

# Policy Analysis

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## *How FDA Regulation and Injury Litigation Cripple the Medical Device Industry*

by Charles A. Homsy

### **Executive Summary**

Manufacturers of medical devices face a triple threat in their efforts to develop products to alleviate pain and suffering. The U.S. Food and Drug Administration can drive manufacturers out of business, even when the FDA itself certifies their devices. The personal injury liability system makes it easy for predatory lawyers to force manufacturers of safe products into bankruptcy. And sensationalist media accounts of allegedly dangerous devices add to manufacturers' problems.

Three examples illustrate those problems. In 1974, on the basis of unsubstantiated media reports and lawsuits, and without legislative authority, the FDA forced A.H. Robins to remove the contraceptive Dalkon Shield from the market. Though later reports showed the shields to be safe, A.H. Robins was driven into bankruptcy. Beginning in 1988, Dow Corning's silicone breast implants became the subject of FDA accusations, liability suits, and media hysteria. Although no sound science has ever shown the devices to be dangerous, the manufacturer was driven out of business.

My company, Vitek, manufactured out of the patented material Proplast implants that were used

successfully in some 100,000 patients with distorted, damaged, or destroyed facial structure; joints of the jaw, thumb, and hip; and other body parts. In 1986 reports surfaced about particular jaw implants wearing out. In fact, the problems occurred when underlying conditions were not treated or when patients refused to follow the prescribed treatment. But the FDA and liability lawyers waged a campaign against those implants, driving Vitek out of business. Worse, the FDA also targeted Novamed, a company established to produce other FDA-approved Proplast implants that were not under suspicion, and used questionable court tactics to drive it out of business. Finally, the FDA used its own regulatory leverage and the World Health Organization to drive into bankruptcy a Swiss company established to produce Proplast products that had obtained or were obtaining certification in the Europe Union, Switzerland, and Canada.

European governments allow private companies that meet certain objective criteria to certify medical devices. That approach is less subject to abuse, better ensures patients' access to devices, and could be an alternative to the malfunctioning American approach.

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*Charles A. Homsy holds an Sc.D. in chemical engineering from the Massachusetts Institute of Technology. After five years with the Du Pont Company, in 1966 he established at the Texas Medical Center the first U.S. hospital-based bioengineering laboratory, which he directed until 1990. He was founder and CEO of Vitek Inc. (1971-90) and Novamed Inc. (1988-92), which made surgical implants. From 1992 to 1999 he was scientific director of Swiss companies founded to carry on that work.*

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### Introduction

Medical devices and implants are among the modern marvels that alleviate pain and suffering, prolong life, and add to the quality of life. Those devices are the products of years of research and development by inventors, physicians, and surgeons. The U.S. Food and Drug Administration is charged with certifying that the devices are safe and effective. Unfortunately, the FDA often acts, not principally to protect public safety, but rather to persecute the producers of devices, thus keeping those devices from the public and discouraging their development.

Robert Higgs reports that doctors, hospitals, and emergency medical services find that devices available elsewhere in the world are not on the market in the United States, and thousands of patients are suffering as a result. He emphasizes that the causes of those woes are perplexing, costly, and time-consuming regulations promulgated and enforced by the FDA. He quotes Kshitij Mohan, an industry executive and former FDA official, as saying, "The pendulum may swing back eventually, but the pendulum at FDA is more like the wrecking ball."<sup>1</sup>

Another threat to the medical device industry, often encouraged by the FDA, is predatory liability lawsuits against device manufacturers. Those suits are based on hysteria, not on sound science. Marcia Angell, M.D., in *Science on Trial—The Clash of Medical Evidence and the Law in the Breast Implant Case*, describes an apocalyptic horse bent on crippling the medical device industry: "The FDA banning [of breast implants] was followed by a tidal wave of litigation. . . . The flood of breast implant lawsuits was simply one more manifestation of Americans' fervor for suing one another."<sup>2</sup>

Harvard law professor Mary Ann Glendon notes, "While some lawyers were touting litigation as a quick fix for social ills, others were teaching that for nearly every injury suffered by a private individual there is someone with deep pockets, the government or a large cor-

poration, who can be sued and made to pay."<sup>3</sup>

Angell points to "changes in the pattern of tort cases [that] justify concerns about a litigation explosion. First, mass personal injury litigation—thousands of lawsuits involving the same product or injury—has burgeoned particularly since 1980. And second, the size of jury awards has grown rapidly."<sup>4</sup> Angell adds:

In that decade [the 1960s], according to . . . [Glendon's] thesis, we began to turn to the courts to rectify nearly all social ills and injustices. This has become an expensive habit, she argues, which is accompanied by atrophy of the more traditional, but slower methods of affecting change—including the political process. People sue one another, instead of voting. As lawsuits have proliferated since the 1960s, the character of the legal profession has itself changed.<sup>5</sup>

Helping to promote irresponsible lawsuits and FDA actions are sensationalist media reports that are anything but objective and balanced, and that distort the truth about the issues involved. Often the FDA itself stokes such media fires.

The examples of three types of implants— intrauterine contraceptives, breast implants, and temporomandibular joint implants—illustrate the problems with the current FDA approval system and the liability system in this country and show why many device manufacturers shut down or move off shore.

### The Dalkon Shield "Mistake"

An early case of a medical device's being driven from the market by the FDA, lawsuits, and media hysteria concerned the Dalkon Shield, an intrauterine contraceptive device, or IUD. This birth control device, popular in the 1960s and early 1970s, was manufactured by A.H. Robins Co. and marketed until June 1974.

In 1974 the media, noting that lawsuits involving IUDs were growing in number, highlighted allegations that the Dalkon Shield was causing more septic spontaneous abortion and death than were other IUDs. Acting on those allegations, the FDA asked A.H. Robins to remove the Dalkon Shield from the market even though at that time the agency had no statutory authority to actually ban medical devices; its jurisdiction was limited to pharmaceuticals. Such impulsive behavior is FDA's characteristic response to controversy before the facts are in. However, a FDA report later in that year stated that the allegations concerning abortions and deaths were not in fact proven.<sup>6</sup>

Nevertheless, that erroneous allegation was followed by the unsubstantiated accusation that the Dalkon Shield was causing pelvic inflammatory disease (PID) more often than were other IUDs. Thus, in this as in other cases, the FDA action fostered litigation and fanned the media fire. Congressional hearings followed, with calls for the extension of the FDA mandate to cover devices as well as drugs. That occurred in 1976 with the passage of the Medical Device Amendments to the Food, Drug and Cosmetic Act.

After the removal of the Dalkon Shield from the market there followed a steep decline in the number of IUD users. It has been estimated that because 2.3 million American IUD users were forced to use other, less-effective methods, there were 160,000 additional unintended pregnancies per year.<sup>7</sup> Was this a case of the government's acting wisely to protect the public from dangerous products? The full story leaves a different impression.

### **Data from Prospective Clinical Trials, 1970–75**

There were several different types of prospective clinical trials used to study IUDs, including the Dalkon Shield. Prospective trials are the best way to evaluate a treatment. Seven trials were prospective, randomized-comparison clinical trials involving 1,372

Dalkon Shields and 2,589 other types of IUD. This most rigorous methodology involved random allocation of devices to successive patients. PID was reported in three of the studies but was in no way identified as an alarming problem.

There were 25 nonrandomized prospective studies involving 14,000 users of the Dalkon Shield and 45,508 users of other IUDs. In none of those studies was the Dalkon Shield associated with a greater risk of PIDs than the other IUDs used for comparison. Indeed, none of those investigators noted PIDs as a special problem.

