

**Propast-Teflon Jaw Implants and FDA Review Standards for Medical Device:
A Case Study**

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Introduction

Most of us take for granted the complexity of our human anatomy. We rarely question the fluidity of our gait or the facility in our fingers. But the human skeleton is made up of tendons, muscle, flesh and 206 bones of differing length and size, all of which must achieve together mechanical harmony. So it is not surprising that the workings of the small and seemingly unimpressive temporomandibular joint (TMJ) have long been ignored as part of human function.

The complex nature of the TMJ, coupled with its seemingly small and unassuming role in human function, have only recently begun to attract more scientific attention.¹ TMJ disorder affects approximately 30 million Americans with approximately one million new diagnoses every year.² Increasing complaints pertaining to TMJ pain have lead researches to explore new treatment options, including invasive surgery.³

¹ Deborah N. Baird, *The Temporomandibular Joint Implant Controversy: a Review of Autogenous Alloplastic Materials and Their Complications*, 8 J. Nutritional. & Env'tl. 289, 289-90 (1998) (indicating that since the 1970's, the treatment of TMJ disorders has grown substantially. As a result of new found knowledge, surgical interventions have increased).

² *Id.*

³ *Id.*

All medical devices, including jaw implants, must be reviewed for safety and effectiveness by the Food and Drug Association (FDA) prior to widespread use.⁴ While the FDA has established a system whereby all medical devices, regardless of level of risk, are subject to a degree of scrutiny, the agency has allowed some to fall through the cracks.⁵ One such device, the Proplast-Teflon jaw implant, damaged thousands of patients across North America.⁶

In the early 1980's, a company named Vitek, Inc. began general distribution of its new Proplast-Teflon implant, designed for surgical replacement of dysfunctional discs in the TMJ. Although Vitek had obtained FDA-approval for use of the implant in humans, implanted patients began to experience serious health-related problems by the mid-1980's.⁷ While the FDA sent letters to hospitals and surgeons, warning them of safety risks associated with the implant, it was too late; many patients were suffering already from irreversible and life-altering symptoms related to Vitek's product.⁸

The purpose of this paper is to examine FDA policies regarding approval of medical devices in humans, and more specifically, how these policies relate to the emergence and subsequent failure of Vitek's Proplast-Teflon interpositional jaw implants (IPI). This paper will be divided into four sections: the first will provide an historical overview of TMJ disorder and its treatments, including the Proplast-Teflon discal jaw implants; the second will analyze the evolution of FDA policies as they pertain to medical devices, and the way in which Vitek's jaw

⁴ Ellen Flannery, *Should it be Easier or Harder to Use Unapproved Drugs and Devices?*, 16 *Hastings Ctr. Law Rep.* 19, 18 (1986).

⁵ *Id.*

⁶ <http://www.tmj.org/biomaterials.asp>.

⁷ <http://www.fda.gov/cdrh/consumer/tmjupdate.html>.

⁸ *Id.*

implants appeared on the market without undergoing the stringent pre-market approval (PMA) process; the third will explore flaws in the FDA's medical device policies leading to misclassification of Vitek's IPI and circumvention of PMA; and the fourth will evaluate the human and legal ramifications of Vitek's failed jaw implants. In its conclusion, this paper will surmise that the Vitek disaster was not an anecdotal example of FDA carelessness, but rather, the result of murky regulatory drafting and an inefficient and careless scheme for device oversight.

I. TMJ Disorders and the birth of Proplast-Teflon Jaw Implants

A. *TMJ and its early treatments*

The TMJ is comprised of nerves, muscles, cartilage, fluids, and bone.⁹ It functions in partnership with its contralateral joint¹⁰, and serves as a hinge for the lower mandible, allowing it to move backwards and forwards, side to side and up and down.¹¹ The TMJ facilitates eating, chewing, laughing, and speaking.¹² It is one of the most complex joints in the body.¹³ And for those who suffer from a TMJ disorder, the importance of this very small joint is all too apparent.

TMJ disorders have been recognized since the time of Hippocrates in the fifth century BC.¹⁴ They can involve “pain in the jaw, temples, face, and the area in front of the ear.”¹⁵ Many sufferers experience limited jaw opening, clicking, locking, popping, headaches, neck

⁹ Damaris Christensen, *Moving Temporomandibular Joint Research into the 21st Century*, 1 J. of the TMJ Ass'n 9, 9 (2001).

¹⁰ Baird *supra* note 1 at 389.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ G. Dimitroulis, *The Role of Surgery in the Management of Disorders of the Temporomandibular Joint: a Critical Review of the Literature Part I*, 34 Int. J. Oral Maxillofac.Surg., 107, 108 (2005)..

¹⁵ Baird *supra* note 1.

pain, shoulder pain, fatigue, tinnitus and depression.¹⁶ Because practitioners and scientists have tended to lack an understanding of the TMJ, many patients have been, and continue to be referred for psychological evaluation of a physiological condition.¹⁷ As a result, a number of patients never receive adequate treatment for their TMJ dysfunction, while other may rush into jaw surgery when conservative modalities may suffice.¹⁸

This history for treatment of TMJ disorders is centuries old. In the 19th century, practitioners might have treated a jaw disorder using a chin strap; but they soon shifted to surgical treatments, a trend that spanned into the mid-1950's.¹⁹ By the 1970's, "a watershed in the history of TMJ surgery," surgical intervention for the TMJ "gained momentum in North America" and new procedures developed with a focus on the articular disc of the TMJ as a root of the disorder.²⁰ Unfortunately, many surgical techniques resulted in disaster as practitioners performed thousands of alloplastic jaw implants between 1978 and 1986, many of these later failing.²¹ Any "initial euphoria of TMJ surgery turned to despair as surgeons were faced with a generation of patients who had multiply operated and painfully degenerated joints."²² Among these failed alloplastic materials was the Proplast-Teflon jaw implant, designed in the early 1970's by Vitek founder, Dr. Charles Homsy.

