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Commentary

Biomaterials Science at a Crossroads: Are Current Product Liability Laws in the United States Hampering Innovation and the Development of Safer Medical Implants?

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Biomaterials are indispensable components of all medical implants and devices. The number of patients benefiting from biomaterials is dependent on the definition used to define medical implants and devices. Using a very stringent definition that included only major, permanently implanted devices (such as heart valves, hip replacements, vascular grafts, cosmetic implants), it was estimated that in 1988 about 11 million Americans carried at least one medical implant in their body (1). When patients using contact lenses, transdermal drug delivery systems, dental implants, and other extracorporeal devices are included, the number of Americans using biomaterials-based medical devices increases to over 30 million.

Many of the currently used implants and devices are life saving and a disruption in their supply could have catastrophic consequences to millions of people. Consequently, the medical device industry has grown into a significant sector of the nation's economy, producing over $43 billion in annual sales and being one of the very few manufacturing sectors maintaining a significant positive trade balance in spite of increasing competition from European and Asian manufacturers (Table 1).

Today, the priorities of researchers exploring the basic science of material-tissue interactions, the demands of the prevailing health care providers, the legal framework relating to malpractice and product liability, and the national interests in maintaining public health and a strong economy are inextricably intertwined. As a consequence, the viability and success of the biomaterials research effort in the United States is tangled with the fate of the domestic medical device industry. Because of this linkage, political decisions made on such "non-scientific" subjects as product liability or health care reimbursement procedures will profoundly affect the future of biomaterials science and the ability of the domestic medical device industry to maintain its role as a global provider of medical implants and devices.

Biomaterials research as a scientific discipline is a sound, vibrant, and highly interactive field that has, over the last decade, lead to important scientific breakthroughs in our understanding of cell-materials interactions (2). These breakthroughs have the potential to provide us with biologically functional replacements for a wide range of organs and body parts, leading to fundamental improvements in the way we treat and repair trauma or aging related diseases. At the same time, biomaterials science and the medical device industry are held hostage to powerful legal, regulatory, and economic forces that can choke off scientific innovation and prevent our advancing scientific knowledge from being developed into clinically useful products. Perhaps the most frustrating experience of scientists and small companies alike is the realization that the ultimate success of their efforts is often unrelated to the quality of their scientific work or the quality of their products. Biomaterials science and the medical device industry in the USA are now at a crossroads: While optimists point to the huge potential of the underlying science, pessimists argue that the business and legal climate in the United States has become so unfavorable that the demise of the U.S.-based medical device industry is a real possibility.

Table 1. The Medical Device Industry at a Glance[a]

Estimated total annual production (1993)	$43 billion
1988–1993 average annual growth in production	9.2%
Average R&D spending (% of sales in 1992)	6.7%
(for comparison: Pharmaceuticals 11.5%, Electronics 6.0%, Aerospace 4.4%)	
Overall trade surplus in 1994	$5 billion
Diversity: FDA registered medical device suppliers	18,250
Companies employing less than 50 people	72%
US share of the global output of medical implant and devices (1995)	46%

[a] Data from "The Dialog of Device Innovation" published by the Health Care Technology Institute, November 1993; "The Forces Reshaping the Performance and Contribution of the United States Medical Device Industry", Report by the Wilkerson Group to HIMA, June 1995; "Report on Public Policy Reform and the United States Health Care Technology Industry", HIMA, February 9, 1995.

Biomaterials Science: The Optimistic Viewpoint

Currently, medical device designers are limited to a relatively small number of off-the-shelf materials that were not

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originally designed to be used in medical implants (Table 2). The result of this material-imposed limitation is that the vast majority of all currently available implants are made of simple industrial plastics and metals. These materials do not provide a biologically functional interface with the surrounding tissue. As a consequence, virtually all currently available implants elicit a mild foreign body response at the implant site. In a recently convened workshop on "Biomaterials and Medical Device Science" (2), about 100 of the nation's leading experts reached the conclusion that the materials base of the medical device industry is out-dated and that "materials and devices endowed with biological structure and function must be designed and developed" (2).

