I think Mr. Pops had a response he wanted to——

Mr. POPS. Well, thanks. Thanks very much.

I wanted to make sure we make the distinction between devices and drugs, and also within drugs, not all drugs are created equal, and that many drugs that are approved by the FDA are incremental or additive products to a class of drugs that already exists. But where most of the companies like ours are, "ours" meaning the biotechnology industry, almost by definition, we're working on drugs to address unmet clinical needs. To the extent that we find ourselves competing against Merck or J&J or Roche or Ciba Gigy, we've probably picked the wrong target. So, as a result, we tend to go after some of the diseases that are more difficult to treat, where there are no therapies; for example, brain tumor, like what my company is working on; Lou Gehrig's Disease, a new drug has been developed for that; certain types of cancer and certain types of degenerative diseases of the brain.

These are hard scientific issues, and a result, the development timelines can be quite protracted. The scientific challenge is very, very high. The cost is very, very high. What we've found in our experience—and I think this is true for many biotechnology companies—is that the attitude in Europe toward unmet clinical needs, new drugs to fulfil unmet clinical needs, is a little bit more forgiving, a little bit more generous; i.e., it's driven by the physician's logic that we need new drugs to treat these types of diseases because these patients are dying or they're experiencing very poor quality of life. That does not imply that the standards of safety and efficacy are any lower, but I think it implies rate and commitment to getting these new types of drugs onto the market.

And for the biotech industry, in particular, which is the subset of what this panel represents, that biotechnology industry, the fact that the U.S. is developing these types of drugs, is a tremendous national asset. We're the only country in the world that develops these types of drugs, because of things like the orphan drug legislation and giving us incentives to go after these drugs, and the ability to get them approved on a timely basis in Europe, and eventually in the U.S.—this is why the biotechnology industry exists. So I think it's important to draw that distinction as we go forward.

Mr. GUTKNECHT. Mr. Magazine?

Mr. MAGAZINE. A lot of the discussion thus far has been with regard to what we call PMA devices, pre-market approval. The law says—and those are the breakthrough devices like the new generation of pacemaker, and so on. The law says that they must be cleared by FDA within 180 days; that's the law. Right now, FDA is averaging over 700 days, that's an average of over 700 days.

These devices are critically important. But last year, just to give you a comparison, there were, I believe, 42 PMA applications to FDA, 42. We have another whole set of devices that do not, by and large, go through clinical trials. They are called 510(k)s. These are fairly simple. These are incremental improvements in the device. The nature of device innovation is incremental improvement, working with clinicians and doctors and hospitals to improve a device for the patient.

Last year there were about 5,000 510(k)s that were filed with FDA. The law says those devices should be approved in 90 days or cleared in 90 days. They're now averaging a total elapse time of about 170 days. That's an average.

I grant you that there is some improvement at FDA. We have seen the backlog come down quite a bit. We've seen some improvement in the time, but the fact of the matter is that, even when we talk about total elapse time of 90 days or 180 days for PMA, we're talking about the time that FDA is involved in the process. But the total time from beginning of innovation to marketing a product is far more than those averages, because of the requirements that a company is heaping on the—that FDA is heaping on the companies that they have to do before they even come to FDA to start that process. Some of those requirements we believe do not meet either the letter or the spirit of the 1976 Safe Medical Device Act or the 1980 amendments, such as the definition of efficacy.

So I wanted to point out to the Committee that we are spending a lot of time on very important devices that are breakthrough devices, that require clinical trials, and so on, but there's a huge pool out there of devices that can save and enhance lives that are not being approved in a timely fashion, and for which more and more requirements are being heaped upon them.

Mr. GUTKNECHT. I'm going to now turn to Representative Seastrand. Do you have any questions?

Ms. SEASTRAND. Yes. Thank you, gentlemen.

I became aware of problems with the FDA in 1970, and in 1983 my husband was told he had cancer. Nine surgeries later, seven and a half years later, looking to doctors in China, Mexico, it really took us on a great adventure, and I think that, thank you, that you're all there trying to help people such as my husband. Unfortunately, he died, but I look to other patients, as you say that you have devices there that are out there to help people such my husband, and I become very frustrated, not only to the patients, but also to know that the brain drain, as was stated, moving to other places in the world.

I look to my central coast of California, Santa Barbara and San Luis Obispo. We're losing people. We're losing jobs. And here we have technologies that can be useful to those patients as well as to the economy.

It was stated that we need to review the system, and, obviously, we need to look to what Europe is doing and to see how we can implement that, as far as I'm concerned. But tell me this: nothing was brought up about tax incentives compared to jointly funded government/industry programs in terms of stimulating the medical technology innovation, and I'd like to hear from the gentlemen. I know Mr. Chevalier is—has companies in Santa Barbara, and I welcome you. I would like to hear from you, your opinions in this area.

Mr. CHEVALIER. You're specifically asking regarding tax incentives and moving to Europe?

Ms. SEASTRAND. Yes.

Mr. CHEVALIER. Tax is not my area. So I'll tell you, I mean, clearly, Europeans want to attract industry. They have a very highly-trained technology base of folks, a labor pool to draw from. But I specifically can't give you tax incentive information. If you'd like, I'll be more than happy to provide it to you, but personally it's not something that I deal with on a regular basis, and so I'd rather not just talk about it off the cuff. But I can give you that information, if you'd like.

Mr. POPS. Maybe I can offer something on that. Particularly for the small companies, as I said in my opening statement, anything that relates to capital formation will have a huge positive impact on the creation and substance of new companies, and really it's the new companies that are the lifeblood and the driving force of some of the newer innovations that are current.

So one of the things that we think would have a real positive effect on that would be some type of capital gains tax legislation, such as some of the proposals that are being considered right now. The ability to unlock some of these—the numbers vary of the number of trillions of dollars of frozen capital gains there are in the system, but to the extent that these could be unlocked and directed in some way toward industries or technologies that are deemed to be in the best interest of the Nation, I think you'd see a massive effect on the flow of capital into these types of companies. And with capital, we make progress, and you can almost plot progress as a function of capital in these types of industries.

Many of these diseases and many of these medical problems will succumb to directed, intense research for an extended period of time. It also relates to what's happening here in Washington with respect to the National Institutes of Health and NIH funding. A lot of the technology that ends up in companies and eventually ends up in front of the FDA for consideration for the treatment of patients originated at some core level through government funding at the NIH. So if we turn off the spigot back 10 years earlier in the process, where the basic discoveries are occurring, we're going to dramatically impact our access to new medical therapies five, six, seven, ten years from now.

Mr. MAGAZINE. Mr. Chairman, first a disclaimer: our board very specifically does not want us involved in tax issues, but let me just say that, from previous experience, my personal view is that a look at the R&D tax credit, which is—the issue is whether or not to make it permanent or increase or improve it, prove it, rather, year

by year, will give some stability to all industries that are research-intensive.

Secondly, in Europe I think it should be pointed out that there really is a nurturing of industries in Europe. It's a nurturing that has to do with making sure they feel at home; they want to be there; that they can operate. It doesn't mean weak regulatory processes. We have no reason to believe that it's easier in Europe than it is here, but tax policy, a range of issues, can have a major positive impact on where an industry settles.

There's competition right now. There's worldwide competition for our device industry. I've actually seen letters from other countries to medical device companies citing the Wilkerson study, talking about the problems in this country, and trying to lure them to those countries. Tax policy is one of the issues that they cite.

Mr. GUTKNECHT. Representative Johnson?

Ms. EDDIE BERNICE JOHNSON OF TEXAS. Thank you, Mr. Chairman, and thank you for conducting this hearing, and thanks to all the witnesses who are here. I apologize for being a little late this morning. I had a prior meeting.

I have listened with interest to the panelists, and I am very, very interested in attempting to make a win/win situation here from a patient standpoint, as well as products that are produced for patients' services. And I have to be aware that the FDA approval process is troubling. I'm not so certain, however, that it is troubling because people just want a job to be trouble. I think it's troubling because of demands on this America from people to know that they are getting something of quality.

And what I'm really interested in trying to ascertain is, how can we—what do you suggest that can be a part of FDA's reform that would both protect the public, protect the liability of the public, and the liability of the companies, as well as speed up the process, because in the business that you're in with technology and various devices that increase the quality and length of life, the state of the art changes fairly rapidly, and perhaps not as rapidly in medical devices as in other technologies, but it will speed up because the speed of things are moving because of our technology research.

And I—in my district is a well-known, large medical center and teaching hospital, and we are very proud of the fact that we have four Nobel Prize winners there in various types of research. And there's real concern about the cuts in Medicare affecting the patient end of that support. We know that, without research, we are not going to arrive at the most cost-effective approaches that increases our quality of life as we begin to live—as we have begun to live longer.

So I'd like to get perhaps, why is it that R&D is moved, is being moved out of the country, a larger percentage than what we'd like? What is it that's different about the other processes, and where does—in the process of that, we're also asking for a lengthening of liability time. The whole reason I think that many of the rules came into being is to protect the public, and I don't want to ignore that fact.

So I'd like to—you can tell that I'm really rumbling in my mind as to where do we go from here. How can we affect change and protect people and protect our companies that's doing the research and

our medical schools and teaching hospitals? Now anybody who wants to give me a quick answer to that rambling question, I take it—

Mr. HOLVECK. Well, let me wade into it with an interesting approach, because I don't know that we can just lay it all on the doorstep of the agency to do all of what you ask. I think what we're talking about in one step is the product, the product design, and in some cases the effectiveness of it. I think we heard that engineering has a level of capacity in insuring that. I think we've also heard there's such quality standards as ISO 9000 and USGMP, but I think one of the elements—it always gets down to the bottom line, the user, and I think the health care delivery system has to play a role in what you ask, meaning that, when you go to a hospital, you are subjected to a level of treatment. Do you know that that treatment is the best treatment or the outcome of that treatment? Where is the database to support?

I think as we move now into more managed care within the health care environment, that's going to be more of an increasing element in assuring that you are getting the quality and you are getting the outcomes that you want. I think as managed care becomes more sophisticated, much the way any industry has a warranty, if you would, or a guarantee, you are going to start to see the marketing practices of health care delivery systems saying that an appendectomy or a cardiac intervention has a long-lasting element of so many average, the repeats that come back. Those types of elements I think will go a long way in getting what I think you're asking for: is the population getting quality-effective care?

So it's not always just on the doorstep of the products themselves; it's how those products are delivered to the populace and how we measure the outcome once they're delivered. And right now our system doesn't have the measurement entirely. Hospitals deliver their care, and when you're discharged, you may come back in next week, and the cycle starts up again.

So the measurement and the outcome is still an information system that has to evolve, and I think it's a part of what you ask. It's not always just the product design, albeit it has to be critical, but it's also how it's delivered and then tracking that delivery across a wide population, another view.

Ms. EDDIE BERNICE JOHNSON OF TEXAS. Thank you.

Mr. FINKELSTEIN. I'd like to just add one comment to that. I think that another issue is the ability, or lack of ability, to communicate between manufacturers, FDA, patients, physicians. We find ourselves in a situation where our product has cleared a specific field of use, as I said earlier, urology and oncology; yet, we cannot communicate with physicians about the state of the art of its use in those fields because it always alludes to specific diseases, and the FDA has told us that we can never talk about its use in a specific disease; for example, its use for cryosurgical ablation for prostate cancer, even though it's approved in the field of urology and oncology. So we can't offer physicians or patients or anybody peer reviewed medical journals, the dozens of abstracts and journals, and all the information that would be necessary to make an informed decision as to whether or not our product is appropriate for that physician and that patient to use. That creates confusion. It

creates oftentimes an issue where a patient does not receive the most informed or the best medical care for his or her condition.

So I think the issue of communication, and how it's—how promotion of products is, generally cleared products is dealt with by the agency leaves a lot to be desired in terms of its improvement, and I'm talking about communication for legally-marketed products, not for off-label use, which is a whole separate issue.

Ms. EDDIE BERNICE JOHNSON OF TEXAS. Thank you.

Dr. BRINKER. I think it's important not to lose some perspective because some of the comments that are addressing particular issues here tend to be somewhat discerning. The fact of the matter is that American medicine gives the greatest and highest level of technology to the greatest portion of its population on a continuing basis than any other country in the world.

I've had people, colleagues in other countries, that had to stop doing angioplasty because their annual budget for these procedures went off. So that the wait time for procedures is elongated, and patients that don't have enough money to go out of the public system don't get procedures.

I think that we're doing a good job overall in delivering health care. I agree that we need more outcome research; we need to change; we are changing to a managed care environment. We need to reorganize the way we deliver health care. But the specific issue about regulation should be removed a little bit from the thought that we're not doing the best for our overall greater society in this country, because I don't think that's clear.

As far as the issue of regulation, you're hearing, again, mostly one side of the story. The FDA is not here to debate particular issues that might portend to any one of the situations, and I think that that's unfortunate.

Also, the FDA has by law certain responsibilities that make its task more problematic. It has to look at labeling, for instance, and prevent misbranding, and the Medtronic dual sensor pacemaker is an example of the quandary. In general, the FDA doesn't ask for any device to be superior to another device unless there is a labeling claim that there is superiority. So that in any device that I've ever looked at no company has ever had to show that it was better in their device than any other device on the market. But if a company wants to claim that it's better, or if there is an implied claim such as two sensors are better than one sensor, then the FDA is in a quandary because it can't allow that claim to be made unless there's legitimate evidence for that claim.

So I think that some of the responsibilities of the FDA are by law and can be alleviated by law, if that's the problem. The other more general problems I think have been hit at. There's a lack of communication; there's a lack of the feeling that there's a joint effort to get new technology to people as quickly as possible, and I think that some of this—well, this can only be addressed, I feel, appropriately by a greater degree of communication, and perhaps some sort of blue ribbon panel to sit down with both the FDA and the medical industry, as well as consumers and the medical health care delivery people in general, to arrive at meaningful ways to get new devices into the market at gradually expanding levels at an earlier

time. I think all this can be done, and can be done quite easily, if we get all the sides together to agree to that.

Mr. GUTKNECHT. Mr. Pops?

Ms. EDDIE BERNICE JOHNSON OF TEXAS. Thank you.

Mr. POPS. There's an important attitude shift that has to occur, and that is right now I think this moniker of protecting the public health is focused disproportionately on making sure that a product that could possibly hurt some fraction of the population doesn't get into the population, without as much weight being placed on the number of patients who are being hurt by its not being on the market while these deliberations are ongoing.

I think if you talk to people who spend a lot of time interacting with FDA staff, you find that at the highest levels of the organization there's a real keen understanding of this, but at the more working level there's a lot of concern about approving drugs or devices that potentially could do harm, and that's a worthy concern, but we have to also factor in the other equation: what happens to the patients who aren't getting these therapies? And some of the figures are in the testimony that's been provided to you, but literally this applies to thousands and thousands of patients who are not able to access new therapies.

Specifically, you should look at both BIO. The biotechnology industry organization and HIMA have provided specific FDA advise or reform concepts, and there will be legislation, hopefully, that will be introduced on this matter. And I would encourage you to hold hearings on that, talk about that with a broad audience, with representatives from FDA, because you'll find that FDA and industry aren't so far apart on this; it really relates to how it actually gets enacted in the way that people do business every day, and sponsorship and co-sponsorship of that type of legislation would really be of real benefit to all of us, I think.

Ms. EDDIE BERNICE JOHNSON OF TEXAS. Thank you. Thank you, Mr. Chairman.

Mr. Chairman, before I relinquish, I'd like to request unanimous consent to submit for the record my opening statement, as well as correspondence I received from the medical school in my district.

Mr. GUTKNECHT. Without objection.

[The prepared statement and attachment of Ms. Johnson follows:]

PREPARED STATEMENT OF EDDIE BERNICE JOHNSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Madam Chairwoman.

I am pleased to welcome our two panels this morning, and I look forward to their responses to our questions.

Throughout the long history of the FDA, political pressures have often caused the Agency to become a favorite target for advocates of regulatory reform. It appears that in this session of Congress that will again be the case, given the Speaker's recent comments criticizing the Agency.

From a medical point of view, I am concerned that with the proposed cuts in Medicare, which passed the House last week as part of budget reconciliation, important clinical trials of drugs and medical devices will be severely jeopardized.

In fact, Madam Chairwoman, I have with me today a letter from the University of Texas Southwestern Medical Center at Dallas, which I would ask unanimous consent to enter into the record at this point.