Thirty-nine straight-assignment studies included 25,807 Dalkon Shield users. Only two investigators mentioned PID in their reports. One study of 43 Dalkon Shield users reported a one-year PID rate of 4.8 percent and a 5 percent sexually transmitted disease (STD) rate among the patients generally: STDs were correlated with cases of PID. The second report, on 46 Dalkon Shield users, simply observed that no significant rates of PID were found.

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### **The "Case-Control" Epidemiological Study, 1976–78**

With lawsuits increasing, a "case-control" epidemiological study, usually known as the Women's Health Study, was carried out at 16 hospitals in nine cities across the country. The case-control methodology assembled histories of patients who had developed PID and retrospectively tracked back in time the treatments received by those women. The data were compared with those on a similar-sized group of women who did not develop PID. The groups were matched as closely as possible in all risk factors except the target variable, IUD use. Such matching is difficult to do and in the WHS study was seriously compromised.

The first paper with results from the case-control WHS finally was published in 1981 in *Obstetrics and Gynecology*, some seven years

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after the controversy began.<sup>8</sup> The paper compared data on 1,447 IUD users and 3,453 nonusers and concluded that IUDs in general, not just the Dalkon Shield, increased the risk of PID. It found the relative risk to IUD users compared with nonusers to be a highly significant 1.6 (i.e., users had a 60 percent greater frequency of PID than did nonusers).

A sister report,<sup>9</sup> published in 1983 in *Obstetrics and Gynecology*, was directed specifically at the Dalkon Shield. However, it was based on relatively small numbers of users of the device: 35 of 285 in the case group and 15 of 778 in the control group. It concluded that the relative risk of PID for users of the Dalkon Shield was a very large 7.1. With that study generating new lawsuits, A.H. Robins declared bankruptcy in 1985. By that time the company had defended itself in about 7,000 lawsuits. The Dalkon Shield Claimants Trust then distributed almost \$3 billion in payments to about 200,000 women.<sup>10</sup>

But in 1991 and 1992 reports from the Department of Biostatistics at the University of Washington/Oregon Health Sciences University<sup>11</sup> and from the Center for Research on Population and Security at Research Triangle Park in North Carolina<sup>12</sup> reanalyzed the 1981 and 1983 papers. The results were published in the *Journal of Clinical Epidemiology* and in *Fertility and Sterility*, respectively. They showed that when nonusers of any contraceptives (as opposed to nonusers of IUDs) were used as the comparison group, the relative risk for all IUD users was 1.02. There actually was no risk from IUD use among all women (including women with a history of PID who had been excluded from the earlier studies). That result reflected the substantial protective effect against PID provided by oral contraceptives and barrier methods such as IUDs. The earlier studies had not taken this into account in reaching their findings.

The authors discussed a number of other relevant biases in the methodology of the WHS and the sister report that undermined the reported findings of those studies. A further conclusion of the new analyses was that

all studies of IUDs, including the WHS, measured the performance, not of different IUDs, but, rather, of providers who inserted those IUDs. The earlier papers had downplayed that point. That is to say, it was probable that health care providers who inserted the devices wrong rather than the devices themselves caused the PID.

The 1992 report also observed that in 1968 the World Health Organization, the advisory committee on Obstetrics and Gynecology of the U.S. Food and Drug Administration, and the American College of Obstetrics and Gynecology jointly concluded that PID was not an important problem in IUD use. The report also pointed out that approximately 1 million of the 50 million women of reproductive age in the United States experience an episode of PID each year, an incidence of 2 percent per year. Further, 90 percent of those women who had had an episode of PID never used an IUD. In fact, it was not contested that sexually transmitted diseases accounted for the overwhelming majority of PID cases.<sup>13</sup> That fact raised the suspicion that STDs were also a major cause of PID in IUD users.

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In 1996 R. J. Beerhuizen, of the Department of Obstetrics and Gynecology, University of Ghent, Belgium, reported that PID among IUD users was strongly related both to the insertion process and to the background risk of sexually transmissible disease.<sup>14</sup> In 1998 a report by S. L. Kimble-Haas of the Public Health Service Hospital at Pine Ridge, South Dakota, noted that the stigma against IUDs continued to sharply limit their use while "rigid patient-selection guidelines and strict aseptic insertion techniques can provide safe, cost-effective, and highly efficacious contraception for monogamous women."<sup>15</sup>

In 1998, in a case appealed by the Dalkon Shield Claimants Trust, the U.S. Court of Appeals for the First Circuit decided that the trial court had erred in preventing admission of evidence of the plaintiff's STD history.<sup>16</sup> But the ruling came too late. The FDA,

predatory lawsuits, and media hysteria had brought down a \$2.5 billion company, curtailed availability of IUDs to American women, disrupted research and development in contraception using barrier devices, and rewarded plaintiffs' attorneys for this mayhem with \$1 billion.

## The Silicone Breast Implant “\$4.3 Billion Mistake”

Silicone breast implants are another example of a product driven from the market by the FDA and media hysteria. Commercial marketing of those products in the United States began in 1964. When the Medical Device Amendments were enacted in 1976, the implants continued on the market as “grandfathered” preamendment devices.<sup>17</sup> This meant that they had to be placed in one of several categories. Class I means the products are de facto safe; Class II means they are safe and effective after review of data and thus can be sold; Class III means more data are needed to show them to be safe and effective before sales can commence.

But the FDA waited until 1982 before proposing to assign breast implants to Class III. It was not until 1988 that the FDA actually made that classification official. That meant that the manufacturers had to stop sales and to submit evidence of safety and effectiveness of the implants not later than July 9, 1991.

The real problem came with a wave of lawsuits against implant manufacturer Dow-Corning. Ralph Nader's group, Public Citizen, entered the scene in 1988, petitioning the FDA to ban breast implants. Both the Nader organization and the Association of Trial Lawyers of America established clearinghouses to help lawyers clone promising lawsuits. The attitude of the lawyers and activists was “Never mind the evidence, everyone who might be doing wrong probably is.”<sup>18</sup>

The clamor intensified in December 1990 when the TV show *Face to Face with Connie Chung* blamed the FDA for permitting the

sale of risky breast implants.<sup>19</sup> Such TV coverage led a Swiss newspaper to report that medical specialists had noted the appearance of a new syndrome, called “media scare reactive disorder,” a disorder of psychosomatic and psychological origin. The symptoms, provoked by misinformation from the media, went from panic to loss of confidence in one's physician.<sup>20</sup> A congressional hearing followed at about the same time with more criticism of the FDA.

Thus in April 1992 FDA commissioner David Kessler announced a virtual ban on silicone breast implants. That set off a headlong rush to the courts by lawyers filing 10,000 suits that named Dow Corning and other manufacturers as defendants for alleged injuries caused by implants. All the lawsuits were consolidated as a class action in that year. Two years later a proposed \$4.3 billion settlement was approved by Federal Judge Sam C. Pointer. Dow-Corning would pay about \$2 billion of that amount; the rest would be paid by other manufacturers. One billion dollars of the \$4.3 billion was specifically set aside for plaintiffs' lawyers.