B. The emergence of Vitek's Proplast-Teflon Interpositional Implant (IPI)

¹⁶ *Id.*

¹⁷ Patricia Brown, *TMJ Syndrome*, 80 *Am. J. of Nursing* 1, 1 (1980).

¹⁸ James Friction et al., *Long-Term Study of Temporomandibular Joint Surgery with Alloplastic Implants Compared with Nonimplant Surgery and Nonsurgical Rehabilitation for Painful Temporomandibular Joint Disc Displacement*, 60 *J. Oral Maxillofac Surg* 1400 (2002).

¹⁹ Dimitroulis *supra* note 9.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

In March, 1983, Vitek notified the FDA of plans to market its Interpositional Implant (IPI) for disk replacement after discectomy to treat TMJ disorders.²³ Dr. Charles Homsy, a chemical engineer, developed Proplast as a surgical material in the late 1960's while conducting prosthesis research at Methodist Hospital in Houston, Texas. Homsy was interested initially in the use of Teflon as a biomedical implant, and by 1968, had invented Proplast, a soft, porous material which was patented in 1976.²⁴ At first, surgeons used Proplast for orthopedic surgery as a stabilizing head for femoral and total hip prosthesis.²⁵ But Homsy soon realized that if he combined Proplast with Teflon (PTFE) resin, the duo might work for disc-replacement in the jaw joint; Proplast's porous nature allegedly would encourage adhesion between the host tissue and the implant's foreign material, and the PTFE would withstand wear from the joint. By 1982, Vitek had created two types of Proplast: Proplast I, composed of Teflon and Graphite, and Proplast II, its aluminum-oxide analogue.²⁶

II. A history of FDA policies governing medical devices evolve, and the appearance of Vitek for public use

FDA policies governing approval of medical devices have long lagged behind those for new drugs.²⁷ The 1938 Federal Food, Drug and Cosmetic Act (FDCA) authorized the FDA to prevent misbranding or adulteration of fraudulent devices, but not to exert premarket review applied to new drugs.²⁸ Perhaps as a reflection of inadequate agency scrutiny, the number of

²³ *Id.*

²⁴ *Id.* at 6.

²⁵ J.N. Kent et al, *Pilot Studies of a Porous Implant in Dentistry and Oral Surgery*, 30 J. Oral Surg. 608 (1972).

²⁶ Westfall et al., *A Comparison of Porous Composite PTFE/Graphite and PTFE/Aluminum-Oxide Facial Implants in Monkeys*, 40 J. Oral Maxillofac. Surg., 771, (1982).

²⁷ Flannery, 16 Hastings Ctr. Law Rep. 19, 18-19 (1986) (stating that Class III medical devices pertain to "all implanted or life-supporting or life-sustaining devices").

²⁸ *Id.*

fraudulent or unsafe devices on the market continued to multiply.²⁹ While Congress broadened FDA's policing power over drugs in 1962, similar premarket review and approval powers for medical devices were not established until 1976.³⁰

A. FDA's 1976 Amendments

The Medical Device Amendments of 1976 created a regulatory scheme linking the degree of risk inherent in any new medical device to the amount of control the FDA could exert over its approval process.³¹ It classified devices into three categories: Class I, Class II, and Class III, the last requiring the most stringent limitations on approval,³² since these were intrusive implanted, life-sustaining or life supporting devices.³³ According to the 1976 Amendments, all new devices were presumptively categorized as Class III even if they were "low-risk."³⁴

Most Class III devices were subject to a stringent Premarket Approval (PMA) process.³⁵ The PMA system, pursuant to 21 CFR 814 §360e(c), required a manufacturer to submit, along with other information, an application comprising all known reports pertaining to the device's safety and efficacy; "a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device"; "a full description of the methods used in,

²⁹ *Id* (noting that these devices included: lead nipple shields, causing lead poisoning in nursing infants, contraceptives leading to genital infections, and economic frauds, for example, boxes with colored lights which claimed to cure "virtually every disease").

³⁰ *Id.* at 18. Flannery opines that these Amendments were due in part to failure of the Dalkon Shield.

³¹ *Id.*

³² <http://www.fda.gov/history>. "Class I devices (e.g. tongue depressors and gauze), are "subject to Good Manufacturing Practices (GMP); Class II devices are subject to the same controls as Class I devices and the same product-specific performance standards supposedly developed by the FDA ... Class III devices ... must pass an FDA approval process similar to that required for new drugs; that is, before marketing can begin, Class III devices have to be proven safe and effective in extensive clinical trials, and submit to and pass an FDA premarket approval process."

³³ Flannery *supra* note 22.

³⁴ *Id.*

³⁵ John Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 Food & Drug L.J. 57, 58 (2002).

and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples of the device (when practicable); and "specimens of the labeling proposed to be used for such device."

The PMA is a time-consuming process for both manufacturers as well as the FDA, the latter requiring an "average of 1,200 hours [of review for] each submission."³⁶ Therefore, manufacturers might have chosen to avoid PMA if the proposed device was "substantially equivalent" to a device already on the market prior to 1976.³⁷ Under the Act, the burden fell to the device manufacturer to decide whether or not to submit a 510(k) Premarket Notification, a process designed to "grandfather" in a device if it met with a test of "substantial equivalence"³⁸ when compared with a device already on the market prior to May, 1976.³⁹ The majority of biomaterials designed for reconstruction of the jaw joint were released for medical use and commercial consumption before 1976, prior to the enactment of the 1976 Medical Devices Amendment Act.⁴⁰ If a manufacturer failed to satisfy the FDA that its device was "substantially equivalent," or if the device had been "significantly changed or modified" in "design, components, method of manufacture, or intended use" from an older model, the agency required PMA.⁴¹

³⁶ *Buckman Co. v. Plaintiffs' Legal Comm*, 531 U.S. 341; 121 S.Ct. 1012 (2001), (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470;116 S.Ct. 2240 (1996)).

³⁷ <http://www.fda.gov/cdrh/devadvice/overview.html>.

³⁸ Chai *supra* note 20.