In the letter, which I would ask the witnesses to comment upon at the appropriate time, the Executive Vice President for Clinical Affairs, Dr. Willis Maddrey,

notes that academic health centers are heavily dependent on Medicare funds to develop and test devices to provide a full range of advanced diagnostic and therapeutic procedures. The doctor concludes by stating that the academic center needs the support provided by Medicare in order to fulfill its mission.

Medicare obviously provides a crucial portion of the support needed for research and development generally and for teaching and research hospitals. With this support possibly being eroded, I hope the panels can give us their opinion as to future funding sources for this type of technological development activity.

SOUTHWESTERN
THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER AT DALLAS
WILLIS C. MADDREY, M.D., M.A.C.P.,
EXECUTIVE VICE PRESIDENT FOR CLINICAL AFFAIRS
October 30, 1995.

The Honorable Eddie Bernice Johnson,
U.S. House of Representatives,
1721 Longworth HOB,
Washington, DC 20515

DEAR CONGRESSWOMAN JOHNSON: Thank you for the opportunity to comment upon the impact Medicare cuts will have on medical centers and teaching hospitals. Teaching hospitals are especially vulnerable in the clinical trials and new medical devices fields.

A key mission of the academic health center is to create new knowledge and apply this knowledge in appropriate clinical trials. The availability of experienced faculty to translate research advances into new therapies and new medical devices for clinical care is necessary to direct and interpret these efforts. The academic health center is heavily dependent on Medicare funds to develop and test devices to provide a full range of advanced diagnostic and therapeutic procedures.

Please let us know if we can provide additional information. We need the support currently provided by Medicare in order to continue to fulfill our missions.

Sincerely,

WILLIS C. MADDREY, M.D.

Mr. GUTKNECHT. The bells that you heard going off here a few minutes ago are—we're being called to the floor for a vote. I think what we'll do is we'll recess the Committee or the Subcommittee until about 11 o'clock, and unless there are a series of votes, we should be back here at about 11:00. So, until then, the Committee stands in recess.

[Recess.]

Mr. GUTKNECHT. If we could try to bring the Subcommittee back to order—Representative Johnson, did you have any other questions? Otherwise, I'll turn to Representative Calvert.

Ms. EDDIE BERNICE JOHNSON OF TEXAS. No.

Mr. GUTKNECHT. Representative Calvert?

Mr. CALVERT. Thank you, Mr. Chairman. I apologize for being unable to be here earlier today and missing the opening statements of our witnesses. I would have found them very interesting, but I find the subject matter that we're having this hearing on extremely important to the American public, and I wanted to come and at least ask a couple of questions.

I think many Americans today would be surprised—living in the United States, we obviously believe that we have access to the best of everything, the best food, the best health products, the best quality of life. But I think people would be surprised to hear that Europeans have first access to the newest and most innovative medical technologies.

It seems to be the key findings of a study referred to as the Wilkerson study, which I've looked at. If that's the case, and I'd

like to point this question to Mr. Magazine, what is the average delay between introducing new products here in the United States and in Europe? What's the comparison, Mr. Wilkerson? "Mr. Magazine," I should say.

Mr. MAGAZINE. The study, Congressman, the study shows very clearly that the delays are ranging from an average of one to three years with about 17 percent—now this is based upon a survey of—the largest survey of manufacturers ever accomplished. Seventeen percent of the respondents indicated that the delay for them is longer than three years, and 7 percent of the respondents indicated that they were not—they would not be introducing products at all in the United States anymore. There's definitely a tendency to move to Europe, to get on the market in Europe, while waiting out the regulatory process here in the United States.

That one-to-three-year average delay translates—and the Wilkerson study has a methodology that goes into this—translates into lost lives, lost opportunity, lower productivity, a range of issues that they go into in some depth, but the average is one to three years.

Mr. CALVERT. So not only does our mortality rate rise because of these delays, according to the Wilkerson study, many deaths that could be attributed to these types of delays, but not only that, we're losing a major industry to Europe and other places in the world because they're unable to operate here in the United States effectively; is that—that would be your conclusion?

Mr. MAGAZINE. That's absolutely correct. If I could take just a minute, perhaps I could cite a couple of the more salient statistics that came out of this survey.

More than 50 percent of manufacturers and 87 percent—87 percent—of development-stage companies—those are companies that are being created, forming their first—doing their first clinicals or manufacturing their first products—are doing their clinical trials overseas. Sixty-six percent of the manufacturers and 84 percent of the development-stage companies cited the unpredictability of the review process in the United States. Now that's a change.

We at HIMA have done periodic surveys over the years, and we've found for quite some time that companies were moving overseas for a variety of reasons, in some cases lower wage rates, in some cases—in many cases, trying to get closer to their customers, and so on and so forth, and we encourage that. We think those are good reasons to be overseas.

But now we're finding that they're moving overseas for the wrong reasons, not just to be close to the customer or close to other markets, but because they can't get their products to market in the United States. And that, that situation, has definitely worsened in the last 24 months.

Once—and I mentioned, those statistics I gave you were with regard to clinical trials. Once clinical trials are moved offshore, companies find that, to be most effective, research and development must be relocated to be close to clinical trials. Forty-six percent of manufacturers and 55 percent of development-stage companies are increasing their research and development activities in Europe. And I think what's critical here is not just that they're moving to Europe, but they're probably not coming back. Once they go to Eu-

rope and have that scientific and technological infrastructure, changing the regulations, changing the behavior, the philosophy of FDA is not going to cause them to necessarily turn around and come back. And so we've got this drain of talent that's going to Europe that, in all likelihood, is going to stay there.

What's critical is that the situation be changed, so that we stem the tide, so that we don't have this continued outflow. The ultimate—clearly, this affects the industry, the economics of the industry, but the most important part of all of this is that patients are not getting access to the most advanced medical technologies.

As Mr. Chevalier mentioned earlier, what we're finding is that patients in the United States are getting second, third, fourth generation products, while patients in Europe are getting first generation products manufactured by American companies, and that's a disgrace.

Mr. CALVERT. But I agree with you, it is a disgrace. We've seen that we're uprooting a major industry and moving it offshore, and, hopefully, this is the first of many meetings where we can resolve this issue.

And I thank you for the time, Mr. Chairman.

Mr. GUTKNECHT. Thank you.

Representative Lofgren?

Ms. LOFGREN. I wonder if I could yield to Ms. McCarthy, who has a conflict, and follow her?

Mr. GUTKNECHT. Absolutely. Representative McCarthy?

Ms. MCCARTHY. Thank you, Mr. Chairman, and I really do appreciate the opportunity to participate in this hearing this morning. Clearly, the statutory language for FDA that was drafted in the early 1900s needs to be revisited and updated by the Congress, particularly those done prior to the 1940s.

I wanted to ask Mr. Holveck and Mr. Brinker, and anyone else on the panel who wishes to comment on that, to do so, and to also discuss with us the off-label usage and how we in the Congress and the FDA might make that more current, because the restrictions I know that are in place don't allow companies to disseminate information to doctors, and this has certainly a potential down side. I know we in the Congress are concerned about the patient, as is the FDA, but—because that third party usage may not be scientifically tested. But, please, if you would comment on off-label use for this Committee, Subcommittee, I would most appreciate it.

Mr. HOLVECK. Well, you asked two questions, and let me—let me first address the statute issue, which I think is an issue that does go unnoticed. In fact, one of the issues that Centocor is particularly trying to get a statute changed in is that one of this Committee's Members talks about the pacemaker, and people can understand that, and we're talking about a test kit that's in the same class. Now is that an FDA problem or is that a statute? It's a statute issue, and the statute really has to be changed. What does it take to get a statute changed? Two to eight years.

Okay, whose fault is that? Well, I think in some cases you could say it's a joint responsibility, in the sense of what it takes to get statutes changed. It's very quick to write them; it's hard to get them replaced.

I think the agency is very supportive of changing the statute, but, again, they're frustrated, too. So I think that's—I just want to put that forward.

You then bring forward with your next question about off-label use. Off-label use has a negative connotation. It sounds like that one is trying to circumvent the regulatory claim in which it's studied under. I think there—that is not the intent. I think there is—as any product goes through its life cycle, gets evolved.

I think we also heard here that in Europe there are many products that are used. I think that there could be a greater "recognization" of products, their use in Europe, the practice of medicine. The practice of medicine today is not that different from Europe in the U.S.

There could be a greater recognition of the practice of medicine. Products that are in Europe or the use of products that may be different in terms of the claim, but undeniably used, and there's experience; there's medical history that has been peer reviewed—I think could speed along the broadening of claims, rather than have to reinvent the wheel.

So when we speak of generations of products, where we have an early generation here versus a multiple generation, some of that is just the fact that we do not want to recognize work that has been done in Europe, for whatever reason, and I don't think that's fair. I think that their science is good. I think their patients, their practice of medicine, their ability to track and historically document use takes a lot of the risk out.

There is a way of looking at off-label use. Off-label use in many cases is just an evolution. It's published; it's peer reviewed. I think if there is enough data to support that use over time, it can be incorporated and broaden the claim without a lengthy whole other study, which costs industry time, and I think also prevents the public from seeing that practice of medicine evolve, which is normal with any technology. So that's a view.

Ms. MCCARTHY. Thank you.

Dr. Brinker?

Dr. BRINKER. Yes, thank you. I'd like to address the off-label use question. It's sort of a pet peeve of mine, especially in the cardiology field for a lot of devices, and this is mostly a function of devices rather than medical therapy evolve and are used for other things.

I think there are methodologies for bringing off-label uses under a labeled format. It's expensive, though, and very often the industry doesn't want to foot the bill for that. What is necessary, I think, is a mechanism, and there does exist a mechanism, but I think it should be facilitated, in which good study, scientific valid study—and I don't necessarily think that every article that appears in a peer review journal is adequate to justify an extension of labeling, because most of these extensions of labeling involve an establishment of a new indication which has very wide marketing implications. And I think that you can't expect a less rigorous examination for this new indication than you would for the original indication.

So my feeling is that, if the sponsor doesn't want to undertake a formal study to validate off-labeling use, then it could be investigator-or physician-initiated, and that there should be a mecha-

nism—and there is a mechanism, if it's so sought out—for the individual physician or group of physicians to petition for an IDE to evaluate the off-label use of a device, to validate it, and if it is validated, to have that, with the sponsor's approval, be integrated into the labeling, so that it could be done appropriately.

One of the problems with off-label uses, there's no accountability. There's one doctor at X that says, "I've had great results doing this," and then a lot of doctors hear him and say, "Well, he can't be wrong. I'm going to do it." And their results are poor. Devices get lost in the vascular system. Catastrophes occur. Deaths occur, and they're never reported. It's device-related phenomenon. They're never even registered. Devices aren't even registered in these patients often, not necessarily for large devices like pacemakers, but for devices such as biliary stents that get lost in the circulation when they're tried to be placed in a vein graft.

And I think that the best thing that can be done is for valid study to be done to document the use of these things, for physicians to then be educated appropriately on how to use them, and for a surveillance mechanism that you, Congress, have initiated through the Safe Medical Device Act to be responsible to help us track these things and to bring it into acceptable practice.

Ms. MCCARTHY. Thank you, Mr. Chairman, and thank you, Ms. Lofgren.

Mr. GUTKNECHT. Well, I think Mr. Magazine and Mr. Pops and Mr. Chevalier would like to respond as well, if that's all right. Mr. Magazine?

Mr. MAGAZINE. Just a quick comment: it seems to me there's an important principle here, and that is that the Congress never intended for FDA to be the arbiter of medical practice. Physicians need to have flexibility. That's what has made American health care the best in the world, is the fact that physicians have a direct relationship to their patients with nobody getting in between.

If you looked—the gentleman mentioned doing valid studies. Even if you did valid studies, they'd never get through the FDA. There are so many potential uses of these devices that FDA could never review the studies and approve uses in a timely fashion.

A certain amount of trust seems to me has to be put in physicians to follow both ethical and legal standards. And I don't think we've had any indication in this country that that's not the case. Yes, you're going to have some outliers. Yes, you're going to have some problems, just like on occasion you're going to have some medical devices that will fail and be a problem, and nobody makes light of that.

But there needs to be a sharing of information between manufacturers and physicians, so that physicians know the various uses of devices. They can do it now. I mean, they can use a device in just about any way they wish if there's some scientific evidence that it's useful. This has not been a problem in the past, and it seems to me, it seems to HIMA, that there needs to be an opening up of the process.

Mr. GUTKNECHT. Mr. Pops?

Mr. POPS. I was going to echo one of the points that Dr. Brinker brought up from a different perspective, and that is the explosion of information—take the Internet for an example—is real, and I be-

lieve strongly that physicians should have access to peer reviewed information with respect to off-label uses of pharmaceutical products to make sure that they're at least getting access to information that is peer review, whether or not that's the ultimate and perfect type of validation of the clinical trial, because, guess what, that information is going to be out there anecdotally, on the Internet, through discussions, and so I think it's better to have more information; more information is better than less information is a general principle. And to the extent that a pharmaceutical company can provide peer reviewed information, that may be incrementally better than nonpeer reviewed information that's available from other sources.

The other point is that the whole health care industry, as we all know, is changing, and reimbursement is becoming a major issue and managed care is being fairly fierce about reimbursing for off-label uses of pharmaceutical compounds and medical devices. I think that's—the wind is at our back in that sense, in that we're getting more and more control over off-label use of these types of devices and drugs because the reimbursers aren't going to reimburse for them unless they have cost-effectiveness data that supports their use in a large patient population.

Mr. GUTKNECHT. Mr. Chevalier?

Mr. CHEVALIER. Let me just add one other perspective to this which I think is important. With the Internet out there today, the dissemination of medical information is occurring online rapidly around the world. I can tell you as a manufacturer there isn't a day goes by that a physician doesn't call up and ask us questions about whatever.

And I'll give you one example. We have an implantable drug infusion pump which you can implant for the delivery of chemotherapeutic agents, drugs to treat Alzheimer's, and so forth. We look at various combinations, if you like cocktails, of chemotherapeutic agents that physicians have chosen to use. We have certain drugs that are formally approved by the FDA in that pump, but we also study these cocktails, if you like, these combinations of drugs, to make sure that our pump does operate correctly when a physician so chooses to use that cocktail.

Now when that physician calls us, we are precluded from delivering any information regarding our internal studies on that particular device-drug combination because that is an off-label use. Is Medtronic going to pursue the approval of that combination? No. The simple reason is it's far too costly and it takes too long, and next month there will be a slightly different cocktail that the medical profession has chosen to use.

And I think patients need to be—have available to them the most recent thinking in terms of the best chemotherapeutic agents for treatment of their cancer, but manufacturers ought to be able to at least discuss what they do know about that drug-device combination with the physician, so that the physician at least, in choosing that combination, does so with the best information available, not just what's out there on the Internet. But the present situation today is we're precluded from doing that. We have to say we're sorry, but we can't discuss this, the information we have in-

house, but all we can do is refer them to the published literature. And I think that's not serving patients like myself well.

Mr. GUTKNECHT. Mr. Finkelstein?

Mr. FINKELSTEIN. Yes, I'd like to add one additional comment. I find certain aspects of FDA's promotional policy to be irrational. As I said earlier, our product was specifically cleared for use in urology and oncology as a cryosurgical tool to destroy tissue in those specific fields. We, however, have been told by FDA that we can never say the word "prostate" or "cancer" or any anatomical description. And, in fact, if you want to carry it to an extreme, my testimony that I've submitted to each of you is considered off-label promotion of our product. It's used in 130 hospitals in the United States; 6,000 men have been treated, and there are dozens of peer review journals on this specific use.

So, to us, it's an irrational policy and one that we can't comprehend, and it goes on and on. We've received warning letters or a warning letter, and then we, as I said earlier, were sued based on that. So it gets beyond even whether off-label use should be allowed or off-label promotion should be allowed to aspects of it that are irrational, in my opinion.

Mr. GUTKNECHT. I am advised that Ms. Jackson Lee has a question. Ms. Lofgren, if you don't mind—do you have to leave or——

Ms. JACKSON LEE. Go ahead.

Mr. GUTKNECHT. Ms. Lofgren?

Ms. LOFGREN. Thank you very much.

This has been very helpful to me, to listen to the discussion here today, because I think it is an issue of extreme importance to the country. I came—I've only been in the Congress for 11 months, and before coming here I had a lot of questions about the way we deal with bringing new medical advances to market. And I can recall when I was in local government I had a special interest in mental health issues. The fight we had to bring Closepine to schizophrenics in America, and I was stunned that, by the time it finally was released in the United States, there was only 18 months left on the patent.