Judge Pointer in August 1996 appointed an independent national science panel. The panel included experts in the fields of immunology, epidemiology, toxicology, and rheumatology. The panel was charged to review and critique the scientific literature concerning a possible causal link between silicone breast implants and connective tissue diseases and related signs and symptoms as well as immune system dysfunction. On December 1, 1998, the panel's completed report presented no evidence linking silicone breast implants to systemic diseases such as connective tissue disease.<sup>21</sup>

In contrast to the FDA in America, European authorities, except in France, continued to allow use of silicone breast implants. The British Ministry of Health conducted three separate studies on breast implant safety and exonerated the implants in each instance.

On the other hand, the British tabloids and TV talk shows emulated their American

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counterparts with scare stories on the dangers of breast implants. Even the normally reliable *Economist* ran a negatively slanted story, "Silicone Valediction," on May 20, 1995. In response to criticism about the story, its author, Peter Haynes, U.S. business editor, agreed that

any article that ignored the large number of scientific studies which question the link between the implants and auto-immune diseases would indeed be superficial. My original article . . . did indeed make the point in some detail. Unfortunately, an editor in London saw fit to remove the relevant sentences . . . in order to cut the article's length.<sup>22</sup>

The malignant triad of the FDA, plaintiffs' lawyers, and the media once again brought a segment of the medical device industry to its knees and curtailed an important patient treatment.

## The Case of Proplast

My own struggles with the FDA, the media, and trial lawyers show that the silicone breast implant and IUD cases were not exceptional but in fact illustrate major problems that plague medical device producers. Attacks on the material known as Proplast and products made from that material have meant that patients have been denied implants and suffered needlessly.

After working for six years on Teflon polymers at the Delaware research center of the Du Pont Company, I became interested in the use of Teflon for biomedical implants. In 1966 I went to work at the Methodist Hospital and Baylor College of Medicine, both in Houston, and by 1968 had invented Proplast for which broad patent protection was granted in 1976. This soft, 80 percent porous material, formed with Teflon and a second hydrophilic (water-attracting) material, could be fashioned into implants to serve

as lattices to guide the body to create its own tissue of needed shapes and types. Such implants allow the body to restore itself; in the end, 80 percent of the body part will be made of the patient's own tissue. This work marked the beginning of tissue engineering.

In 1970 I founded Vitek Incorporated, with the blessing of the hospital that housed my laboratory, to make needed implants from Proplast and to recycle profits back into research. The research resulted in 20 more patents, and, with more products, the business grew.

The FDA proposed approval of Proplast as a Class II material, subject to certain regulations, for use as a dental device in 1980 and as an ear, nose, and throat device and a general plastic surgery device in 1982. Final approval for dental applications was granted in 1987 and for ear, nose, and throat and general facial plastic surgery applications in 1988. In making those approvals, the FDA concluded that "the safety and effectiveness of Proplast has been established through long-term clinical trials."<sup>23</sup>

In the years that followed, Vitek developed more than 30 products that employed Proplast and were used in more than 100,000 patients. Most of those products were made entirely of Proplast and were used to reconstruct such body parts as chins, ears, cheekbones, skull bone, and pelvic bones. Four were devices in which the Proplast was laminated to another substance to anchor the latter in the body by tissue in-growth. Two of the devices were for temporomandibular, or jaw, joint implants (TMJ implants); a third was to replace the trapezium bone of the thumb that allows grasping; the fourth was for hip joint replacement. Successful use of the products is documented in more than 125 peer-reviewed publications.<sup>24</sup>

## Striking at Jaw Implants

The only implant products containing Proplast to be targeted in multiplaintiff suits were those for the TMJ, particularly the Interpositional Implant (IPI), which was a cushion in the joint. This joint cushion was formed

by laminating Proplast to a Teflon product. The IPI was designed in 1982 by Dr. John Kent, an oral surgeon at the Louisiana State University School of Dentistry, on the basis of seven years' prior clinical experience with a similar lamination sold for plastic surgery uses. The FDA approved the IPI for marketing in early 1983. "You may market your device subject to the general controls provisions of the Federal Food, Drug and Cosmetics Act . . . until such time as your device has been classified under section 513."<sup>25</sup> The FDA did not make a final classification of the IPI or other TMJ implants until 1992.<sup>26</sup> Such delays are part of the problem with the FDA process.

Dr. Kent designed the implant for patients whose TMJ discs had been destroyed by injury, malocclusion or jaw misalignment, bruxism (the grinding of teeth), and sometimes all three. The disc acts as a cushion for the jaw bone to slide over as the mouth is opened and closed. The product had the best success rate of the various products designed to deal with this very difficult problem.<sup>27</sup> However, if underlying clinical problems such as bruxism and malocclusion were not fixed, the implant would wear out, just as had the natural tissue.

By late 1986 I had heard of instances of the devices wearing in this manner, and I convened a conference of 12 surgeons who had reported both successes and failures. Their consensus report to the FDA and to the entire membership of the American Academy of Oral and Maxillofacial Surgeons found fault not with the implant itself but, rather, with the way some surgeons were using it or the refusal of some patients to follow the treatment plan advised by the surgeons, or both.<sup>28</sup> However, as soon as the IPI controversy among oral surgeons surfaced, I stopped all promotion of the device, permanently, as it turned out. In 1988, after several lawsuits had been filed, I could no longer obtain product liability insurance. Thus I removed the IPI implant from the market.

In 1988 I also formed a company, Novamed Inc., to manufacture non-TMJ devices made of Proplast. The new company

was able to obtain product liability insurance since Proplast was FDA approved and was not itself subject at that time to any lawsuits.

As was the case with breast implants, the FDA delayed classifying the IPI and all other TMJ implants until 1992, four years after Vitek stopped selling them. Under the Device Amendments of 1976 to the Food, Drug and Cosmetic Act<sup>29</sup> the FDA should have classified those products in a timely manner as either Class I, de facto safe; Class II, safe and effective after review of data and sellable; or Class III, in need of data to show safety and effectiveness before sales could commence. The FDA could have stopped sales at any time between 1976 and 1992 and asked for more data. But it waited for years after the devices were no longer being made or sold to decide that more tests were necessary.

### **Litigation**

Alleged problems with the IPI were the excuses for personal injury lawsuits against Vitek beginning in 1987. The suits named multiple defendants including

- Vitek Inc., which had manufactured the IPI;
- Novamed, Inc., which had not;
- Du Pont, which supplied the Teflon for the IPI;
- the Methodist Hospital and Baylor College of Medicine;
- sundry oral surgeons;
- myself as CEO of Vitek;
- my wife as a member of the Board of Directors of Vitek (she handled employee payroll and health insurance); and
- Corning Corporation and various other hapless companies not connected with the IPI.

Vitek successfully defended the first two suits at jury trial. The third was lost in late 1989, but defense lawyers advised that judicial error would be reversed on appeal.

Vitek went bankrupt in 1990 when its liability insurers became involved in a coverage

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dispute and stopped paying defense lawyers. The bankruptcy court negotiated a \$22 million settlement of product liability insurance obligations for itself to administer. Because those proceeds were also to be used to defend the officers of the company, the court issued a stay against any suits that named my wife, myself, and Novamed. This served to preserve as much of the insurance funds as possible for claimants against Vitek instead of having those funds eaten up in legal costs.

An indication of the problems with the litigation over the IPI was seen in cases against Du Pont. Dr. Myron Spector, a bioengineer who was retained by plaintiffs' lawyers, gave a deposition in consolidated lawsuits in Arizona in November 1989.<sup>30</sup> He opined that Du Pont never should have sold Teflon to Vitek because of known problems with Teflon. He referred to publications of Dr. John Charnley in the United Kingdom and Dr. John Leidholdt in the United States.

