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Rx: Just What the Doctor Ordered: International Standards for Medical Devices

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COMMENTS

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I. INTRODUCTION: WHY ARE MEDICAL DEVICES MAKING THE FRONT PAGE?

Medical devices have been a great source of private revenue and public concern over the past decade.[1] The day after the birth of this Comment, an eleven-day-old healthy baby was electrocuted to death in a large United States hospital because of a design defect with an infant breathing monitor.[2] He was just one of many babies electrocuted by that medical device in the past eight years. In 1991, a Medline motor-driven feeding device was discovered to have so many design defects that it caused electric shocks and over-feeding, result-

* I would like to thank Christina Martini, my editor, who left me with words of wisdom and cut out the rest; Rosemary Gullikson, my classmate, for her encouragement; my parents, Marcia and Marshall Tarre, for their blessings; my children, Emily and Daniel for their unbelievable patience; and Richard Chapman, my husband and best friend, for his guidance and support during this déjà vu experience.

1 The Commerce Department declared that the three fastest-growing sectors of the United States economy over the past five years were all in medical technology. Julie Kosterlitz, *Device Makers Get Up-Close-And-Personal*, 1993 THE NAT'L J. 1968.

2 The design problem that would permit such a mistake was first detected in 1985 by the U.S. Food and Drug Administration, which issued a nation wide warning after the electrocution of several babies. (discussing the apnea monitor manufactured by Corometrics Medical Systems). *Error Suspected in Baby's Death*, CHI TRIB., Aug. 26, 1993, § News, at 1.

ing in regurgitation, aspiration of fluids and death.[3] In 1990, a General Electric magnetic resonance imaging machine was found to burn patients.[4] That same year, a blood sugar diagnostic device with multiple design defects caused users to experience insulin shock or death.[5] Even patients merely recuperating in electric hospital beds were injured when design flaws resulted in beds breaking and falling.[6]

Additionally, there has been much front page publicity about injurious design defects with ventilators,[7] defibrillators,[8] pacemakers,[9] silicone breast implants,[10] back screws,[11] and lasers used for eye surgery.[12] Manufacturers sell these medical devices in the United States and abroad. Although Congress has reacted to such catastrophes by creating several new laws to regulate medical devices, it has failed to diagnose accurately and treat the root of the problem. Currently, the United States Food and Drug Administration (FDA) is considering making changes to existing regulations. However, these proposed changes again are inadequate to cure the ills of the American medical device crisis.

Medical devices have existed in the United States since the late 1700's, when President George Washington bought brass and iron

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3 THE GRAY SHEET, Sept. 16, 1991, at 22, *available in* LEXIS, GENMED Library, Gray Sheet File (Medline recalls Dynafeed Enteral Feeding Pumps).

4 THE GRAY SHEET, Oct. 22, 1990, at I&W-5, *available in* LEXIS, GENMED Library, Gray Sheet File (General Electric Signa Brand Magnetic Resonance Imaging System sold nationally and internationally).

5 THE GRAY SHEET, Sept. 3, 1990, at 10, *available in* LEXIS, GENMED Library, Gray Sheet File (Electronics Assembly Corporation manufactured the Blood Glucose Sensor).

6 THE GRAY SHEET, Aug. 25, 1986, at 10, *available in* LEXIS, GENMED Library, Gray Sheet File.

7 Burnell Life Pulse Ventilators were used for critically ill infants. THE GRAY SHEET, Aug. 17, 1992, at 17, *available in* LEXIS, GENMED Library, Gray Sheet File.

8 THE GRAY SHEET, Aug. 25, 1986, at 10, *available in* LEXIS, GENMED Library, Gray Sheet File (discussing Hewlett Packard defibrillator).

9 *Device User Education, Product Quality are Linchpins of Action Plan III, Slated for January 1989 Implementation. FDA Commissioner Young Tells HIMA*, THE GRAY SHEET, Mar. 21, 1988, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File (discussing Cordis Gamma Series Pacemakers).

10 Geoffrey Cowley, *Calling a Halt to the Big Business of Silicone Breast Implants*, NEWSWEEK, Jan. 20, 1992, at 56.

11 Nearly one in three back screws, which were used in spine surgery, broke due to design defects causing patients permanent nerve damage. *20/20: The Secrets of the Back Screws-Crippling Operations*, (ABC television broadcast, Dec. 17, 1993)(discussing Steffe Back Screws manufactured by Acromed Corp.).

12 *Manufacturers Receiving Notice of Adverse Findings Letters for Failure to Submit MDR Reports to FDA*, THE GRAY SHEET, June 25, 1989, at 7, *available in* LEXIS, GENMED Library, Gray Sheet File (discussing design defect found in Weck ophthalmic argon laser).

rods to eliminate bodily diseases.[13] Over two hundred years later, with the aid of complex technology, medical devices such as artificial heart valves and kidney dialysis machines continue to prolong thousands of lives each year. Medical technology has obviously progressed over the centuries. Unfortunately, medical device regulation has not kept up with these advances. To date, there are no mandatory laws requiring all medical devices to demonstrate that their design and materials are safe prior to sale.[14] 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.[15] Without the laws to require such testing, manufacturers sell medical devices with disastrous design defects. This in turn, as already noted, has led to serious injury and even death.

By contrast, the newly emerging European Community has accomplished in only eight years what the United States has not achieved in two hundred years. Despite the fact that the European Community consists of twelve individual nations[16] with different languages, it had the foresight to gather its resources to remedy the problem, through legislation, before it surfaced. The European Community's ex ante approach requires scrutiny of the design and materials of all medical devices in the pre-production stage before launching them on the manufacturing line.