And I want, and I think all of us do, and all of you do, safe pharmaceuticals and devices, but there's also a down side for patients if they can't get a therapy that is needed. And I guess the question, as Mr. Tanner said early on, how do we strike the balance, No. 1, for safety, but also looking at the down side of not allowing things to come in.

And I'm trying to sort through structurally what do we need to do that's different, and I guess this is a question. One option that I'm hearing is that the FDA could continue to have very rigorous standards on the issue of safety, but perhaps the issue of outcomes could be deferred or handed off to someone else. And, as I'm thinking through that, I'm wondering, how does that—where does that leave patients and providers of care, because I think HMOs and insurers want to know that something is effective before they pay for it. Right now, the FDA actually does provide that guidance to the financial world. If the FDA were no longer to play that role, and that, of course, would speed processes, how would you deal—I mean, what—how would the country deal with the reimbursement issues?

Dr. BRINKER. I'd just like to say one thing. Interestingly enough, the FDA, as obviously everybody here might expect, has taken the opposite tact to what you suggested. In a new device or drug, very often it's much more difficult to establish safety than it is to establish efficacy, because you need large numbers of patients enrolled in trials in which the risk to the patient of a device or drug is relatively low.

And the FDA has bought off on the concept that you needn't need to statistically show that, for instance, a new device is as safe as standards, but you need to have some reasonable confidence that it is, and that during the post-market surveillance period, after approval, the ultimate safety of the device will be established. I think that's good, and that decreases the number of patients that need to be enrolled in trials.

I am, on the other hand, worried about the abandonment of the need to establish effectiveness of a product. It seems to me that a company that has a potential—I mean, here is a number of devices, potentially lifesaving. We need to give our patients this or they're going to die. They can get it in Europe; why can't we do it here? And not to be able to show that it's effective, I think these great advances should be able to be demonstrably effective in small numbers of patients. And I think that we need that information.

Mr. GUTKNECHT. Mr. Magazine?

Mr. MAGAZINE. You've asked a couple of questions, and, first, we believe that the amount of regulation should be commensurate with the risk of the device. It doesn't make any sense to treat all devices equally.

In that regard, there's no reason, in our view, for FDA to be regulating class I devices, the simplest devices. And, in fact, the FDA and the White House have come out in favor of a gradual elimination of some Class I's from the product approval process, and we think that all Class I's and some Class II's, actually, should be eliminated, and most of the effort put on the higher-risk devices.

On the issue of efficacy, I don't think anybody is arguing that FDA shouldn't—I should say most people are not arguing that FDA should not be involved in looking at safety and efficacy. The question becomes, how do you define efficacy? According to the law, efficacy is that the device should do what the manufacturer claims it should do and should be labeled accordingly. What FDA is doing, however, at least recently, is getting into relative efficacy; that is, comparing one therapy or one device with another, making you prove that yours is better than the other; clinical utility, which is looking at health outcomes.

With the change in the health care delivery system and the move toward managed care, more and more managed care organizations are going to be requiring outcomes data, cost-effectiveness data, technology assessment. That's the real world out there. And you're not going to be able to sell your products or market your products to managed care unless you can meet the requirements of the managed care establishments.

FDA, in our view, should not be involved in efficacy beyond the definition of the law.

Ms. LOFGREN. Maybe outcome, so to distinguish between the cure and——

Mr. MAGAZINE. Well, we don't believe they should be involved in outcomes, either. They have found it exceedingly difficult to get products through their regulatory process even without outcomes data, but as they start to dabble in outcomes, then you're looking potentially at a tremendous lengthening of the process, and it also would be duplication because the managed care organizations are going to require it anyway.

So I think there are a number of things that can be done to speed up the process, but I think we have to be very careful about looking at the symptoms of the problem versus the root causes of the problem. The symptoms is—the symptoms are that products are not getting approved in a timely fashion, but the root cause of that is a heaping on of additional requirements on manufacturers that, in our view, don't make a lot of sense.

Ms. LOFGREN. Any other?

Mr. CHEVALIER. I would just add one thing to what Mr. Magazine said. I think that the issue of effectiveness is something that needs to be addressed. The question is, does it get addressed within the regulatory process or not? And I think that if you look at the European system, the Europeans specifically said it's not part of the regulatory approval process and it should be left to the academic community and the payor community to decide if, indeed, the outcomes, however you want to define that, do justify reimbursement, and at what level.

Now I think, just to give you two quick examples, two breakthrough therapies which we can all relate to: in the past year, we've released two therapies. One is for the treatment of tremor associated with Parkinson's Disease. I think we're all familiar with the debilitating aspects of tremor. That whole device and therapy is approved now in Europe; it won't be approved in the U.S. for three to five years.

Another therapy deals with incontinence, urinary incontinence primarily, which is a predominant condition in women later on. And everybody can understand what the quality-of-life aspects are related to that. But how long do we wait to evaluate the long-term outcomes of that therapy before we decide that that needs to be something that's going to be reimbursed? Can we demonstrate that it's safe? Yes. Can we demonstrate that, yes, you do have urinary continence and control? Yes. Is it a situation where we need that the FDA or the regulatory body should be in a position of saying five years from now, or however, yes, that's something that should be reimbursed, or is that something that society in general, with physicians, with payers, and patients, decides that that's the therapy that they want to have access to.

And I suspect if you look at it from that perspective, patients will say, particularly in those kinds of conditions, "I don't have any other options, and the quality-of-life limitations that I have clearly warrant that type of therapy." Now society, at some point in time, is going to have to decide whether they're going to pay for that or not. I submit that should not come within the purview of the regulatory body before it becomes released to the market for commercialization.

Ms. LOFGREN. Can I ask just—oh, Dr.—I have one other question.

Dr. BRINKER. I would just like to maybe correct two potential misapprehensions here. One is that the FDA does not require the proof of a benefit of a device over another device unless claims are made to that point for approval, as was said before.

The other thing is that the FDA doesn't take in cost effectiveness into its accountability of effectiveness. They will approve a billion dollar device that does the same as a $2 device, and they can approve it on the same panel meeting. It's not in their purvey to do that, but they do want to see effectiveness devices demonstrated.

Now there are life-threatening devices such as implantable intercoronary stents that are approved with relatively little follow-up, but just enough to show that they are meaningful. And I think that when you're dealing with implantable devices, you don't want to have a situation that we have had on occasion where devices not only fail, but fail in a dangerous way, so that you're faced with, as we are right now, 25,000 Americans, with a pacemaker lead that can fail. A little wire in it that does nothing but maintain its shape can eat through the plastic and perforate the heart and kill a patient. There have been a couple of deaths reported and 30 patients that have had—needed emergency surgery. On the other hand, taking out that lead prophylactically has resulted in five deaths in 2,000 patients because of the difficulty in dealing with patients that have implantable fibrous products.

And, again, I realize that there's always a tradeoff between the benefits and the potential disadvantages, and we can't be 100 percent, but I don't want to throw away the baby with the bath water here. I think we have to be cognizant of some of the things we do. We have to be respective of the potential problems that might exist.

Ms. LOFGREN. Can I——

Mr. CHEVALIER. Can I just correct one thing which I think needs to be stated? The FDA is on record this year saying that they will maintain their options of requiring outcomes and cost-effectiveness data to approve class III devices.

Mr. GUTKNECHT. Mr. Pops?

Mr. POPS. Again, I am trying to be the voice of the small biotechnology companies in this as well. With respect to the issue of safety and efficacy at FDA, I think nobody in the biotechnology industry would argue that efficacy be removed as a criterion for judgment by FDA, particularly since safety itself is not an absolute standard; safety is really only valuable in the context of efficacy because certain treatments for life-threatening diseases may be fairly toxic, but compared to the disease itself, it's quite acceptable. So you need the ying and the yang to understand whether the safety is acceptable or not.

I think that what needs to be done, what needs to be done is—can be seen in the more finer detail in some of the proposals that have been provided to you, but just—if you just step back and look from 30,000 feet at what's happening, it costs us on the order of $250 to $350 million to develop a new drug. That's a lot of money. It doesn't need to cost that much money. And that, the amount, the fact that it costs so much money to do is limiting in the development of new potential breakthrough therapies.

We have small companies of 50, 60, 100 people that have the scientific capability and the manufacturing capability to make new drugs, but often we're constrained just by the enormous expense of getting it through the lengthy regulatory process. And I think that it can be made better.

Mr. GUTKNECHT. Mr. Magazine?

Mr. MAGAZINE. I just want to respond briefly to Dr. Brinker's comments. We've heard this morning several examples of situations that have resulted in deaths, three deaths here, five deaths there, seven deaths there, leads, and so on. And nobody minimizes the impact of this. Absolutely nobody in our industry minimizes it, and nobody wants it.

Mr. GUTKNECHT. Especially the manufacturers.

Mr. MAGAZINE. Especially the manufacturers; that's what I mean. And the don't want it for social reasons, but they also don't want it for economic reasons because of product liability. Nobody wants to take chances.

But we must look at the other side of the equation. We're seeing a delay of introduction of lifesaving products of an average of one to three years. Those are products on the market in Europe, and this report lists 100 of them, and the Wilkerson Group says that's just the tip of the iceberg. They've cited a number of these devices and indicated the potential mortality, economic loss, and quality-of-life issues related to it.

For example, technology to reduce restinosis following angioplasty, on the market in Europe, a delay of one to three years will result in the United States in 3,600 deaths, a loss of $1.2 billion, 240,000 repeat procedures, 10,000 heart attacks, 8,400 emergency surgeries.

Mapping and ablation for atrial fibrillation and ventricular tacticardia, 25,000 deaths. We're talking about real people here. Now, granted, we don't want products on the market that are going to injure people or affect their quality of life or cause death, but there's got to be some balance in the equation. And right now it's all tipped in the wrong direction.

Mr. GUTKNECHT. We're pleased to have with us now the Chair the Full Committee, Chairman Walker, and if he has some questions or comments, we'd like to entertain those.

Mr. WALKER. Thank you, Mr. Chairman. I'd like to, first of all, ask unanimous consent that the statement that I had prepared be included in the record.

Mr. GUTKNECHT. Without objection, so ordered.

[The prepared statement of Mr. Walker follows:]

PREPARED STATEMENT OF HON. ROBERT S. WALKER, CHAIRMAN OF THE COMMITTEE ON SCIENCE

The development and commercialization of medical technologies represent the epitome of what innovation and free enterprise can do for the good of humanity. Safe, effective medical products provide earlier diagnosis, reduce suffering, and save millions of lives. In America, we have come to expect spectacular advances in medical technologies almost as a matter of routine. Our medical products set the standards in the global marketplace—and have substantially improved the quality of health care worldwide.

While we expect our regulators to keep unsafe products *off the shelves,* we must expeditiously get new, innovative, life-saving products *on the market.* But the pendulum has swung too far in the direction of "zero-risk" policies. Today, it takes up

to 14 years and nearly $400 million to get a drug approved in the United States, while in Europe, medical products are approved in less than ⅓ the time with no indication that quicker approval increases patient risk. Most American medical device companies, initially introducing new products overseas, anticipate delays of up to 3 years before they can get approval in the United States. These delays not only have severe economic consequences—but are also devastating for our patients who need these products to alleviate medical distress.

For just 10 diseases and conditions, this 3-year delay will result in the lost opportunity to save 50,000 American lives. *And that's for products developed with American technology—that are available now to patients overseas.*

Ninety percent of new drugs are developed from U.S. technology, but 70 percent are marketed initially in other countries. The majority of our medical device companies now market or plan to market products abroad that are not approved in the United States. Many American companies are being forced to move research and development, clinical trials and manufacturing overseas because the prospects for marketing in the United States are so much more unpredictable.

This steady erosion of our medical industry, caused by over-regulation, is costing us jobs, hurting our quality of life, and undermining our technological competitiveness. The future affords spectacular opportunities for new, innovative, breakthrough medical technologies and Americans deserve quicker access to reasonably safe and effective, state-of-the-art medical technologies and the improved quality of life they make possible.

Today, in America, you can use an illegal drug to commit suicide. But your doctor cannot prescribe for you a life-extending drug, that is approved for use overseas but not in the United States. This situation is intolerable and it must change.

I thank our Subcommittee Chair, Mrs. Morella, for her leadership in convening this very important review of the status of our medical technology industries.

Mr. WALKER. Also, I'd like to welcome Mr. Holveck to the panel this morning and thank him for being with us, and, indeed, all the panel. I'm sorry I haven't been able to get here for some of the testimony, but what I've heard so far is very interesting and very useful.

I know that some of the concentration here has been on the whole business of some of the opportunities for new innovative breakthroughs that we would get that would be lifesaving in nature. I'd like to deal with a little different aspect of it, if I could, that I think also was speaks to a concern in the area. It bothers me, for example, that today in America you can use an illegal drug to commit suicide, but your doctor can't prescribe to you a life-extending drug that's approved for use overseas, but not in the United States.

I just think that we're talking about a situation which is intolerable, but then what makes it additionally intolerable, in my view, is, if we know how to manufacture that drug in this country, and we've developed that drug in this country, and it's available for use overseas, we can't manufacture it here and send it overseas, where it's legal to use it. Instead, FDA says that you can't manufacture anything here that's not going to be used here, and that may be 10 years down the pike. And if I understand correctly—and correct me if I'm wrong—what's happening in industry, as a result of that, is the manufacturing facilities for a lot of new drugs that were developed in this country are now being built in foreign countries, being built in the countries of our competitors, and when, in fact, we do finally get the approval in this country to utilize those drugs, we will, in fact, be importing them from the manufacturing facilities that were built overseas rather than producing the drugs in the United States. Is that, in fact, an accurate description of what is going in terms of the global trade situation here?

Mr. HOLVECK. Chairman Walker——

Mr. WALKER. Yes?

Mr. HOLVECK. In fact, that's been a moving target, and it certainly was as strict as you say and black and white as you said back in the mid-eighties. In 1986, we did make a step forward, and it was considered a bold step forward, to allow it to exist for 21 countries. So the United States has now allowed a registration to ship unapproved device and drugs overseas to 21 countries.

Now I would say that's a selective process. How are we going to now update that list of 21, because since 1986 there has been a continued growth in the world, and I think the Pacific Rim is a very good example, and you could take other parts of the world that have gone higher in their social-economic state and in their education, but they're not on the list. So, again, we have a statute in place that needs to have some dynamics to keep up with the world, and, again, our industry gets penalized by it.

So, yes, the outcome is that we are limited, and in order to avoid that and the access to more countries, or generally thinking, because there isn't that dynamic aspect in our statutes, companies do go overseas because what's in the statute today may be fine, but tomorrow it may be altered. So, yes, the outcome of what you say is correct.

Mr. WALKER. So at a time when we have an increasing global marketplace, what we've done is help freeze ourselves and American jobs out of the global marketplace. It's not just that we're costing Americans lives as a result of the nonapproval of drugs, which is obviously the most important thing, but, in fact, we're costing them jobs; we're costing the economy growth. We are suggesting that development of drugs in this country is, in fact, something that can end up being penalized rather than being enhanced by the regulations. It just seems to me that we are, in continuing to regulate as though this were still the world that existed in the 1950s and 1960s, and doesn't recognize that things have changed in 30 years in a major way.

And to follow up on that, what I'd like to have somebody do is characterize the European quicker approval process versus the FDA's process in terms of patient risk. I mean, are patients in European countries that have developed a quicker approval process more at risk than patients in this country? Is there any evidence of that?

Mr. MAGAZINE. I'll just make a comment, and then I'm going to suggest that Mr. Chevalier repeat what he said earlier, because he really is deeply involved in the European system through Medtronic.

But we've seen no evidence whatsoever that the European system is any less safe than the American system. In Europe they use a system of notified bodies. There's a contractual relationship between the companies and these third parties to do reviews. Those reviews are based upon very strict standards. It's a standards-based approach. This is not so much a privatization as it is a public-private partnership. And we think it's working very well and it's something that we at HIMA believe we should be taking a close look at here in the United States.

One of the major issues with regard to third party review, it seems to us, is that at FDA there's a real problem in keeping up

with new technologies. Technology is exploding, medical technology is exploding. It's changing every day. There are new concepts, new products, and so on, and FDA simply cannot keep up.