In the 1992 trial a Du Pont lawyer cross-examined Dr. Spector, and the following, paraphrased from the court record,<sup>31</sup> came to light:

- Dr. Spector states he has written, in his chapter of an encyclopedic work on biomaterials and implants in 1982, that it is too early to draw conclusions about Proplast. He does not mention the Charnley or Leidholdt reports on tissue reaction to Teflon published in the 1960s.
- Dr. Spector goes on to say that he knew worrisome things about the Teflon in Proplast in the 1982-84 period and these problems are the ones concerning Teflon reported on by Charnley and Leidholdt.
- Dr. Spector admits that Dr. Homsy, in his chapter in the same 1982 encyclopedic work, discusses the Charnley and Leidholdt reports. He has forgotten about the chapter.
- Dr. Spector admits that he did not publish his concerns or mention them at all until he gave the deposition in November 1989.

- Du Pont confronted him with his own writings in a 1986 request to Du Pont for funding in which he advised that Teflon should be further investigated for potential as artificial cartilage for human joints. His report made no reference to Charnley or Leidholdt, and he requested \$400,000 to continue his work. Du Pont declined to continue the funding.

Du Pont won this lawsuit and scores of others that went to trial—at a cost of more than \$50 million. A few cases were settled for a standard \$950 per case—an amount much less than the legal cost of winning a summary judgment.<sup>32</sup> The lawsuits hinged on misleading testimony by a so-called expert witness who had been refused research funds by Du Pont and who might therefore have been prejudiced in the case.

Most lawsuits against Du Pont ended either in summary judgment or victory at trial. An analysis of several cases by the judges of the Sixth Circuit Court of Appeals not only cleared Du Pont but showed that Vitek was not negligent in developing its devices:

Dr. Homsy was also aware of the Leidholdt study as evidenced by a chapter he wrote in *Biocompatibility of Clinical Implant Materials* entitled "Biocompatibility of fluorinated polymers and composites of these polymers." In this chapter, Dr. Homsy questioned the experimental methods of Dr. Leidholdt by noting that [Teflon] PTFE [one of the materials used in the devices] was used in conjunction with dissimilar metals, thus potentially contributing to the inflammation observed.

The court found further:

The record . . . demonstrates that Dr. Homsy's writings were an effort to *distinguish* the [Charnley and Leidholdt] studies, not to disregard them. His

correspondence to Du Pont and professional writings explicitly noted the experimental contrasts between his work and that of Drs. Charnley and Leidholdt. Furthermore, Dr. Homsky carefully developed means and methods to address the concerns raised in those studies in creating Vitek's protheses.

The bottom line:

We [the Court] also believe that the District Court wrote properly that [Teflon] PTFE and FEP were not defective in and of themselves.<sup>33</sup>

The Fifth, Seventh, and Ninth Circuit Courts of Appeal found analogously for Du Pont.<sup>34</sup>

The Baylor College of Medicine and the Methodist Hospital also were forced to defend themselves against charges that, since some tests on components of the IPI had been conducted at those facilities, they were negligent as well. Further, Methodist had licensed the manufacture of Proplast to Vitek. Baylor and Methodist were variously accused of sundry failures to warn that Teflon was not safe to use in the body and was dangerous in the TMJ, even though the case specifically concerned the IPI implant.

Methodist Hospital's insurers ended most suits with a \$30 million settlement.<sup>35</sup> Legal costs likely added another \$5 million to \$6 million to the bill. Settlement was apparently a simple economic decision to avoid even more litigation expenses.

Baylor, however, refused to settle, and most of the cases were dismissed in summary judgments for the defendants at both the lower and appellate court levels. Even so, Baylor's legal costs were substantial.

## The FDA's War on Proplast

The FDA's role in the case of Proplast and the TMJ and IPI implants illustrates the

problems with the federal government's treatment of medical device manufacturers. The FDA delays for years classifying or approving devices. If adverse publicity or lawsuits arise concerning a product, the FDA often will act against the product and its manufacturer, even if the evidence of a real problem is questionable and patients who rely on those devices suffer if the products are pulled from the market.

In July 1988, following a number of IPI lawsuits, the FDA inspected the Vitek factory. This time it listed nine problems. Some focused on handling procedures; five concerned why Vitek did not report complaints about products to the FDA. Vitek explained that those cases did not result in permanent or serious injury and that they had been reported in published literature. That approach to such complaints was in accordance with the FDA's own criteria, set forth in its mandatory device reporting regulations.

The FDA's response was to inspect Vitek once again in March 1989. By this time Vitek manufactured only TMJ implants. Proplast implant manufacturing had been assumed by Novamed Inc., in order to get product liability coverage for its unblemished non-TMJ Proplast products. The FDA continued to make charges and Vitek continued to refute them. Even though the FDA admitted in its responses that many of its inspectors' allegations had been appropriately answered, it would often repeat older charges.

In April 1990, under FDA pressure, Vitek issued a Warning Letter and Alert to surgeons and patients regarding the IPI. The FDA's language mirrored allegations in the various identically worded IPI lawsuits now arriving regularly at Vitek. It was clear that the "free market in accusations" was located on a thoroughfare between the FDA and the plaintiffs' bar.

In May 1990 the FDA demanded that Vitek conduct an effectiveness check of surgeon awareness of the alert. Vitek complied. In June Vitek went bankrupt because of a product liability coverage dispute among some of its insurers. The FDA demanded in

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July that I personally undertake to ensure effectiveness anyway. However, the Vitek bankruptcy trustee had forbidden me to act on Vitek's behalf. In September the FDA again demanded that I undertake new notification of Vitek's customers and their patients about IPI problems, which would have violated the court's order.

The FDA was not satisfied with making certain that TMJs were not longer produced. It then targeted Proplast, one of the two components in those devices, a biomaterial that the FDA had certified as safe and effective. Specifically, the FDA turned its inspection weapons on Novamed Inc., which had been formed in 1988 to make non-TMJ Proplast implants. After inspections in July and August 1990, Novamed was accused of multiple "manufacturing deviations" in the processes that had always been approved in the pre-1988 inspections. Many charges were simply repeats of the earlier charges against Vitek that had been refuted.

Unable to claim any defect in the products made with the same Proplast material that a federal judge determined was uniformly above average,<sup>38</sup> the FDA claimed that the entire manufacturing process for the nondefective products was itself defective. Catch-22 at work!

Two consulting firms, Shotwell & Carr, Inc., Dallas, Texas, and Kadow Associates, Ltd., Chicago, Illinois, with expertise in FDA regulatory compliance were hired by Novamed to audit its plant and the FDA inspection reports. Their report addressed each alleged "deviation." The FDA never responded to this report. The firms concluded, "It seems that the FDA has no significant interest in the firm's actual behavior and/or written responses."<sup>39</sup>

Also of relevance, inspectors from the United Kingdom had certified the Novamed factory and its Proplast products for export to the UK in 1988 and again in 1989.

In February 1991 the FDA seized the inventory of Novamed's plant. This action meant that Novamed could not use the FDA's "ombudsman" office that helps busi-

nesses with problems with the FDA. In a federal court in Houston it was revealed that this seizure had been authorized on the basis of an FDA affidavit swearing that Novamed made the TMJ implants. In fact, Novamed had been formed explicitly to make only non-TMJ implant, litigation-free Proplast products. At the hearing on Novamed's motion to rescind the seizure, Novamed's counsel stated these facts and counsel for the FDA made a revealing response:

Your Honor, it doesn't matter what they say about how effective the products are. It doesn't matter what their experts say about how good their company is. It only matters that the FDA says that it's not good. Congress gave plenary power to the FDA in this Act to regulate all items of manufacture. They did not give any power to Dr. Homsy or any of his delegates or any of his experts, and that is why the case is ripe for summary judgement.