This Comment demonstrates why the FDA should amend its medical device regulations to emulate those of the European Community. There are two major benefits of a single set of international standards. First, a single set of international standards assures safe medical devices both in the United States and on the international

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13 The device was eventually deemed fraudulent. Peter B. Hutt, *A History of Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 100 (1988) [hereinafter *History*].

14 *Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Revisions Being Considered; Request for Information and Comments*, 55 Fed. Reg. 24,544 (1990)(to be codified at 21 C.F.R. § 820); THE GRAY SHEET, June 25, 1990, at 6, *available in* LEXIS, GENMED Library, Gray Sheet File.

15 A study commissioned by FDA revealed that based on a random sample of one hundred design-related incidents, "proper design controls would have prevented about 73% of the incidents." *Design Controls Would Apply to 16 Types of Class 1 Devices Under GMP Revision; Requirements Regarding Qualifications of Consultants Also Suggested*, THE GRAY SHEET, Nov. 22, 1993, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File.

16 France, Belgium, Luxembourg, Holland, West Germany, Italy, Denmark, Ireland, United Kingdom, Portugal, Spain, and Greece. Mitzi Elkes, *Europe 1992: Its Impact on Non Tariff Trade Barriers and Trade Relations with the United States*, 44 FOOD DRUG COSM. L.J. 563, 566-67 (1989).

market. Second, the United States will have a greater opportunity to export medical devices to the newly prosperous European Community resulting in greater financial returns and job opportunities for Americans.

Part I of this Comment discusses the current federal legislation governing the production of medical devices in the United States and points out how the first vital link in ensuring public safety is missing from the manufacturing chain. Parts II and III define medical devices and describe the chronology of regulation in the United States. Part IV discusses the history of the European Community and its consumer policy approach to medical devices. Part V compares and contrasts the United States' and the European Community's approaches to medical device regulations and the need for reform. Part VI presents recommendations regarding future legislation for American medical devices in light of the European Community's approach and current FDA regulations. Part VII examines the drawbacks and benefits of new legislation.

II. MEDICAL DEVICES: WHAT ARE THEY NOW, AND WHAT WERE THEY BEFORE LEGISLATION?

A. Definition of Medical Devices

Medical devices pervade our health care experiences throughout our entire lives, from fetal monitoring equipment and ultrasound imaging before birth, to the life support systems and even suicide machines when death is imminent.[17]

A medical device is defined as "any instrument, implant, or other article recognized by the National Formulary or the United States Pharmacopeia and designed to cure disease by affecting a patient's physical structure or bodily function without relying principally on some type of chemical action."[18] Simply stated, devices include all health care items other than drugs.[19]

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17 SUSAN B. FOOTE, MANAGING THE MEDICAL ARMS RACE 3 (1992) [hereinafter MANAGING].

18 21 U.S.C. § 321(h) (1993); David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357 (1987); *See*, Phelps v. Sherwood Medical Industry, 836 F.2d 296 (7th Cir. 1987)(discussing heart catheter); Brooks v. Medtronic, Inc., 750 F.2d 1227 (4th Cir. 1984)(discussing heart pacemakers); Perfetti v. McGhan Medical, 662 P.2d 646 (N.M. Ct. App. 1983), *cert. denied*, 662 P.2d 645 (N.M. 1983)(discussing mammary prosthesis); Terhune v. A.H. Robins Co., 577 P.2d 975 (Wash. 1978)(en banc) (discussing Dalkon shield intrauterine device); MANAGING, *supra* note 17, at 9.

19 MANAGING, *supra* note 17, at 9.

Medical devices range from the cutting edge of technology to the mundane. Their scope encompasses the very complex such as artificial arteries,[20] x-ray machines, and penile implants, to simple bedpans, stethoscopes, and pregnancy test kits.[21] Presently, the FDA regulates approximately 1,800 types of medical devices.[22] However, predictions estimate that by the year 2000 there will be over 100,000 new and improved medical devices on the market.[23]

B. The History of Medical Devices Prior to Federal Legislation

Although food, drug, and cosmetic products have been defined as articles of commerce and therefore subject to government regulation for centuries, medical devices have only recently been recognized as a separate and distinct category of health products necessitating their own unique form of government regulation.[24]

In ancient times, long before recorded history, simple medical devices such as splints, wooden crutches, and rudimentary dental devices were used by many cultures.[25] By the eighteenth century, many worthless medical devices were created by profit-driven swindlers.[26] During the 1700's in Europe, "animal magnetism" medical devices were sold to improve the buyer's health, but they were eventually proven ineffective.[27] At the same time, the first known medical device was marketed in the United States to eliminate disease, but it was eventually exposed as fraudulent.[28] Many useless devices were on the market, including one that claimed it could restore diseased organs back to health by remote control![29] Despite the public's growing con-

20 Scientists have invented about sixty artificial body parts which have touched the lives of at least eleven million Americans. Almost six percent of these patients have more than one implant. Abigail J. Moss, et al., U.S. Dep't of Health and Human Services, *Use of Selected Medical Device Implants in the United States, 1988*, 1988 DHHS PUBLICATION (PHS) 91-1250, Advance Data No. 91 (1991) [hereinafter *Use*].

21 21 C.F.R. §§ 800-1299 (1993).

22 *Agency Implements Safe Medical Devices Act; Food and Drug Administration*, FDA CONSUMER, Nov. 1991, at 5. The FDA has regulatory authority over a stunning $960 billion worth of products which is twenty-five cents out of each consumer dollar spent. John Schwartz, *Building New Consensus To Improve Public Safety*, THE WASH. POST, July 15, 1993, § 1, at A25.