³⁹ Establishment Registration and Premarket Notification Procedures, 42 Fed. Reg. 163, 42522-53 (Aug. 23, 1977). Under this Act, the "Commissioner believes that the manufacturer is the person best qualified to make this determination. If appropriate, FDA will notify the manufacturer that the premarket notification that was submitted need not have been submitted so that he may be aware that premarket notification is not required in such a situation. From such experiences, FDA may eventually draw some guidelines as to when a premarket notification submission is not required."

⁴⁰ Chai, *supra* note 38.

⁴¹ 42 Fed. Reg. 163, *supra* note 34.

B. The FDA grants Vitek's IPI 510(k) Premarket Notification status

In seeking approval of its IPI, Vitek sought 510(k) PMN, that is, it would be prohibited from commercial distribution of its device until the FDA had issued a letter of substantial equivalence.⁴² In 1983, Vitek notified the FDA of plans to market its IPI to treat TMJ problems and claimed that the device was substantially equivalent to existing silicone sheeting devices;⁴³ the FDA authorized sale of the Proplast-Teflon implants under the substantial equivalence theory.⁴⁴ In a 1983 letter to Vitek, the FDA stated that the manufacturer could “market [its] device subject to the general control provisions of the Federal Food, Drug and Cosmetics Act ... until such time as [its] device ha[d] been classified under section 513”⁴⁵ It was not until 1993, however, that the FDA made its final classification of the IPI, from a Class II to a Class III device.⁴⁶

In the interim, Vitek began distribution of its implant, its authority hinging, in retrospect, on what appears to be a scarcity of probative scientific literature.⁴⁷ Studies generated prior to the sale of the IPI reveal that while scientists conducted studies testing the safety and efficacy of Proplast materials in *general*, few examined its specific role as a disc replacement therapy.

⁴² *Id.*

⁴³ <http://www.fda.gov/cdrh/consumer/tmjupdate.html>.

⁴⁴ *Id.*

⁴⁵ Charles A. Homsy, *How FDA Regulation and Injury Cripple the Medical Device Industry*, 412 Policy Analysis 1, 7 (2001) (quoting FDA, Office of Medical Devices, Letter to Charles A. Homsy, sent in 1983).

⁴⁶ *Id.*

⁴⁷ Baird, 8 J. Nutritional. & Env'tl. 289, 299.

In 1970, Homsy published the first article evaluating the biocompatibility of different materials in their selection for surgical implantation.⁴⁸ He indicated that animal implantation studies were essential in order to examine the way in which implant materials and normal tissue could bond together to form an integrated unit. Because of the complex nature of animal studies, Homsy performed in vitro research in order to predict potential mechanical changes of the Proplast material during soft-tissue implantation.⁴⁹

Although still early in the process, Homsy's initial decision not to include animal studies relating to Proplast discal implants persisted throughout the majority of the research period. Although Homsy and his partner and designer, Dr. J. Kent, published an article in 1972 evaluating the use of Proplast in dogs, monkeys and humans, it *only* related to alveolar ridge augmentation and titanium roots and *not* to discal implants.⁵⁰

Between 1973 and 1982, researchers published a number of other studies with positive reviews of Proplast implants. Again, however, these studies consistently lauded Proplast in contexts unrelated to the jaw disc (e.g. in facial reconstruction or augmentation)⁵¹, and involved short-term follow-up or small patient populations.⁵² Furthermore, the bulk of studies praising Proplast were authored by Homsy and his team at Vitek.

⁴⁸ Charles Homsy, *Biocompatibility in Selection of Materials for Implantation*, 4 J. Biomed. Mater. Res. 341 (1970).

⁴⁹ *Id.*

⁵⁰ JN Kent et al. *Pilot Studies of a Porous Implant in Dentistry and Oral Surgery*, 30 J. Oral Surg. 608 (1972).

⁵¹ RL Westfall et al. *A Comparison of Porous Composite PTFE/Graphite and PTFE/Aluminum-Oxide Facial Implants in Monkeys*, 40 J. Oral Maxillofac. Surg. 771 (1982); see also Gallagher et al. *Comparison of Silastic and Proplast Implants in the Temporomandibular Joint after Condylectomy for Osteoarthritis*, 40 J. Oral Maxillofac. Surg. 627 (1982); J.N. Kent et al., *Temporomandibular Joint Condylar Prosthesis*, 41 J. Oral Maxillofac. Surg. 245 (1983); Block et al., M.S. Block et al., *Proplast Augmentation for Post-Traumatic Zygomatic Deficiency*, 57 Oral Surg. Oral Med. Oral Pathol. 123 (1984).

⁵² For example, Charles Homsy et al. *Materials for Oral Implantation: Biological and Functional Criteria*, 86 J. Am. Dent. Assoc. 817 (1973); also, E.C. Heinds et al. *Use of Biocompatible Interface for Binding Tissues and Prosthesis in Temporomandibular Joint Surgery*, 38 Oral Surg. Oral Med. Oral Pathol. 512 (1974).

Had Homsy and his colleagues expanded their research to include specifically disc replacement therapies, they may have uncovered clues hinting at potential flaws in the design of their device. While Homsy was experimenting with Proplast in alveolar ridge augmentation, another team of researchers was looking at placement of Teflon sheeting in the mandible to stop bony re-ankylosis after jaw surgery.⁵³ Even though they did suggest that repetition would be unlikely in the jaw, an allegedly non-load-bearing joint, they indicated signs of Teflon fragmentation with hip implants.⁵⁴

Belief in the jaw as a non-load-bearing joint persisted generally within the scientific community until 1987, when a graduate student at the University of Iowa published an article evaluating the use of Proplast-Teflon implants.⁵⁵ Although Homsy might have argued that this lack of knowledge should dispel any belief in Vitek's culpability, acceptance of the scientific theory would have faltered under adequate testing of the IPI. In fact, in 1991, after declaring bankruptcy, Homsy and Kent engaged in a public feud; Kent wrote a letter to the *Journal of Oral Maxillofacial Surgery* indicating that had Homsy tested Proplast using a TMJ simulator, bearing a 20 lb load, he would have noticed rapid failure of the implant.⁵⁶ Another researcher noted that reports had circulated anecdotally as early as 1984 to indicate that Proplast implants were displaying significant morbidity.⁵⁷

⁵³ H.P. Cook et al. *Teflon Implantation in Temporomandibular Arthroplasty*, 33 *Oral Surg. Oral Med. Oral Pathol.* 706 (1972).

