



White House Press Release

To The House Of Representatives:

The White House

Office of the Press Secretary

For Immediate Release

May 2, 1996

To The House Of Representatives:

I am returning herewith without my approval H.R. 956, the "Common Sense **Product Liability** Legal Reform Act of 1996."

I support real commonsense **product liability** reform. To deserve that label, however, legislation must adequately protect the interests of consumers, in addition to the interests of manufacturers and sellers. Further, the legislation must respect the important role of the States in our Federal system. The Congress could have passed such legislation, appropriately limited in scope and balanced in application, meeting these tests. Had the Congress done so, I would have signed the bill gladly. The Congress, however, chose not to do so, deciding instead to retain provisions in the bill that I made clear I could not accept.

This bill inappropriately intrudes on State authority, and does so in a way that tilts the legal playing field against consumers. While some Federal action in this area is proper because no one State can alleviate nationwide problems in the tort system, the States should have, as they always have had, primary responsibility for tort law. The States traditionally have handled this job well, serving as laboratories for new ideas and making needed reforms. This bill unduly interferes with that process in **products** cases; moreover, it does so in a way that peculiarly disadvantages consumers. As a rule, this bill displaces State law only when that law is more favorable to consumers; it defers to State law when that law is more helpful to manufacturers and sellers. I cannot accept, absent compelling reasons, such a one-way street of federalism.

Apart from this general problem of displacing State authority in an unbalanced manner, specific provisions of H.R. 956 unfairly disadvantage consumers and their families. Consumers should be able to count on the safety of the **products** they purchase. And if these **products** are defective and cause

harm, consumers should be able to get adequate compensation for their losses. Certain provisions in this bill work against these goals, preventing some injured persons from recovering the full measure of their damages and increasing the possibility that defective goods will come onto the market as a result of intentional misconduct.

In particular, I object to the following provisions of the bill, which subject consumers to too great a risk of harm.

First, as I previously have stated, I oppose wholly eliminating joint **liability** for noneconomic damages such as pain and suffering because such a change would prevent many persons from receiving full compensation for injury. When one wrongdoer cannot pay its portion of the judgment, the other wrongdoers, and not the innocent victim, should have to shoulder that part of the award. Traditional law accomplishes this result. In contrast, this bill would leave the victim to bear these damages on his or her own. Given how often companies that manufacture defective **products** go bankrupt, this provision has potentially large consequences.

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(Over)

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This provision is all the more troubling because it unfairly discriminates against the most vulnerable members of our society -- the elderly, the poor, children, and nonworking women -- whose injuries often involve mostly noneconomic losses. There is no reason for this kind of discrimination. Noneconomic damages are as real and as important to victims as economic damages. We should not create a tort system in which people with the greatest need of protection stand the least chance of receiving it.

Second, as I also have stated, I oppose arbitrary ceilings on punitive damages, because they endanger the safety of the public. Capping punitive damages undermines their very purpose, which is to punish and thereby deter egregious misconduct. The provision of the bill allowing judges to exceed the cap if certain factors are present helps to mitigate, but does not cure this problem, given the clear intent of the Congress, as expressed in the Statement of Managers, that judges should use this authority only in the most unusual cases.

In addition, I am concerned that the Conference Report fails to fix an oversight in title Ii of the bill, which limits actions against suppliers of materials used in devices implanted in the body. In general, title Ii is a laudable attempt to ensure the supply of materials needed to make life-saving medical devices, such as artificial heart valves. But as I believe even many supporters of the bill agree, a supplier of materials who knew or should have known that the materials, as implanted, would cause injury should not receive any protection from suit. Title Ii's protections must be clearly limited to nonnegligent suppliers.

My opposition to these Senate-passed provisions were known prior to the Conference on the bill. But instead of addressing

these issues, the Conference Committee took several steps backward in the direction of the bill approved by the House.

First, the Conference Report seems to expand the scope of the bill, inappropriately applying the limits on punitive and noneconomic damages to lawsuits, where, for example, a gun dealer has knowingly sold a gun to a convicted felon or a bar owner has knowingly served a drink to an obviously inebriated customer. I believe that such suits should go forward unhindered. Some in the Congress have argued that the change made in Conference is technical in nature, so that the bill still exempts these actions. But I do not read the change in this way -- and in any event, I do not believe that a victim of a drunk driver should have to argue in court about this matter. The Congress should not have made this last-minute change, creating this unfortunate ambiguity, in the scope of the bill.

In addition, the Conference Report makes certain changes that, though sounding technical, may cut off a victim's ability to sue a negligent manufacturer. The Report deletes a provision that would have stopped the statute of limitations from running when a bankruptcy court issues the automatic stay that prevents suits from being filed during bankruptcy proceedings. The effect of this seemingly legalistic change will be that some persons harmed by companies that have entered bankruptcy proceedings (as makers of defective **products** often do) will lose any meaningful opportunity to bring valid claims.

Similarly, the Conference Report reduces the statute of repose to 15 years (and less if States so provide) and applies the statute to a wider range of goods, including handguns. This change, which bars a suit against a maker of an older **product** even if that **product** has just caused injury, also will preclude some valid suits.

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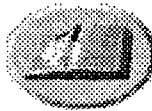
In recent weeks, I have heard from many victims of defective **products** whose efforts to recover compensation would have been frustrated by this bill. I have heard from a woman who would not have received full compensatory damages under this bill for the death of a child because one wrongdoer could not pay his portion of the judgment. I have heard from women whose suits against makers of defective contraceptive devices -- and the punitive damages awarded in those suits -- forced the **products** off the market, in a way that this bill's cap on punitives would make much harder. I have heard from persons injured by **products** more than 15 years old, who under this bill could not bring suit at all.

Injured people cannot be left to suffer in this fashion; furthermore, the few companies that cause these injuries cannot be left, through lack of a deterrent, to engage in misconduct. I therefore must return the bill that has been presented to me. This bill would undermine the ability of courts to provide relief to victims of harmful **products** and thereby endanger the health and safety of the entire American public. There is nothing common sense about such reforms to **product liability** law.

William J. Clinton

The White House,
May 2, 1996.

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To comment on this service: feedback@www.whitehouse.gov

Biomaterials / Nina

- SAP - veto announcement said biomaterials

is laudable effort to address serious problem

Paralyzed Veterans of America

- patient-doctor disease groups

- ~~Public Citizen~~ Consumers Union Kristin Rand -

→

- UNHCR alliance - trial lawyers / consumer grps.

- didn't say anything until conf. report being signed

- Dow - coming bankruptcy plaintiff ^{committee} ~~attys.~~

- judge allowed them to spend \$ on this bill

- breast implants

(but since have been down med)

- Since P.L. veto msg.

- Lindsey was negotiating on 5 items.

- people didn't feel Lindsey was sincere

- Commerce / Judiciary -

Karen w/ Evelyn

- 31,000 -

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5th-8th & Seema. —  
Held May 29th



MEDICAL DEVICE  
MANUFACTURERS  
ASSOCIATION

FOR IMMEDIATE RELEASE

June 26, 1996  
6:00 P.M. Release

CONTACT:

Jeffrey J. Kimbell  
(202) 898-5700

## **MDMA Expresses Disappointment with Medtronic v. Lohr Supreme Court Decision**

Washington, D.C.—The Medical Device Manufacturers Association (MDMA) whose 100 members are known for their innovative contributions to health care improvements, respect the opinion of the United States Supreme Court handed down today in the Medtronic v. Lohr case, which was heard on April 23, 1996. MDMA recognizes the limited application of the 5-4 split decision opinion on medical devices subject to the most commonly used premarket notification [510(k)] requirements.

The Supreme Court decision does not affect those devices which have been approved for safety and effectiveness by the U.S. Food and Drug Administration (FDA). It also has no bearing on whether the plaintiff, Ms. Lohr, could support her claim on the merits against the manufacturer of the device which maintained her life as well as the lives of tens of thousands of other human beings.