23 MANAGING, *supra* note 17, at 4.

24 *History, supra* note 13, at 99.

25 *History, supra* note 13, at 99.

26 "Magneto-Conservative Garments" claimed to cure: "paralysis, kidney disease, liver disease, lung troubles, rheumatism, nervous prostration gout, stiff joints, locomotor ataxia, writers cramp, loss of memory, giddiness, varicose veins, and every other form of disease." MANAGING, *supra* note 17, at 35.

27 *History, supra* note 13, at 99-100.

28 *History, supra* note 13, at 100.

29 MANAGING, *supra* note 17, at 36.

cern over health and longevity, as evidenced by consumers' willingness to buy these quack devices, there was no regulation of medical devices. Still, even at this early point in American history, it would appear to have been a sound idea to regulate devices to ensure their safety and to protect consumers. However, this regulation did not happen, and would not happen for a long time.

Surprisingly, the public and legislative spotlight focused only on food and drugs. In the early 1900's, Congress enacted nationwide legislation authorizing federal regulations of food and drugs. The first of this legislation was The Biologics Act of 1902,[30] sparked by the deaths of ten St. Louis children from contaminated vaccines.[31] Four years later, Congress enacted The Pure Food and Drugs Act of 1906.[32] However, this was watered down by compromises, amendments, and adverse court rulings, and could only be weakly enforced by an inadequate government staff.[33] Shockingly, the legislative history of the 1906 Act does not make any mention of medical devices,[34] which enabled medical device creators to continually exploit the sick but hopeful.[35]

A turning point for devices came in June 1933, when New Deal legislation attempted to modernize and expand the 1906 Act.[36] A 1933 report by the FDA first recognized that mechanical devices were capable of extreme harm and, therefore, needed legislative controls.[37] Five years later, Congress enacted the Federal Food, Drug and Cosmetic Act of 1938 (Act),[38] the first legislation to acknowledge and regulate medical devices. Ironically, as soon as the Act was passed, real problems began.

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30 The Biologics Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1902); *History, supra* note 13, at 100.

31 Frank E. Young, *A Golden Anniversary of Consumer Protection*, FDA CONSUMER, June 1988, at 4.

32 The Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat 768 (1906).

33 Young, *supra* note 31.

34 *History, supra* note 13, at 101.

35 By 1929, FDA had recognized problems due to lack of device regulations when it collaborated with the United States Postal Office on seventy-three mail order medical device fraud cases, including an insole device for the treatment of rheumatism and kidney disorders. *History, supra* note 13, at 101.

36 *History, supra* note 13, at 102.

37 MANAGING, *supra* note 17, at 43.

38 The Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. §§ 301-395 (1993)).

III. The History of "Regulated" Medical Devices

A. The Food Drug and Cosmetic Act of 1938

Superficially, it appeared as though the 1938 Act would put an end to medical device problems. The Act provided the FDA with its present statutory authority to take formal or informal regulatory action against the adulteration or misbranding of food, drugs, devices and cosmetics. The Act deems a device "adulterated" if it contains filthy material, is prepared under unsanitary conditions or differs from the quality represented in its labeling.[39] Furthermore, the Act deems a device "misbranded" if its labeling is false or misleading.[40] The enforcement remedies available to the FDA include criminal prosecution of individuals and firms guilty of prohibited acts, injunctions against such acts and seizures of adulterated or misbranded goods.[41]

The Act generally treated medical devices and drugs as similar products. However, Congress made one significant distinction. Congress deliberately separated the terms "medical devices" and "drugs" when it added a pre-market notification requirement for the safety of new drugs.[42] Congress included this separate requirement in the legislation because of a drug-related tragedy that killed more than one hundred people the year before the Act was passed.[43] Yet, Congress did not add comparable pre-market notification provision for medical devices.[44] Thus, although medical devices were the FDA's "children," it had no rules to enable them to safely cross the street to the marketplace.

B. 1940's Through the Mid-1970's

For the next thirty-eight years, medical devices began shedding their fraudulent reputation as they became more instrumental in the

39 Pub. L. No. 75-717, § 501, 52 Stat. 1049 (as amended 21 U.S.C. § 351).

40 *Id.*

41 The FDA has also relied on informal remedies not explicitly provided in the Act, such as publicity, recalls, and regulatory letters: these now comprise the primary routine enforcement tools of the agency. Peter B. Hutt & Richard A. Merrill, Food and Drug Law 12-13 (2d ed. 1991); Typically, FDA enforcement annually results in 25,000 import detention, 8,000 "inspectional observations" of violations, and about 9,000 other measures, ranging from warning letters to voluntary corrections, product recalls, seizures, injunctions, and criminal prosecution. James S. Benson, *FDA Enforcement Activities Protect Public*, FDA Consumer, Jan.-Feb. 1991, at 7.

42 *History, supra* note 13, at 104.

43 Elixir sulfanilamide, a new liquid form of the drug sulfanilamide, was tested for flavor, appearance, and color, but not for safety: it killed over one hundred people. Young, *supra* note 31.

44 *History, supra* note 13, at 104.

growth of health care technology. Following World War II, there was a flood of new lifesaving medical devices sold in the market requiring the FDA's attention.[45] This period was so productive in the area of medicine it was labeled the "therapeutic revolution."[46] As a result, the FDA increased its effort to ensure the safety and effectiveness of these new devices and to protect the public against lingering fraudulent devices.[47] Still, there was no concern with the safety of device design or its materials.