If the FDA comes to court and tells you under oath and gives you adequate evidence to show that they're acting as they are chartered by Congress to do, then, the Court has—has really no discretion as far as approving it. Review of FDA action would have to be only under the Administrative Procedure Act. So, we would—we would claim that—that they just can't contest what we've done.<sup>40</sup>

Novamed's counsel replied:

Your Honor, I understand that's the government's position; and it's the only position they could possibly take because they cannot support what they have done. Mr. Longoria [the FDA counsel] would have you believe that the government can come in here with a false and misleading affidavit, get an ex parte

order putting a company which has a clean record out of business, and that neither the company nor the Court can do anything to stop it.

The Court rescinded the seizure. But while the judge was away for the weekend, the FDA found a second judge to stay the rescission. When the first judge returned he summarily lifted the stay.

The drama moved to Washington, D.C., to a meeting with officials of FDA's Offices of Medical Devices and of Compliance and their lawyers. I had volunteered to attend with my counsel to work out some sensible solution to the matter. While that meeting was in progress the FDA obtained another stay of the rescission from the Fifth Circuit Court of Appeals in New Orleans. As the FDA's lawyer acknowledged, the object of the seizure was to shut down Novamed.<sup>41</sup> Unfortunately, a year passed before the Fifth Circuit decided that the federal court in Houston had erred in not providing Novamed a quick trial.

In the end the seizure was held to be legal on the basis of a single transgression of the FDA's Good Manufacturers Practices guidelines that did not involve the safety or efficacy of the products.<sup>42</sup> The judge might not have wanted another of his decisions in the case overturned.<sup>43</sup> An FDA official is reported to have said, "We have depended on the ability to selectively target companies . . . and to issue findings without fear of being second guessed by some tinhorn judge."<sup>44</sup>

The FDA had to be aware that its claims were false. Charles McConachie, a former principal of the Department of Justice, Office of Consumer Litigation, wrote to John Fleder, the then-director of that office, in March 1991:

The information relied upon in the enforcement decision [seizure of Novamed's products the prior month] is flawed, fabricated, factually wrong, or based on the false premise that the subject observation is required in law or regulation.

Based on the foregoing we submit that the inspection(s) and the resulting seizure are fatally flawed.<sup>45</sup>

Moreover, throughout the entire fiasco, surgeons sent letters to the FDA praising the safety and efficacy of Proplast implants for general applications as well as in the TMJ. Pleas that came through members of Congress were deflected by the FDA with the argument that the matter was in the courts. The FDA was at war not just with Vitek and Novamed but also with surgeons and their patients. The FDA apparently paid attention only to lawsuit allegations or other communications from the plaintiffs' attorneys and their clients.

In 1995 I learned from one of the firms that had audited the FDA's inspections of Novamed that

two members of the FDA team that "went after you" expressed their eagerness not to be associated with the way things worked out. I am persuaded that individually most of the people within FDA who were involved in your case recognize what they have done but the agency is not capable of a retraction or even loss of face. Individually, they feel compelled to continue their position for fear of the consequences if they show any weakness.<sup>46</sup>

**Throughout the entire fiasco, surgeons sent letters to the FDA praising the safety and efficacy of Proplast implants for general applications.**

## The Battle Moves Offshore

The FDA not only persecuted Proplast in the United States, it also acted against Proplast products overseas. While the Proplast issue was before courts in the United States, Novamed officials were trying to obtain approval from European authorities to sell various Proplast products in that market. But the FDA was able to block me from taking experimental hip implant samples to Europe for a technical meeting with a distributor who was sponsoring a clinical

## The import ban repeated the misstatements of the December 1990 Safety Alert.

evaluation of the implant under Dutch government approval.

The reason for the meeting was to respond to the FDA's general prohibition on export of any company's implants for clinical study abroad when they had not already received FDA approval for use in the United States. This bizarre policy was reversed in 1993 by specific action of Congress. But in 1990 the Dutch distributor needed the samples to decide if the device could be manufactured in Europe. They were labeled "Not for Clinical Use," and their transfer was approved by Novamed's counsel, Hogan & Hartson, a premier Washington, D.C. law firm specializing in FDA matters. A Swiss company, Promotus S.A., was founded by Dutch and Swiss investors in large part to manufacture the hip implant. The wife of one of the Swiss had received one of the hip implants as part of the ongoing prospective clinical trial.

In February 1992 I gave up on manufacturing in the United States and took employment as scientific director of Promotus S.A., the Swiss company that was to manufacture Proplast facial implants, block, and sheet. I also continued development of a new implant for hip replacement and implants for the urinary system.

In May 1992 the FDA placed an import ban not only on TMJ implants but also on the unblemished Proplast facial implants, block, and sheet used for plastic and reconstructive surgery. The import ban repeated the misstatements of the December 1990 Safety Alert.<sup>47</sup> In this alert the FDA confused the IPI, of which Proplast was a component, with all Proplast implants. Thus, the wrath of the FDA was directed away from the IPI, which in any case it had approved for marketing, to Proplast, which it had decreed a Class II, safe and effective, implant.

Interesting also, the 1990 FDA Safety Alert stated that the TMJ implants "may be associated with implant perforation, fragmentation . . . which may result in progressive bone degeneration." But the source cited for this statement contained the following:

In many patients these underlying problems were not treated and lead to failure of their own natural meniscus tissue. Attempting to reconstruct a TMJ following a meniscectomy with any interpositional implant system is doomed to failure if untreated external articular problems are not corrected. This is likened to replacing worn out parts on an overworked piece of machinery. Without attempting to reduce the work load of the machine more parts will require replacement with each repair becoming more complex.<sup>48</sup>

In other words, the devices could not be blamed for problems if the underlying conditions or causes were not treated. The FDA knew that but still pressed its vendetta overseas against Proplast.

The FDA notified the World Health Organization and the Swiss health authorities of its import ban. In his letter, Stuart L. Nightingale of the FDA focused on "a highly problematic product called Proplast."<sup>49</sup> That focus was ludicrous since the FDA had issued marketing licenses for Proplast in the United States and since the product's Class II status remained in effect. The WHO accepted the FDA's advice to issue a worldwide alert on all of those products.<sup>50</sup> It referenced the FDA domestic Safety Alert and repeated its misleading language. The WHO repeated the same misstatements that confused the then long-defunct IPI with other unblemished products, formed entirely of Proplast, used in plastic, orthopedic, and general surgery.

The Swiss health authorities responded with a special inspection of the Swiss factory and certified that it was in compliance with operative international standards. But the WHO alert greatly damaged the Swiss company's business. Its attempts to correct the WHO's errors were unsuccessful. The WHO stated that all it does is transmit information from the FDA to member states; thus, it would not question the FDA's probity.

In August 1995 Swiss company officials

met with FDA officials and subsequently submitted to them a letter specifically identifying their concerns about the FDA's errors, promulgated through the WHO alert, equating Proplast itself with the TMJ implants. But in a January 17, 1996, letter the FDA summarily rejected those complaints and stated that it had grave concerns about Proplast in all product forms, again referencing its concern about TMJ implants. The FDA ominously stated that it was going to rescind the American marketing licenses for Proplast non-TMJ products.