The MDMA believes it is important to reduce costly and unnecessary litigation against device companies whose primary goal is to save lives and make life better for all human beings who need medical care. The extensive and pervasive regulations imposed on device manufacturers by the FDA justify exemption from products liability complaints. The MDMA is disappointed that the Supreme Court did not apply this opportunity to devices subject to the onerous premarket notification process, but is satisfied that members of the high court recognized that some federal requirements do give rise to preemption and that devices subject to premarket approval (PMA) by the FDA are not affected by this decision.

On behalf of the MDMA, Vice Chairman Wayne K. Barlow stated "This is a setback for medical device innovation and will likely change some elements of research and development for small, entrepreneurial companies, like my own. I agree wholeheartedly with the disappointment expressed by Medtronic. This decision has more of an impact for the small companies, who tend to be far more innovative. The 5-4 split decision does, however, show the differences the court had in the case. It is now up to the next Congress to achieve some level of tort reform. Let us hope the next election brings us a few more Senators who understand the importance small businesses have on the U.S. economy and how much we need protection from frivolous lawsuits."

-More-

The MDMA filed an amicus curiae brief with the Supreme Court of the United States in Medtronic, Inc. v. Lohr, supporting the position of Medtronic on preemption because the product at issue, a cardiac pacemaker lead, was cleared for marketing through the 510(k) procedure—by far the most common type of FDA clearance procedure for devices manufactured by MDMA's members. Because of a split among the Federal Circuit Courts in recognizing preemption of claims in the context of 510(k) cleared devices, MDMA believed it was particularly important to supplement the Supreme Court's review of the arguments with cogent information concerning the 510(k) procedure and to reinforce certain preemption arguments. The Court of Appeals for the Eleventh Circuit had dismissed all of the plaintiffs' claims, except design claims, as being barred by preemption.

Cross-petitioners Lohr argued that state-law claims to recover money damages for personal injuries caused by alleged defective medical devices are not preempted by the Medical Device Amendments of 1976, and that the 510(k) process is not sufficient to preempt their specific claims. MDMA made three primary arguments in its brief: (1) Congress intended to balance the burden on device manufacturers by imposing federal requirements and preempting parallel state requirements; (2) preemption flows from the broad term “requirements”, including those imposed by the FDA's device clearance process, post-market requirements, and enforcement activity; and (3) not only are claims of violations of FDA regulations inconsistent with the statute's prohibition of private enforcement and grant of prosecutorial discretion to the FDA, state tort litigation cannot possibly lead to consistent interpretations of FDA requirements.

The Medical Device Manufacturers Association is a national trade association based in Washington, D.C. that represents 100 independent manufacturers of medical devices, diagnostic products and health care information systems. The MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. To achieve these goals, the MDMA represents its members' interests with regard to the laws and regulations administered by the Food and Drug Administration (FDA) and any interpretation or application of those laws and regulations.

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# In this issue:



Daniel Kirsch, CEO & Chairman, Electromedical Products International and Senator Phil Gramm (R-TX) after a meeting in Mineral Wells, TX.

- **Biomaterials Update**
- **Letter from Chairman Martin**
- **CHI Study Results**
- **MDR Update**
- **MDMA Activity and Accromed Brief**
- **New Member Profiles**



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**Effective July 15, please note our new address**

# MDMA CRITICAL ISSUES

## MEDICAL DEVICE MANUFACTURERS ASSOCIATION Report

### WITH NEWS FROM NMDC

JUNE 1996

ISSUE 39

## Biomaterials Access Update: *Plaintiff's Suits Creating Chaos for Device Innovators*

As President Clinton vetoed the Product Liability Reform bill last month, an important provision of the bill that limited the liability of raw material manufacturers who supply to the device industry was also killed. Since the Product Liability bill's defeat Congressman George Gekas (R-PA), an ardent supporter of the device industry, reintroduced the "Biomaterials Access Assurance Act of 1996" on May 16 as H.R. 3468. The bill would establish uniform rules governing product liability actions against raw materials and bulk component suppliers to medical device manufacturers and for other purposes. The bill has 40 co-sponsors as of June 20 with Rep. Howard Berman (D-CA) as the lead democrat and co-sponsor.

The crisis for the device industry and ultimately for the American public is simple. If there is not some shield established against the suppliers to our industry from frivolous lawsuits, they will continue to refuse to sell to our industry. MDMA has signed a letter with the California Health Care Institute and hundreds of doctors addressed to both Senator Barbara Boxer (D-CA) and Senator Diane Feinstein (D-CA) asking for their support and leadership in resolving this public health dilemma. The letter cites a 1995 U.S. Department of Health and Human Services study which concluded "the current (lack of biomaterials) situation will have an immediate and significant adverse impact on health

care and may eventually shift basic biomaterial research overseas."

Matthew J. Iverson, a partner of Burditt & Radzius (Chicago, IL), wrote an excellent synopsis of the plight of the portion of the device industry that needs the raw materials to manufacture pacemakers, heart valves, shunts and other implantable devices. His piece was printed as a legal backgrounder earlier this year for the Washington Legal Foundation (Washington, D.C.). In the piece he explains the experience of DuPont in the jaw implant litigation. DuPont sold \$600,000 worth of Teflon™, Dacron™ and Delrin™ to our industry out of \$10.5 billion in annual sales for those 3 products. Their litigation costs for that \$600,000 in sales to our industry totaled \$8 million. All of the suits occurred because minuscule amounts of Teflon™, costing a few cents, were incorporated in each jaw implant. When the manufacturers of the implants, Vitek, went bankrupt, plaintiff's lawyers came after DuPont.

In its current form, H.R. 3468 would eliminate the biomaterials crisis. According to Mr. Iverson, "The biomaterial supplier could not be sued provided its raw material or component, incorporated in a medical device, did not violate:

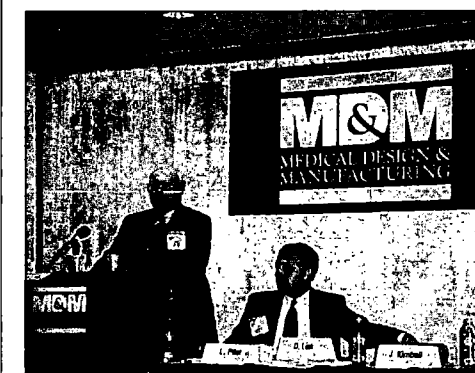
- Any specifications about the raw material provided to the biomaterials supplier (not expressly repudiated by the biomaterial sup-

plier prior to acceptance of delivery of the raw material or component parts), or

- Any contractual requirements imposed in the contract between the biomaterial supplier and the person who contracted for delivery of the biomaterial at issue."

For a copy of the legal backgrounder, please call the Washington Legal Foundation, (202) 588-0302.

•MDMA•



MDMA gave a presentation on June 5, 1996 at the MD&M-East Conference and Exposition in New York City. Pictured above are David Link, EXPERTech Associates (Concord, MA) and Larry Pilot, McKenna & Cuneo (Washington, DC) who spoke on behalf of MDMA. Thomas Thompson, Quest Medical (Allen, TX), Dan Jarcho, McKenna & Cuneo (Washington, DC) and Jeff Kimbell, MDMA, also participated in the morning presentation entitled "The Small Manufacturer in the Regulated Industry: Critical Challenges."