⁵⁴ *Id.*

⁵⁵ Donald Primely Jr., *Histological and Radiographic Evaluation of the Proplast-Teflon Interpositional Implant in Temporomandibular Joint Reconstruction Following Meniscectomy* (May, 1987), (Master's Thesis, University of Iowa).

⁵⁶ JN Kent, *Further Lessons about the Proplast-Teflon Jaw Implant*, 49 *J. of Oral Maxillofac. Surg.* 1361 (1991).

⁵⁷ SL Bronstein et al., *Temporomandibular Joint Surgery: Patient-Based Assessment and Evaluation*, 110 *J. Am. Dent. Assoc.* 485 (1985).

While research supposedly verified Proplast-Teflon's effectiveness, Vitek and Du Pont, supplier of Teflon, were engaged in an ongoing debate. Du Pont had become concerned, during the implant's infancy, with Vitek's intended use of Teflon. Du Pont indicated to Vitek on a number of occasions that its Teflon material was not intended for medical usage and that the company had not conducted appropriate long-term studies to determine whether or not the fluorocarbons were safe for human use.⁵⁸ Du Pont pointed to

several published scientific reports indicating that pure Teflon implants wore badly and had a tendency to disintegrate in load-bearing joints. Consequently, Du Pont required the hospital to sign a disclaimer, acknowledging Du Pont's warnings and agreeing to use its own independent medical and legal judgment as to the safety of Teflon in the implants.⁵⁹

Homsy discounted Du Pont's concerns, however, and signed a disclaimer, indicating that research in animal and human subjects had proven Proplast-Teflon implants as safe and effective.⁶⁰

It is unfortunate that Du Pont's concerns were so easily dismissed with a letter of disclaimer, and that the FDA failed to notice the inadequacy of scientific research prior to 1983. If the FDA had conducted a thorough examination of published studies relating to Proplast, while paying closer attention to Vitek's communications with Du Pont, perhaps many patients would have been spared unnecessary suffering.

III. Who is to blame?

⁵⁸ *In re TMJ Implants Liab. Litig. v. E.I. Du Pont De Nemours and Co.*, 97 F. 3d. 1050, 1053 (1996).

⁵⁹ *Id.* at 1054 (quoting Statement of Policy Regarding Medical or Surgical Uses of Plastic Materials 1 (May 13, 1977), with Dupont stating that its "Teflon fluorocarbon resins ... are made for industrial purposes only. We conduct such tests as are needed to protect the ordinary users of these products but do not perform the detailed, long-term studies which should be made before they are used for medical or surgical purposes. We make no medical or surgical grades and have not sought or received any rulings from the Federal Food and Drug Administration or from any governmental agency as to the safety or effectiveness of these products for such purposes.").

⁶⁰ *Id.*

A. FDA changes its policies, but its response comes too late

By the mid-1980's, patients began returning to their oral surgeons with complaints relating to their IPI's.⁶¹ By the early 1990's, with a growing number of symptomatic patients, the FDA began notifying surgeons of reported implant failures. The agency advised surgeons to follow any patient in whom they had inserted Proplast-Teflon IPI's, and to administer to these patients regular and long-term radiographic examinations.⁶² However, because the FDA's regulations would not require tracking of medical devices until 1984, many patients, especially those who were not experiencing any adverse side effects from the device, remained unaware of implant defects.

If the FDA's 1976 Amendments were designed to remedy the nation's long history of failed medical devices, what went wrong? How is it possible that Proplast-Teflon jaw implants, which would later prove inherently to be flawed, were used in human patients? Who was to blame for product failure and patient harm?

One might attribute the FDA's seemingly inadequate scrutiny of Vitek's IPI to a deficiency in the provisions of the 1976 Amendments. While the FDA did not become aware of public concerns relating to Proplast-Vitek until 1988,⁶³ the heart of the problem lay less with the agency's post-production operations, and more with its pre-sale 510(k) exemption of Vitek's implants.

When Vitek first petitioned the FDA for 510(k) authorization, the company compared its product to silicone, an implant material already on the market. The 1976 Amendments indicated that manufacturers would not be exempt from the PMN requirement if the new device

⁶¹ <http://www.tmj.org/biomaterials.asp>

⁶² *Id.*

⁶³ <http://www.fda.gov/cdrh/consumer/tmjupdate.html>

“significantly changed or modified” in “design, components, method of manufacture, or intended use” a similar pre-1976 device.

A plain reading of the 1976 Act appears to imply that a shift from silicone to Proplast-Teflon should constitute a significant change or modification in device components. Although both the silicone and Proplast-Teflon devices were similarly intentioned, they differed in composition; silicone is a rubber-based material, while Proplast-Teflon is a composite of Polytetrafluoroethylene (PTFE) Aluminum Oxide (II) or Hydroxylapatite (HA).⁶⁴ However, the comments preceding the 1976 Act indicate that:

not every change in design, material, chemical composition, energy source, and manufacturing process is a significant change. Instead the regulation should identify what types of changes are significant enough to require premarket notification submission. The Food and Drug Administration should not require a premarket notification submission for every change in manufacturing process since too many changes are made on a regular basis. The Commissioner believes that FDA should be aware of and determine whether or not a change will increase the safety or effectiveness of the device.⁶⁵

The Act itself, however, provides little extra guidance in determining what constitutes a significant change. The Act defines “significant change or modification” as: “a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g. a *significant* change or modification in design, material, chemical composition, energy source, or manufacturing process, or a change or modification in the intended use of the device.”⁶⁶ The regulations grant the FDA wide discretionary powers to decide what constitutes a modification significant enough for PMA exemption. While courts will often defer to agency

⁶⁴ *Id.*

⁶⁵ 42 Fed. Reg. 163, 42529.