These new biomaterials will be based on a better understanding of the mechanisms that control cell-materials interactions and will provide both carefully tailored physicomechanical and chemical properties as well as biologically functional interfaces with living cells (2). Driven by advances in cell biology and materials design, it is now possible to envision materials that will actively support the attachment and growth of specific cell types and that will provide a "scaffold" for the three-dimensional organization of cells into functional tissues. As such improved materials become available, the replacement of whole organs by synthetic substitutes becomes a real possibility. Considering the limited availability and high cost of human donor organs, the need and economic potential of man-made substitute organs is obvious. However, the real impact of the "biomaterials revolution" is in the envisioned improvements in safety and efficacy of hundreds of medical devices, ranging from "simple" contact lenses to complex devices such as kidney dialysis machines. Over the next 20 years, it will be necessary to redesign a large fraction of the currently available medical implants and devices. This will provide significant commercial opportunities for cutting-edge companies. More importantly, nations with efficient regulatory mechanisms and a supportive business climate will be able to implement the coming advances rapidly and will benefit from better patient care, reduced health care costs, and will establish a leading position in the global market place.

Table 2. Materials Commonly Used in the Manufacture of Medical Implants and Devices

Type of Material	Specific Examples
Biostable polymers and resins,	Polyurethanes, silicone rubber, Teflon®, Dacron®, nylon, polymethylmethacrylate (PMMA)
Biodegradable polymers	Poly(lactic acid), poly(glycolic acid), polydioxanone
Natural and semi-synthetic products	Treated porcine grafts, bovine pericardium, processed cellulose, processed collagen
Metals	316 and 316L stainless steel, Vitallium®, titanium alloys, Co-Cr alloy, Co-Cr-Mo alloy
Ceramics	Aluminum oxides, calcium aluminates, titanium oxides, pyrolytic carbon, Bioglass®, hydroxyapatite
Composites	Apatite composites, carbon coated metals, carbon reinforced polymers

As outlined below, the United States does not provide an optimum business infrastructure to translate effectively the scientific knowledge generated in United States universities and companies into clinically useful products. However, there are attempts to improve the situation: The FDA has recently become significantly more responsive and is accelerating the approval process, the NIH is working on identifying more effective ways to support biomaterials science, and there have been (timid and so far unsuccessful) attempts in congress to reduce the destructive effects of excessive litigation. The optimists maintain that reforms are underway and that the business climate in the United States will improve in time to ensure the future viability of the US medical device industry.

Medical Device Industry: The Pessimistic Viewpoint

The medical device industry faces a number of challenges relating to the *intrinsic* nature of medical research as well as key obstacles that are artificially imposed upon the industry (Table 3). Medical research and product development are expen-

Table 3. Challenges and Obstacles to the Process of Innovation in the Medical Device Industry[a]

Intrinsic Challenges	
High cost	Implant and device development requires significant start-up capital and is by nature very expensive to perform
High risk	Medical devices require high profit margins to compensate for unsuccessful research efforts and for the high development costs
Key Obstacles to the Development of Improved Implants and Devices in the United States	
Product liability	Excessive and costly litigation (often without scientific base or merit) have diverted research and development funds, slowed innovation, and reduced the willingness of major corporations to participate in the market
Comprehensive regulation	Medical device development, manufacture and marketing is highly regulated. The regulatory process discourages fundamental innovation. Compared to European nations, the regulatory process in the United States appears to be slower.
Government control of the health care market	Government control over reimbursements leads to delays and additional risk in the marketing of medical devices and in the testing of experimental devices
Lack of long-term financing for start-up companies	While fundamental innovation in biomaterials science requires a long-term investment view, venture capital funds in the United States tend to focus on short-term gains

[a] Adapted from data contained in "1994 Reference Guide for the Health Care Technology Industry" Health Care Technology Institute, 1994; "Policy Brief: The Dialog of Device Innovation: An Overview of the Medical Technology Innovation Process" Health Care Technology Institute, 1993.

sive and risky. There is little one can do to change these intrinsic characteristics of the way scientific innovation in the medical sciences is translated into clinically useful products. However, in addition, there are now powerful forces in place that tend to create a uniquely challenging environment for the medical device industry in the United States.