The notified bodies in Europe are charged with the responsibility of keeping up with that technology. They have specialists of all kinds who are charged with keeping up with the technology, reviewing the products, making sure that they meet standards prior to any approval.

But our—we have seen no evidence, Congressman, whatsoever that there's any safety risk, any enhanced safety risk in Europe over the United States.

Mr. WALKER. Dr. Chevalier?

Mr. CHEVALIER. Just to give you an idea, I mean, if this is the most recent state-of-the-art pacemaker, if I submit this to the FDA today and to Europe, I will be in the market in three months in Europe; I'll be two to three years before I enter the market in the U.S., and that's the problem I face as a patient.

The contention that the FDA protects patients from harmful devices better than the Europeans is, I submit, simply a myth. If you look at the standards that are used by the notified bodies for the review process, the focus on total quality management systems, and as well as their post-marketing surveillance system, which they call "vigilance," it is as rigorous as anything that we've got in this country. And, clearly, if there is a patient problem with a device in Europe, the manufacturer, as well as the ministries of health in each of the countries in Europe, is well aware of it and informed of it. And to this date, we've seen no evidence to indicate that the devices are performing any less in Europe than what they are in the U.S.

So then the question is, what does the additional review process that's imposed on this device by the FDA buy you, I submit nothing but delay.

Mr. WALKER. Thank you, Madam Chairwoman.

Mrs. MORELLA. Thank you.

I wanted to defer now to Mr. Gutknecht, who had done such a great job chairing this Committee while I was giving a speech on the floor and went to a press conference. I know it's been a very spirited debate. I appreciate it.

I also wanted to get permission from you to submit questions to you for responses. I know we had some members who were here who didn't have a chance who would like to ask more questions. If we may do that, then all members will feel free to submit questions.

Mr. Gutknecht?

Mr. GUTKNECHT. Thank you, Madam Chairwoman. I just wanted to share a little bit of a historical perspective, and I think that's something that this Subcommittee, and perhaps the entire Congress, needs to talk about.

One of the things that really got my attention—and I don't know, Mr. Chevalier, if you could—or, Dr. Chevalier, if you could share with us an article and a comment that was made about a year and a half ago by one of your co-founders.

And, Madam Chairwoman, again, I'd love to get you out to Minnesota to meet some of these people, but Earl Bakken is, without

question, one of the most remarkable human beings that I've ever had the opportunity to meet. And I don't want to—perhaps you can share the story; maybe you know what I'm talking about. He was quoted in the St. Paul Pioneer Press about a year and a half ago about, if he had to do it all over again, about where the company would be located. But perhaps you can share that with the Committee.

Mr. CHEVALIER. Earl, as you know, started Medtronic in his garage in north Minneapolis back in about 1959 or 1960 with his brother-in-law and has since evolved into the company known as Medtronic today.

And in the process of discussing regulatory reform and the impact that the FDA has had on innovation in this country, people have asked Earl repeated, if he were to start, open up his garage today, what would happen. And he has point blank said on many occasions there would be no innovation, because the time it would take, the money it would take, to bring a product such as this, which in today's date, in today's technology is really pretty out of date, but for the patients' lives that were saved back in the early seventies—and the ones before this were even bigger, frankly—those patients got, obtained a quality of life that would not have been available to them had Earl not been able to start his business.

And I think that really gets at the heart of all this, and Earl has been a passionate person in trying to discuss and alert people to the very negative impact that a very strict and even overbearing regulatory environment is having on innovation.

Mr. Magazine talked earlier about the impact on venture capital, and several of our panelists here have talked about that. And the ability to be able to innovate and bring new ideas to the marketplace to meet the list, the huge list of unmet medical needs, and Earl said that, "If I were to do it today, I would have to take my garage and move it from north Minneapolis to Europe because I would not be able to do today what I did back in 1960." And I don't think that's what any of us want.

Mr. GUTKNECHT. And I think that's a very good point, and I bring this from the perspective also of a Representative who represents Rochester, Minnesota, and you think about the Mayo brothers and all that they did. And you look back at some of the technology and the devices and the new procedures that they came up with, and really by today's standards some of them seem incredibly primitive, but at the time it was the best that they had.

And my concern about this whole area is, if you try to create a completely risk-proof society as it relates to new innovation and new technologies, if you wait until all the lights are on green, you're never going to leave the house. And by today's standard, the original pacemaker is incredibly primitive, and if we had to wait until we knew everything that we know today about pacemakers, or any other technology, they would never have gotten started.

And the real concern is not so much about what's happening, with all due respect, not with what's happening to the Medtronics of today, but it's with those very small entrepreneurs or researchers in clinics or hospitals or in universities around the United States who sort of throw up their hands and say, "It's not worth

it. If I have to climb through the maze that's out there today, I'll just keep doing what I'm doing."

And, as a result, I think there's an enormous opportunity cost to future generations of Americans and future generations of citizens of this world, if we hamper ourselves by making the perfect the enemy of the good.

And so you've been very, very helpful, and I don't want to delay this conversation any longer, and I know we've got a couple of—I know that Representative Baker would like to us and we've got another panel, and I, unfortunately, have another meeting to go to, but I just want to thank you, Madam Chairwoman, for holding this hearing and I want to thank the entire panel for coming and sharing with us today, and I hope that we'll have other hearings and can pursue this issue in the future, because I think there are huge costs not only to today's consumers, but future consumers, if we continue to make the perfect the enemy of the good and try to pursue an absolutely risk-proof technology of the future.

So, again, thank you to the panel and thank you to Madam Chairwoman.

Mrs. MORELLA. I think it would be very appropriate for us to pull together also some of the recommendations that have come from your testimony in responses to questions.

I just wanted to ask Mr. Holveck, do you manufacture overseas?

Mr. HOLVECK. Yes, Madam Chairwoman, we do. We made that decision to manufacture our pharmaceuticals overseas. That was a decision that came into play in the early eighties, and as I indicated to Chairman Walker, back in the early eighties we could not ship product that was unapproved. So it was a strategic decision. Not knowing the regulations would change, we did locate and build our manufacturing facility in the Netherlands on the grounds of Lyden University outside of Amsterdam.

It was three years after that, that decision, that the rules were changed to allow 21 countries, but, as I said, in today's market 21 countries is still a limitation. So it is a very dramatic—to the earlier comment, we had to make a decision with a long-term vision and the regulatory environment inhibited that decision. And I think most of what we're hearing today is we have to have a dynamic and regulatory set of statutes and policy that will allow our industry to retain its vigor and in the home base.

Mrs. MORELLA. I think that's probably an appropriate point at which to thank this first panel. You've been here a long time. You've shown a tremendous amount of patience, as well as commitment. I want to thank all of you for being here today. We'll be back in touch and submit the questions.

I'd now like to call on our very distinguished colleague who's been very patient about waiting because he feels this is a very important topic; I agree with him, the Honorable Bill Baker, who is a member of this Committee, who is a Member representing the great State of California.

Thank you, Congressman Baker. We've been awaiting all day your testimony.

STATEMENT OF THE HON. BILL BAKER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. BAKER OF CALIFORNIA. Thank you very much. And I was caught in the traffic because, indeed, it isn't a purely safe world and all the lights, Mr. Gutknecht, were not green this morning; they were all backed up because of accidents on the freeway, and I apologize for being late.

I would like to remind Dr. Brinker that in his examples of the implants, the heart implant and the breast implants, presumably, those have all been through the rigors of this mine field known as the FDA process, and, yet, still we have problems, and we're going to continue to have failures. And I believe FDA's role is to protect society, not prevent them from doing things which may not work for everyone.

I'll give you one little example. When I was a child, Cutter Laboratories put out drops that would make you immune to poison oak. If you were a kid in California and you ran through the bushes, you were going to get poison oak. This didn't work for everybody; it only worked for 90 percent or 60 percent of the people. So you'd have a glass of water, not dangerous in California in those days, and these drops, where you'd have one drop today, two tomorrow, and three the next day, and I think you went up to ten. And for 60 percent of the people, they could run through poison oak and not get it; they had built an immunity because of these drops. But because it didn't work for everyone, they were made illegal by the FDA. That is patently absurd.

I don't care if people eat seaweed, if they want to go dip raisins in gin and then think they're curing arthritis. Fine, as long as there's no harm. FDA should protect the public, not from themselves, but from people who might put a tapeworm in a pill and claim you're going to lose weight. That, you certainly will lose weight, all of it. But we want to be protected; we just don't want the government saying to us, if it works for you, I'm sorry it didn't work for everyone; you can't be protected.

So I think the distinction should be made about what the role of the new FDA in 1995, when we're moving at light speed, ought to be, and it shouldn't be the bureaucracy of the sixties.

I'm here today because I want to give an example, and I'm going to quit, answer Gil's one question, and get out of here, or Ken's. I'm here because of a device known as a sensor pad. It allows women to check themselves for breast cancer for lumps more effectively. It's been held up for 10 years by the FDA. It is not as good, and it says so on the label, as a mammogram. It is not intended to be a substitute for a mammogram. It just makes the women's self-examination more sensitive. They'll pick up more lumps earlier.

Fifty thousand women, 46,000 to be exact, each year die from breast cancer; 150,000 contract breast cancer. My administrative assistant for 12 years contracted breast cancer before they could even feel it. They found it in a mammogram. It had gone to three glands. She had to have chemotherapy and radiation. She was spared because they caught her so early. It was still to tiny to see or feel, but it had already moved on to the glands.

And it is important that we do everything we can to catch this ugly disease early. Yet, this device, because the FDA says it will give you a false feeling of security, if you examine yourself and don't find anything; then you'll think you're all right. How absurd. We encourage women to go out with their hand and give a self-examination to try to catch these early. No one has a feeling of security when they do that, but at least if they find something, they'll come in sooner and be protected earlier.

We've got to do everything we can, and once again the FDA is protecting us from ourselves, not from any danger you might run from this $13 device, not from any problem that you may have from this device, but because you may have a false feeling of security. It's absurd. I appeal to the FDA to come forward with new regulations, stop fighting and dragging their feet, but to cooperate in getting some of these easier devices and easier techniques approved, so that the public can protect themselves.

I'd like to answer any questions you might have, and I'm thrilled to be here. I apologize for being late and for holding up the second panel.

Mrs. MORELLA. Mr. Baker, your entire testimony will be included in the record. We appreciate it.

Mr. BAKER OF CALIFORNIA. Thank you. I'll submit that.

[The prepared statement of Mr. Baker follows:]

REMARKS OF REPRESENTATIVE BILL BAKER (CA-10)
BEFORE THE HOUSE SCIENCE COMMITTEE
TECHNOLOGY SUBCOMMITTEE

MEDICAL TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

November 2, 1995

Madame Chairman, I am pleased to participate in this important discussion on medical technology, specifically concerning a device I am convinced has the potential to save women's lives. The Sensor Pad, produced by Inventive Products, is a device to aid women in the battle against breast cancer, which has been stalled by the FDA in the approval process for over 10 years. Certainly, with nearly 46,000 women dying from breast cancer each year, any product that has the potential to enable women to detect breast cancer should be given top priority by the FDA.

My interest in this issue has been influenced by my own experience. I want to tell you about a close friend of mine who is a breast cancer survivor. Jean Meredith managed my first campaign for elective office and was my staff director for nearly 12 years while I was in the California State Assembly. In March 1991, this extremely capable, vital woman was diagnosed with breast cancer.

The lump was very small and barely detectible; however, it was

malignant and had already spread to three lymph nodes. Jean underwent a lumpectomy and is alive and well today. In fact, she continues to be one of my most valued aides.

Jean's survival was due to early detection. Without it, her chances of defeating this dreaded disease would have been significantly diminished.

Having gone through this experience with Jean, I am deeply aware of the need to improve the prospects of early detection of breast cancer, and to encourage breast self-exams. Doing so is literally a matter of life and death.

This is what makes new technology like the Sensor Pad so essential at this time. The Sensor Pad is one of the most promising devices being developed in the battle against breast cancer. As a non-invasive, easy-to-use, self-examination device, it has the potential to save hundreds of thousands of women's lives. It consists principally of two plastic sheets coated with lubricant. That's it: no involved machinery, no elaborate hi-tech gadgetry, no invasion of the body. It is a method of detecting lumps that is simply more sophisticated than soap and water. While I understand that the FDA is not always given an easy task, there is absolutely no reason why it should take the FDA more than 10 years to complete the approval process of this simple but creative and potentially very useful product.

I understand the need to ensure that medical devices are safe and that they enhance prevention. But I also understand the need to encourage breast self-exams. Manufacturers of the Sensor Pad and many medical professionals who are familiar with the Sensor Pad believe it reduces friction, thus making breast self-exams more convenient for women to perform.

Madame Chairman, I share the frustration expressed by the producers of the Sensor Pad. Since Inventive Products first applied for approval of the Sensor Pad, breast cancer has taken the lives of more than 450,000 women. Many of these women might be alive today had their cancer been detected early enough.

Our citizens wonder why they are being deprived of new products and medicines. We all wonder why inventors are leaving the country and thus denying Americans access to important health technology. The answer lies in the delayed approval process practiced time and time again by the FDA. The overbearing regulations articulated and enforced by the FDA are causing many drug and medical device producers to go to Europe to develop their products. It is no wonder we have an increased trade deficit with 45% of medical device manufacturers saying they will relocate outside the U.S., which in turn translates into a huge job loss to Americans if the industries move out of the country.

Specifically, the FDA's premarket review requirements are the primary impetus for delayed introduction of products into the United States. And because producers -- and their investors -- don't generate any revenues until their product hits the market, they are forced to go to market as soon as possible. That means Europe. Studies show that there are up to 100 specific products that are available in Europe but not the United States.

The difference in availability in Europe and the U.S. is measured in years. Products available now in Europe must wait up to seven years to hit the U.S. market -- even if they were developed here in America. The real tragedy in these statistics is not the lost profits for U.S. companies, not the missed opportunities for U.S. investors, not even the increase in our trade deficit -- it is the potential loss of life incurred by needlessly delaying medical technology in this country. I don't doubt that the FDA means well, but people are dying, we have the technology to help them, and our own citizens must go abroad in order to receive the necessary treatment.

A report prepared by the Wilkerson Group takes a closer look at just ten of these 100 products available in Europe and not the United States. The findings are shocking. The estimated potential costs of a three-year delay in the availability of new technology reveal

a loss of more than 90,000 lives, and a cost of over $15 billion. This doesn't even include the number of individuals who would become disabled or blinded, who would suffer strokes or heart attacks, or who would otherwise experience a profound decrease in the quality of their lives.

We must change this flawed process. We must actively look for ways to halt this approval slowdown and vigorously seek to approve the methods and technologies that will be positive aids to the American people. It is imperative that the excessive stranglehold the FDA has had over small, creative companies stop and that the American people once again are given top priority over the red-tape, bureaucratic monster the process has become.

For the sake of the American people, especially women, we must correct this broken process and end these excessive delays.

I welcome the testimony of our witnesses today as we all work together toward this common goal.

I thank the Chairwoman and the subcommittee members for their time.

-end-

Mrs. MORELLA. But I'd like to—I appreciate your coming, too, and I know the Subcommittee does.

I'd like to know how the sensor pad works. I mean, is it——

Mr. BAKER OF CALIFORNIA. So would I. It's a gel on a little pad that makes your fingers and everything more sensitive. It makes you be able to feel better. I have not used it, obviously. And a hospital in this country has given away, I think, 50,000 of them with terrific response.

Mrs. MORELLA. Really? Really?

Mr. BAKER OF CALIFORNIA. Yes, they can't sell it, but they're waiting——

Mrs. MORELLA. But they can give it away? I'd like to——

Mr. BAKER OF CALIFORNIA. They're waiting to outlast the system; I don't think they'll live long enough, and 50,000 women this year won't.

Mrs. MORELLA. I'm going to certainly explore it. You know, it's interesting because we just completed breast cancer awareness month——

Mr. BAKER OF CALIFORNIA. Yes.

Mrs. MORELLA. And we know one out of every eight women are touched by it, and we know the need for self-examination and the mammograms, and certainly this is a very moving statement that you make about how we have procrastinated so, and we'll look into it.

Mr. BAKER OF CALIFORNIA. This is not the only answer. This is just——

Mrs. MORELLA. No, it's an example.