⁶⁶ 21 C.F.R. § 807.81 (West 2006).

expertise in the implementation of regulations if they contain any ambiguity,⁶⁷ the Act's opening comments indicate that the FDA's discretionary powers are intended in part to reduce the time and cost associated with the review of large volumes of new device applications.

Had the FDA not granted Vitek a 510(k) exemption, it is clear that Proplast-Teflon implants would have fallen into the Class III category of medical devices, which includes implanted materials, and would thereby have been subject to PMA. Instead, under 510(k), Vitek had to submit:

[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement, ... [a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate *and that no material fact has been omitted*, ...and [a]ny additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution.⁶⁸ (emphasis added).

Even with Vitek's assurance that the data submitted were "truthful and accurate and that no material fact had been omitted," and even though Vitek had provided scientific research to support its claim, it is unclear how the FDA overlooked the fact that the scientific research did not relate to the efficacy of Proplast-Teflon as a TMJ disc replacement device. Had the FDA required Vitek to undergo PMA rather than 510(k) PMN, it seems unlikely that the FDA would have allowed sale of the implant as a disc prosthesis based on such tenuous scientific proof. Additionally, had the FDA applied a strict review of available research, or required some kind of

⁶⁷ *Cathedral Candle Co. v. U.S. Intern. Trade Com'n*, 400 F.3d. 1352, 1365 (2005) ("Even if *Chevron* deference does not apply, an agency's construction of a statute that it is charged with administering is still subject to some deference under the standard set forth by the Supreme Court in *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944)).

⁶⁸ 42 Fed. Reg. 163, 42529.

long-term follow-up studies in animals, the agency might have remarked on the poor credibility of data provided.

In a United States Supreme Court case, where AcroMed sought 510(k) approval of its bone screw device in spinal surgery, the Court admitted that the 510(k) process “lacks the PMA’s rigor,” but held that the 510(k) process enables the FDA to elicit additional information from a manufacturer and to impose provisions aimed at “detecting, deterring and punishing false statements made during” the process, including investigations into potential fraud.⁶⁹ “Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.”⁷⁰ Despite the difficulty that careful regulation may impose on the FDA, and while deferral to experts in the field may be advisable, FDA policies lacking rigor place public health at risk. Even Homsy, in response to his forced filing of bankruptcy, expressed anger at FDA’s regulatory policies, analogizing the agency’s treatment of Proplast to its allegedly inaccurate, premature and unscientific removal of Dalkon’s IUD and Dow Corning’s silicone breast implants from interstate commerce.⁷¹ Homsy argued that the FDA should have prohibited sale of the Proplast-Teflon IPI between 1976 and 1992 and asked for more data.⁷²

B. FDA amendments to its 1976 Medical Device Regulations do not fix the problem

The FDA was not publicly aware of complaints relating to the IPI until 1988.⁷³ In 1989, it issued a letter advising Vitek to warn all oral surgeons against implanting any more devices and

⁶⁹ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 342; 121 S.Ct. 1012 (2001).

⁷⁰ *Id.*

⁷¹ Homsy, 412 Policy Analysis 1, 7.

⁷² *Id.*

⁷³ <http://www.fda.gov/cdrh/consumer/tmjupdate.html>.

urged them to monitor those patients who had already had the implants inserted (at least until more data had been established to show the effectiveness and safety of the implants).⁷⁴ Vitek eventually issued a voluntary safety alert advising surgeons of the hazards linked to the IPI and reiterated FDA's patient-monitoring recommendation.⁷⁵ But one month later, the FDA warned Vitek that its voluntary safety alert was ineffective, since some of the consignees had never been notified.⁷⁶

Difficulty with notification is what prompted the FDA to tighten regulations on medical devices in the early stages of Vitek's downfall.⁷⁷ In 1984, the FDA promulgated the Medical Device Reporting Regulations of 1984.⁷⁸ This Act required manufacturers and importers of medical devices to submit reports of injury related to the use of their devices and any potential for device malfunction.⁷⁹ However, the sweep of the act was too narrow; it excluded hospitals and health care centers from mandatory submission of device malfunction and patient injury reports.⁸⁰ As a result, many of these facilities chose not to report injuries since the process could be lengthy and time-consuming.⁸¹

In 1990, the FDA refined the regulations and created the Safe Medical Device Act (SMDA) of 1990, which mandated reporting on the part of hospitals and health care facilities. The Act also required manufacturers to track implant patients so that they could be notified of any defective devices.⁸² In 1992, Congress passed yet another set of regulations, the Medical Device

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ Joseph Levitt, *Medical Device Tracking Regulation*, 48 Food & Drug L.J. 113 (1993).

⁷⁸ Mindy Chapman, *Rx: Just What the Doctor Ordered: International Standards for Medical Devices*, 14 Nw. J. Int'l L. & Bus. 566, 576 (1994).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

Amendments of 1992, which resulted in a delay of the SMDA tracking regulations.⁸³ The burden for ensuring that the tracking system works falls on the manufacturer.⁸⁴ One critic notes, however, and the Vitek incident demonstrates, that none of these Acts or Amendments addresses the root of the problem: ensuring that manufacturers “demonstrate that their devices’ design and materials are safe for consumers.”⁸⁵

When reviewing new medical devices for approval, the FDA faces the inherent tension between ensuring expedient review of new medical devices, and the dangers of over-expediency engendering potential for fatal error.⁸⁶ One frequent criticism of the FDA is that it is too slow in approving new medical devices.⁸⁷ Homsy also believes, however, that FDA regulations pertaining to medical devices can sometimes be too stringent. He argues that 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.⁸⁸

He, along with other critics, suggests that the United States look to the European Union, which allows private companies meeting certain objective criteria to certify medical devices, for regulatory guidance.⁸⁹ One author notes that while Congress has attempted to pass effective rules governing medical devices, it has failed to “diagnose accurately and treat the root of the

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Flannery, *supra* note 22.

⁸⁷ Charles Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives*, 48 R.U.L.R. 883, 933 (2006).

⁸⁸ Homsy, 412 Policy Analysis 1.