Among the key obstacles listed in Table 3, the most controversial issue has been the effect of product liability litigation on the medical device industry. The lack of reasonable protections to raw material suppliers and manufacturers under current product liability laws and the huge cost of medical tort cases set the United States aside from all other nations. The failure of the United States legal system to establish appropriate limits to these costs has been identified as a serious threat to the survival of the medical device industry. Over the last decade, litigation has drained billions of dollars from the medical device industry. These resources, if used in research and development, would have been more than enough to fund all the research and development needed to improve the safety and efficacy of the medical devices that were the subject of litigation. Instead, products that become engulfed in lawsuits are usually withdrawn from the market, the manufacturers are forced into bankruptcy, and all research and development efforts aimed at the improvement of the products come to an end. The net effect of mass tort cases is a loss of available treatment options for the patient, a chilling effect on innovation and the development of better implants, marginal compensation for a small number of patients, while the lawyers who argue the cases are assured of extremely lucrative profits. As shown by the breast implant litigation, scientifically uninformed juries had serious problems in evaluating the complex technical issues discussed at these trials. In one particular case, compensatory and punitive damages in the amount of $14.1 million were awarded to one single breast implant patient. The expected, total cost of the breast implant litigation is estimated to be between $5 billion to $10 billion (with about $2 billion being paid to lawyers). The legal system imposed these huge costs in spite of the fact that there is no conclusive scientific evidence supporting the alleged far-reaching health risks of breast implants. On the contrary, a series of comprehensive and carefully conducted studies published recently (see for example studies performed by the Mayo Clinic and Harvard Medical School (3,4)), indicate a lack of convincing correlations between breast implants and their alleged autoimmune, cancer, or connective tissue health risks. Surprisingly, these carefully conducted and highly objective studies have so far had no impact on the ongoing litigation in which juries tend to react emotionally to the perceived plight of the patient without due consideration of scientific fact or cause-effect relationships.

Litigation relating to the Dalkon Shield intrauterine device (IUD) (5) provides a good illustration of the negative societal effect of the current product liability laws. In this case, the product was indeed defective. Product liability litigation swiftly removed the product from the market and put a previously strong company (A.H. Robins) out of business. However, in spite of the fact that "justice was done", the public interest was not served in an optimum way. In the wake of A.H. Robins' bankruptcy, virtually all IUD's were withdrawn from the market and for over 20 years no new and potentially safer contraceptive devices were developed. Thus, rather than leading to safer contraceptive devices, the Dalkon Shield litigation may have contributed to a situation in which the selection of contraceptive choices for an entire generation of American women was diminished and largely unsatisfactory. In the opinion of the author, the point can be made that the nation would have been better served if a part of the $1.4 billion paid out by the Dalkon Shield Trust Fund to about 185,000 claimants and their lawyers would have been used to invest in research and development of better contraceptive products.

An illustrative example of the effect of litigation on medical innovation is the attack that is currently being mounted against Wyeth-Ayerst, the manufacturers of Norplant. Norplant is a tiny, rod-like implantable contraceptive that has been developed and tested for over 20 years and that is used successfully in many countries. Norplant is one of the few truly innovative contraceptives introduced into the United States market over the last 30 years and represents a welcome addition to the reproductive choices of a large number of women. The FDA has carefully reviewed the product and all available scientific evidence indicates that Norplant is an exceptionally safe and effective medical device. Still, using an aggressive advertising campaign, lawyers have actively recruited "victims" (6,7) and the number of lawsuits has risen from 20 in the first 3-year period to over 235 in the past 12 months alone. Faced with dramatically reduced sales and the increasing financial burden to defend Norplant, it is unlikely that this line of products will be further developed by Wyeth-Ayerst. Although Norplant never accounted for more than 1.8% of the company's total revenues, projections based on the breast implant litigation indicate that Norplant has the potential to force Wyeth-Ayerst into bankruptcy. It appears that the Norplant litigation will have a chilling effect on the willingness of companies to bring truly innovative products to the United States market.

Even when a company successfully defends itself against a wave of lawsuits, the effects of litigation can be highly undesirable from a public health perspective. In the 1980's, Vitek Inc. produced an implant designed to treat temporo-mandibular joint (TMJ) syndrome. This implant contained a small amount of Teflon obtained from DuPont. When it became evident that some of the implants failed due to poor resistance of Teflon to continuous mechanical sheer, a wave of product liability suits drove Vitek into bankruptcy in 1990. It was an obvious strategy of the product liability lawyers to name DuPont in these lawsuits as a defendant simply because DuPont had "deep pockets". Although DuPont was found to be not liable in every one of the 258 cases tried so far, the legal costs already exceed $40 million and there is still a backlog of over 400 cases waiting to go to trial. Considering that sales to the medical market were less than 0.002% of the non-medical market, DuPont reached the only logical business decision: It withdrew its materials, in particular Teflon®, Dacron®, and Delrin® from the medical market. Unfortunately, Teflon, Dacron, and Delrin are among the safest and most biocompatible materials currently available. Since we do not yet have equally reliable replacements, serious shortages of 85 different medical products can be expected. These shortages will affect more than 30 different surgical procedures and reduce the quality of life and level of care given to an estimated 7.4 million patients (8).