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## From the Chairman



When I was elected chairman of MDMA at our annual meeting in May, I stated that there were a number of targeted activities which I believe are essential to take MDMA to the next plateau. We must build upon the accomplishments we have achieved over the past two years, while maintaining a dues structure which is palatable by the entrepreneur and his company. Protecting and advancing the interests of entrepreneurial medical device companies on Capitol Hill, at the Food and Drug Administration (FDA), and with the Executive branch is inherent in the mission of the organization, this should be the role of any trade association. We must, however, continue to stay focused on areas which directly affect our members such as efforts to reform the FDA's product approval process and their enforcement policies, ensure access to biomaterials, create a solid working partnership with FDA and get more actively involved with efforts to achieve product liability/tort reform. My main goal as chairman will be membership recruitment. Growing from 30 members to over 100 in 16 months is quite a feat in itself, but we must concentrate on building upon this success. I believe strongly that competition in any field or market is what drives the entrepreneurial spirit. Complacency or being "fat and happy" leads to stagnation, which is why our industry had to swallow the Safe Medical Device Act of 1990, which established civil penalties on our industry and more importantly eliminated the 90 day deadline for 510(k)'s. Imagine our industry today if we knew that our 510(k)'s could be approved in 90 days!! I hope we can soon return to those days of predictability in both the product approval and enforcement process. To this end our objectives are to develop a mutually creditable relationship with the FDA so that we can join together to ensure that the medical device industry in the U.S. remains strong while also providing safe and effective products in a timely fashion.

Increasing our name recognition in the industry as a whole is an initiative which we have striven to improve in the past 12 months. I believe we have finally reached a level in the industry where people now know where to go to get answers quickly and to maintain a very high level of credibility with the Clinton Administration, FDA and Capitol Hill. You can be assured that each and every membership dollar is being spent to help our industry. I plan to actively encourage CEO's of medical device companies around the country to support MDMA as the trade association in our dynamic industry with a strong bias to get things done, while providing the most cost-effective representation in Washington for the entrepreneur.

Over the past two years we have seen some positive changes in the regulatory environment at FDA. This is the result of a number of factors: frustrated innovators in the industry almost being blindsided by user fees in 1994 which MDMA led the fight to defeat, a new Congress who brought true oversight to a device center that was spinning out of control and because of the efforts of many individuals at the Center for Devices and Radiological Health (CDRH) who began to focus on what should be their primary mission: getting the most safe and effective devices to the American public as expediently as possible. To make all of these elements happen in a short period of time necessitates a coordinated effort on the part of trade associations in Washington to keep an eye on FDA --to let them know what they are doing correctly and to let them know what is wrong. If they overstep the boundaries of statutory rule, Congress needs to know. That is one of the fruits of living in a democratic system with checks and balances. I believe we now have a proper oversight mechanism with the current Congress which simply did not exist a few years ago. The regulatory pendulum swings with the political tides on Capitol Hill and FDA will most certainly shift back to 1993 levels if we do not maintain a strong industry presence with those who write the laws, while working in synchrony with the FDA and those who write the regulations.

I look forward to leading MDMA to the next plateau and I hope I can count on you as members and associates in the industry for support at this time when we need it most.

Sincerely,

Richard O. Martin, Ph.D., P.E.  
President and Chief Executive Officer  
Physio-Control Corporation &  
Chairman, MDMA



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## Medical Device Reporting (MDR) Regulation Update

By July 31, 1996, all domestic manufacturers, including initial distributors of devices must have "written procedures" to implant the revised Medical Device Reporting (MDR) regulation. The revision to the MDR regulation that has been in effect since 1984 are significant and provide some greater flexibility to manufacturers but there are also some new burdens. The FDA expects that manufacturers and user facilities will transmit 150,000 reports a year. This is apparently 50,000 more than the average number of 100,000 reports submitted the last few years.

Two segments of the regulation have been criticized by MDMA and Congress, in particular Representative Fred Upton (R-MI). These controversial provisions relate to:

1. Annual Certification by a Company official
2. Designation and responsibilities of U.S. agents for foreign manufacturers.

The FDA announced on May 31, 1996, in a letter to selected device trade associations that it "intends to exercise its enforcement discretion and not enforce these two specific requirements . . ." while its proposes a rule to address these provisions.

Apart from these two provisions, all other portions of the MDR regulation will become effective on July 31, 1996. Further inquiries in the MDR regulation for MDMA members only may be directed to the MDMA Counsel, Larry R. Pilot at (202) 789-7500.

•MDMA•

## MDMA Continues Legal Activity With Amicus Brief in Reeves v. AccroMed Corp.

On May 24, 1996, the MDMA filed a brief as amicus curiae ("friend of the court") with the United States Court of Appeals for the Fifth Circuit in Reeves v. AccroMed Corporation on the issue of the evidentiary effect of an FDA "not substantially equivalent" ("NSE") determination under 510(k). MDMA filed in the Reeves case because the district court had erroneously considered an NSE finding to be substantive evidence that a medical device was unsafe in a product liability action. This ruling appears to be one of first impression. As sometimes

## New MDMA Member Profiles

### LMD Laboratories, Inc.

LMD Laboratories, Inc. develops, manufactures, and sells effective and efficient in-vitro diagnostic tests for various infectious diseases. LMD specializes in the niche market of diarrheal disease and parasitic serologies. All of LMD's assays use a common format known as Enzyme Linked Immuno Sorbent Assay or ELISA. The ELISA format is the most common format currently in use in developed nations for the in vitro diagnosis of infectious diseases. Two separate ELISA formats have been developed by LMD: the first format is a rapid 20 minute assay for identifying antibodies in sera; the second assay format rapidly identifies various pathogenic organisms in feces. One or both of these formats may be used by a physician to aid in the diagnosis of a patient. LMD currently employs 15 people at the Carlsbad, California location.

### RayMedica, Inc.

RayMedica, Inc. is a development stage company developing a synthetic spinal disc nucleus implant for the treatment of patients with degenerative lumbar disc disease and its associated pain. The company's seven employees work in St. Anthony, Minnesota, a suburb of Minneapolis. RayMedica's Prosthetic Disc Nucleus is undergoing human clinical trials in Germany and the company expects to begin a feasibility clinical study in the U.S. this spring, pending approval of its IDE request.

### Universal Technology Systems, Inc.

Universal Technology Systems, Inc. has been manufacturing therapeutic high volt stimulation devices since the late '80's. In addition, they distribute a line of electrodes, conductive mesh sleeves, socks and gloves, and conductive neoprene products. Based in Jacksonville, FL, UTS distributes their products throughout the United States through a network of independent distributors.

### Orthopedic Technology Research, Inc.

Orthopedic Technology Research, Inc. located in Knoxville, TN is the developer of patented force monitoring technologies for use in a variety of medical applications, including orthopedic rehabilitation products and pressure detective systems for the wearers of diabetic footwear. The company was founded by Frank B. Gray, MD, an orthopedic surgeon, who has developed and patented innovative orthopedic instrument systems that are marketed worldwide by major U.S. orthopedic manufacturers.

OTR, Inc. is set to release the AccuTread Platform, the first of three products that make up the AccuTread System, which is designed to help orthopedic patients comply with prescribed partial weight bearing regimens. The AccuTread Platform is a computer-aided biofeedback device which allows the patient to train in a dynamic environment while documenting patient compliance and providing information for outcome studies. Orthopedic Technology Research, Inc. currently has four employees.

•MDMA•

happens, the FDA determined the device in question was "not substantially equivalent" to an existing device based upon "new questions" raising risks that were more hypothetical than real. MDMA thought it important to give the appellate court an in-depth review of what the 510(k) process does, and does not, involve.

MDMA made four primary arguments in its brief: (1) that a "not substantially equivalent" determination can be based upon hypothetical risks for which no data exists to refute them; (2) that the FDA has since concluded the device at issue was substantially

equivalent; (3) merely because a manufacturer cannot disprove hypothetical risks does not evidence an actual danger; and (4) that the Court impermissibly shifted the burden of proof from the plaintiff to the manufacturer by relying upon the FDA's initial determination.

MDMA is represented in Reeves by Donald R. Stone, Esq. of McKenna & Cuneo, with James M. Beck, Esq. of Pepper, Hamilton & Scheetz acting of counsel. To obtain a copy of the Reeves brief, call or write MDMA's Washington office.