As medical technology soared, the line between drugs and medical devices blurred. In the 1960's, the judicial system struggled to determine whether a medical treatment was a drug and therefore subject to pre-market notification, or whether it was a device and thus virtually free from government scrutiny.[48] This prompted the urgent need to clarify the classification of borderline drugs used as medical devices and to formulate regulations accordingly.

A second legislative turning point for medical devices came in 1970. Dr. Theodore Cooper, Director of the National Heart and Lung Institute, completed a ten-year survey that revealed over 731 deaths and 9,000 injuries from medical devices.[49] The Cooper Committee[50] concluded that the breadth and diversity of new medical devices presented entirely different issues from new drugs,[51] and recommended that the FDA take a different regulatory approach in-

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45 *History, supra* note 13, at 106. Baxter Travenol provided a wartime success story when it developed a container for blood collection and storage which allowed blood banking possible for the first time. MANAGING, *supra* note 17, at 51.

46 Young, *supra* note 31; Even General Electric was inspired by the war and created portable x-ray machines for use on ships and to screen new inductees for tuberculosis. MANAGING, *supra* note 17, at 52.

47 *History, supra* note 13, at 106.

48 AMP Inc. v. Gardner, 389 F.2d 825 (2d Cir. 1968)(two nylon binding devices used to tie off severed blood vessels during surgery were classified as new drugs and not devices); United States v. An Article of Drug, 394 U.S. 784 (1969)(antibiotic disc that was used as a screening device in the laboratory to determine the proper antibiotic to administer to patients and never came into contact with the human body was classified as a drug and not a device).

49 Theodore Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L.J. 165 (1971); MANAGING, *supra* note 17, at 116.

50 "The Cooper Committee consisted of ten government officials-two from the FDA, five from the various parts of the National Institutes of Health, and three from other parts of HEW." *History, supra* note 13, at 109.

51 Devices and drugs are not substantially similar. Many devices are either invasive or implanted in patients for periods of time and pose a complex set of issues; pharmaceutical or biological agents are often given for limited time periods and can be withdrawn easily should adverse events arise. David A. Kessler, Commissioner of Food and Drugs, Response to John Dingell, Chairman, Subcommittee on Oversight and Investigations, U.S. House of Representatives, Concerning Activities at the Center for Devices and Radiological Health, September 8, 1992, 3 FOOD AND DRUG LAW REP. 12, at S-39 (1992).

cluding a classification system based on risk for medical devices. The Cooper Committee Report, along with administrative and legislative activity of that time led to the enactment of the Medical Device Amendments of 1976 (Amendments).[52] For the first time, the Amendments required that the FDA review the manufacturing processes of medical devices before marketing.[53] Unfortunately, this well-intentioned legislation was poorly planned, and created even more regulatory chaos for medical devices.

C. The Medical Device Amendments of 1976

The primary purpose of the 1976 Amendments was to ensure that new devices were safe and effective before sale.[54] The new regulations categorized medical devices into "low,"[55] "medium"[56] and "high"[57] risk classes and outlined different routes a manufacturer could take to market its product.[58] Additionally, the Amendments established the current Good Manufacturing Practices (GMP) as general guidelines for the manufacture, packaging, storage and installation of all finished devices intended for human use.[59] Moreover, the Amendments

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52 The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. § 360c-360k) [hereinafter Amendments].

53 Kessler, *supra* note 18.

54 Kessler, *supra* note 18. *See* Jonathan S. Kahan, *Medical Device Reclassification: The Evolution of FDA Policy*, 42 FOOD DRUG COSM. L.J. 288 (1987); *See Generally* Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511 (1988).

55 Low risk devices, Class I, include stethoscopes, powered toothbrushes, suction snakebite kits, crutches, dental floss, and cold packs. 21 C.F.R. §§ 800-1299 (1993).

56 Medium risk, Class II, includes hearing aids, sickle cell tests, powered wheelchairs, rectal dilators, and blood pressure cuffs. *Id.*

57 High risk, Class III, includes silicone gel-filled breast prosthesis, absorbable powder for lubricating a surgeon's glove, infant radiant warmers, replacement heart valves and bone cement. *Id.*

58 A high risk device, Class III, must obtain FDA approval of a pre-market application (PMA) before marketing the device. Food Drug & Cosmetic Act § 515(a)(codified at 21 U.S.C. § 360 e(a)); A high risk device on the market prior to the 1976 Act may remain on the market pending an FDA regulation calling for PMA's to be submitted for that type of device. Food Drug & Cosmetic Act § 515 (b)(1)(codified at 21 U.S.C. § 360e(b)(1)). However, if a new device, regardless of risk status, is judged to be "substantially equivalent" to a device already on the market prior to the 1976 Act, (or to a post-enactment device that has been found by FDA to be substantially equivalent to a pre-enactment device) a sponsor need not obtain a PMA, but instead may market the device after the submission of a pre-market notification, commonly referred to as a 510(k). Food Drug and Cosmetic Act § 510(k); 513(i)(codified at 21 U.S.C. §§ 360(k), 360c(i)).

59 Established, July 1978, and has not been revised since initial promulgation. 21 C.F.R § 820.1.

"grandfathered in"[60] many of the medical devices already on the market which, in essence, allowed them to escape immediate government scrutiny and to continue to be sold in the marketplace. Although the Amendments established that such devices would eventually have to prove safety and efficacy,[61] they would not have to do so for well over a decade.[62]

However, one final fatal legislative flaw remained: the FDA still failed to require examination of medical devices in the pre-manufacturing stage. The agency did not require manufacturers to make a prototype device and test its design and material under natural use conditions prior to marketing. Therefore, the new federal regulation allowed the manufacturing of medical devices with deadly flaws. Ironically, by this time, American consumers finally felt more confident that medical devices were safe for use when the FDA approved them.