⁸⁹ *Id.*

problem.”⁹⁰ She argues that device regulations have been unable to keep up with new developments in medical technology:

To date, there are no mandatory laws requiring all medical devices to demonstrate that their design and materials are safe prior to sale. A great majority of these design defects could be discovered and corrected if device manufacturers were required to test every device’s design and materials adequately prior to marketing. Without the laws to require such testing, manufacturers sell medical devices with disastrous design defects.⁹¹

On the other hand, the European Community (EU), she argues, has instituted a remedy for the problem that the United States has been unable to fix: pre-production scrutiny of devices, ensuring that defective products never even reach the manufacturing stage.⁹²

There is no indication, however, that EU standards are any more effective than U.S. standards for regulation of medical devices.⁹³ The EU, like the United States, classifies its medical devices according to degree of risk.⁹⁴ In contrast to the United States, however, EU manufacturers of some Class II and all Class III devices must present to a third-party notified body (NB) “conformity to the marketing requirements”; no EU government authority reviews NB decisions to ensure that manufacturers adhere to appropriate regulations.⁹⁵ In the United States, the FDA allows for third-party review of 510(k) applications *only*, and these third-parties are required to report on their findings *directly* to the FDA, which maintains authority to grant or deny 510(k).⁹⁶ However, use of third-party review in the United States is rare.⁹⁷

⁹⁰ Chapman, *14 Nw. J. Int’l L. & Bus.*

⁹¹ *Id.* at 568.

⁹² *Id.*

⁹³ Chai, *55 Food & Drug L.J.* 57, 60. “In 1995, the GAO[General Accounting Office] reported that the EU system had been in effect only for a few years and that the data available was inconclusive as to whether the EU system would be a valuable model for FDA. Furthermore, the GAO suggested that the ability of the EU system in ensuring product safety and an efficient review process would be evident only after additional years of implementation.”

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

Perhaps a more widespread application of third-party review in the United States would help to reduce the volume of 510(k) applications submitted to the FDA, and to alleviate any financial and/or time-related burdens.⁹⁸ Then again, expansive use of independent third-parties creates a risk of forum shopping on the part of manufacturers; third-parties, who, unlike the FDA, have a financial interest in maintaining relationships with the hiring manufacturers, may compromise public health in order to remain competitive with other independent review boards.⁹⁹ One critic recommends the establishment of an international body of representatives from different professional organizations and regulatory agencies to address “ethical issues that arise from device/material problems.”¹⁰⁰ She argues that because of one English scientist’s findings, orthopedic surgeons stopped using PTFE in the early 1960’s because of the material’s adverse effects.¹⁰¹

While FDA rules governing third-party review exist,¹⁰² more extensive use of third-parties would impose on the FDA the burden of third-party oversight; broadening independent

⁹⁷ *Id.*

⁹⁸ Wash, *supra* note 81 at 936, stating that the “FDA has difficulty attracting highly qualified personnel or obtaining sufficient funding to carry out all of its assigned tasks. As a result, it lacks both the manpower to review NDA and PMA applications promptly and the financial resources to acquire more manpower.”

⁹⁹ Chai, *supra* note 87.

¹⁰⁰ <http://www.tmj.org/biomaterials.asp>

¹⁰¹ *Id.* “I have been told by biomaterials scientists that they had “knock-down, drag-out” arguments with Dr. Homsy in the seventies about the danger of using the material in the jaw joint. Thousands of lives destroyed later, we now see that PTFE is resurging in the Bitek hip being manufactured by Dr. Homsy’s company in joint venture with Kobe Steel. He states that over 500 patients in the Netherlands were involved in clinical trials. What are the ethical issues in this scenario, and how are patient’s rights and lives being protected? I am certain that this is just one of many issues begging analysis and action from a bioethics and international law perspective. The GATT treaty, if passed, could open the door for world standardization that could affect the importation of unsafe devices from other countries.”

¹⁰² Chai, *supra* note 87 at 63, stating that “[q]ualified third-parties must have established and implemented policies to prevent any individual or organizational conflicts of interest. FDA suggests what interests would disqualify an entity from participation, including: 1) the ownership, operation, or control of the third-party by a manufacturer or distributor; 2) the ownership or other financial interest of the manufacturer or distributor by the third party; and 3) the provision of consultative services to or the participation in the preparation of the 510(k) for the manufacturer or distributor by the third-party.”

review effectively relieves the FDA from one set of regulatory duties (510(k) review) to replace it with another (third-party regulation).

Supposing that international standards *would* create uniformity in law and more effective regulation, changes to FDA rules still must be addressed domestically. These changes must emerge as clearer drafting and more detailed guidelines for medical device manufacturers and for the FDA in its review process of 510(k) requests.

In order to implement these changes, Congress must amend FDA rules. One possibility is for the regulations to require a predetermined number of animal and/or human studies and follow-up periods (with greater exigencies for greater-risk devices). The FDA should also require submission of impartial, government-funded research studies for specific high-risk, intrusive medical devices. Although this, together with mandatory follow-up periods, would be more time consuming and less cost-effective than current procedures, it might also encourage companies to invest time and money in long-term research, and to ensure their full commitment and faith to the production of their new devices. Learning from the Vitek disaster, the FDA should be responsible also, pre-production, for surveying component part manufacturers to ensure that they have no concerns with use of their product as part of the medical device. One author has suggested that the FDA develop a system “whereby scientific expertise is solicited from academia voluntary societies, industry, and federal agencies.”¹⁰³ She indicates that in 1982, the FDA could have conducted “a simple Medline search on PTFE” that would have warned the agency of its potential dangers.¹⁰⁴

¹⁰³ <http://www.tmj.org/biomaterials.asp>

¹⁰⁴ *Id.*

On a more basis level, Congress must clarify language pertaining to “significant changes” in devices barring them from 510(k). One critic surmises that relying on the 510(k) process as the only means for “assessing the safety and effectiveness of medical devices is contrary to the regulatory scheme designed by Congress” and is highly inefficient, as there is no prescribed time limit for review.¹⁰⁵ Perhaps, if the 510(k) process is failing to protect consumer safety, it should be eradicated and replaced with one comprehensive PMA process:

Relying on the 510(k) process in lieu of a full PMA review may ... create serious safety problems. Because a medical device can pass through the 510(k) process simply by showing it is substantially equivalent to any other previously approved device--even to another device which was reviewed only through the 510(k) process--hidden design or other product flaws may never be detected. At best, the 510(k) process ensures that new medical devices are no less safe than those already on the market in 1976.¹⁰⁶

IV. The Aftermath of Vitek’s Proplast-Teflon IPI.

A. The human toll

In January 1991, the FDA ordered Vitek to remove its IPI from the market.¹⁰⁷ While the FDA had sought actively to prevent further sales of Proplast-Teflon implants in the late 1980’s, and to urge surgeons to warn their patients of potential IPI failure, their efforts at expediency seem poor. By 1986, patients across North America had already begun to suffer injury,¹⁰⁸ and yet, the IPI was not publicly denounced until 1991.

Sources indicate that 26,000 patients, mostly women, underwent Proplast jaw implants.¹⁰⁹ One patient reported that after undergoing IPI surgery to treat minor jaw clicking and headaches, she is now losing sight in one eye, has undergone six surgeries to rebuild her face

¹⁰⁵ Walsh, *supra* note 81 at 947.

¹⁰⁶ *Id.* at 948.

¹⁰⁷ <http://www.tmj.org/biomaterials.asp>

¹⁰⁸ *Id.*

¹⁰⁹ <http://www.mindfully.org/Plastic/Teflon/Jaw-Implants-Fault29jul02.htm>

and jaw, has difficulty brushing her teeth because of limited jaw opening, and ingests ten pills a day to deal with her pain.¹¹⁰ In 1995, surgeons removed from her face what was left of the crumbled IPI, which had disrupted the body's normal immune functions.¹¹¹

Another woman who had undergone jaw surgery with Proplast I noticed burning and itching during jaw movement; exploration determined that carbon and Teflon had scattered in the joint's soft tissue and had been transported to the regional lymph nodes.¹¹² And the suffering has deep psychological as well as physical impact:

Thousands of people have been tormented by searing pain, mangled faces, and crippled mouth and jaw function. Many have endured massive reparative surgery with mixed results. Deep depression, including suicidal urges, has been widespread. Worse, the Teflon is now suspected of causing AIDS-like immune deficiency disorders.¹¹³

Other researchers note that even after removal of joints previously treated with Proplast-Teflon implants, giant-cell reaction is ongoing.¹¹⁴ In asymptomatic patients, clinicians are still unsure about whether to remove Vitek's IPI, or simply to conduct routine radiographic investigations to ensure that patients *remain* asymptomatic, as suggested by the FDA.¹¹⁵ For symptomatic patients, it is probably disheartening to learn about current trends in TMJ surgery which indicate that surgically treated TMJ patients fare no better than patients who undergo conservative, non-surgical treatments.¹¹⁶

¹¹⁰ www.cbc.ca/consumers/market/files/health/medical_devices. She testified that “[t]he pain never stops. It’s a kind of headache you feel – like if you bashed your head in the wall it would be better.”

¹¹¹ *Id.*

¹¹² L. Lagrotteria et al., *Patient with Lymphadenopathy Following Temporomandibular Joint arthroplasty with Proplast*, 4 *Cranio*. 172 (1986).

¹¹³ Mark Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus on Warning Law is Wrong*, 61 *T.N.L.R.* 1125 (1994).

¹¹⁴ CH Henry et al., *Treatment Outcomes for Temporomandibular Joint Reconstruction after Proplast-Teflon Implant Failure*, 51 *J. Oral Maxillofac Surg.* 353 (1993).

¹¹⁵ <http://www.tmj.org/biomaterials.asp>

¹¹⁶ Sanders et al., *Long-Term Study of Temporomandibular Joint Surgery with Alloplastic Implants Compared with Non-Implant Surgery and Non-Surgical Rehabilitation for Painful Temporomandibular Joint Disc Displacements*, 60 *J. Oral Maxillofac. Surg.* 1400 (2002).

Terrie Cowley, founder and director of the TMJ Society, a non-profit organization aimed at raising money and spreading awareness and support for TMJ patients, has spoken with many failed-IPI patients. Herself a longtime sufferer of TMJ who has undergone multiple implant surgeries writes:

[T]he bottom line I so frequently hear is still: "Terrie, I don't want money - just my life back, just to look at my kids and enjoy them for who they are right now, not with tears in my eyes feeling I won't be with them much longer." ... We are in the scientific infancy of implant disease, or whatever you want to call this. We can't care about those manufacturer-financed studies that say not to worry. Live with us one week and see if we don't have reason to worry.¹¹⁷

B. Resultant Litigation

In addition to human suffering, Vitek's failed implants created a surge of litigation. Patients have had little luck in recovering any damages, raising certain ethical issues.

In November 1989, Du Pont informed Vitek that it would no longer fill the company's orders for Teflon because of a burgeoning lawsuits relating to Du Pont's role in the manufacture of the implants.¹¹⁸ And in 1991, after Homsy declared Vitek bankrupt, he fled to Switzerland. For that reason, patients have had to pursue defendants other than Vitek in seeking recovery.¹¹⁹ Many patients filed suit against Du Pont, their main cause of action: Du Pont's failure to warn of Teflon's human health hazards; but the majority of cases have been dismissed in Du Pont's favor, based on theories of strict liability exemptions for manufacturers of component parts.¹²⁰ Others have argued that Du Pont's raw materials were defective, but again, most courts

¹¹⁷ <http://www.tmj.org/biomaterials.asp>

¹¹⁸ *In re TMJ Implants*, 97 F.3d. 1050.

¹¹⁹ 61 TNL, see above.