•MDMA•

# FDA Update

## FDA's Economic Impact on California Outlined in Health Care Study

The California Health Care Institute (CHI) and Ernst & Young have added yet another study to those already released over the past 18 months on the economic impact the FDA is having on U.S. medical device and drug companies. "Exporting an Industry: The Impact of FDA Regulation on California's Biomedical Industry" reinforces the themes and conclusions drawn from The Wilkerson Group, the Hudson Institute, the American Electronics Assn. (AEA) and others on a national scale. This excellent analysis on the State of California, the fifth largest economy in the world, has significant impact anytime, but in a presidential election year and with 52 electoral states at stake, they can be multiplied exponentially.

The rapid technology expansion of the medical device and pharmaceutical industries in the 1990's undoubtedly creates market conditions for many entrepreneurs. These conditions can change overnight if the regulatory impact forces those seeds of innovation overseas. For any biomedical research and development (R&D) stage company to be successful, the following four interrelated factors must be satisfied according to this study: breakthrough science, secure intellectual property protection, inventory confidence, and Food and Drug Administration (FDA) approval. Lately, however, the FDA's apparent inconsistencies and unpredictabilities have contributed to the frustration and inefficient behaviors of many companies all over the country, but specifically in California.

According to CEO's from a representative sample of California health care technology companies, the FDA generates redundant and major regulatory obstacles to prevent market success. With no relation to safety, the FDA process stimulates investor uncertainty, which restrains investment and limits companies' ability to pursue a variety of potential consumer products. As has been the case in previous studies, companies now

focus on making incremental changes to existing technologies, rather than focusing R&D efforts on breakthrough or new technologies. Because of different reviewers' application standards and FDA personnel changes due to a high common turnover rate, additional months or years may be required for review. As a result, such companies are forced to concentrate resources on "one product" and abandon other potential promising innovations.

In addition, the FDA often fails to meet the statutory timeliness for the review of new products. From fiscal year 1989 to fiscal year 1994, the average review times rose from 348 to 823 days. Because of such delays, many companies have to downsize in order to cut operating costs. For example, one California biotech company was told that its New Drug Application (NDA) would be reviewed within six months. However, the NDA was approved twenty-four months later. During the period of review, the company continued spending \$2 million per month. To avoid bankruptcy, the company laid off 25% of the workforce. Should the FDA had a timely review, 50 jobs worth \$2.1 million in salaries would not have been jeopardized.

As home of a third of the biotechnology and medical device companies in the U.S., California has attained global leadership in biomedical R&D. This developing and growing industry employs 165,000 in the state alone. Along with the academic biosciences community, these companies make up California's third largest high-tech sector. Congressman Brian Bilbray (R-CA) has been quoted in hearings earlier this year as saying that his "district alone has more biotechnology companies than Japan and Germany combined."

However, because of the FDA's operational habits, 70% of the health care technology companies in California have shifted their manufacturing and R&D overseas in order to compete in international mar-

kets. Many have relocated company operations to Europe simply because European review, in contrast with the FDA, of new medical technologies is more efficient and timely. Despite the fact that 67% of the companies have fewer than 100 employees, the total lost in jobs in CA due to high burn rates and long drug and device development cycles has cost between 13,000 and 18,500 (between \$700 million and \$1 billion in lost annual salaries) for the biotech industry in the last five years. The medical device industry amounted between 4,840 and 6,455 jobs (between \$227-303 million in lost annual salaries).

Although more and more jobs are being shipped outside the U.S., California still remains as the world's most attractive location for biomedical innovations. Company CEO's agree that legislation aimed to change and remold the FDA into a more efficient and timely institution with a smoother review process is absolutely necessary. MDMA welcomes CHI and other regional groups energies into the fight for much needed FDA reform. For more information on the California Health Care Institute (CHI) or to get a copy of the study contact William Bold at (619)551-6677.

•MDMA•



Brad Gary, Vice President of Allergan; William Bold, Director of Public Policy, California Health Care Institute (CHI), and David Gollaher, Ph.D., President, CHI.



## Marketing Strategies Enhance Success of Clinical Trials

by: Irene E. Barbieri

No one can argue that in this business saving time means saving money. Getting medical devices to market faster and with the least investment in company resources is a goal embraced by most manufacturers, if not all. Critical to this process is avoiding delays in initiating clinical trials by recruiting the "right" number and the "right" types of patients from the outset. A recent informal evaluation by FDA's Office of Device Evaluation of the causes of delays in clinical trial initiation found "common problems" included: "lack of a mature, well-thought out trial design that includes how patients will be identified and assessed" and "insufficient sample size to support sponsor claims". Also, the 1993 Temple Report's retrospective review of applications listed "a failure to enroll a sufficient number of patients to answer the primary study questions." Although these studies do not outline specifically the extent of these problems and their relationship to poor marketing strategies and practices, the issues are real for manufacturers. While nothing can substitute for a well-designed clinical trial study and a well-managed protocol, the application of simple marketing concepts can enhance success, and in many cases, prevent problems and unnecessary delays in the premarket approval (PMA) process.

### Input to Study Protocol Development

Include marketing staff on the study design planning team and in strategy sessions. The need for clinical and regulatory expertise in developing the clinical trial protocol is unquestioned, but it is also important to have someone on the team who can evaluate how the proposed study design will impact the ease of patient recruitment as well as the ultimate commercial viability of the product.

Match the marketing claims to a sufficient market for the product, one that

promises commercial viability. The study's objective and hypothesis broadly identifies the types of patients to be studied and the marketing claims lays the foundation for marketing the device and its benefits. Marketing research should substantiate the number of potential patients that can benefit from the product based on the marketing claims. Evaluate the patient inclusion/exclusion criteria's effect on the size and character of the study population. The study population defines the indications for the device and the selection criteria ultimately defines the market for the product. Marketing should determine whether the proposed study population is critical for commercial success.

### Managing the Protocol Design Process

Develop a recruitment strategy that takes into account the complexity of the current healthcare delivery system. Managed care organizations in their role as gatekeepers make it more difficult today to reach and attract some groups of patients for clinical trials. For example, patient referrals may be dictated and limited by patient and physician membership in certain managed care organization, and contractual affiliations with providers can also complicate referral possibilities. A well-developed recruitment strategy traces the average patient's movement through the healthcare system and seeks effective marketing channels and partnerships to communicate with and attract patients.

Select investigational sites that are located in geographical areas having an adequate demographic and epidemiological pool of patients from which to draw upon. The site selection process should include a market assessment of what geographic locations offer significant clusters of patients with the given patient profile. Information of this nature is often available through various state and federal data bases or marketing research services.

Also, if possible, avoid geographic areas where there may be competition for the same pool of patients with others who are doing studies.

Evaluate investigational sites for their historic and projected ability to recruit patients with the clinical profile required for the trial. The most renowned medical institutions may be poor candidates for recruiting the types of patients needed for a study. For example, tertiary care medical centers may not possess the referral relationship to treat patients with conditions treated most frequently in primary care settings. A review of hospital discharge data for the appropriate ICD-9 diagnosis or procedure codes which reflect the study population can help in projecting the number of patients a particular site can recruit.

Provide sufficient marketing and public relations tactical support to investigational sites. Every site will have different management, marketing and public relations resources and skills available to attract and recruit patients. Assessing the strengths and weaknesses of each site and helping to fill the gaps, to the extent possible, offers better chances for clinical trial success. Also, providing adequate patient and physician incentives to participate in the study can have a significant impact on a recruitment program.

Viewed through the marketing prism, clinical trials offer manufacturers a unique window of knowledge and experience about potential opportunities and obstacles in getting a medical device to market. Marketing strategies when used judiciously can be valuable tools in the process.

*Irene Barbieri is a marketing adviser to medical device manufacturers and president of The Abingdon Group based in Arlington, Virginia (703) 379-4924.*

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that really was my second. I think our discussion earlier sometimes we are in the not appreciate it. When have been so many reasons as you look across the being done will be seen in the sustaining of implanted as a result

phenomenal achievement remain elements of risk that you said just now. I say about it, Dr. Galletti you know, Ms. Phillips I thank God everything the risks to patients as

patients that none of here is a sort of an idea which fails, one after which is made entirely after it was first built. an inexorable process of putting devices in the It will repair or control of life, but eventually final decay of our body realistic. maraculous aspect of some ct, at the same time we tations.

you want to get into this? Dr. Hill may do with the ly related to immediate action.

you and your patients

underscore two points that difference and the medical a supplier of a material e device itself represents tested, it must be tested

perspective, most of our time, and these devices can be easily 3 to 5 times ear. So these devices see identically they have not environment may change ways predict that. So it is ways of documenting 10,

15, 20 years down the road how devices are performing, and we are not good at that yet.