D. Reactionary Regulations for Unsafe Medical Devices

Big problems with medical devices began to surface in the decade following the Medical Device Amendments of 1976. For example, an estimated sixty thousand to eighty thousand Americans received insufficiently tested jaw implants for temporomandibular joint disorder (TMJ).[63] Such devices were supposed to relieve joint pain where the jaw and skull connect. However, the devices legally dodged any serious regulatory evaluation because the FDA considered them similar to jaw implants already on the market under the Amendments and, therefore, grandfathered them into the stream of commerce without any review.[64] The implant was breaking down and fragmenting as a result of simple chewing.[65] Consumers began to complain of pain in

60 "Grandfathering in" refers to a high risk device on the market prior to the 1976 Act which was allowed to remain on the market pending an FDA regulation calling for Pre-Market Approval's (PMA's) for that type of device. Food Drug & Cosmetic Act § 515 (b)(1)(codified at 21 U.S.C. § 360e(b)(1)); In practice, FDA has required few PMA's for devices on the market prior to the 1976 Act. Peter B. Hutt et al., *The Standard of Evidence Required for Pre-market Approval Under the Medical Device Amendments of 1976*, 47 FOOD AND DRUG L.J. 605, 607 n.16 (1992).

61 Food Drug and Cosmetic Act § 513 (a) (1) (codified at 21 U.S.C. §§ 360c(a)(1)-(2).

62 Food Drug & Cosmetic Act § 515 (b)(1)(codified at 21 U.S.C. § 360e(b)(1)). In the Safe Medical Devices Act of 1990, Congress directed FDA, within a specified time frame, to evaluate all high-risk devices on the market prior to 1976 where no regulation requiring a pre-market approval application had been made. Hutt, *supra* note 60.

63 Judy Foreman, *Danger Cited in Teflon Jaw Implants*, BOSTON GLOBE, June 5, 1992, at 11.

64 John Wilkins, *For TMJ's Tortured Sufferers, Implants Cause Aching Regret*, SAN DIEGO UNION TRIB., July 25, 1993, at A1.

65 *Id.*

the jaw and ear area, nausea,[66] infections, dizziness, hearing and sight loss.[67] By 1984, one of the developers of the Vitek TMJ device revealed that there were numerous reports of problems associated with its device and admitted, "we have a calamity of unbelievable proportions on our hands."[68]

The FDA soon reacted with more legislation. The FDA's Medical Device Reporting Regulations of 1984[69] required manufacturers and importers of medical devices to submit reports of death and serious injuries associated with each device in addition to reports of potentially harmful device malfunctions.[70] However, this regulation left out hospitals and health care facilities who only had a voluntary obligation to report medical device problems. Consequently, those facilities seldom reported such deaths or serious injuries because such reporting was time consuming and optional.[71]

Again, in an ex post fashion, the FDA promulgated the Safe Medical Device Act of 1990 (SMDA)[72] which made it mandatory for the previously unregulated health care facilities and hospitals to report medical device problems.[73] The SMDA also required manufacturers to track implant patients so that they could be identified, followed, and notified promptly of dangerous and defective devices. However, two years later, Congress enacted the Medical Device Amendments of 1992,[74] which sadly delayed the SMDA tracking regulations.[75] No new device laws have been enacted since then. How-

66 Anne Rochell, *Implants 'A Health Fraud'*, ATLANTA J. AND CONST., Sept. 25, 1993, at E1.

67 Wilkins, *supra* note 64.

68 Philip J. Hilts, *F.D.A. Issues Warning on Jaw Implants That May Disintegrate in the Body*, N.Y. TIMES, June 5, 1992, at A14.

69 49 Fed. Reg. 36,326-36,351 (1984).

70 Since the reporting law took effect in 1984, the FDA has not only been inundated with some 69,000 reports of medical device problems from manufacturers and importers, but it has also seen the number of known problems reported annually skyrocket from around 2,500 to between 18,000 and 20,000. Sana Siwolop, *The Importance of Lobbying*, FIN. WORLD, Aug. 21, 1990, at 58.

71 A 1986 GAO report estimated that only about fifty percent of device problems occurring in hospitals were reported outside the hospital, and fewer than one percent were actually reported directly to the FDA. U.S. Dep't of Health and Human Services, *FDA Requires Health Care Facilities to Report Death and Injury from Medical Devices*, PUB. HEALTH REP., March-June, 1992, at 238-39.

72 The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990)[hereinafter SMDA]. SMDA required the establishment of an office to deal specifically with international harmonization issues for medical devices. SMDA also gave authority to add preproduction design validation controls to the device GMP regulations.

73 Physicians offices are exempt. SMDA, *supra* note 72.

74 Medical Device Amendments of 1992, Pub. L. No. 102-300, 106 Stat. 238 (1992).

75 THE GRAY SHEET, Aug. 16, 1993, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File.

ever, there is currently a proposal by the FDA to require design validation of medical devices.[76] Disturbingly, it recommends that not all devices should have to prove they are designed safely.[77]

The Medical Device Reporting Regulations of 1984, Safe Medical Device Act of 1990, and the recent Medical Device Amendments of 1992 all fail to locate and correct the root of the defective device problem. Although the cause of many of the device problems seems obvious, none of the laws require manufacturers to demonstrate that their devices' design and materials are safe for consumers. And now, although the proposed regulation looks like it is going in the right direction, it is not going far enough.