In support of the attempted rescission, the FDA presented more than 500 reports of alleged problems with all Proplast non-TMJ implants. But only 9 reports were about such implants. The rest had to do with implants that did not include Proplast or were TMJ implants, and the large majority of the latter were made by manufacturers other than Vitek. The Swiss company, pointing this out in an October 1997 letter, observed that

the FDA has exceeded the agency's statutory authority, violated the . . . [license] holder's right to due process, contravened the Agency's own policy and reversed its own decision on substantial equivalency with absolutely no basis in the record or in science for doing so.<sup>51</sup>

The FDA backed off; the marketing licenses and the Class II safe and effective status continue in force today.

In 1996 and 1998, respectively, in spite of the FDA's campaign of misinformation, Canada and the European Union granted regulatory approval for the importation of Proplast products made in the Swiss factory. And, since valid American marketing licenses for non-TMJ Proplast products still existed, Swiss company representatives met with FDA officials in October 1998 to discuss the company's desire to sell Proplast implants in the United States. The regulatory summary and labeling information required by the FDA were provided for public release, and the

FDA was invited to inspect the Swiss factory. The director of the FDA's Office of Science and Technology, Donald E. Marlowe, stated that he had no problems with the implants.

But the representative from the FDA's Office of Compliance continued to reiterate the same old concerns about the IPI, which at that time had not been made for a decade, and the alleged manufacturing deviations that had produced the "uncontrovertibly excellent Proplast products."<sup>52</sup> The FDA dragged its feet for months on setting a date to inspect the Swiss factory. Unable to outlast the FDA's intransigence, the Swiss company went into bankruptcy in June 1999. Thus, the Compliance Division had settled the old score with Novamed for showing the FDA's cupidity in open court.

## Who Is Harmed?

The FDA's efforts to drive products off the market, with little regard for whether those products are truly dangerous or not, as well as media hysteria and predatory lawsuits, ultimately harm the patients who are deprived of the products.

For example, from the mid-1970s to the late 1980s oral surgeons made great strides in the use of TMJ implants. A major lesson that they had learned from years of treating patients was that conservative treatment of TMJ dysfunction was not very effective because of the complexities of the disease and patients' difficulties in complying with treatment plans.

In light of those facts, surgeons realized that the next step after failed conservative treatment should be replacement of the entire joint. This is analogous to what orthopedists came to understand regarding hip dysfunction. Partial hip joint replacement has been displaced by the total hip implant. Dr. John Kent of LSU and Dr. Kevin McBride at Vitek developed the most successful total TMJ replacement.<sup>53</sup> But the TMJ product from Vitek was removed from the market by litigation and the FDA's dysfunctional regulatory regime. And the threat of such actions

**In spite of the FDA's campaign of misinformation, Canada and the European Union granted regulatory approval for the importation of Proplast products.**

## The ultimate losers in the Proplast case are the patients who are deprived of devices or implants that could ease their suffering.

against new products has discouraged medical and scientific researchers in the United States from taking the risks involved in trying to improve TMJ surgical treatment.<sup>54</sup>

Many of the Proplast products have no comparable substitutes. Surgeons continue to request them since the bankruptcy of the companies that produced them. The Proplast-coated hip implant, which has undergone clinical trials in the Netherlands for seven years, has proven itself to be a major advance over the technology available in the United States.<sup>55</sup> The FDA itself approved clinical trials of artificial bladders that depend on Proplast for the tissue interface; the prospective clinical trials have been under way for several years with the express permission of the Urological Devices Division of the FDA.<sup>56</sup>

The reports that the FDA sent to the Swiss company making Proplast products were revealing. They recorded the dreadful consequences of the use of total replacements using the TMJ alternative to the Vitek product. Today many surgeons have returned to the old procedure for joint replacement, which involves transfer of a rib. By steamrolling Vitek, the FDA set back the care of patients with severe TMJ disorders.

The TMJ Association, formed to advocate patients' needs, recently has been upset because a National Institutes of Health panel has poured cold water on the idea of establishing a registry to identify the location of every implanted device.<sup>57</sup> The NIH panel believed that such a registry was not feasible for reasons of logistics and the threat of litigation. More problematic is that the physician/surgeon is the "gatekeeper" in the transmittal of information regarding patients. Vitek had complete records of surgeon customers, and the FDA accessed those records during inspections so patients could be contacted during the FDA's recall and notification procedures. Of course, Vitek, as well as Novamed, is now out of business.

Many producers of materials required by implant makers, including Du Pont, discontinued all sales to the permanent implant industry after 1993. The supply of implants

widely used in surgical repairs and other applications remains in jeopardy. The Biomaterials Access Assurance Act of 1998 was passed to provide some protection for manufacturers against unfounded liability claims. The law limited the liability of suppliers to "genuine fault" and established an expedited procedure so that suppliers could avoid litigation and incurring heavy legal costs. But Du Pont still will not sell to implant manufacturers because the "genuine fault" limitation does not, in fact, prevent enormous and unrecoverable legal costs.<sup>58</sup>

Again, the ultimate losers in the Proplast case and many other cases concerning medical devices are the patients who are deprived of devices or implants that could ease their suffering and allow them to live more normal, comfortable lives.

## The Litigation Problem

The litigation problems faced by medical device manufacturers should be clear from the Dalkon Shield, silicone breast implants, and Proplast cases. Nicholas Wade of *New York Times Magazine* observed:

Science and law are two different systems of inquiry that diligently seek truth. It is distressing enough when they arrive at discordant answers. But in a number of recent cases (silicone breast implants, contraceptive spermicide, Agent Orange, Bendectin morning sickness drug), courts have endorsed legal theories of causation that merit credence only where the earth is flat.<sup>59</sup>

In *The Litigation Explosion*, Walter Olson stated, "For all the many successes of American society, our system of civil litigation is a grotesque failure, a byword around the world for expense, rancor, and irrationality."<sup>60</sup> Peter Huber and Robert Litan suggest in *The Liability Maze* that "the uncertainty of the tort system is its greatest vice, magnifying

risks of liability while disconnecting them from unduly risky conduct.<sup>61</sup>

In an extensive survey of the legal profession, *The Economist* noted:

Japan . . . having studied the American product liability system, thought it an unsuitable model. "America", says Mr. Hamada, a commercial law specialist, "believes that justice will somehow come about through a free market in accusation."

America does have the world's freest litigation market. The crucial difference with other countries is that juries decide cases and set damages. "Pain and suffering" and, to a lesser extent, punitive damages, have made America's legal system at once more costly and more unpredictable. Coupled with minimally restrictive civil procedures (called "deregulated combat"), they create a legal structure that practically invites abuse.

*The Economist* concluded that

discovery accounts for 60% of the time and money spent on lawsuits. . . . All this might be acceptable if the American legal system proved, in the end, to be an efficient means for resolving disputes and compensating injuries. But it isn't. Of the billions of dollars paid out each year for liability, just half goes to plaintiffs. The other half—or two-thirds in complicated cases such as asbestos—pays for "transaction costs" for which read "lawyers' fees."<sup>62</sup>

Litigation can result from errors in design, materials, and manufacture of a medical device or from surgical mistakes. However, in the United States frivolous litigation is fostered by easy access to the courts, the low cost of filing a lawsuit, and contingency-fee compensation with little cost penalty to the plaintiff for failure to prevail. Plaintiffs' lawyers can easily clone lawsuits, forcing manufacturers to

defend against the same charges in many cases, which drives up legal bills and drives manufacturers into bankruptcy.