Senator LIEBERMAN. I do not have any further questions. Mr. Reily or Ms. Phillips, do you want to add anything based on what you have heard?

Ms. PHILLIPS. Mr. Chairman, I have a list that was given to me of some materials used in implantable medical devices that are going to be subject to withdrawal that I would be happy to provide for the record.

Senator LIEBERMAN. I appreciate that, and we will print it in the record.<sup>1</sup>

Ms. PHILLIPS. The suppliers include Dow and DuPont and some of the materials are Dacron and Teflon. The list also shows what they are used for.

Senator LIEBERMAN. Let me thank all of you. This panel has been very helpful, and I appreciate very much that you came forward. Mr. Reily, I do not know how much time you have in Washington or whether you have been here before. I do not know what the exact nature of the bribe was, but I would tell you that the National Zoo is a great place to visit when you are here.

Mr. REILY. Thank you very much.

Senator LIEBERMAN. Kids love it.

Thanks very much. Good luck. God bless you.

Senator LIEBERMAN. The final panel, final witness, will be Kristen Rand, counsel for Consumers Union. Ms. Rand, thanks for your patience in coming on as the last witness. We appreciate your being here, and we look forward to your testimony now. We know you have a somewhat different view of the general subject of product liability reform, but we wanted to give you an opportunity to be heard this morning.

#### TESTIMONY OF M. KRISTEN RAND,<sup>2</sup> COUNSEL, CONSUMERS UNION

Ms. RAND. We appreciate that very much, Mr. Chairman. I am Kristen Rand. I am counsel in the Washington office of Consumers Union. We are the publisher of Consumer Reports Magazine.

I am testifying today also on behalf of Public Citizen's Congress Watch and the Consumer Federation of America. All of our organizations appreciate the opportunity to share with you our views regarding the problems of medical device materials suppliers.

Consumer access to safe, effective medical devices is of great concern to all of our organizations. We recognize that many people's health and even lives depend on the continued availability of well-designed and safe medical devices. We are also aware of the problem of manufacturers refusing to supply raw materials that are critical in the production of a variety of devices. And at least one of my colleagues from the consumer community has met with a device manufacturer to explore this issue.

We are committed that if there is a danger that consumers will be denied access to safe medical devices because of the lack of availability of raw materials that is indeed a problem, and we

<sup>1</sup> See page 154.

<sup>2</sup> The prepared statement of M. Kristen Rand appears on page 143.

would like to work with you to find a solution to this problem. But before we rush to implement changes that might seriously affect device regulation or the civil liability system, we need answers to the following questions: Does a problem really exist? And this hearing has gone a long way towards convincing me that this is a real problem. And if it is, what exactly is the scope of the problem? And what remedy is warranted?

We just want to make sure that any remedy implemented is not overly broad and does not needlessly dilute the civil liability system. And the reason for our caution is explained by our experience in the area of medical device regulation.

The past few decades are replete with examples of manufacturers making assurances to Congress and the public that a particular device is safe and claiming that its availability is threatened by the product liability system. When we have investigated these specific examples, we have almost without fail discovered that the device at issue is unreasonably dangerous or defective.

This experience has forced us to be skeptical and not accept at face value the claims made by the device industry and manufacturers.

For example, the Vitek, which has been referred to earlier, was offered in a past Congress—as a victim of the product liability system, it was alleged that it was safe and was being driven off the market by excessive product liability. We now know that that device was defective.

I also would just like to say a word about the costs associated with this litigation in that it is our view that the product liability system is not the prime source of litigation costs, but empirical data shows that suits by firms against one another in contract disputes far exceed those of product liability suits. And I would like to offer this article from the *Wall Street Journal* to be made part of the record.<sup>1</sup> The opening sentence states the problem succinctly: "Businesses may be their own worst enemies when it comes to the so-called litigation explosion."

Senator LIEBERMAN. Were those contract disputes related to negligence or—

Ms. RAND. No. They are just your standard contract disputes where businesses enter into contracts, and this actually has a graph that shows that product liability suits are dwarfed by just general contract disputes. I think you might be interested in looking at this in more detail.

Senator LIEBERMAN. I think you would agree that in the case we have talked about, in the DuPont case, clearly the concern of DuPont and the other raw material suppliers here is not related to contract disputes, but related to their fear about product liability suits.

Ms. RAND. I understand that, but my point is that we think there is too much focus on the product liability system when there are other aspects of the litigation system that deserve scrutiny. And I would also point out that in DuPont's case, I understand that they are being dismissed from these suits where they were the supplier for the raw materials for Vitek and that they must repeatedly show

<sup>1</sup> See page 155.

that they did not know of the danger or that their component was not defective, and that consumers have that same problem in suits where they pursue suits involving the same product and have to repeatedly prove the same facts.

So there may be something there that we could explore that would address both of those problems.

Senator LIEBERMAN. Obviously I do not disagree that there isn't too much litigation in this society generally. There is. But that fact, at least in my response, does not diminish the particular effects that we have heard described today of product liability litigation.

Ms. RAND. Well, I understand the specific point, and I think that working together we can probably come up with a narrowly tailored solution that gets at the problem where there is a component that we know is safe and that there are repeated suits on exactly the same fact pattern. I think that is what we are talking about. And the consumer community is not interested in court resources being expended in relitigating the same issue over and over again, but we do want to maintain the ability of consumers to pursue lawsuits if there is a reasonable belief that a component or product is unsafe or defective.

Senator LIEBERMAN. Yes, understood. And, again, not to belabor it, I want to give you an opportunity to give your testimony. But there are different ways in which people are consumers. I understand and respect your right to protect—your interest in protecting the right of consumers who suffer from negligence and negligently made products to sue and be reimbursed. But obviously Ms. Phillips, Thomas Reilly, and millions of others who have the implanted medical devices that are so important to them are also consumers. And we want to protect them from the loss of access to those products as a result of fear of suppliers of too much liability litigation.

Ms. RAND. Well, we completely agree with you that consumers' access to safe medical devices must be maintained, and that is one reason we are thankful to be part of this process, because if this really is as severe a problem as it on its face appears, we would like to work to find the solution. Because, obviously, access to devices that are life-saving is as important as access to the courts if you are the victim of a defective device.

Senator LIEBERMAN. Absolutely. Why don't you go ahead? I will try to control my interventions.

Ms. RAND. My testimony walks through some of what has been proposed in the context of the broader product liability legislation, and I will not belabor those points. I will just conclude by saying that the consumer community views civil liability for manufacturing and marketing dangerously defective devices as an irreplaceable incentive for the production of safe medical devices.

We also think that Federal regulation of medical devices by the FDA is inadequate. There are many cases of defective devices that have slipped through the approval process. Therefore, we feel very strongly that any action designed to remedy problems that device manufacturers may be experiencing with suppliers must not consist of blanket liability shields. We have not yet had a chance to look at your draft legislation, and we will be happy to do that and give you our comments on it. We hope we can engage in a constructive dialogue to find an answer to this problem.

Thank you.

Senator LIEBERMAN. I thank you, Ms. Rand, and I appreciate the spirit of your testimony. I would look forward to working with you and the other consumer groups to see if we can come up with a solution that protects the broadest understanding of the rights of consumers as we have described them.

You know, the continued active role of FDA in all this is very important, and as you know, the broader product liability reform legislation, S. 687, which is before Congress, does put a fair amount of emphasis on that FDA approval.