E. The Aftermath of American Device Legislation: Current Quality Problems in Medical Devices

Fortunately, American device legislation is not completely inept. Recent device regulations require the health care industry to report incidences of injury-causing devices to the FDA, and in turn, the FDA reviews that data. A recent study reveals medical device manufacturers filed reports for more than ninety-eight percent of all products that were subject to serious recalls by the FDA.[78] This statistic, however, must be considered in light of the differences between the recalls of devices due to violations of the manufacturing processes, governed by the good manufacturing practices (GMP), and those due to design flaws, not subject to regulations.

1. Good Manufacturing Practice Quality Problems

An FDA report disclosed that forty-seven percent of device-related quality problems were GMP-related violations, or deficiencies which occur in the manufacturing phase.[79] For example, intravenous administration kits packaged with beetle-like insects are obviously not

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[76] 58 Fed. Reg. 61,952 (1993) (to be codified 21 C.F.R. pt. 820) (proposed Nov. 23, 1993).

[77] FDA is proposing to exempt ninety-five percent of Class I devices from proving design validation. *Design Controls Would Apply to 16 Types of Class 1 Devices Under GMP Revision; Requirements Regarding Qualifications of Consultants Also Suggested*, THE GRAY SHEET, Nov. 22, 1993, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File.

[78] Siwolop, *supra* note 70. The European Community does not file device incidence reports like those filed with the FDA, and therefore comparable statistics are unavailable. Telephone interview with George Lesser, Publisher, Europe Drug and Device Reports (Nov. 5, 1993).

[79] Dep't of Health and Human Services, Public Health Service, Food and Drug Admin., HHS Pub. FDA 90-4235, *Device Recalls a Study of Quality Problems*, 4-6 (1990) [hereinafter *Recalls*]; THE GRAY SHEET, April 30, 1990, at 10-11, *available in* LEXIS, GENMED Library, Gray Sheet File.

in compliance with the packaging regulations of the GMPs.[80] In another example, the Bjork-Shiley heart valve which has been implanted in 86,000 patients worldwide, and is possibly responsible for nine hundred deaths, malfunctions when a welded part fractures under the stress of normal blood flow.[81] The company disclosed that most of the malfunctioning valves were made by one employee.[82] This disaster is an example of a GMP violation of failure to control variations in the manufacturing process.[83] Manufacturers that violate GMP standards are subject to the FDA's police powers.

2. *Pre-Production Design Defects*

However, the spotlight for proposed change is on a different area of quality problems for medical devices. The same FDA report also disclosed that forty-four percent of the quality problems that led to recall action during the 1983-89 period were pre-production in nature and caused by defects incorporated into the design or manufacturing process during the design phase.[84] Unfortunately, this pre-production process is not subject to FDA regulations or police powers.

Clearly, the design phase is the single most important phase in the life cycle of a device.[85] Without a good design, device performance cannot be improved, no matter how carefully a device may be manufactured or how perfectly a GMP program is drafted.[86] For example, balloon catheters malfunctioned when fluids could not go through them as designed.[87] The problem was due to the catheter's blueprint, not the balloon material.[88] This defect could have been prevented if adequate care had been exercised in establishing physical and operational requirements for the device including consideration of the user and his environment.[89] Testing should have been done

80 THE GRAY SHEET, May 21, 1990, at I&W-5-I&W-8, *available in* LEXIS, GENMED Library, Gray Sheet File.

81 Geoff Boucher, *Engineer Says Test Proved Shiley's Valve's Value; Courts: Despite 'Devastating' Results, The Device Was Not a Medical Failure, He Tells Jurors Hearing Recipient's Lawsuit*, L.A. TIMES, Aug. 28, 1993, at B8.

82 *Id.*

83 *Recalls, supra* note 79, at 8.

84 *Recalls, supra* note 79, at 3.

85 *Device User Education, Product Quality are Linchpins of Action Plan III, Slated for January 1989 Implementation, FDA Commissioner Young Tells HIMA*, THE GRAY SHEET, Mar. 21, 1988, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File.

86 *Id.*

87 *Recalls, supra* note 79, at 5 (discussing Ingram Trocar catheters).

88 *Recalls, supra* note 79, at 5.

89 *Recalls, supra* note 79, at 5.

before initiating the design effort, and certainly, before the release of the design to production.[90]

Another example of pre-production design defects are component design inadequacies.[91] Component design inadequacies include selection of components that have inadequate strength or quality, and are incompatible with other components, or the environment in which the device is used.[92] For example, catheters were recalled after it was discovered that their hubs cracked when swabbed with alcohol.[93] Evidently, in selecting raw materials to be used for the hub, insufficient consideration was given to conditions under which the catheter would be used and the substances with which it would come in contact during use.[94] Such design defects could have been prevented by design and material testing in the design phase.[95]

A final example of defective designs is found in the computerized software used in medical devices such as respirators, cardiac monitors and ultrasound equipment. A study of software-related recalls from 1983 to 1991 indicated that over ninety percent of all software-related device failures were due to design errors from failing to validate software prior to routine production.[96] Alarmingly, there are numerous medical device elements that need to be analyzed before production. However, none of them are inspected until the manufacturing stage. Generally, when the problems surface, the harm has already occurred.