Mr. BAKER OF CALIFORNIA. You know, women don't rush in and say, "Gee, I'd like a mammogram. It's been a year." I mean, it's kind of like expecting a 21-year-old or 22-year-old, when they fall off our health insurance, to demand of their parents that they go out and start shopping for health insurance; they don't, and I can understand why women don't. I mean, we don't go in to have our lower colon checked very often, let me assure you, because I just had the mispleasure of doing that. Now let me tell you, I'll stretch that five years to fifty years, if I can, on the next one.

[Laughter.]

So I understand people don't do that. We want them to do it. We want them to go in and have a mammogram, but for many reasons they don't. This would enhance their ability to check themselves, and if they feel a lump, they'd rush in the next minute.

We don't depend on this device to save us from breast cancer. Livermore Lab is—and Barbara Boxer and I had a press conference on this a year ago—they're using laser technology to shoot through, as we do trying to find Saddham Hussein sitting in his bunker—we've taken military technology; we shoot through the breast and find calcium deposits before they can even become cancerous, and because of that enhanced vision from using laser technology, Fisher Imaging is going to come to public, if they live long enough, with that device that will really enhance our ability to catch cancer earlier.

So this is not intended to be the be all/do all of cancer detection. It's just one more technique a person in their own home can use to detect cancer.

Mrs. MORELLA. And I guess using this is anecdotal evidence of the need to push forward and to be more visionary, I suppose, in terms of looking for what might assist people healthwise.

Mr. BAKER OF CALIFORNIA. Yes.

Mrs. MORELLA. Mr. Calvert?

Mr. CALVERT. I just had a comment from the testimony earlier today and what examples that Bill's giving us, that we have a major industry in this country, especially in our home State of California, biotech, and we have some very innovative companies who have come up with some very exciting potential solutions to problems, and we're being given a lot of obstacles by the FDA.

And I think back in the fifties, sixties, when General Motors, Ford, Chrysler thought that there was nothing wrong with the status quo, that they could continue to produce the way they had been producing and never lose market share. In this case, not only are the patients suffering, but we're relocating a major industry away from California. We can't afford to lose any more industry anywhere in this country, and not only for the protection of the patient, but to protect a major growth industry, I would hope that we could reform FDA and put it back on the right track. So I appreciate your coming here, Bill, and sharing your experiences.

Mr. BAKER OF CALIFORNIA. Thank you, Mr. Calvert. I think we want to re-establish the fine role that FDA has played in saving lives and not turn them into the IRS. I think they have a lot at stake. If they would offer streamlining of their own agency, it would help. We shouldn't have to bring them before this Committee and beat them up. But they have done a fine job protecting people, but they don't have to micromanage every step of the way.

It wouldn't cost us that much to send someone to Europe and see if people are dying all over the street from faulty medical devices and bad prescriptions. They can buy prescription drugs off the shelves in Europe. Are they ruining their health by doing that? It wouldn't take us that hard, that long to find out. So I think we've got to streamline the FDA and restore the lustre to that agency. They're becoming in my district the butt of a lot of jokes.

Mrs. MORELLA. I still think we need the FDA.

Mr. BAKER OF CALIFORNIA. That's correct.

Mrs. MORELLA. Again, we're looking for that kind of balance, as I mentioned before.

Mr. Gutknecht had to leave for a meeting, but he did indicate that a Committee, Subcommittee, that he's on that deals with regulatory reform actually had the inventor of the sensor pad appear before them, and he has referred to me the fact that there is even a video on it, which I am going to get, and to——

Mr. BAKER OF CALIFORNIA. Great.

Mrs. MORELLA [continuing]. view and see where we go from here.

Mr. BAKER OF CALIFORNIA. These people are from the Plains State. I don't know them from Adam. I met them once. They're not from my district, and their product has nothing to do with me. It just seems that anything we can do to enhance public awareness in this disease, in the ability of people to treat themselves in their homes as a first step, is important.

Mrs. MORELLA. Thank you.

And Ms. Jackson Lee had been here earlier, too, and I'd certainly like to defer to you for any comments, questions.

Ms. JACKSON LEE. Madam Chairperson, I thank you, and it will be a comment. I'd like to be able to forward some of my inquiries in writing.

Congressman Baker, I'm glad that you're here, and I thank the chairwoman for allowing me. I'm a member of the Full Science Committee, but I'm not on this Subcommittee. So I'm appreciative of being able to make one or two comments, and that goes somewhat to the previous panel and to your comments.

I appreciate your tone of striking a compromise and reasoning, what role the Food and Drug Administration can play. I happen to be trained as an attorney and practiced for some years and worked extensively with an emerging biomedical technology group in the city of Houston, and they are now thriving, and many of the industries are thriving. But, of course, they raise some of the same issues about how fast they can get their product to the market. The questions of safety are certainly important for our consumers and constituents. If there ever is a place for compromise, it is here.

And I know most of what we speak about has come about through legislation. So the regulatory aspect of the Food and Drug Administration has—they're really responding to what we in Congress have told them to do. And I think it's important that we do do, in essence, the R&D work. We need to go and look at the European—excuse me—foreign approval process and determine how that works today in present-day society on the backdrop of what we all remember, some of us who either remember by way of history or were there, the thalidomide babies, which looms high above everyone's minds and hearts, though in contrast to that, of course, we're concerned about a cure for cancer, a cure for AIDS, and a variety of other devastating diseases that we have.

So my comment would be, in combination to those absent panel members that were here earlier, and I had the chance to hear them and then I had to go to another hearing, is that we should come at this from a perspective of compromise with research and development. Where can we take, how far can we go on the limit of making sure Food and Drug works efficiently and effectively to cultivate this industry and, as well, to save lives, but yet how do we get the real data of what works and whether or not the foreign European approval process is one we want to emulate or modify.

And, Congressman Baker, I'm not sure if you want to comment on that, but those are my words, and I hope we'll have an opportunity to be able to work in that direction. And I'll submit some other questions to the other panel.

Mr. BAKER OF CALIFORNIA. Let me just address that, and I believe you're right on. Congress did not intend, when they passed the laws, for people to wait 10 years for a lifesaving device. So somewhere between our passing a safeguard, known as FDA, and our ability to bring important innovations to market have been a stack of rules that would probably fill this room. So this is why I call upon FDA to clean their own house and don't wait for us to pass another law, because our law will be far-reaching and won't ever hit the mark. So they've got to tell us how to get well, and

I think the experience in Europe could be viewed positively by our own bureaucratic mechanism to see, are there holes in that?

We're doing the same thing with social security, if you will. We want to go to Chile and find out, how has privatization worked in the past 10 years? We don't have to guess about it. We don't have to speak about it.

Now this new Congress wants to use science-based technology to regulate, whether it's the EPA and the environment or in pharmaceuticals. We don't want to guess. We don't want to make political statements. We want the scientists to come forward and say, "This is what we've found, and, therefore, you need this kind of regulation."

So I agree 100 percent with what you're saying and look forward to working with you, because I, too, am on this Committee, in finding that happy medium, so that we can restore the lustre to FDA and continue to protect the public, at the same time allow Americans the same ability to have lifesaving devices as Europeans have.

Ms. JACKSON LEE. Thank you, Congressman Baker, and I think that's the way we should be headed.

And, Congresswoman Morella, thank you, and I yield back the balance of my time.

Mr. BAKER OF CALIFORNIA. Thank you, Chairman.

Mrs. MORELLA. Thank you, Ms. Jackson Lee.

And we've already gotten permission that there is no objection to having questions that you submit, and other members of the Subcommittee submit, to members of the first panel and to Mr. Baker.

Mr. BAKER OF CALIFORNIA. Thank you again.

Mrs. MORELLA. Thank you very much. We really appreciated your testimony.

Let's call the second panel up, who have been ever so patient: Mr. Kenneth Kaplan, who is with the Department of Architecture and Planning at the Massachusetts Institute of Technology in Cambridge; Dr. Ian Hunter, Department of Mechanical Engineering at MIT in Cambridge; Dr. Harvey Eisenberg, Chairman and Chief Executive Officer, Health Technologies and Wellness Corporation, Newport Beach, California, and General Peter Kind, Senior Vice President, SARCOS Research Corporation, Salt Lake City, Utah.

Welcome, welcome. Thank you. Thank you. I hope that you have gained something or it has confirmed what you already knew or gave you some further insights hearing from the first panel. I know it did take a long time, and your being here and giving us your expertise on this important issue is very valuable to us.

I wondered if we might start off and I might ask each of you gentlemen if you would kind of describe your special research areas. I guess we could start off with Mr. Kaplan and move from—to the——

STATEMENTS OF KENNETH L. KAPLAN, DEPARTMENT OF ARCHITECTURE AND PLANNING, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MASSACHUSETTS; IAN W. HUNTER, DEPARTMENT OF MECHANICAL ENGINEERING, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MASSACHUSETTS; HARVEY C. EISENBERG, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, HEALTH TECHNOLOGIES AND WELLNESS CORPORATION, NEWPORT BEACH, CALIFORNIA; AND PETER A. KIND, LIEUTENANT GENERAL, RETIRED, SENIOR VICE PRESIDENT, SARCOS RESEARCH CORPORATION, SALT LAKE CITY, UTAH

Mr. KAPLAN. Thank you, Chairwoman. It's a delight to be here, and I thank you very much for inviting us.

My name is Kenneth Kaplan. I'm a principal research scientist and also an architect at MIT in the Department of Architecture and Planning, and also collaborate with the Research Lab Electronics.

My area of specialization and expertise is in what I will call advanced health care environments, and I've been developing a research agenda in that area that derived out of some past experience in DOD-funded research, but now, from that research, I've seen an extraordinary opportunity and implications for some new technologies to be delivered into the home and work environments. I think that area of research has been one that's been primary in my—a growing interest of my own, and I'm glad to be here today to share the vision we see for future health care delivery to the home, and some of these technologies will enable that to happen. These are emerging technologies that are coming through, and as an architect my interests are to see that these technologies are brought to the user in a friendly, comfortable way. Certainly, there's a concern for the builder environment that it's done cheaply and on time.

And I think that, as you'll hear some of the other speakers speak of some of these technologies, my research is in looking how these technologies can reside in the home in a comfortable way, be a part of the environment, including the furniture, the bathroom, the kitchen. There's some marvelous opportunities here which we can, if we could understand how they would work, will, I think, bring a tremendous vision to people throughout the world, not just in the United States.

Mrs. MORELLA. That sounds pretty exciting, particularly with the beginning of an emphasis on home health care, too——

Mr. KAPLAN. Yes.

Mrs. MORELLA [continuing]. and reaching rural communities.

Dr. Hunter?

STATEMENT OF IAN W. HUNTER

Mr. HUNTER. Yes, I want to thank you very much for inviting me.

I'm an associate professor in mechanical engineering at MIT, as well as being an adjunct professor of surgery and of biomedical engineering at McGill University. I run the biorobotics group in the Newman Lab at MIT, and am the current director of the new Information Science and Technology Lab at MIT, which has its flagship

project, in fact, total home automation and health care consortium project. So it's right on the topic.

Our particular laboratory has developed microrobot technology, all sorts of varieties: microrobots for single cell surgery, microsurgical robots. We're working on tethered microrobots to go in the body, and we're also, in terms of futuristic work, working on key technologies to allow us to build fully autonomous microrobots that can go inside the body for drug delivery, sending out diagnostic information, and performing surgery.

We develop all sorts of technologies, including artificial, very powerful artificial muscle fibers, new laser imaging techniques. So I would regard myself as representing instrumentation physics, as it might be used in the—in advances in the medical area.

Thank you.

Mrs. MORELLA. Dr. Eisenberg, thank you.

STATEMENT OF HARVEY C. EISENBERG

Dr. EISENBERG. I'm one of those people who used to build some of those instruments in his garage back at the beginning of a field that we call now interventional radiology and cardiology, and have lived through the process of developing instrumentation in the field of academics and then in the private sector as an entrepreneur, and working as a consultant to industry in the medical technology area.

I think all of us are here because we believe that there is, in fact, a solution to many of the health care delivery problems, and that that solution can be mediated through technology. I think people like myself, on the other hand, have lived through the realities of technology development and know that, from the time you have something fully developed until the time you can get it out to the public for real use is a seven-to-ten-year process all by itself, without a lot of the regulatory inhibitions that are put on top of that that we heard in the past panel session.

Just the simple process of developing an education, physicians, and ultimately deploying to patient use on a purely medical device basis of it being properly implemented, is difficult enough, and at a time when technology is on an incredibly rising curve of what you can do—I mean, what we used to dream about 20 and 30 years ago is now becoming reality through an exponential curve of acceleration of technology development, and it is no longer acceptable to live through the processes that we lived through in prior years, to wait for these things to happen.

Mammography, cardiac catheterization, we accept these things as gold standards today, but having been involved in the development of those fields, I can tell you they're old. Mammography hasn't changed much since we were working on it in the sixties. Cardiac catheterization hasn't changed all that much, either.

And, yet, the ability to drastically improve and change those procedures is here and now. And I think we're looking for some pragmatic ways to make this happen. It can happen, and I think all of us at this table see a part of a vision of the way that it can happen in the short term, not the long term.

The areas that I've been working in myself has been creating instrumentation which creates an infrastructure for a number of

major programs, a single development program that can, is in the process of creating a sensor device imaging technology that, in a single examination, can not only visualize the human body down to microscopic level in seconds, picking up early-stage diseases—we want to implement preventive medicine. We've all talked about the concept of preventive medicine.

I think the health care debate, one of the things that came across clearly, that it was pretty much agreed to on both sides of the House, was the one way that we can get medicine to a stage of producing better outcomes without necessarily increasing the cost, and maybe even decreasing the cost, is to shift our emphasis from dealing with disease at the late tertiary stages to moving it to the early stages, where it's really a lot less costly and easier to deal with.

And there is a multifaceted way that you can do that, and I think that we'll, hopefully, address some of those issues in these discussions. But we've been involved in developing technologies that will provide the real tools for implementing things like preventive medicine, not only for the process of early detection, but using high technology, which too many of us consider to be a cold and impersonal approach to people, to make the approach of medicine a very personalized process, where the technology itself can be used to let patients walk through their own body and get truly motivated into the process of preventive medicine, into the discipline of preventive medicine, and then giving them tools, through the telemedicine network, to actually be taught what proper nutrition is in the home, to be taught new and true techniques of stress management, which is becoming an increasing part of all of our lives, and increasing studies are coming out that show how profound the impact of things like nutrition and stress are in diseases like arterial sclerosis and cancer, our No. 1 health care problems, let alone the issue of motivating people in more profound ways to stop smoking.

And the very same tools that create that kind of instrumentation, which is based on advanced computer technology and the way you move information around, creates the same basic infrastructure for the real working modules of telemedicine, with how you can actually get physicians to communicate with each other and work at a much higher level of knowledge base in every decision they make in their practice, and the way they deal with each individual patient, as well as being able to take a lot of health care out of not only the hospitals, but even out of the physician's office and back into the home, where I think most people would prefer it to be in the first place.

And I think that this whole range of possibilities is not in the future; it's here and now. And how we make it happen in the here and now I think is what most of us here are concerned about.

Thank you.

[The prepared statement of Dr. Eisenberg, Dr. Hunter, Dr. Jacobsen and Mr. Kaplan follows:]

Written Testimony of

Harvey Eisenberg, M.D.
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Steven C. Jacobsen, Ph.D
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Kenneth L. Kaplan
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Before the Subcommittee on Technology of the House Science Committee

Medical Technology Development and Commercialization

November 2, 1995

22-055 0 - 96 - 5

PROLOGUE

A working group of scientific, academic, and business leaders has been formed for the purpose of exploring an immediate opportunity to revolutionize the national health care system including combat casualty care through imminent advanced technology development.

Despite important advances by the medical community in diagnosing and treating acute and chronic medical conditions, integrating these advances into a truly effective national health care delivery system for all remains problematic. Many Americans, for example, have no or limited access to advanced health care delivery because of economic or geographic constraints. In many of our more isolated communities, advanced health care is largely inaccessible.

Recent unique advances in remote diagnostic and treatment technologies offer opportunity for change. Newly developing telemedicine systems offer a way of uniting advanced medical expertise and supporting technologies to patients and their physicians. Technologies are now emerging for integrating medical expertise to be delivered via telemedicine networks to satellite locations, such as community health centers, rural hospitals, and ambulatory services. The cornerstone of this approach is a continued development and implementation of advanced telemedicine networks for the transmission and distribution of complex medical images, patient records, and other information. A system of health care delivery can be extended into the home. These same technologies offer the potential for a health care system with an effective preventive medicine component. Recent health care debates and opinions of several Surgeon Generals have concluded that the most effective way to improve outcomes in health care, while holding or reducing costs, would be to shift the emphasis from dealing with disease at late, symptomatic, tertiary care stages to early stages – a preventive medicine approach – where treatment is both far less costly and efficacious for better outcomes. The keys to implementation are early detection, motivation, and personalization of preventive care. This can be developed effectively and efficiently only through an investment in advanced medical technologies.