The above discussion illustrates two key tenets of the product liability system as practiced in the United States. The first tenet is the standard of "Strict Liability" which entails holding the manufacturer of a medical device or any of its components or raw materials liable for any injury caused by

the product, irrespective of the care taken by the manufacturer in making the product safe. Strict Liability represents the risk inherent in the product, not the conduct of the manufacturer. Since "zero risk" is simply impossible for even the best medical device, the standard of Strict Liability ensures that any medical device manufacturer or raw material supplier can be exposed to tort action. The second tenet is the doctrine of "Joint and Several Liability". This doctrine holds that any party connected with the development or manufacture of a product can be held responsible for any injury caused by the product. This doctrine enables lawyers to reach for companies with deep financial resources even if these companies had only a remote or incidental connection with the incidence of injury. The combination of "Strict Liability" and "Joint and Several Liability" precipitated the severe crisis in the supply of raw materials to the medical device industry: As shown in Table 2, the most widely used raw materials for medical implants and devices are common engineering plastics that are supplied by large companies (such as DuPont) to many different markets. Faced with the fact that the medical market size is negligible compared to the other market segments, while exposing the companies potentially to billions of dollars in liability, even the most responsible raw material suppliers have little choice but to withdraw from the medical market.

A study commissioned by the Health Industry Manufacturers Association (HIMA) and conducted by Aronoff Associates (9) investigated the lack of suitable raw materials for the manufacture of medical devices and predicted that a major part of the United States based medical device industry will be lost over the next few years (Table 4).

Some of the predictions spelled out in Table 4 can already be confirmed by statistical evidence. Until 1992, the medical device industry was the second fastest growing American industry, providing 64% of the global sales of medical devices. After 1992, growth slowed and the United States world leadership position has begun to erode. In 1995, the U.S. share of global sales had dropped to 46%.

Recognizing that "zero risk" is not achievable in medical devices, attempts have been made to introduce reasonable standards of conduct and rational, science-based judgements into product liability laws for medical devices. These efforts resulted in the Common Sense Product Liability and Reform Act (H.R. 1075) which was passed by the House on March 10, 1995, and the Product Liability Fairness Act (S. 565) which was passed by the Senate on May 10, 1995. At the time of writing this commentary, the two slightly different versions were still awaiting reconciliation proceedings. The optimists point to these two bills as evidence that the necessary reform of product liability for medical devices is forthcoming. The pessimists point to the fact that the two bills are apparently in legislative "limbo" and that there is a real possibility that further congressional action on these two bills may be delayed indefinitely.

Table 4. Main Conclusions of an HIMA Sponsored Market Study[a]

- A biomaterials crisis will occur unless substitute materials are found and approved for marketing.
- Patients will not have access to life-saving medical implants. This situation will affect 85 permanent implant products, more than 30 surgical procedures, and about 7.4 million patients[b]
- A primary source of medical implant innovation will vanish with the demise of small manufacturers.
- Major segments of the medical implant industry will move overseas.
- The USA will loose its leadership in the medical implant field.

[a] Adapted from a market study conducted by Aronoff Associates (9).
[b] Estimates from HIMA and the Biomaterials Availability Coalition (8,10).

SUMMARY

The large and spectacular legal proceedings against major raw material suppliers and medical device manufacturers have lead to a wide ranging discussion about the contributions of medical devices and implants to our national health care, the plight of individual patients who have suffered from allegedly defective products, and the effect of our current product liability laws on the economic viability of the medical device industry, one of the technologically most advanced and research intensive manufacturing sectors.

Although the discussion about the safety and efficacy of currently available medical devices and implants has been emotional at times, several important conclusions can be reached:

First, the medical device industry is a vital component of our health care system. Currently, about one in 10 Americans benefits from some medical implant. As the United States population continues to age, and as scientific breakthroughs lead to wider applications for medical implants, the number of patients who will benefit from a medical implant will undoubtedly increase even more. It is obvious that we as individuals and the public interest are best served by ensuring that the economic viability of the medical device industry in the United States is maintained: A guaranteed supply of safe and efficacious implants will improve the medical treatment afforded to the individual patient and reduce overall health care costs.