They are not easy. They are there to protect us, and we want to make sure that those who do not follow the FDA procedures are in that sense not protected. And, again, I would point out the breast implant case where the FDA did not grant its approval, and there are other cases where FDA approval may have been received, but then other FDA directives were not followed, such as the case of the injectable bovine collagen which you refer to in your testimony.

But let's agree that we will look forward to your comments on the proposed legislation. I appreciate the fact that you have been here all morning listening to the testimony and feel that—I am not trying to put words in your mouth—at least it appears a case has been made that you do not want to deny consumers access to these devices. And I hope we can come to a recommendation and a remedy that we all can agree on. So I thank you for that.

Ms. RAND. Thank you, Mr. Chairman.

Senator LIEBERMAN. I thank all the witnesses. We are going to leave the record of the hearing open for 2 weeks. We may have some additional questions for the witnesses. You may have some additional statements that you would like to put in the record. But, again, in my opinion, the case is really a clear one that we have these miraculous devices that are keeping people alive and improving the quality of life, that these devices are now, by my hearing of this testimony, definitely endangered by the decisions made by raw materials suppliers as a result of their fear of lawsuits. And we simply cannot let this happen. There is too much on the line. And I am committed to seeing if as part of product liability reform or health care reform this year that we make sure that we avoid this crisis and keep people healthy and, incidentally, keep people employed in this important industry.

I thank everybody for a very constructive morning. The hearing is adjourned.

[Whereupon, at 12:00 p.m., the Subcommittee was adjourned.]

## APPENDIX

### PREPARED STATEMENT OF PAUL CITRON

Good morning, Mr. Chairman and Members of the Subcommittee. I am Paul Citron, VP Science & Technology for Medtronic, Inc. Among my responsibilities is assuring that our company is technologically positioned to develop and produce high quality innovative products that treat disorders of the circulatory and neurological systems. Medtronic, by the way, is a leader in producing therapeutic medical devices to improve the cardiovascular and neurological health of patients around the world.

It has only been 40 years since the first development of medical device technology which has allowed physicians to effectively replace body parts that have been damaged by disease. A progression of innovative therapeutic technologies have restored health to millions of patients in the U.S. and around the world.

The brief history of medical device breakthroughs begins in the 1950s when large diameter vascular grafts permitting the replacement of dangerously weakened major blood vessels were first developed. In 1958 the first electronic device, the cardiac pacemaker, was implanted. This revolutionary technology stimulated hearts with too slow a rate—to a rate approximating normal. With this technology, the heart was once again able to pump sufficient quantities of blood to meet the majority of the patients' hemodynamic requirements. Without pacemakers, patients typically experience sharply limited ability to conduct daily living tasks, suffer from fainting episodes, and experience premature death. The 1960s saw the emergence of the mechanical heart valve as a practicable replacement for defective natural valves. Implanted medical devices such as these offered therapy where previously none was available. In many instances, they offered patients the possibility of saving and enhancing their lives. Perhaps the clearest example of the life saving capacity of medical devices has been the development of implanted defibrillators. This emerging technology is capable of detecting dangerous heart rhythms which can lead to fibrillation—or detecting the fibrillation itself—and automatically delivering a precise shock to the heart to restore normal rhythm. Carefully selected patients who receive such devices would have been likely victims of what is aptly known as "sudden cardiac death syndrome." Instead, they have been able to lead longer productive lives. But the increasing unavailability of materials used to produce these critical technologies jeopardizes their future availability.

It is important to note the hostile biological environment in which implanted medical devices must function. The body has created a formidable set of defenses against foreign materials. The body recognizes these materials as being potentially dangerous and vigorously sets out to consume, destroy, or isolate them. These defenses work well. Unfortunately, the body does not recognize medical devices as allies and seeks to destroy them as if they were deleterious rather than beneficial. Only a limited number of specialized materials such as certain polyurethanes, a small number of other polymers, solid silicone rubber, and an equally small number of inert metals and exotic alloys have been found, when used in properly designed devices, to be clinically acceptable for direct implantation and contact with tissue and body fluids. These materials are used to construct the implant itself or serve as the protective barrier to shield other components which are not themselves clinically acceptable for implantation. Without such materials therapeutic implants would not be possible.

As if the requirement of clinically acceptable tissue responses was not enough, implantable materials must also be biodegradable. That is, they must have intrinsic physical and mechanical properties to withstand the rigors of the application in which they are used. As an illustration of this, a prosthetic mechanical heart valve is expected to function flawlessly for the patient's lifetime while being subjected to wear forces and large pressure-induced forces as it opens and closes. It is not unrealistic for a valve to experience in excess of 600 million opening and closing cycles.

versity based programs in bioengineering—and 12 specialized bioengineering societies with about 20,000 members. AIMBE was established for the purpose of unifying the bioengineering community and promoting the engineering approach for enhancing health and quality of life through innovation and appropriate use of technology. AIMBE's focus is on the development of public policy. We have concluded that the recent embargo on materials used for the fabrication of implantable devices is a major public policy issue which threatens the care of critically ill patients, endangers innovation and scientific progress in basic and clinically oriented research, and affects competitiveness and employment in an industry segment in which the U.S. currently has the undisputed leadership.

AIMBE's perspective on the Biomaterials Crisis is expressed in a letter to the Editor of *Science* magazine published in today's issue of that journal. I quote:

"A recent review in *Science* (1) pointed out significant opportunities in the creation and characterization of biomaterials which are essential components of therapeutic implants. As pointed out in that same review, materials which are reasonably biocompatible with use in the human body (e.g. polyester for vascular grafts, polyurethanes for pacemaker leads, silicone elastomers for hydrocephalus shunts) are becoming increasingly difficult to obtain from primary producers, and may soon disappear altogether from the U.S. scene. The reason is that chemical companies such as DuPont, Dow, Dow-Corning and others have determined that unpredictable and excessive liability costs of doing business with manufacturers of implantable medical devices no longer allow unrestricted sale of standard polymers to these customers. Under current U.S. product liability laws, any remote supplier of commodity materials can be joined in lawsuits involving medical products which are alleged to have failed unexpectedly, not lived up to expectations, or caused complications.

Since the sales of such materials represent but a tiny fraction of the business of chemical companies, but account for a major part of their liability or legal costs, it is more expedient for them to opt out of the medical device market.

This embargo, which already affects the main sources of fluorinated polymers (e.g. Teflon<sup>®</sup>, polyacetals (e.g. Delrin<sup>®</sup>), silicone compounds, polyurethanes and polyesters (e.g. Dacron<sup>®</sup>), is progressively extending to other elements of medical devices, i.e., the small, but essential amount of PTFE powder which enters into the fabrication of batteries for cardiac pacemakers, or the electric components of such devices, as well as to the specialty metals used for pacemaker casings and joint replacement prostheses. The resulting crisis could bring to a halt the fabrication of implantable devices in the U.S., resulting in a shortage of widely-used, FDA approved devices on the U.S. market, inadequate treatment for thousands of patients, and the loss of jobs in a major sector of U.S. industry. Other potential consequences include a shortage of materials for artificial organ and cell transplantation research, the loss of engineering and medical experience as material fabrication and clinical trials are shifted abroad, the closing of career opportunities for graduates of U.S. training programs, and a diminished incentive to develop new materials since the know-how of industry is needed to assure quality-controlled production.

This is a complex situation which increasingly resembles the crisis already faced by the U.S. small aircraft manufacturers, most of whom have gone out of business or into bankruptcy because of liability losses. The same fate threatens the U.S. medical device industry. NIH leadership is needed in addressing this issue and in directing research to establish a scientific base for technological advances in the field of medical devices and implants. The Health Industry Manufacturers Association (HIMA) is coordinating efforts with the FDA to establish "equivalence" criteria for substitute materials in shortage areas, and keep critical devices on the market (2).

In the short run, the most effective remedy would be to change tort law to bar product liability claims against remote suppliers of "off the shelf" commodity materials and components of devices which have received FDA approval. The entire liability burden would then fall on the device manufacturer, who could decide whether or not to market a device.