¹²⁰ *Id.*

dismissed the plaintiffs' claims.¹²¹ One Court of Appeals, for example, held that Defendants' raw materials were not inherently flawed, and that Du Pont had discharged any duty to warn through their disclaimer, especially to a "sophisticated purchaser like Vitek."¹²²

Others still, both as individuals and as a class, have filed suit against surgeons and hospitals. In *Budding v. SSM Healthcare System*, the plaintiff sued a Missouri hospital for implantation of a Vitek IPI, which led to a tumor at the back of her skull, causing "severe pain, numbness, seizures, and nerve weakness."¹²³ The Missouri Supreme Court held that the plaintiff would be able to claim of negligence against the hospital, but could not bring an action under strict products liability since such a cause of action was not recognized by the Missouri General Assembly.¹²⁴ The author of one article indicates that if a plaintiff is prohibited from bringing an action against a hospital for "transfer" of a product, a "plaintiff may not have any remedy for their damages if the manufacturer is no longer in business or went bankrupt due to other law suits."¹²⁵

Resultant lawsuits demonstrate the difficulties and frustration faced by plaintiffs in seeking to recover for their physical and emotional suffering. Should there not be an ethical obligation for restitution on the part of at least one key player in the Vitek disaster? Perhaps the FDA, in its central role as the policing body, should compensate IPI patients. Rather, Vitek's failed IPI mainly has generated new rhetoric and debate regarding both FDA policies and the

¹²¹ *In Re TMJ Implants Product Liability Litigation*, 97 F.3d 1050, 1054 (1996), where the 8th Circuit Court of Appeals affirmed the lower court's decision and dismissed plaintiffs' liability suit against Defendant since individual component parts were not inherently defective, it was only that the IPI design was flawed. *See also La Montagne v. E.I. Du Pont de Nemours & Co.*, 41 F.3d 846 (2nd Cir. 1994).

¹²² *Id.*

¹²³ 1999 WL 709801 (Mo. Ct, App. 1999), *rev'd*, 19 S.W.3d 678 (Mo. 2000)

¹²⁴ Kitsmiller, Julia D. "Missouri Products Liability is "Budding" (Again): *Budding v. SSM Healthcare System* and the end of the Strict Products Liability Cause of Action against Hospitals." 69 UMKC L. Review 2000.

¹²⁵ *Id.*

future of warning doctrines.¹²⁶ Legal scholars continue to engage in discussion about fault, ensuring product safety, and the role of surgeons, hospitals, and manufacturers in device failure.¹²⁷

Ultimately, regardless of fault, the burden of failure falls on patients and their families. Somewhere in the chain, between the birth of an idea and its implementation and subsequent collapse, one body, at least, needs to keep careful watch on device development. The FDA, as a regulatory agency, must assume this role.

Conclusion

Since the early 1900's, the FDA has been undergoing changes in its regulations as they pertain to medical devices. The most significant of these occurred in 1976 with the Medical Device Amendments, which granted the FDA authority to impose Premarket Notification or Approval of medical devices, depending on how intrusive their function. The agency made available to manufacturers, however, the option of avoiding a more stringent review process for the less stringent 510(k) procedure. Under this system, manufacturers are required to prove that their current device is "substantially equivalent" to another device found on the market prior to 1976. Despite rules designed to ensure that manufacturers submit a body of data to prove effectiveness and safety of their device, Vitek's IPI is but one example of a system in need of reform.

In the early 1980's, Homsy and his team of researchers produced the Proplast-Teflon jaw implant to replace defective discs in patients with TMJ disorder. Only three to four years later,

¹²⁶ Hager, *supra* note 107.

¹²⁷ Julia Kitsmiller, *Missouri Products Liability is "Budding" (Again): Budding v. SSM Healthcare System and the End of the Strict Products Liability Cause of Action Against Hospitals*, 69 UMKCLR 675 (2001).

these implants began to deconstruct under the load of the jaw joint. Patients suffered, among other symptoms, giant cell reaction, facial deformation, chronic pain, and psychological disorders. They turned first to surgeons and hospitals for answers, and then to courts and the legal system for some kind of justice. But the majority of their legal actions resulted in disappointment, since Homsy had fled to Europe, and courts, almost always, found Du Pont, as a mere component part manufacturer, not liable for damages.

In order to prevent recurrence of any similar incident, it is necessary that Congress change FDA regulations relating to medical devices. While the agency implemented tracking and reporting criteria in the mid-1980's, these measures do not reach far enough to address the heart of the issue – avoiding defective devices *before* they are used in human subjects. In order to do this, it is paramount that the FDA engage in careful and scrupulous evaluation of medical devices in the pre-production stage. This may entail more definite guidelines for device manufacturers, and for the FDA. Congress must redraft the current Amendments to the Medical Device Act and adopt a clearer definition of what constitutes deviation in a new device from an old device. Additionally, if the FDA is still unable to ensure, to the best of its ability, safety and effectiveness of medical devices, it is perhaps advisable that the agency eradicate the 510(k) system and replace it with widespread implementation of the PMA regime.

In the early eighties, the TMJ was dubbed the “money joint”¹²⁸ because of oral surgeons’ income-earning capacity in performing jaw surgeries, and their growing popularity among TMJ sufferers. Now, when many of these patients require removal of their IPI, insurance companies,

¹²⁸ <http://www.tmj.org/biomaterials.asp>

who had refused previously to pay for conservative therapies, but had agreed to pay for implant surgeries, have refused to cover explantation procedures. Symptomatic patients suffering from defective Proplast jaw implants continue to pursue litigation both in the United States and in North America, and to live with the life-altering consequences of the IPI.

If the FDA fails to amend its current regulations or its practices relating to device oversight, public consumers will be justified in their mistrust of the FDA and by extension, the healthcare system in general. Surgeons and patients will have to assume a more investigative role in the safety and use of their own medical devices. This solution would be both inefficient and troubling, however, especially with rapid advances in technology and in the development of more intrusive and elaborate medical devices. As a government agency with its specific task to protect public health, the FDA owes an ethical duty to its consumers to carry out its mission with diligence and care. Hopefully, Congress and the FDA can at least learn from the Vitek incident; although many patients continue to suffer from failed IPI's, perhaps the Vitek disaster will serve a positive role as a catalyst for re-evaluation and amendment of current FDA medical device policy.