The operation of current liability laws and the functions of the FDA also constitute a serious contradiction in public policy. The FDA must certify that medical devices are safe and efficacious. Those determinations are based on years of clinical tests. And the FDA tends to err on the side of conservatism, requiring more rather than less documentation. Yet even with a government seal of approval, a manufacturer of a device can still be subject to liability lawsuits based on the charge that devices are not safe.

One way to deal with this problem would be to return to the tried and true method of enforceable contracts. When competent, prospective patients authorize a doctor, in writing before a witness, to use devices certified by the FDA for treatment, and when the devices are implanted by a surgeon duly licensed and trained to perform the procedure, the law might mandate arbitration before litigation. Surgeons, their scientific and engineering colleagues, their institutions, and the manufacturer could be made immune from a personal injury lawsuit until arbitration among the patient's representative, bioengineers, physicians, scientists, and manufacturers concludes that malpractice by the surgeon or malfunction of the device, or both, has occurred. Further, tort law might be changed to place the cost of the arbitration on the party declared to have responsibility for the injury. Any party not liable could have its costs reimbursed by the parties held liable.

If no party is held liable, the plaintiff could be required to pay for the arbitration. The right to file a lawsuit is preserved, but at trial the jury would be told the results of the arbitration. The plaintiff would pay litigation costs of all parties if the jury awarded less than the sum recommended by the arbitration panel.

This is not a new idea. When the rule of law was first emerging in Mesopotamia, some 4,000 years ago:

**One way to deal with this problem would be to return to the tried and true method of enforceable contracts.**

**The FDA's system for approving medical devices is seriously flawed. The European Union has an approach that provides at least some checks on the arbitrary power of government officials.**

The best element of Hammurabi's famous code was a plan to avoid litigation. Every case was first submitted to a public arbitrator whose duty it was to bring about an amicable settlement without recourse to law. It is a poor civilization from which we may not learn something to improve our own.<sup>63</sup>

This basic principle would help protect producers of medical devices as well as other citizens and businesses that find themselves victims of nuisance lawsuits.

## Routes to Reform

The FDA's system for approving medical devices is seriously flawed. The FDA delayed years before classifying silicone breast implants and Proplast TMJ products. Further, even after the FDA certifies a product for sale, it can still harass manufacturers if it has public relations or institutional reasons to do so. Part of the problem is that the FDA's powers are broad and open to arbitrary use by vindictive agents. Thus, instead of ensuring that safe and effective medical devices get to patients as quickly as possible, the FDA's approach can deprive patients of such devices.

The European Union, by contrast, has an approach that provides at least some checks on the arbitrary power of government officials. The EU maintains a set of rules for regulating devices in a clearly written and highly specific Medical Device Directive.<sup>64</sup> By contrast, FDA guidelines often give great leeway and thus opportunities for FDA bureaucrats to make subjective judgments. The Medical Device Directive is based on widely accepted international standards and requires device manufacturers to demonstrate conformity with its requirements for a full-quality system. This covers all aspects of manufacture: certification of raw materials; factory design; manufacturing and quality assurance protocols, including periodic and timely audits both internal and by third-party consultants;

design verification and validation; labeling; risk analysis; employee competence and training; complaint handling; and postmarket surveillance. Moreover, compliance with the directive must be demonstrated at least yearly.

Unlike the system in the United States, the certification of compliance is performed by private firms that themselves have been certified by the EU to perform this task. These firms are companies long established in the field of quality assurance consultation. Device manufacturers thus can choose a certifying company with particular knowledge of the medical problems that their devices address. The EU mandates that at least one member of a certification team must be a professional bioengineer with experience in the general area of the company's business. By contrast, FDA inspectors often do not have expertise to match the facilities they are certifying. Genatis S.A. (successor to Promotus S.A.), the Swiss company making Proplast products, chose a Dutch certification firm, TNO, which had an inspector who had been both an academic and an industrial bioengineer and who had direct experience in studies with the Proplast products of the Swiss company. There was only a limited learning curve for that inspector.

TNO's certification team made a preliminary visit to assess Genatis's overall documentation of its quality system. This visit allowed the company to make certain that it had an adequate format for the necessary documentation and gave inspectors a chance to make suggestions on how to improve the quality system itself. The actual certification inspection was a thorough three-day affair. Some deficiencies in organization of the quality system were noted but were noncritical and easily corrected, eliminating the need for a return inspection. Proplast implant materials were certified on June 12, 1998.

Under the EU system, limited inspections occur annually after certification and are mainly concerned with postmarket surveillance. The specific certificate number and logo for any approved device must be dis-

played on all packages of the product sold in an EU nation. The certificate number and logo announce that the product meets the rigorous EU standards

In the case of Genatis, the cost for TNO's services was a reasonable \$20,000, borne by the company itself. This cost was limited by the large number of positive articles on the Proplast implants in publications that deal with several areas of medical specialty. The entire process was devoid of controversy or rancor because the requirements were clearly set out as was the format for showing compliance. Those features greatly enhanced the efficiency of the inspection and eliminated ambiguity. Subjective interpretations by the inspectors were absent, in sharp contrast to my experiences with the FDA.

## Conclusion

W. W. George, president of Medtronic Inc., one of the great medical device innovators, wrote:

Unfortunately, the U.S. is currently suffering a steady depletion of its medical technology base that has for so long dominated the world market. This trend is evident in the movement of research, development and manufacturing operations to overseas locations—the end result of U.S. export restrictions, reimbursement policies, product liability, and, most of all, a regulatory system that is perceived as unpredictable and unfriendly to innovation.<sup>66</sup>

Medtronic shifted its research and development and manufacturing operations overseas, as have many other important medical device innovators.

The FDA's approval regime, threats of liability suits, and unfounded media horror stories have a particularly adverse effect on smaller, innovative companies. A Standard and Poor's database recently showed only 2.8

percent of device companies with fewer than 50 employees.<sup>66</sup> This is a sharp decrease from 10 years ago.

For the device industry, and the patients who may benefit from its products, the bell is tolling; the ringing lesson of their plight is that reform of the system is needed now. Robert Higgs writes,

The FDA's follies are precisely the sort of actions that one expects a powerful government bureaucracy to take—self-serving, irresponsible, heedless of injuries it causes so long as they are ignored by the news media, and vindictive against whistle-blowers.<sup>67</sup>

Until the FDA and the liability system are changed, this sad situation will continue.

**The FDA's approval regime, threats of liability suits, and unfounded media horror stories have a particularly adverse effect on smaller, innovative companies.**

## Notes

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2. Marcia Angell, *Science on Trial—The Clash of Medical Evidence and the Law in the Breast Implant Case* (New York & London: W.W. Norton, 1997), chap. 4, pp. 69–70.
3. Mary Ann Glendon, *A Nation under Lawyers* (New York: Harper Collins, 1994), quoted in *ibid.*, p. 70.
4. *Ibid.*, p. 71.
5. *Ibid.*, p. 72.
6. FDA, Press release 74-63, December 20, 1974.
7. This section is based on S. D. Mumford and E. Kessel, "Was the Dalkon Shield a Safe and Effective Intrauterine Device? The Conflict between Case-Control and Clinical Trial Study Findings," *Fertility and Sterility* 57 (June 1992): 1151–76.
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9. N. C. Lee et al., "Type of Intrauterine Device and Risk of Pelvic Inflammatory Disease," *Obstetrics and Gynecology* 62 (1983): 1–6.