Better solutions may be generated through discussion with all involved parties. However a temporary resolution is urgently needed if we are to avoid a shortage of chronic implants for critically ill patients.

I would like now to dispel some common misconceptions that relate to the field of biomaterials for chronic implants, and conclude by suggesting some steps that could be taken to alleviate the impending crisis.

First some facts to keep in mind when addressing this issue. The overwhelming majority of materials incorporated into chronic implants are standard, commodity plastics, metals or ceramics widely used in non-medical products. The term biomaterial is only justified inasmuch as these materials meet definite, stable specifications and are processed and potentially modified to fabricate implantable or blood contacting devices. Therefore clinical biocompatibility characterizes the entire,

assembled device and cannot be assumed from its constituent materials. Second, there is no such thing as a universally biocompatible material for all applications. The very same polymers which function satisfactorily in one type of implant (e.g. the teflon mesh in the suture ring for a cardiac valve) can prove disastrous in another context (e.g. the teflon articular surface of a temporo-mandibular joint). Third, the quality and reproducibility of polymeric materials used for chronic implants (e.g. Dacron polyester for vascular grafts) is directly related to the amount produced and the experience of the manufacturer. Since the quantities used for medical devices are vanishingly small compared to other industrial applications, it is not surprising that reliable materials have largely been obtained from major suppliers of chemical products developed for non-medical uses. It is not impossible to fabricate reliable polymers on a small scale, but the cost will be orders of magnitude higher than is presently the case. Finally, we should not forget that the body environment is warm, humid and corrosive, and that under such harsh conditions some degradation is unavoidable in chronic implants. Unrealistic expectations all too often cloud our evaluation of replacement parts for the human body. Wear and aging affect the implant as much as they affect the person who receives it. The concept of a permanent, failure-proof medical device is an ideal to strive for, but for the moment it remains unobtainable in 100 percent of the cases. In this regard, it is paradoxical that we should hold chronic implants to a higher standard than drugs, where side effects and failure to achieve the desired effect are, within limits, broadly accepted.

What recommendation can I formulate to meet the biomaterials crisis? Ideally, measures should be taken to convince remote suppliers of commodity materials or components for medical devices to keep them available to the U.S. medical device industry. This may require a narrowly defined change in the law to provide relief or remedy for ultimate liability claims against providers of standard, off-the-shelf elements of approved devices.

Second, the National Institute of Standards and Technology could undertake collaborative programs with industry to target R&D and establish a strategic reserve to insure the availability of materials which are essential for the manufacturing of medical devices and which have proven life-saving for critically ill patients. This would establish reliable sources of standardized, specifications-meeting, quality-controlled commodity polymers designed to interact with blood or other body tissues.

Third, the Food and Drug Administration, in concert with other Federal agencies, should build on the data bases which will result from the federally mandated medical device tracking system to develop a National Implant Data Retrieval and Analysis structure. Such information will allow statistically valid evaluation of chronic implants, and the materials and components thereof, and provide a perspective on patient-related versus device-related failures, which are often confused.

Lastly, the National Institutes of Health should prioritize programs that expand the science underlying the clinical use of chronic implants. This would include the mechanisms of degradation of biomaterials, the fundamental processes in the interactions between materials and body tissues, the individual and species-specific differences in bioreactivity to materials, and the development of non-invasive implant monitoring techniques applicable to man.

Hopefully out of the present crisis will come new insights into the success or failure of implants, better rehabilitation of critically ill patients, and preservation of therapeutic approaches for which there are currently no substitutes. Thank you for the opportunity to express these thoughts to you today.

#### PREPARED STATEMENT OF M. KRISTEN RAND

Mr. Chairman, members of the Subcommittee, I am Kristen Rand, Counsel in the Washington Office of Consumers Union, the publisher of *Consumer Reports*. Thank you for the opportunity to share our views regarding medical device materials suppliers. I am testifying today on behalf of Consumers Union (CU) Public Citizen's Congress Watch and Consumer Federation of America (CFA).

Consumer access to safe, effective medical devices is of great concern to all of our organizations. We recognize that many people's health and even lives depend on the continued availability of well-designed and safe medical devices.

We are also aware that device manufacturers complain that many suppliers of raw materials are refusing to furnish substances critical to the production of a variety of medical devices.

If there is a danger that consumers will be denied access to safe medical devices because of a lack of availability of raw materials, that is indeed a problem. Before we hurry to implement changes that might affect device regulation, however, sev-

eral key questions must be answered: (1) does a problem really exist? (2) if it does, what is its scope? and (3) what remedy, if any, is warranted?

We appreciate the opportunity to be here today not only to present the views of our organizations but also to help accurately evaluate the situation.

Particularly with regard to medical devices, our organizations always proceed with extreme caution. The past few decades are replete with examples of manufacturers making assurances to Congress and the public that a particular device is safe but claiming that its availability is nevertheless threatened by the product liability system. Almost without fail, we later discover that the device at issue is unreasonably dangerous or defective. This experience has forced us to be skeptical and not accept at face value claims made by the device industry and manufacturers. One example of proponents of liability "reform" making misleading claims about the safety of a device is the Vitek jaw implant.

In 1990, Malcolm Skolnick, a professor of biophysics at the University of Texas testified before the Senate Commerce Committee that jaw implants manufactured by Vitek, Inc. and used to treat a condition known as temporomandibular joint dysfunction were safe but that Vitek was in danger of being driven out of the market by frivolous the product liability suits. When we investigated this claim, however, we discovered that the FDA had, a month prior to Professor Skolnick's testimony, required Vitek to distribute a letter to oral surgeons warning of the device's tendency to fragment. FDA later issued its most stringent recall order for the device. In addition, a Subcommittee of the House Government Operations Committee uncovered evidence suggesting that there were serious problems with the Vitek implant as early as 1986. The late Congressman Ted Weiss who chaired hearings on the issue concluded, "There is evidence that the overwhelming majority of the grafts and implants will eventually fail if they haven't already."<sup>1</sup>

Incidents such as the Vitek implant force us to very carefully evaluate any claims made by medical device manufacturers about the effects of liability on their products.

From our perspective, it is imperative that any fix designed to ensure the availability of devices not end up hurting consumers more than helping them. At this time, since there is no specific proposal from those seeking relief it is difficult for us to determine if we could reach an agreement regarding a specific remedy, but we are interested in reviewing alternatives that may be offered to resolve the issue. Meanwhile, we can identify some proposals which have been discussed in the context of medical device availability which we strenuously oppose.

In general, we are opposed to changes in the civil justice system that would result in diminution of the rights of consumers to recover fair and adequate compensation through the courts.

#### *Limitation on Joint and Several Liability is Not the Answer*

The Health Industry Manufacturers Association (HIMA) supports the limitations on joint and several liability contained in S. 687, the "Product Liability Fairness Act." We find their stated position on the joint and several provision somewhat confusing. HIMA has stated that raw materials suppliers "may be brought into litigation and held liable for damages, even though the supplier has no direct role in the material's ultimate use as a biomaterial. As a direct result of this predicament, three major raw materials suppliers recently announced that they would limit or cease altogether their shipments to medical device manufacturers."<sup>2</sup> We find this fear on the part of materials suppliers odd in light of the fact that courts are routinely dismissing suits against suppliers who sell components to manufacturers that make devices later found to be defective. For example, a Federal court in Hawaii recently granted summary judgment to Du Pont and Dow Corning in a case alleging injuries from an implant manufactured by a bankrupt company. The court refused to hold the suppliers liable where an inherently safe component part is used in a defective end product.<sup>3</sup> Other courts have dismissed similar cases.<sup>4</sup> All of these cases involve Dow Corning and/or Du Pont supplying materials for the Vitek jaw implant discussed above. Manufacturers are clearly not in danger of being held lia-

<sup>1</sup> Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives, June 4, 1992.

<sup>2</sup> HIMA written testimony before the House Subcommittee on Commerce, Consumers Protection and Competitiveness, February 2, 1994.