Second, the scientific foundation is now in place to develop significantly improved medical implants. In the near future, it will be possible to design synthetic or semisynthetic materials with a biologically active interface. Tissue engineering will lead to replacements for body parts and organs that feel and behave much more like natural tissue than the currently used implants manufactured from metals and simple engineering plastics. Promising advances in drug targeting, the use of proteins and peptides as drugs, and gene therapy also benefit from novel biomaterials-based delivery systems. While countries with responsive regulatory, legal, and business infrastructures will be able to translate these scientific breakthroughs effectively into clinically useful products, the development effort in the United States has begun to lag behind its European and Asian competitors.

Third, product liability has emerged as a significant obstacle to the development of improved products based on fundamental breakthroughs in basic science. Although some have claimed that the threat of product liability is fostering innovation, this author has reached the conclusion that in the way the legal system operates today, the current product liability laws have stifled innovation and delayed/prevented the development of safer implants to replace those that were allegedly defective. Currently, there is mounting evidence that a legal system that affords substantial financial gain to lawyers who initiate lawsuits irrespective of scientific and rational basis is not promoting better treatment options for the individual patient and is not in the best national interest.

Fourth, over the last decade, product liability litigation has drained billions of dollars from the medical device industry

and tens of billions of dollars from the health care system as a whole. If spent on research and the development of improved implants and medical treatments, only a fraction of these enormous resources would have been sufficient to correct most of the product deficiencies that gave rise to the lawsuits in the first place.

In the final analysis, everyone stands to gain by the adoption of rational, fair, and just standards governing the conduct of the medical device industry. As a consumer and potential user of a medical device, the author does not recommend dismantling the deterrence provided by good product liability laws. The issue is not to protect companies from lawsuits, but to redirect valuable resources from unproductive legal costs back to R&D efforts leading to better products. Likewise, it would be wrong to deny lawyers fair compensation for their efforts, but is it really appropriate that lawyers' fees and profits could exceed $2 billion in the breast implant litigation alone? Finally, is it really in the best public interest that it is legally possible to sue the company that provided the ink that was used in printing the label affixed to a medical implant that may have been defective? The answers given by Congress and state legislators to these type of questions will determine to which extent extremely promising breakthroughs in basic biomaterials and implant science will be translated into innovative and improved medical devices by companies operating in the United States.

REFERENCES

1. A. J. Moss, S. Hamburger, L. L. Jeng and L. J. Howie. Use of selected medical device implants in the United States, 1988, *Advance Data from Vital and Health Statistics of the National Center for Health Statistics,* Vol. 191, U.S. Department of Health and Human Services, Washington, DC, 1991.
2. P. Eisenberger. Executive Summary of the NIH Workshop on Biomaterials and Medical Implant Science. *NIH Workshop: Biomaterials and Medical Implant Science,* Bethesda, MD, (1995).
3. S. E. Gabriel, W. M. O'Fallon, L. T. Kurland, C. M. Beard, J. E. Woods and L. J. Melton. Risk of connective-tissue diseases and other disorders after breast implantation. *New Eng. J. Med.* **330**:1697–1702 (1994).
4. J. Sanchez-Guerrero, G. A. Colditz, E. W. Karlson, D. J. Hunter, F. E. Speizer and M. H. Liang. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *New Eng. J. Med.* **332**:1666–1670 (1995).
5. T. M. Lenard. *The future of medical innovation,* The Progress and Freedom Foundation, Washington, DC, 1995.
6. G. Kolata. Will the lawyers kill off Norplant? *New York Times* (1995).
7. G. Cowley. The Norplant Backlash: Is it dangerous, or are lawyers exploiting it? *Newsweek:* 52 (1995).
8. Health Industry Manufacturers Association. Information Document: Biomaterials embargo: Potentially affected permanent implants, 1994.
9. Aronoff Associates. 350 East 52 Street—Suite 11D, New York, NY 10022. Market Study: Biomaterials Supply for Permanent Medical Implants, March 1994.
10. Biomaterials Availability Coalition. P.O. Box 14293, Washington, DC 20044. Medical procedures/patients affected by a biomaterials shortage, April 1994.