Emerging technologies are being developed which have the potential to significantly reduce medical costs by providing an early transition from hospital intensive care to general hospital care, and from general hospital care to out-patient and home health care. This focus targets hospital diagnosis and therapy by incorporating miniature devices which will allow for the care of ambulatory patients. Specific technologies in development that will significantly impact medical practice include remote, non-invasive sensing of physiologic parameters and location over a wireless communications link, ambulatory drug and intravenous fluid infusion devices.

The incidence of front-line battlefield mortality from injury can be greatly improved in the future. The solution for proper treatment demands development of a highly advanced technology-assisted response capability.

The Department of Defense has begun to address these needs by developing programs that encourage leading academic institutions, defense industry and small, leading-edge companies to form product and systems teams which can dramatically re-engineer the health care system. The technology infrastructure currently exists to significantly improve the quality, cost efficiency and availability of health care. This includes considerably reducing the mortalities from combat casualties and preventing our most prevalent killers of men and women – heart disease, stroke, and cancer. Advanced health care can be simultaneously taken to the combat zone and delivered into the home anywhere in the globe.

The following offers a glimpse, and a glimpse only, of what are some of the newer technologies that exist today. The technologies described have been developed in several places – the private sector, the Department of Defense, and universities.

EXAMPLES OF ADVANCED MEDICAL TECHNOLOGY PROGRAM DEVELOPMENT OPPORTUNITIES

1. Advanced Medical Imaging and Medical Computer Workstation Technology

Enhanced medical imaging sensor and computer technology represent the core elements of 6 programs; each which will simultaneously improve the costs, quality, availability, and outcomes of health care to people of all ages and economic status. These specific programs are:

- Preventive Medicine
- Compacted Diagnostics
- Surgical and Therapy Simulation
- Minimally Invasive Image Directed Robotic Assisted Surgery

- Telemedicine Workstations and Sensor/Notebooks for Physicians and Paramedicals

- Home Health Care Sensor/Computer Notebooks

This technology compendium includes the creation of a single mobile device, capable of non-invasively scanning the entire body in 5-10 seconds and rapidly producing interactive 3D and 4D color graphic imagery of body anatomy with near microscopic resolution. The device will simultaneously study physiology and biochemistry.

Detection of a wide variety of pathology at a sub-millimeter size, level, and disease processes at significantly earlier stages than current testing allows is possible.

Single comprehensive tests of health status can replace multiple tests currently being employed. Invasive testing like diagnostic heart catheterization can be minimized. Simulation of therapy procedures will provide the outcome gains achieved by warfare simulation. Minimally invasive micro-instrumentation for outpatient surgery can be made routine. The visualization of the body structure, leading from the surface of the patient to the site of a pathology will allow interactive guidance for micro-instrumentation to reach the point of abnormality.

Direct vision endoscopic or microscopic surgery will be guided by continual interactive assessment of how anatomy, physiology and biochemistry are being altered before the procedure is completed. This should greatly improve surgical outcomes. In combat casualty care, comprehensive evaluations will be possible in minutes, with minimally invasive telemedically-assisted surgical solutions to lethal problems like massive internal hemorrhage, delivered by combat medics who can be assisted by medical telepresence in front-line mobile modular treatment units.

There will be a family of computers supporting these devices ranging from 20-30 Gflops down to 300 Mflops high performance, low-cost computer notebooks used by the physician at home, office, or in the operating room. Simulation to guide surgery or act as a high performance personal computer for voice or video communications, access to other physicians, medical records, database, informatics, expert decision-making algorithms, libraries, will extend health care capabilities. Collaborative development efforts involve system integration of computers, sensors, and networking solutions, including office and home deployment of medical services.

Computer technology is also being used to create a powerful motivation by taking the patient on a graphic, visual voyage through their own body and showing disease developing years before it will become symptomatic. Disease reversal programs have been shown effective in arteriosclerotic cardiovascular disease (heart attack and strokes), cancer, emphysema and arthritis. A relatively inexpensive telemedicine-based home health care network can be developed. Early intervention involves reinforcing the immune system through nutrition, exercise physiology and

stress management. Since arteriosclerosis is not a normal aging process, but a chronic inflammatory disease largely involving the immune system, stress is felt to play a significant role. These reversal programs include the organization of leading psychiatrists and psychologists working in the area of psychosomatic medicine (mind-body control), developing programmatic materials to teach stress management, along with nutritional training. This personalized approach to preventive care will be delivered into the home through telemedicine. Pediatric care, and catastrophic care to the elderly can be largely taken out of the nursing home into the home with on-line 24-hour services linked to a national system of expertise. Specialists will be enabled to distribute their expertise through telemedicine, augmenting generalists who will be given practical access through telemedicine. (See the attached article from The Economist, October 28, 1995, entitled, "The Invisible Man", page 98.)

2. Advanced Medical Micro-Instrumentation

Surgery remains a manual skill that is analogous to hand-crafted metal work before the advent of modern machine tool technology such as milling machines and lathes. Limitations in manual dexterity, precision and sensitivity constitute a major problem in current surgical practice. Prototype micro-surgical robots, capable of performing micro-surgery with a speed and precision far in excess of even the best microsurgeon, have been developed. Micro-surgical robots may be controlled by a surgeon via force reflecting teleoperated interfaces. Surgeons hold a pseudo-surgical tool which is part of the surgeon interface. Movements of this pseudo-tool are detected and, after performing safety checks and removing unwanted hand tremor, are relayed via the system computer to a micro-surgical robot. The micro-tool held by the micro-surgical robot performs the same movements as the pseudo-surgical tool held by the surgeon. Forces experienced by the micro-surgical robot are scaled up and fed back to the surgeon via the force reflecting interface. Force scaling enables microscopic cutting forces to be felt. Micro-surgical and surgical robots are not designed to replace surgeons, rather their purpose is to enhance the dexterity and precision of surgeons and to perform new and more precise surgical procedures. These technologies will also enable surgical expertise to be projected to remote locations once low-latency, high-band width communication networks become available. Indeed, a surgeon in the United States could perform remote surgery on a patient elsewhere in the world.

Almost half a million North Americans underwent coronary bypass surgery last year with a total cost of almost 20 billion dollars. A new micro-surgical robot under development for heart surgery will allow surgeons to perform coronary bypass surgery, on freely beating hearts, without the need to stop the heart and bypass it with a heart-lung bypass machine. This system will have six micro-surgical robots under the control of a single heart surgeon

and will effectively provide them with three pairs of teleoperated "hands". In a subsequent version of this system, each micro-surgical robot will enter the chest through small ports. Thus, the system will eventually avoid the need for open chest surgery, eliminate the necessity to stop the heart (which causes most of the current complications associated with heart surgery), and provide the surgeon with more "hands" (reducing the need for additional surgical participating personnel). The net result will be reduced surgical time, minimized surgical intervention, more rapid recovery time, fewer personnel, reduced cost, and better patient comfort and care.

In the near future, robotic technology will advance to the point where small tethered robots will be able to self-propel themselves to specific locations within the body under the control of surgeon/clinician "drivers". Such robots will deliver drugs, perform microsurgery and send out diagnostic information. Future development of new spectroscopic high resolution 3D imaging systems can be miniaturized and embedded in micro robots to enable 'in-situ' optical biopsy.

3. Diagnostic Monitoring and Location

Applying communication and information science advances to medical care now can: a) permit the determination of human physiologic state remotely so that medical attention is directed promptly to casualties; b) determine the exact location of the casualty; c) use physiologic data and protocols to guide initial triage evaluation and management; d) monitor and record physiologic data during ongoing medical evacuation; and, e) avoid discontinuity and reduce risk of care during transport to and through higher levels of care.

It is possible to integrate medical protocols to provide diagnostic and therapeutic guidance and create and maintain longitudinal medical records. Device control protocols can also permit therapeutic devices to communicate with, and be controlled by the communications. Protocols, such as Asynchronous Transfer Mode (ATM), will enable seamless transmissions to national centers of expertise.

Beyond the contributions to military casualty and civilian emergency medical care, diagnostic monitoring and location is recognized for its potential value in general health care in the United States. Personal monitoring addresses the current emphasis on reducing health care costs by providing an early transition from hospital intensive care to general hospital care, and from general hospital care to out-patient and home health care.

4. Miniature Drug and Intravenous Fluid Delivery Systems

Intelligent micro-machines have been developed for the delivery of drugs and fluids based on microprocessor control and novel actuation systems. These pump devices can provide instrument level precision and accuracy that is sufficiently inexpensive for one-time, disposable use. In the past, medical devices combining high performance with low cost have not been feasible due to technological limitations in miniaturization and electronic intelligence. These limitations have been overcome through the recent electronic advances of the microchip industry. State-of-the-art technologies have been exploited in electronics and miniaturized precision mechanical actuation to design two novel pumps that facilitate ambulatory, in-home drug and fluid therapy. This new generation of pumps is projected to cost 10-fold less than any other currently available pump with similar capabilities. Costly in-hospital care (greater than $2,500/day) can become less expensive out-patient care (less than $200/day) without compromising the quality of therapy – substantially increasing the quality-of-life for patients.

These new pumps address the two most prevalent needs of parenteral therapy:

1) Automatic, unattended administration of precise drug dosing regimens to maximize therapeutic outcome and eliminate drug induced toxicity, and;

2) Volume replacement therapies, including total parenteral nutrition of severely debilitated patients.

The pumps are configured and sized to meet high volume delivery of dilute solutions (mini pump; 1 to 200 mls/hr; 12.7 cm x 5.1 cm x 2.3 cm; 196 grams) and low volume delivery of concentrated drug solutions (micro pump; 0.01 to 7 mls/hr; 5 cm x 2 cm x 1 cm; 15 grams). Anticipated specific applications for the mini pump include intravenous volume replacement with options for addition of antibiotics, analgesics, or chemotherapeutic drug agents. The micro pump is directed to delivery of all classes of drugs by the most appropriate parenteral route, including site-specific delivery of drugs such as, tumor-direct delivery of chemotherapeutic agents, targeted thrombolytic administration, anesthetics, and anticoagulation of post-operative patients, especially in the geriatric population.

5. Minimally Invasive Micro-devices for Therapeutic Procedures

Health care costs can be reduced by the use of less invasive therapies that utilize shorter hospital stays and rehabilitation times. Additional cost savings are realized through more effective treatment of diseases like stroke and cancer that have no viable medical alternatives. Treating cancer in a less invasive and site-specific manner reduces hospital stays, palliates symptoms and allows for more productivity during the course of therapy. Less invasive therapy for stroke reduces neurological damage, treatment costs and increases post-trauma productivity. A new line of micro-catheters, guide wires and less invasive devices are being developed to advance therapies through new capabilities. This technology provides effective and minimally invasive access to disease locations throughout the body, allows for identification of tissue, and assesses the metabolic state through direct sensing and through compatibility with magnetic resonance methods.

6. Advanced Health Care Environments

Telemedicine systems that extend the health care delivery system direct into the home and community offer a way to improve outcomes in health care by increasing preventive care and by bringing advanced medical expertise and supporting technologies to the actual patient user. Experience with existing telemedicine initiatives illustrates the potential for these approaches; new research and development activities will carry this potential to a much higher level. In this vision, the home is a pivotal point of preventive care for all end users. The elderly and chronically ill could best be served in their home environments, and eventually, all Americans can benefit from primary preventive care provided in a home setting.

In order to make this vision possible, the home can be transformed into an active data acquisition component of the health care delivery system. Living units can be linked with health care providers via an efficient telemedicine network so that direct consultation between patient and physician can occur.

More than consultation is possible. The home itself can become an active health-status monitoring device. Critical home environments, the bathroom, kitchen, and bedroom areas, can be equipped with an array of different kinds of sensory technologies that can monitor the health-status of occupants. Devices exist or can be developed which would allow common health measures to be non-invasively obtained, recorded, and, if appropriate, reported to a health care provider for expert analysis and treatment response.

The home as a health care environment would include visual and auditory systems for health care instruction, automated medicine dispensers for users with difficulties in following prescribed medication regimens, and other devices. Potentially applicable technologies include: various biosensors for measuring chemical changes in body fluids (e.g., urine), scanning systems for skin condition assessment and body geometry, auditory systems for hearing analysis (in itself a measure of other conditions), eye inspection systems, respiration analysis systems, different types of sensors and transducers for automatic weight measurements, and others. The emerging world of "smart" materials offers many exciting possibilities. Devices based on these different technologies can be embedded in common architectural elements (e.g., toilets, showers, walls). Ultimately, many of these same technologies could become directly "wearable".

Different combinations of devices could be configured to respond to the needs of varying user groups. General needs for many elderly, such as verification of medication intake, vary dramatically from the needs of the chronically ill with specific health issues. A modular design response is needed so that different home environments can be configured and reconfigured in many alternative ways.

While the home can be a focal point for many health care activities, some must invariably be done outside. While not a problem in some areas, many communities are in remote locations not near centralized services. However, many of the advanced technologies now available only in central locations.can be brought to remote areas quickly and efficiently through the development of special "health care modules". These modules would be designed to accommodate insertable submodular units housing specialized medical technologies. These same modules could be internally reconfigured quickly as needs change. Assemblies of modules can provide full hospital service.

These new architectural environments would combine the best of health care modalities. New virtual environment design interfaces and simulation technologies would enable both health care personnel and users to participate in their design. New computer-aided design and manufacturing technologies could be employed to implement these designs, which would also give a technological boost to the housing production industry in this country. There are many reasons for doing so. Appropriate advanced technologies, properly and comfortably integrated into our homes with these new collaborative design tools, can provide the affordable innovative products and services while enhancing the quality of health care. The home environment is the ultimate goal for establishing a health care system of excellence.

EPILOGUE

Technology can now support major advances in the quality of health care delivery and further reduce costs on a national scale. However, we lack a plan and a strategy to take advantage of the new technology and to implement them in a cost-effective way. In view of the importance of health to individual well-being and national productivity, we recommend a two-part program:

1. For the near term, sustain or increment existing research and technology-programs which will enable application of information, communications and medical technology to medical care.

2. Commission a Blue Ribbon Panel specifically to assess current capabilities, to investigate technical applications and to develop a plan and an implementation strategy to achieve the accelerated development and implementation of advanced medical technology. Our national health and productivity will be improved if we pursue these most promising opportunities.

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Diagnostics

The invisible man

SOUPING-UP motor-bikes is a well-established art. Souping-up medical equipment, though, is a novelty. Health Technologies & Wellness (HTW), a company based in Newport Beach, California, is just such a soup kitchen. It has taken a standard machine and turned it into something that it hopes doctors will be eager to be seen riding around on—a multi-purpose one-stop diagnostic device known as the AngioCat.

The AngioCat is a turbo-charged version of the latest Siemens computerised-tomography scanner. These scanners are basically advanced X-ray machines; the AngioCat is very advanced indeed. The electron beam that generates the X-rays moves so fast that the AngioCat can assemble enough data to paint a three-dimensional picture of the innards of a human body in 30 seconds.

This won't hurt a bit

It is HTW's snazzy computer hardware and software, though, that take the data and do the actual painting. And the fineness of the brush-strokes (the picture is made of slices a tenth of a millimetre thick) means that early signs of disease that would otherwise be undetectable show up. Harvey Eisenberg, who used skills learnt as a radiology researcher at the University of California, Los Angeles, and at Raytheon, an American defence contractor, to design the system, reckons it can pick out early signs of heart disease, cancer and osteoporosis.

Early detection is what Dr Eisenberg hopes will give the AngioCat its edge. Existing tests for coronary heart disease, such as electrocardiography (which measures the electrical potential across a heart) or angiography (where a tiny camera is inserted into a coronary artery) work only when the flow of blood in the arteries is already restricted. But blood-flow may stay close to normal even when 70% of an artery is blocked. And coronary-heart-disease patients can have a life-threatening heart attack even when their blood-flow is not badly restricted, if a clot forms in a damaged passage (see previous story).