IV. The European Community and Its Approach to Medical Devices

A. Overview: The European Community and Medical Devices

In sharp contrast to the United States, the European Community has taken an ex ante approach to the problems associated with the safety of medical devices. Unlike the United States, which allows defectively designed devices on the market and later attempts to chase them down and seize them, the European Community requires all medical device manufacturers to demonstrate the testing of their de-

90 *Recalls*, *supra* note 79, at 5.
91 *Recalls*, *supra* note 79, at 5.
92 *Recalls*, *supra* note 79, at 5.
93 *Recalls*, *supra* note 79, at 5.
94 *Recalls*, *supra* note 79, at 5.
95 *Recalls*, *supra* note 79, at 6, 15; *See generally* The Gray Sheet, Mar. 21, 1988, at 5, *available in* LEXIS, GENMED Library, Gray Sheet File.
96 58 Fed. Reg. 61,952 (1993) (to be codified at 21 C.F.R. § 820) (proposed Nov. 23, 1993).

signs and materials prior to market entry. No device in the European Community escapes design validation testing.

B. The History of the European Community and Consumer Legislation

The European Community[97] was originally formed after World War II to unite the nations of Western Europe and stimulate economic recovery and growth.[98] This goal became a formal political event when these nations signed The Treaty of Rome[99] in 1957 to establish the European Economic Community, also known as the "Internal Market" or "Common Market."[100] Under the Treaty of Rome, the nations hoped to eliminate obstacles to the free movement of people and resources by 1969.[101] However, they did not achieve that goal because of fiscal crises and a cumbersome bureaucratic infrastructure.[102] Yet, by the end of that period, European Community legislators recognized the need to protect consumers.[103] Due to organizational obstacles, the European Community took sixteen years to achieve formal consumer legislation.

In 1985 consumer legislation was officially recognized in the European Community when the "Commission's White Paper on Completing the Internal Market" was published.[104] It contained the "New Approach to Technical Harmonization and Standardization," which gave a new urgent priority to health and safety protection.[105] Moreover, it identified the national differences found in standards, legal requirements of manufactured goods, manufacturing sophistication and consumers' expectations, as genuine obstacles to free trade among the member states.[106] These problems were generally over-

97 France, Belgium, Luxembourg, Holland, West Germany, Italy, Denmark, Ireland, United Kingdom, Portugal, Spain and Greece. Elkes, *supra* note 16, at 566-67.

98 Joseph Tretler, Jr., *The Role of the American National Standards Institute in International Device Standards*, 45 FOOD DRUG COSM. L.J. 151, 152 (1990).

99 Treaty Establishing the European Economic Community, reprinted in TREATIES ESTABLISHING THE EUROPEAN COMMUNITY 207 (1977).

100 Elkes, *supra* note 16, at 563.

101 Elkes, *supra* note 16, at 563.

102 Elkes, *supra* note 16, at 563.

103 In Paris, The Community Heads of State and Government declared that an improvement in the quality of life must be the primary objective of economic development. This requirement obviously necessitated a Consumer Policy. EC Commentaries, 1992 Coopers & Lybrand Europe, *Consumer Policy*, Mar. 18, 1993 at 2.

104 *Id.*

105 *Id.*

106 *Id.*

come two years later, in 1987 under the Single European Act[107] which focused on consumer protection.[108]

C. The Single European Act

The Single European Act (SEA)[109], also known as the "Blueprint for 1992,"[110] became effective on July 1, 1987, and amended the Treaty of Rome.[111] The SEA incorporated the European Community's new goals of creating a single internal market free of all trade barriers by the end of 1992,[112] and granting consumers a "high level of protection."[113] The European Community members realized that free trade of products and services required certain standards, regardless of where those products and services originated.[114] This philosophy also carried over into the area of medical devices.

D. The European Community's Approach to Medical Devices

The European Community designed a unique and efficient system for regulating medical devices. In 1992, the European Community instituted "European Community Directives," which contain broad "essential requirements" for groups of products,[115] but not the specific standards the product must meet to get certified.[116] The "essential requirements" refer to the product itself, such as the materials from which a medical device can be manufactured.[117] The Directives propose that all medical devices must be certified according to a standard before the manufacturers can affix a "CE" mark to it.[118] A "CE" mark, "Communaute Europeanne," indicates that all pertinent

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107 Single European Act, reprinted in TREATIES ESTABLISHING THE EUROPEAN COMMUNITY 1005 (1977).

108 Elkes, *supra* note 16, at 563.

109 Single European Act, *supra* note 107.

110 Elkes, *supra* note 16, at 568.

111 Tretler, *supra* note 98, at 153.

112 The Single Internal Market program is an ongoing process. Some changes were in effect before 1992 and some were delayed until after 1992. Bob Straetz, *European Community Single Internal Market Opens*, BUS. AM., Jan. 11, 1993, at 8.

113 *Consumer Policy*, *supra* note 103.

114 Gary Spizizen, *The ISO 9000 Standards: Creating a Level Playing Field for International Quality*, 11 NAT'L PRODUCTIVITY REV. 331 (1992).

115 *Consumer Policy*, *supra* note 103; Michael J. Miller, *U.S. International Standards Strategies*, 46 FOOD DRUG COSM. L.J., 311, 312 (1991).