<sup>3</sup> *Kealoha v. E.I. du Pont de Nemours & Co.*, DC Hawaii, No. 92-00282, February 24, 1994.

<sup>4</sup> See e.g. *Bond v. E.I. du Pont de Nemours & Co.*, Colo Ct App. No. 92CA0624, June 3, 1994 and *Lamontagne v. Du Pont Co.*, DC Conn, No. 3:91 (CV 142, September 29, 1993).

ble merely for supplying safe components even when the devices into which they are incorporated are found to be defective.<sup>5</sup>

Although courts are dismissing cases against component manufacturers where there is no evidence that the suppliers know that their materials were being used in a dangerous manner, we feel strongly that the potential for liability must remain where a defendant does know that a manufacturer is using a component in an unsafe manner.<sup>6</sup> In addition, it is important to try not to encourage manufacturers to turn a blind eye should suspicions be raised that its components are being used in an unsafe manner.

Blanket protection for manufacturers of raw materials or device components is inappropriate and unacceptable. Determining whether a particular component manufacturer has sufficient knowledge of a hazardous use of its components is a fact specific inquiry that is best made on a case by case basis.

#### *A Bar On Recovery of Punitive Damages for Devices Approved by FDA is Not the Answer*

HIMA has also expressed support for the FDA defense contained in S. 687. This provision would bar recovery of punitive damages in a case involving a drug or medical device approved by the FDA, unless there was fraud perpetrated on the agency. Our organizations are adamantly opposed to this comprehensive protection for medical devices from liability for punitive damages. History clearly demonstrates that despite the appearance of a thorough and extensive regulatory regime, the FDA has not been able to adequately protect the public from manufacturers who knowingly or recklessly market dangerous medical devices. There are far too many examples of instances where FDA could not by itself adequately protect the public from dangerous, defective medical devices.

Examples of dangerous devices that managed to get through the FDA approval process include:

- *Injectable bovine collagen.* In 1981 the FDA approved bovine collagen as a device. FDA accepted the manufacturer's clinical data despite serious gaps in the information including: lack of adequate follow-up; lack of representative clinical subjects for the type and age of the population that would use the product; and FDA failure to review safety information prior to pre-market approval. Subsequent to pre-market approval, adverse reactions apparently associated with the product began to occur. The reactions included serious autoimmune diseases. In 1991, FDA Commissioner Kessler acknowledged that there was an association between bovine collagen injections and autoimmune reactions.

Meanwhile, the manufacturer engaged in continuing violations of FDA regulations including underreporting of adverse reactions, unreported label changes and making misleading claims of efficacy.

It is worth noting that the manufacturer of bovine collagen actively sought approval of the substance as a medical device rather than as a drug. A member of the board of directors of the manufacturer testified in a deposition that the time-consuming drug approval process could have damaged the firm's chances to market the product.<sup>7</sup>

- *Theratronics radiation equipment.* FDA approved the Therac 20 Linear Accelerator in 1977 for use in the treatment of cancer. In 1983, the company introduced the Therac 26. In 1986 and 1987 the device was associated with three deaths of patients undergoing cancer therapy. When the FDA undertook an internal review after the three deaths, the agency could not locate any record of the device's pre-market approval. Apparently, the company had submitted an application, had received approval but FDA had failed to keep records of the approval.

Between 1984 and 1988, five deaths were associated with malfunction of a Theratronics linear accelerator and a number of incidents associated with over- or underexposure to radiation were reported. It was not until 1991, however, that FDA prohibited the importation of the device. The Subcommittee on Oversight and Investigation of the House Energy and Commerce Committee<sup>8</sup> determined that in the

<sup>5</sup> Moreover, in all of the cases cited above, the manufacturer of the defective device, Vitek Inc., was bankrupt. This fact argues contrary to manufacturers' often repeated concern that innocent "deep-pocket" defendants are forced to pay when other culpable parties are judgment proof.

<sup>6</sup> This is the law, for example, under the Connecticut Product Liability Act. This was the rule applied in *Lamontagne*, supra.

<sup>7</sup> Deposition of Terry Knapp, MD in *Ramey v. Collagen Corp.* (Texas).

<sup>8</sup> *Less than the Sum of Its Parts: Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration's Center for Devices and Radiological Health.* A report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, May 1993.

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case of Theratronics, FDA had failed to (1) ensure that the manufacturer had demonstrated either safety and efficacy or substantial equivalence before premarket approval; (2) take timely and decisive action when problems were exposed; and (3) conduct necessary inspections upon requests of the agency's own inspectors. As a result of these failures, the Subcommittee report concluded, "a machine was allowed on the market that actually killed patients seeking to benefit from it, and that may have been ineffective in treating life-threatening diseases."

Unfortunately, there are many more examples we frequently cite including the Bjork-Shiley heart valve, silicone breast implants, and Copper-7 IUD illustrating FDA's inability to adequately police the medical device industry and to provide assurance that medical devices are safe for their intended use.

Deficiencies in FDA oversight of the medical device industry are acknowledged by the agency itself. In November of 1993, the agency proposed to make medical manufacturers follow quality standards during the design phase as well as during production. In announcing the proposal, the agency cited a figure blaming design flaws for 44 percent of problems that force manufacturers to recall defective products.

#### Conclusion

Currently, Federal regulation of the medical device industry is simply inadequate. Civil liability for manufacturing and marketing dangerously defective medical devices provides an irreplaceable incentive in making medical devices safer and in ensuring that consumers who are injured by defective devices are compensated. Therefore, our organizations feel very strongly that any action designed to remedy what problems medical device manufacturers may be experiencing with suppliers must not consist of liability shields.

Our resistance to remedies involving changes in the tort system should not be read as refusal to engage in discussions of other types of proposals. If we are satisfied that a real problem does exist, we would be happy to explore remedies that do not limit consumers rights to recover when they are injured by dangerous medical devices.

Some options that we are willing to explore with the manufacturers could include indemnification for litigation expenses or government subsidies for production of vital raw materials.

Thank you.

#### PREPARED STATEMENT OF BARBARA A. JACOBY

Today I come before you the fortunate beneficiary of the latest in biomedical development for cardiovascular application. I say fortunate because through the combined efforts of engineering, medicine and materials, treatment specific products are created to repair/replace malfunctions in the body. Few outside the biomedical field fully appreciate the role raw materials (plastics, silicones, metals and ceramics), play when used to make the component parts that become the products to fix our bodily malfunctions. Further, they have little empathy for the time and cost necessary to run biocompatibility and clinical trials plus the special training necessary prior to general release.

I speak from experience both as an "active" patient/consumer and as an applied development engineer. I practiced a heart healthy lifestyle and had few of the typical heart disease candidate characteristics. I followed a nearly fat free vegetarian diet, never consumed alcohol or tobacco, exercised regularly and tried to relax. Though my hypertension was controlled with medication and my cholesterol was extremely low, my disease progressed undetected. Initial diagnosis of arterial blockages followed swiftly after mild mid-chest discomfort and three incidents of unstable angina (chest pain at rest and/or during sleep). The attempted percutaneous transluminal coronary angioplasty (PTCA), commonly referred to as the "balloon", failed resulting in an extremely large blood clot and total blockage of the right coronary artery (RCA). During this interventional procedure my vital signs turned negative and I left the catheterization lab with several high tech biomedical devices to protect and stabilize my heart. I am most thankful for the temporary pacemaker, the intraaortic balloon pump and intracoronary Urokinase (the expensive medication that dissolves blood clots quickly and save many lives) available to me.

My options, I was told, now were 1) aggressive medical therapy to control the heart's rhythm, spasms, and angina with considerable restriction physically or 2) coronary artery bypass grafting (CABG) otherwise known as "bypass" which is an invasive open heart, major surgery procedure under general anesthetic. I elected to follow the medical therapy program while investigating the current status on interventional techniques. As my angina worsened, the cardiologist insisted "bypass" was my only option and to forget the interventional devices for they were "many years

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