Post-mortem studies have suggested that there may be a better predictor of heart disease than reduced blood-flow: the extent to which the inner surfaces of blood vessels are smeared with plaque. This is the material actually responsible for furring up the arteries. The AngioCat measures the formation of plaque directly—and can do so well before any constriction in blood flow is apparent.

Plaque contains calcium, and calcium absorbs X-rays. Because calcium appears early on in the development of arterial plaque, patients can assess their personal health risks quickly—as much as ten years before circulation is affected. At such an early stage any alteration they make to their diet or other personal habits should be much more effective. And the AngioCat can instantly check up on the success of such efforts—something that has previously been impossible.

As well as looking for plaque, the AngioCat can also screen those larger repositories of calcium, bones, to see how they are faring—any thinning, the sign of incipient osteoporosis, would show up quickly. And tiny malignancies in the lungs—the earliest stages of cancer—should also be detectable. Indeed, so tiny will they be when first detected that they can safely be monitored to see if they grow into something threatening that requires action—or just vanish, as it were, in a puff of smoke.

Mrs. MORELLA. Thank you for that statement.

We're going to be seeing some demonstrations, aren't we, at one o'clock?

Dr. EISENBERG. Yes, at one o'clock, there's a technology fair downstairs in which some actual demonstrations of these technologies that are being used in patients at this time, or in development for use in patients, are today in stages—

Mrs. MORELLA. It sounds like a great educational tool, that concept of the virtual activity, reality kind of thing, and kids in school could grow up knowing what they should do with their body for safety and health, as well as curing others.

General Kind?

STATEMENT OF PETER A. KIND

Mr. KIND. Thank you for the opportunity. Thank you for the opportunity to be with you today and for the hearings that you're holding on this very important topic.

I guess you can tell by my title that I had a lot of time in the Army, and in that time I worked in communications, in automation software, audio-visual sorts of things, and I culminated my 33 years as the director of information systems for Command Control, Communications and Computers, for the Army.

After my retirement, I began a sojourn with the Software Engineering Institute at Carnegie-Mellon University, with which I am still associated, and I'm also an adjunct professor of computer science at the University of Utah. But my principal roles right now are as senior vice president of SARCOS, as you can see by the intro, that is a research and development company that does technical transfer, located in Salt Lake City.

I'm here for my boss, who has laryngitis, but my colleagues and I hope I can discharge his duties sufficiently to tell you some of the things that we do in the company. I've been with them a year, and it's really an exciting group. My purpose here is to help share with you some of the things that technology can do.

Our theme is information-driven machines that move. We're multidisciplined. We take things from a number of different areas and make things happen.

In telemedicne, we have a device that will be on display at the science fair you just addressed, called the Personal Status Monitor, that allows the reading of body vital signs not invasively; a combination of that with location, and then transmitting that to other people in the chain of command and the combat medics. What this does, it will save lives, first of all, by letting us know where our soldiers are down to the individual level in a way that's never been done before, automatically, so the soldier doesn't have to divert himself from what he's doing to send that information in.

But it will also alert when he becomes a casualty, and so it will help us find him in that first golden hour when so many of the casualties take place, and perform the lifesaving steps on him, and get him on the way back to higher levels of care.

Microelectro-mechanical systems are the combinations of electronics and mechanical items and materials in very, very small sorts of application, which then allow you to do things that haven't been done before or go different places that haven't been gone be-

fore. An example of some very small systems is an IV pump that will allow the dispensing of concentrated medicines in lieu of the much larger pumps. You can see it's very portable and could be taken with. It allows the drug dispensing through another device. This has 12 different doses that could go on an animal and be dispersed over periods up to a year. You decide when to do it.

Without going into a lot of detail at the present time, we also do things in virtual reality and in the telemedicine world, cylindrical lithography, which is one of the most exciting, that allows you to make very small, steerable catheters, and these, then, allow you to go places like into—or will when the research is completed—will allow you to go into places and actually do operations or do biopsies, see what you're doing, administer small doses of application-specific medicine at the point where it makes the most difference and without the bad effects, side effects, that happen when they are administered in the general case throughout the body.

So it's a variety of things, a very exciting thing in technology, can do some very, very good things for us, for our people, and for our national productivity.

Thank you.

Mrs. MORELLA. I have probably about another seven minutes with you, and then I think we may have more than one vote on the floor. What we may do is then just allow the Subcommittee to submit further questions. I know we're going to have a number of questions for the panel, if that would be all right. We'll see you at the foyer then at one o'clock.

But I wanted to ask you, you know, we talk about health care costs, and so many people will say, well, one of the reasons that health care costs are escalating is because of the propensity to use medical technology where it might not be necessary, just to use it because it's there, and that seems to be a rather convincing point. On the other hand, you are coming, I think, to this Subcommittee and you are saying medical technology is going to actually reduce medical costs. Are these incompatible concepts? I mean, can technology also increase the cost? I mean, should we be more aware of who is able to take advantage of medical technology? Should it be a free-for-all? I just wondered if any or all of you might want to comment on it. Do you want to start off on that?

Dr. EISENBERG. I think that the issue with technology in general is really always twofold, is: what is it that you want to develop? And the second is how you use it.

We—our concern is what technology is possible and what it can accomplish. That is, in fact, a separate issue from how you would deploy it and use it.

The technologies that I'm working on will create the tools for preventive medicine. We talk a lot about preventive medicine, but how do you implement it? If everyone agrees that this is a major direction that the Nation needs to go in, in order to improve outcomes and cut costs, I think people will generally accept it. If you pick diseases up at early stages, even long before they're symptomatic, and the tools exist to stop, and even reverse those diseases, like arterial sclerosis and even cancer, then you're intervening at a stage where it is, indeed, far less costly, and the treatments are the simple things of what you eat and how you deal with stress in your

life, not the big rotorouters to do angioplasty or the newest technologies to do bypass surgery.

In fact, the studies in general and recent publications have even indicated that bypass surgery and angioplasty don't really extend people's lives. It improves their quality of life, takes away their symptoms, but except for a few selected examples of certain kinds of lesions, it doesn't extend people's lives. And, yet, we pour large sums of money into these areas. Our whole thought of heart disease is toward angioplasty and bypass surgery, and they're the bandaids. The real treatment is the disease-reversing processes that relate to the fundamentals that are inexpensive and can be mediated to individuals in the most inexpensive ways.

So other areas are compacted diagnostics, the ability to create a single instrument that would study anatomy, physiology, and biochemistry in a single examination, providing you the ability in seconds, literally seconds, to address a diagnostic problem, whether it's a combat—a downed soldier in the field in a combat MASH van, where the casualties are coming at you in large numbers and quickly, and you need to make rapid, comprehensive diagnostics, or the simple diagnostic process that we go through today which can largely be mediated, and should be mediated, pretty much on an outpatient basis. These are cost-effective issues.

The ability to train a surgeon to do his operation in a matter of seconds in a desktop/laptop computer before he actually operates on the patient is called simulation training. General Kind, next to me, knows very well from his military experience the wonderful improvements in our kill ratios that we got from air and tank warfare by simulation training. We'd like to turn that into lifesaving outcomes in terms of having a surgeon know what he's going to do before he gets in there or teaching a surgeon the 26 variations in the blood supply to the gall bladder before he does his first gall bladder operation, and doesn't—a number of people have died on the table because of lack of that knowledge.

The ability to do image-directed, minimally-invasive robotic-assisted surgery is, again, one of the collaborative programs in development here; the ability to guide a surgical procedure with great precision, the way we guide a bomb to its location, but to be able to guide instruments from the outside to the inside of the body in a precise image-directed way, the instrumentation itself able to do exotic and new kinds of surgical techniques in the most minimally-invasive way——

Mrs. MORELLA. So you see this as a reality right now?

Dr. EISENBERG. Yes.

Mrs. MORELLA. I think it's absolutely fantastic——

Dr. EISENBERG. Yes, absolutely.

Mrs. MORELLA [continuing]. that we can, in fact, do that.

I'm rushing you along. P.S., I hope the bypass surgery is something that's going to continue since my husband had it eight years ago, and I think it made—I think it came at a critical time. So it was absolutely imperative.

Maybe I'd just get a couple of comments from each of you before I have to leave you. Mr. Kaplan, you wanted to comment on that?

Mr. KAPLAN. Yes, I just want to say, from the architectural design point of view, I think I see an enormous way to save money,

particularly in the facilities. This is now one of the biggest—a doctor said to me, "The most expensive medical device is the hospital itself," the running of the hospitals, the functioning of the hospitals, not to say that there's not some great hospitals, some of the best in the world in this country, but I think there's—in using advanced simulation to think about how to design these facilities more efficiently, to do that in a computer simulation, to look at not only what the hospital is, the cares of excellence, but what a small clinic might be, a portable clinic, and what the home might be.

You know, what is the future of health care in the home? What would be the products, the services, the devices that are part of a chair, part of the environment of the bathroom, where people could afford these devices, not unlike some of the consumer products that we have already in our homes that allow us to have access, control of information.

I think there's a cost saving in this and there's also a quality-of-care benefit in trying to redistribute the facility, if you will, out to the home. And I think that a lot of us believe this, but I also feel that there's R&D to be done on the cost outcomes of this, and to do that in association with the technologies.

Mrs. MORELLA. Excellent.

Dr. Hunter, did you want to comment on that?

Mr. HUNTER. I just have a brief comment. At the moment, there are effectively no high-tech medical mass markets. All the mass markets are effective low tech, drugs and bandaids. I think we can expect vast decreases in the cost of high technology, medical high technology, once mass markets open up, and these mass markets will open up when we start to have health care, high-tech health care devices in the home.

So I have high hopes that, in fact, the sophisticated, high-tech medical device costs will come down dramatically as these new mass markets open up, as well as, of course, bringing costs down. We heard that the early prevention/detection early on, these devices will, in general, will, in fact, improve health care.

Mrs. MORELLA. And you're trying to develop the need for the mass market at MIT?

Mr. HUNTER. Yes, we're certainly working on a number of key technologies.

Mrs. MORELLA. Encouraging it and demonstrating it can be done.

Mr. HUNTER. Indeed.

Mrs. MORELLA. We can continue our discussion at the fair at one o'clock which is in this building, in Rayburn.

I did want to ask unanimous consent, and with no objection, I would like to forward some of the cases that we discussed on the first panel and some of the points that you have brought up in your combined testimony, which I have before me, to the FDA, the Food and Drug Administration, for their responses. I think it would be fair to hear from them in terms of how they respond to the issues that have been brought up.

But, General Kind, I didn't give you an opportunity for the last sentence.

Mr. KIND. I would very quickly give you an example on costs. If the cost of hospital care is around $2,500-plus per day here, and it easily goes very high to three times that, if you add in special

care, and you can get a person out of the hospital and in a home care environment using things like we've talked about here, at a cost of about $200, you have a factor of 10 to 1 savings.

Mrs. MORELLA. It's a very, very good point. I can just see all kinds of possibilities. In fact, we've—I've heard from the National Institutes of Health that, if we can even arrest a particular disease for five years, like Alzheimer's, Parkinson's, a number of the others, there's a tremendous medical savings that actually occurs. So I can see this being used for the young, for the elderly, for all of us.

Thank you very much. We'll pick up the questions at the technology fair. I hope you will all be there at the Rayburn foyer. Thank you. Thank you very much.

The Subcommittee meeting is now adjourned.

[Whereupon, at 12:38 a.m., the Subcommittee was adjourned subject to the call of the Chair.]

[The following material was received for the record:]

NEMA
Setting Standards for Excellence

STATEMENT OF THE DIAGNOSTIC IMAGING AND THERAPY SYSTEMS DIVISION

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

FDA REGULATION OF MEDICAL TECHNOLOGIES

SUBMITTED TO THE SUBCOMMITTEE ON TECHNOLOGY
HOUSE SCIENCE COMMITTEE
HON. CONNIE MORELLA (R-MD), CHAIRMAN

NOVEMBER 2, 1995

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Manufacturers Association

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NEMA appreciates the interest shown by the Subcommitee on Technology of the House Science Committee relative to the impact of the current FDA framework for the regulation of medical devices on the competitiveness of the U.S. medical technology industry, and is pleased to submit this statement for the record in conjunction with the November 2 subcommiitee hearing.

NEMA, the National Eelectrical Manufacturers Association, is the nation's largest trade assocation representing America's electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than ninety-five percent of the nation's manufacturers of computed tomography, x-ray imaging, nuclear imaging, diagnostic ultrasound, magnetice resonance imaging, and radion therapy equipment. In addition, the division represents manufacturers of extracorporeal lithotripters and picture archiving and communications systems.

As the nation approaches the twenty-first century, the challenge to re-think the manner in which we govern ourselves has never been greater. In no area of public policy is the challenge greater than in the health care arena. Highlighting this public agenda are two crucial public policy issues: how to improve and enhance the competitiveness of the U.S. medical device industry, and how to ensure continued public access to safe medical technologies. The current FDA product review process for medical devices represents an attempt to balance the task of protecting the public health and safety with the equally important and compelling task of ensuring patient access to new and innovative health care technologies. Although effective when originally enacted in 1976, the current regulatory framework for the approval of medical devices suffers from a lack of cohesion and predictability, and lacks the ability to respond to the rapid pace of innovation in medical technology.

In perhaps no area of the medical device industry is the pace of innovation so rapid as in the diagnostic imaging industry. State of the art technologies such as magnetic resonance imaging and computed tomography are dependent upon a constant rate of innovation and require a regulatory framework which adapts to this rapid pace of technological change. Ironically enough, at the very time at which product development cycles for new medical devices have gotten shorter, product review times for new medical devices have gotten longer. For the American consumer, this means continued delays in access to safe and innovative health care technologies. And for the American worker, this means a loss of jobs as U.S. firms move their research and development efforts offshore.

NEMA believes that the current FDA product approval process lacks the ability to respond to this constant pace of innovation, and as such, undermines the competitiveness of the U.S. medical device industry, traditionally one of the nation's most competitive. For the period 1990 to 1993, U.S. exports of medical products grew at an average rate of 10.5% per annum,[1] reaching $8.1 billion in 1993.[2] This large volume of exports translated into a trade surplus of nearly $3.2 billion for the medical technology industry in 1993.[3]

As this large trade surplus readily attests, an investment in medical technology means an investment in jobs for American workers. In 1993, for example, more than a quarter of a million workers were employed by the U.S. medical technology industry, with the greatest number of workers concentrated in the Southeast and Western regions of the country.[4] The industry accounts for a payroll of nearly $9.8 billion,[5] and is indicative of the type of globally-competitive, technology based industry which the U.S. must foster to enhance our competitiveness as we move into the next century. Already the U.S. enjoys a competitive edge in the medical technology industry as thirteen of the twenty largest medical technology businesses in the world are based in the United States (Appendix I).

Unfortunately, however, at the very time at which it is most crucial to ensure U.S. competitiveness, an increasing number of U.S. manufacturers have begun moving jobs offshore, at least partially in response to increasing FDA product review times for medical devices. Appendix II provides an overview of the average review time required to process a 510(k) submission, the most common route to market for incremental changes in medical technologies. Recent CDRH estimates place the average product review time at 142.7 days for a 510(k) submission,[6] as opposed to the ninety day time frame set forth in the Medical Device

[1] U.S. Department of Commerce, Bureau of the Census, Manufacturing and Construction Division, Office of Microelectronics, Medical Equipment and Instrumentation, August 1994.

[2] Ibid.

[3] Ibid.

[4] Health Care Technology Institute, "Employment Trends for the Health Care Technology Industry," Healthcare Data Stat, March 1994 (Alexandria, Virginia: Health Care Technology Institute, 1994)

[5] Ibid.

[6] U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation, Program Operations Staff, May 1995.

Amendments of 1976. As Appendix III reveals, product review times for some diagnostic imaging modalities are now approaching three hundred days, well over the ninety day time frame stipulated in the 1976 Medical Device Amendments.