10. "Birth Control Device, Court Case Nears End," *Financial Times*, December 17, 1999.

11. R. A. Kronmal, C. W. Whitney, and S. D. Mumford, "The Intrauterine Device and Pelvic Inflammatory Disease: The Women's Health Study Reanalyzed," *Journal of Clinical Epidemiology* 44 (1991): 109-22.

12. Mumford and Kessel.

13. R. M. Pitkin, "The Return of the IUD," *Obstetrics and Gynecology* 72 (1988): 119. See also D. L. Sackett, R. B. Haynes, and P. Tugwell, *Clinical Epidemiology: A Basic Science for Clinical Medicine* (Boston: Little Brown, 1985).

14. R. J. Beerhuizen, "Pelvic Inflammatory Disease in Intrauterine Device Users," *European Journal of Contraception and Reproductive Health Care* 1, no. 3 (1996): 237-43.

15. S. L. Kimble-Haas, "The Intrauterine Device: Dispelling the Myths," *Nurse Practitioner* 23, no. 11 (1998): 58, 63-69, 73.

16. *Anita Baker v. Dalkon Shield Claimants Trust*, Appeal from the United States District Court for District of Massachusetts, No. 98-1214, to the U.S. Court of Appeals for the First Circuit, [www.law.emory.edu/1circuit/sept98/9811214.01a.html](http://www.law.emory.edu/1circuit/sept98/9811214.01a.html).

17. 90 U.S.C. § 539 (May 28, 1976). In the statute, the powers to regulate medical devices (implants) are vested in the secretary of health, education, and welfare. In practice, the powers are delegated to the secretary's subordinate, the commissioner of food and drugs, who heads the FDA. In both cases, the powers are vested in persons selected by the executive branch of our government. Thus, Congress (i.e., the people) immediately loses direct control of the agency that it has created.

18. Angell, pp. 156-57.

19. *Face to face with Connie Chung*, December 10, 1990, transcript available from Burrelle's Information Services.

20. *Tribune de Genève*, March 31, 1994

21. Richard Tomkins, "Implants 'Not Linked to Illness,'" *Financial Times*, December 2, 1998.

22. Peter Haynes, Letter to Charles Homsy, June 12, 1995.

23. *Federal Register* 47, no 12 (January 19, 1982): 2818.

24. Some of those are L. A. Whitaker, "Aesthetic Augmentation of the Malar-Midface Structures," *Plastic and Reconstructive Surgery* 80 (1987): 377-46; J. N. Kent, R. L. Westfall, and D. M. Carlton, "Chin and Zygomaticomaxillary Augmentation with Proplast, Long-term follow-up," *Journal of Oral Surgery* 39 (1981): 912-19; H. W. Hörl, M. Klöppel, and E. Biemer, "Prefabricated Free Flaps with Vascularized Polytetrafluoroethylene (Proplast II)," *European Journal of Plastic Surgery* 17 (1994): 144-50; F. B. Kessler et al., "Proplast Stabilized Stemless Trapezium Implant," *Journal of Hand Surgery* 9A (1984): 227-31; G. G. M. Keet and W. C. Runne, "The Anaform Femoral Endprosthesis: A Proplast Coated Femoral Endoprosthesis," *Orthopedics* 12 (1989): 1185-90; D. P. Griffith and M. J. Gleeson, "The Prosthetic Bladder—Perhaps the Technology Has Arrived," *Scandinavian Journal of Urology and Nephrology*, Supplement, 142 (1992): 109-22; R. P. Clark et al., "Closure of Dural Defects with Proplast," *Annals of Otology* 5 (1984): 179-82; and R. W. Neuhaus, B. Greider, and H. I. Baylis, "Enucleation with Implantation of a Proplast Sphere," *Ophthalmology* 91 (1984): 494-96.

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26. *Federal Register* 21 (April 1, 1992): 317.

27. L. N. Estabrooks et al., "A Retrospective Evaluation of 301 TMJ Proplast-Teflon Implants," *Oral Surgery, Oral Medicine, and Oral Pathology* 70 (1990): 381-86.

28. "Dear Doctor" letter from Vitek, Inc., to all members of the American Academy of Oral and Maxillofacial Surgeons, July 31, 1987.

29. See 90 U.S.C. §539.

30. *C. Bennett, D. Collins, et al. v. Du Pont*, Consolidated cases Nos. 241189, 242272, 244377, 247830, 245695, 257137, 254353, 226189. Superior Court of the State of Arizona, County of Pima, November 29, 1989.

31. *D. Collins v. E.I. du Pont de Nemours Inc.*, Case C-244377, Superior Court of the State of Arizona, County of Pima, September 18, 1992. Case selected to represent all consolidated cases.

32. "A Discovery by Du Pont: Hidden Costs of Winning, The Teflon Maker Has Won Summary Judgement in 47 Jaw Implant Suits—and Learned It's Too Risky to Be a Supplier," *Business Week*, March 27, 1995. Ross Schmucki, attorney for Du Pont, said that he did not foresee the company's selling Teflon to the medical implant industry for fear that a relationship once again would make it part of the litigation chain.

33. *D. Jacobs et al. v. E.I. du Pont de Nemours & Co.*, U.S. Court of Appeals for the Sixth Circuit (file

95a0312p.06), October 19, 1995, <http://www.law.emory.edu/6circuit/oct95/95a0312p.06.html>.

34. Opinion of the U.S. Court of Appeals for the Ninth Circuit in *Kealoha v. Du Pont et al.* and *Wolfe v. Vitek et al.*, May 3, 1996, <http://www.vclip.org/Fed Ct/9th/opinions/9415688.htm>; and Opinion of the U.S. Court of Appeals for the Seventh Circuit in *Styke v. Du Pont*, November 18, 1994, <http://www.kentlaw.edu/7circuit/1994/93-3947.html>.

35. "Methodist Will Pay \$30 Million to Settle Jaw Implant Claims," *Houston Chronicle*, May 4, 1995.

36. *Federal Register* 47, no 12 (January 19, 1982): 2818.

37. FDA, Certificate of Products for Export, signed by Ann Holt, associate director of compliance, May 26, 1988.

38. "Uncontroverted evidence was presented by physician consumers of the devices in question that the products manufactured by Novamed and OSMI were above average products which failed at a lower rate than other similar products." Finding of fact, *U.S. v. Novamed*, Case H-91-610, U.S. District Court for the Southern District of Texas, February 1992. In spite of this finding the judge felt that the medical device statute gave the FDA the right to seize the products of a company for only a single alleged violation of the Good Manufacturing Guidelines. Those guidelines permit an inspector to find infractions where there is only a difference in opinion and are therefore open to easy abuse.

39. Shotwell & Carr, Inc., and Kadow Associates, Ltd., Letter to Novamed Inc., May 24, 1991.

40. Emergency Motion to Rescind Order and Warrant for Arrest, Request for Temporary Restraining Order and Request for Preliminary Injunction, *U.S. v. Oral Surgery Marketing and Novamed Inc.*, No H-91-610, U.S. District Court for the Southern District of Texas, Houston Division, March 11 1991, transcript of proceedings before the Honorable David Hittner, March 13, 1991.

41. "Our action in seizing everything has, in effect, according to what they said, shut them down." *Ibid.*

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