Interestingly, as product review times have increased for 510(k) submissions, so has the trend of U.S. medical device manufacturers to relocate offshore. Appendix IV provides an overview of direct foreign investment by U.S. firms. Note in particular the correlation between product approval times and net foreign investment. In 1992, for example, as the average product review time for a 510(k) submission approached 125 days, capital outflow from the medical device industry approached one billion dollars for the first time in U.S. history. This trend is confirmed by a June 1994 Gallup survey of medical device manufacturers which reveals that 29% of manufacturers surveyed reported that delays in 510(k) approvals have led to decreased investment in U.S. operations and increased investment abroad.[7] The same survey reveals that 17% of manufacturers surveyed have moved their manufacturing operations abroad due to difficulties associated with the 510(k) approval process, and 40% of manufacturers have reduced the number of U.S. employees due to difficulties in obtaining 510(k) approval.[8]

In addition to the jobs lost by U.S. workers as a result of overseas investment, delays in product review times oftentimes mean that U.S. patients are increasingly being denied access to safe and beneficial technologies which are currently being marketed abroad. A 1993 survey by the Health Industry Manufacturers Association reveals that this trend exists across product lines, with cardiovascular devices being marketed most frequently abroad (53%), followed by orthopedics (22%). One third of all the devices listed in the HIMA survey were marketed for at least three years abroad while awaiting approval in the U.S., while almost 60% had been available abroad for more than six months before receiving FDA approval. Moreover, 35% of the devices available abroad were less expensive than substitute therapies, and about 60% were comparable in price.[9]

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[7]The Gallup Organization, "Survey of Medical Device Manufacturers concerning the Strategic and Economic Impact of the Federal Regulatory Process," (Princeton, New Jersey: The Gallup Organization, June 1994), p. 28.

[8]Ibid.

[9]Health Industry Manufacturers Association, "Product Approvals Overseas Project," in Less Than the Sum of Its Parts, House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, (Washington, D.C.: U.S. Government Printing Office, May 1993), Appendix XIV, pp. 234-237.

In summary, medical device regulation in the U.S. has suffered from a lack of consistency which is imposing increased costs on U.S. firms as the result of unnecessary delays in product approvals. These increased costs, in turn, have led many U.S. manufacturers to relocate offshore, thus resulting in a loss of jobs for U.S. workers. Finally, the unpredictability of the device approval process in the U.S. has led many companies to seek approval for their products overseas before marketing their products in the U.S., thus denying U.S. patients access to safe and beneficial health care technologies.

The time has come to re-examine the vital mission of FDA's Center for Devices and Radiological Health in light of the increasing complexities of today's global marketplace. As a recent report prepared by the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee maintains, if the whole is in fact "Less than the Sum of Its Parts," perhaps the time has come to evaluate the underlying structure of the whole itself -- that is to re-evaluate and re-assess the ability of FDA's Center for Devices and Radiological Health to fulfill its mission as the U.S. approaches the twenty-first century.

The time to reform the current framework for the regulation of medical devices is now, as the nation prepares to compete in the global economy of the future. While short-term actions can be taken to remedy existing inefficiencies in the areas of product review and enforcement, the time has come for the establishment of a new regulatory framework predicated on the notion of a public-private sector partnership, which leaves enforcement responsibilities in the hands of FDA, but delegates the more resource intensive tasks of product review and inspection to third party entities. NEMA believes that this framework will build upon the strengths of the current system for the regulation of medical devices while at the same time provide the flexibility to adapt to the constant pace of medical innovation.

NEMA has developed a series of recommendations designed to make this public-private partnership a reality. These recommendations, set forth in Appendix V, are discussed in greater detail in the NEMA position paper, *Re-Inventing the Regulation of Medcial Devices II: Towards a Public-Private Partnership for Device Regulation*. Copies of this posision paper will be provided to subcommittee members upon request.

NEMA appreciates this opportunity to provide written testimony to the subcommittee, and looks forward to working with subcommittee members in the weeks and months ahead towards making this public-private partnership a reality.

Appendix I

Twenty Largest Medical Technology Businesses in the World 1993

Baxter	Smith and Nephew (Great Britain)
Johnson & Johnson	**Eli Lilly**
Siemens (Germany)	**U.S. Surgical**
Abbott	**Medtronic**
3M	**Pfizer**
Becton Dickinson	Boehringer Mannheim (Germany)
General Electric	**Bard**
Bristol Myers Squibb	**Hewlett-Packard**
Miles (Germany)	Toshiba (Japan)
Ohmeda (Great Britain)	Philips (Netherlands)

U.S. based firms identified in bold face type. It should be noted that a number of foreign manufacturers, although headquartered abroad, nevertheless employ a significant number of U.S. workers.

Source: Health Industry Manufacturers Association

APPENDIX II

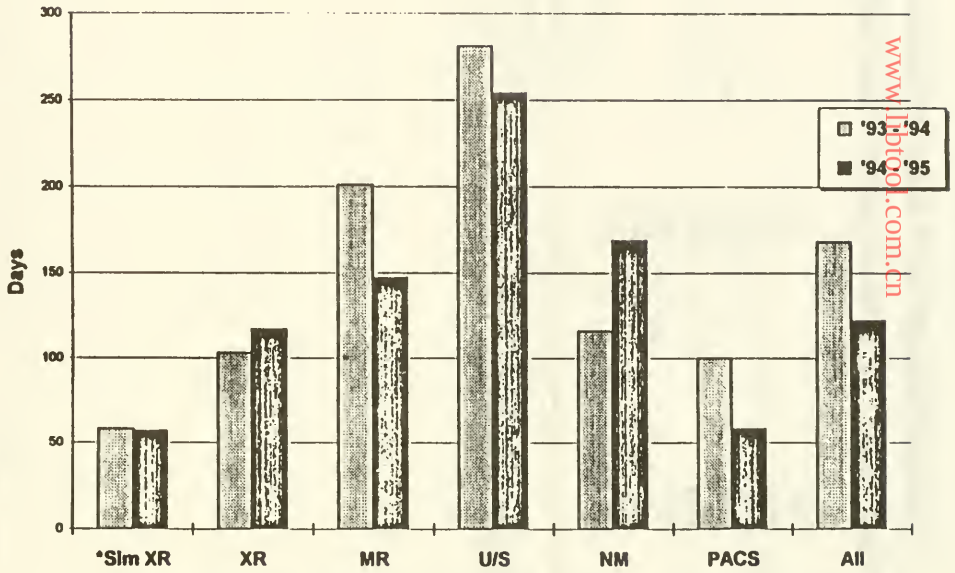
AVERAGE REVIEW TIME FOR 510(K) APPLICATIONS

FISCAL YEAR	AVERAGE REVIEW TIME (DAYS)
1987	69
1988	78
1989	82
1990	98
1991	102
1992	125
1993 (MAY)	187
1994	210

SOURCE: U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF DEVICE EVALUATION, PROGRAM OPERATIONS STAFF, DECEMBER 1994.

APPENDIX III

510(k) Mean Processing Time



*Sim XR means (simplified) 510(k) based on certification to standards. Devices are X-Ray imaging (XR), Magnetic Resonance imaging (MR), Ultrasound imaging (U/S), Nuclear Medicine imaging (NM), and Picture Archiving and Communications Systems (PACS).

9/15/95

APPENDIX IV

FOREIGN DIRECT INVESTMENT BY U.S. MEDICAL DEVICE FIRMS
(in millions of Dollars)

YEAR	FOREIGN DIRECT INVESTMENT	CAPITAL OUTFLOWS	AVERAGE 510(K) REVIEW TIMES
1980	887	-	
1985	(777)	6	
1989	2,564	333	82
1990	3,119	321	98
1991	3,389	321	102
1992	4,044	993	125
1993	-	-	187
1994	-	-	210

SOURCE: U.S. DEPARTMENT OF COMMERCE, BUREAU OF ECONOMIC ANALYSIS; SURVEY OF CURRENT BUSINESS, (JULY 1993), P. 123. DATA ON AVERAGE 510(K) REVIEW TIMES PROVIDED BY U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF DEVICE EVALUATION, PROGRAM OPERATIONS STAFF, DECEMBER 1994.

RE-INVENTING THE REGULATION OF MEDICAL DEVICES: NEMA RECOMENDATIONS FOR FDA REFORM

I. Enhancing the Product Review Process

- Strike the $23.5 million in medical device user fees from the FY 1996 FDA budget. Reallocate medical device program resources to ensure that an equitable balance of resources is devoted to product review and enforcement surveillance activities.
- Revise the definition of a class II device so as to permit FDA to make use of voluntary consensus standards as the mechanism for ensuring the safety of most class II devices.
- Limit FDA's authority to require clinical data in conjunction with a 510(k) submittal to life-sustaining devices.
- Eliminate FDA's authority to promulgate performance standards for class II devices.
- Clarify the criteria for determining the need for a 510(k) submittal.
- Exempt medical devices that are approved in non-U.S. markets from export control requirements as set forth in H.R. 1300.

II. Streamlining Postmarket Surveillance

- Eliminate all user and distributor reporting requirements.
- Limit medical device reporting requirements for manufacturers to reports of deaths and serious injuries.
- Eliminate current law requirements for manufacturer certification of MDR reports.
- Amend current law recall authority so as to provide the opportunity for a hearing prior to the issuance of a cease distribution and notification order.
- Deny FDA the authority to delay the approval of new product submittals as a result of GMP violations.
- Prohibit the FDA from engaging in cost-effectiveness determinations.
- Impose limitations upon the FDA's authority to regulate the off-label use of a medical device. Limit FDA regulation of industry promotional practices.

III. Uniformity in Regulatory Requirements

- Require FDA to harmonize proposed medical device GMP regulations with relevant international quality assurance standards.

- Amend Section 803 of the Federal, Food, Drug, and Cosmetic Act to require FDA to complete action and implement a mutual recognition agreement with the European Union in the area of medical device GMP no later than January 1, 2000.

- Amend Section 521 of the Federal Food, Drug, and Cosmetic Act to establish federal law pre-emption over state laws in the areas of GMP inspections, postmarket surveillance, and performance standards. Further amend Section 521 such that a state is expressly prohibited from the assessment of any fees with respect to the regulation, registration, and licensure of a medical device, and to prohibit the states from establishing regulatory requirements which duplicate current law requirements for the regulation of medical devices.

IV. Third Party Review

- Provide FDA with the statutory authority to delegate product review and GMP inspection activities to accredited third party entities. It is NEMA's intent that the review of medical devices by accredited third party organizations be the only level of review required for such products. No additional level of FDA review would be required.

APPENDIX V

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Peter A. Chevalier, Ph.D.
Vice President
Chief Quality and Regulatory Officer

November 9, 1995

The Honorable Connie Morella
Chair, Subcommittee on Technology
Committee on Science
2319 Rayburn House Office Building
Washington, DC 20515

Dear Madam Chairman:

Thank you for allowing me to testify before the Subcommittee on Technology last week on the impact of government regulation on medical device innovation. I appreciate the opportunity to share my concerns and those of Medtronic with the members of the Subcommittee.

Finding appropriate solutions to the problems identified during the hearing, especially the efficiency of the FDA product approval process, is vital to the future competitiveness of the U.S. medical device industry. Hearings such as the one you organized are important to keep these issues on the crowded congressional agenda.

I would like to respond to one specific statement that was made by another witness during the hearing. Dr. Jeffrey Brinker, a researcher from The Johns Hopkins School of Medicine and member of the FDA's cardiology advisory panel, stated that the Agency does not require proof of relative effectiveness for medical device approval decisions. Unfortunately, that is not the case.

The attached article clearly shows that the FDA continues to assert its ability to require data sufficient to establish that a submitted device is at least as effective as approved alternatives. Dr. Bruce Burlington, Director of the FDA Center for Devices and Radiological Health, states that the FDA believes "Congress intended the agency to look beyond the mere claims of the manufacturer and to look at the health of the populous as the product is being used when considering what safety and efficacy is about." This is despite the fact that the growth of managed care and the increasing importance of cost-effectiveness is providing for this function to be carried out elsewhere in our health care delivery system.

As I stated during the hearing, the role of the FDA should be to determine that a device meets necessary safety criteria and performs the function stated on its labeling. Determinations as to relative effectiveness, which are in essence evaluations of medical outcomes, should be left to

medical practitioners, where the experience and expertise necessary to make such decisions clearly lies.

Recognizing the extraordinary burden a premarket evaluation of medical outcome imposes upon manufacturers and the harm created for patients who must wait significantly longer for device approvals, nearly every other industrialized country has rejected relative effectiveness requirements as part of the medical device approval process. If we are to ensure that the United States continues to be the source of innovative medical technologies and our patients receive the best available medical technologies in a timely manner, we must do so, too.

Again, thank you for inviting me to address the Subcommittee. I hope we will have the opportunity to meet again as Congress works toward resolution of these important issues.

Sincerely,

MEDTRONIC, INC.

Peter A. Chevalier, Ph.D
Vice President
Chief Quality and Regulatory Officer

PAC:drw

Attachment

cc: Sue Myrick, MC
Ken Calvert, MC
Gil Gutknecht, MC
Andrea Seastrand, MC
Todd Tiahrt, MC
Barbara Cubin, MC
John Tanner, MC
Paul McHale, MC
Eddie Bernice Johnson, MC
Karen McCarthy, MC
Zoe Lofgren, MC

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Monday, March 27, 1995

DEVICE EFFICACY DEFINITION GOES BEYOND LABELING CLAIMS to include effect on patient health, FDA Center for Devices and Radiological Health Director Bruce Burlington told a meeting of the House Medical Technology Caucus March 24 in Washington, D.C. Asked whether the Device Center was interpreting safety and efficacy too broadly, Burlington responded that, based on the legislative history of the 1976 medical device amendments, "Congress intended the agency to look beyond the mere claims of the manufacturer and to look at the health of the populous as the product is being used when considering what safety and efficacy is about"

The CDRH Director's comments conflict with interpretations of the statutory definition "effectiveness" put forth by device industry groups, most recently by the Health Industry Manufacturers Association in its March 17 citizen petition to FDA on agency reform. In its petition, HIMA argues that the agency has gone beyond the definition of effectiveness contained in the 1976 amendments — whether "the device will have the effect it purports or is represented to have" — to require that devices must demonstrate clinical utility.

HIMA believes that "the definition of effectiveness focuses on how the device is 'represented.' Thus, if a device is represented as having exceptional clinical utility, the sponsor must prove those claims. Absent such claims, however, there is *no* requirement in the effectiveness definition that the sponsor prove that a device has clinical utility."

Although HIMA asks FDA to take administrative steps to "return" to the definition of effectiveness contained in the medical device amendments (specifically calling for the revocation of a May 1991 Office of Device Evaluation "blue book" memo on the need for devices to show clinical utility), Burlington's comments on the interpretation of the term may signal the need for statutory changes to achieve the device industry's goal.

Legislative changes also will be necessary, minority House Commerce staffer Kay Holcombe told the technology caucus, to affect some of the "fundamental" changes to the device review process put forth by industry groups, such as allowing third-parties to review and approve devices or basing U.S. approval on approval obtained in other countries. "Things like third-party review, European approvals are fundamental changes in the statute that we would need to make in a statutory way, Holcombe said.

Matt Gallivan, HIMA's associate VP-Europe and the Americas, agreed that much of the talk about use of third-parties in agency functions "would be a very fundamental change and would probably require legislation." However, Gallivan added that "there's been a lot of work to harmonize [good manufacturing practices requirements] for medical devices" in the international community and noted that European "notified bodies," government-certified testing houses that approve devices in the European Union, conduct GMP inspections in the U.S. for EU device approvals. "It's not that large a leap at all," Gallivan said, to imagine using those same bodies "for U.S. GMP inspections as soon as the U.S. catches up with the European 'gold standard' with quality systems."

Commenting on FDA export reform legislation (HR 1300/S 593) introduced March 22 by Rep. Fred Upton (R-Mich.) and Sen. Orrin Hatch (R-Utah), Holcombe said she believed the bill "was moving in the right direction in terms of reducing the workload at FDA" and thought "the statute needs to be changed," since the agency is unable to further streamline the export process under the law. The Upton/Hatch measure would allow export of all FDA-regulated products without agency approval to the approximately 80 countries that comprise the World Trade Organization, the international body created under the General Agreement on Tariffs and Trade.

While refusing to talk about specific legislation, Burlington said "generally" the agency was in agreement with Holcombe's statements. He added: "there is clearly a conception in some parts of the American community that there is an obligation to prevent dumping of low-quality products in the third-world...and even that we should apply the same [U.S.] consumer protection standards to all non-U.S. citizenry." However, Burlington noted, "there are contravening views that say: 'It's kind of silly, all you're doing is forcing industry overseas, they'll make the products over there, not here, and we'll export jobs and not products.'" Finding a balance between the two positions is "fundamentally a political issue," according to Burlington, "and I welcome the fact that Congress has chosen to come to grips with it."

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