116 Margaret L. Moses, *Europe's New Product Safety Rule: Caveat Vendor*, N.J.L.J., Dec. 28, 1992, at 11.

117 Spizizen, *supra* note 114, at 332.

118 U.S. Dep't of Commerce, Int'l Trade Admin., *Medical Devices* 3 (1993).

European Community legal requirements for the product have been met[119] enabling sale in any member country.[120]

In general, the Directives impose an obligation on manufacturers, distributors and importers to market only safe products.[121] Additionally, they mandate informing the consumer of risks involved in the product's application.[122] Whenever the use of the product may be dangerous, the manufacturer must adopt measures to ensure consumers will be informed of such risk.[123]

European Community Directives on medical devices explicitly offer the manufacturer a choice between two standards to demonstrate that the product meets the "essential requirements" for product certification procedures.[124] One standard, the "type examination" is a traditional product certification which involves testing of the individual product itself.[125] The manufacturer must take each specific product to the national test house of every member country.[126] For some medical devices, clinical studies may be part of the process. This "type" method may take up to one year[127] to get a product certified in various countries due to product complexity, testing method and correspondence. This certification process is expensive and time consuming.[128]

The alternative standard attempts to eliminate the cumbersome type examination.[129] This second standard under the Directives, based on "quality assurance" techniques,[130] focuses on *systems* for managing quality rather than on the product itself.[131] Registration of a quality system is intended to ensure that a comprehensive plan is in place according to the original certified design specifications.[132] The plan should detail the product's life from inception and testing,

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119 Moses, *supra* note 116.

120 *Consumer Policy*, *supra* note 103.

121 *Consumer Policy*, *supra* note 103; Moses, *supra* note 116.

122 Moses, *supra* note 116.

123 Moses, *supra* note 116.

124 U.S. Dep't of Commerce, *supra* note 118.

125 March J. Laree, *Wisconsin Firms Take ISO on the Road*, CORP. REP. WIS., Aug. 1992, at 17; U.S. Dep't of Commerce, *supra* note 188.

126 Laree, *supra* note 125.

127 Laree, *supra* note 125.

128 Laree, *supra* note 125.

129 Laree, *supra* note 125.

130 U.S. Dep't of Commerce, *supra* note 118.

131 Quality standards are developed either in "response to inconsistencies that develop over time in the manufacture of a particular product or in anticipation of a new product or service." Spizizen, *supra* note 114, at 333.

132 Spizizen, *supra* note 114, at 333.

through how it will be serviced during consumer use. Only accredited agencies perform the required tests and issue certificates of conformity[133] authorizing a device to bear the "CE" mark. The European Community Directives cite the International Organization for Standardization 9000 series as a recommended standard for fulfilling quality assurance requirements.[134]

E. The International Organization for Standardization

The International Organization for Standardization (ISO) is a treaty-based organization founded in 1947[135] including over ninety Member countries.[136] ISO encourages the international trade in goods and services through the formation of global standards.[137] The standards use classical manufacturing technology to describe the essentials of a sound quality-assurance system.[138] The role of standardization provides a common ground and establishes a clear technical language through which companies, industries and countries may communicate.[139]

The ISO 9000 Series standards were published in 1987.[140] Forty nations have adopted the Series, or a similar version, as their national standards.[141] The ISO 9000 Series is not a European invention; many countries outside of Europe, including the United States, participated in the development process through ISO technical committees.[142]

Essentially, the standards require a third party, or a notified body, to perform a "head-to-toe" examination of the entire production process. These standards compel companies to document their quality control systems at every step of the manufacturing chain by identifying those areas that are causing quality control problems, and correcting those problems before manufacturing and selling the product.[143] The ISO 9000 Series standards do not apply to specific prod-

133 They are also referred to as "notified" bodies. U.S. Dep't of Commerce, *supra* note 118, at 4.

134 Moses, *supra* note 116.

135 James M. Gomez, *O.C. Medical Device Companies Await Marketing Breakthrough in Europe; Sales: The Plan By 12 European Nations To Create Closer Economic Ties May Provide A Bonanza For Local Firms*, L.A. TIMES, Aug. 9, 1992, at D1.

136 Spizizen, *supra* note 114, at 333.

137 Spizizen, *supra* note 114, at 333.

138 Laree, *supra* note 125.

139 Tretler, *supra* note 98, at 153.

140 Spizizen, *supra* note 114, at 333.

141 Spizizen, *supra* note 114, at 333.

142 Spizizen, *supra* note 114, at 333.

143 James Callari, *EC'92: Boon or Bust for U.S. Processors; Europe in 1992*, PLASTICS WORLD, Jan. 1992, at 36.

ucts, but are in effect, only a certification of the manufacturing process.[144]

The Series consists of five sets of standards or criteria numbered sequentially from 9000 to 9004.[145] The ISO 9001, the most complex standard, covers twenty production-related elements.[146] One critical feature of the ISO 9001 is that it mandates pre-production design controls requiring the manufacturer to demonstrate that the design and the materials of the device are safe for its intended use,[147]an essential element missing from the current FDA regulations.

The European Community, with exceptional foresight, pinpointed the origin of many medical device disasters and designed preventative legislation to avert such foreseeable tragedies by requiring manufacturers to demonstrate that a device's design and materials are safe for consumers before going to market. Sadly, the United States is just starting to recognize that its regulatory system, originally set up for medical devices over fifty years ago, and endlessly amended, is disastrously deficient.

V. The United States' Approach to Medical Devices Compared to the European Community's Approach

A. Comparing and Contrasting the United States' Regulations to the European Community's Device Directives

There are several superficial similarities between the United States' and the European Community's approach to medical devices. Both countries separate devices into three types of categories. The American system, under FDA authority, divides all medical devices into three classes based solely on consumer risk. Class III, the highest-risk devices are implantable devices such as breast, penile, and heart valve implants. Class II consists of medium-risk devices such as electrocardiographs, tracheostomy tubes, and neonatal incubators. Class I contains lower-risk devices such as ice bags, tongue depressors, and elastic bandages.

Similarly, the European Community classifies medical devices into three categories; however, this division is based on product simi-

144 Mary Saunders, *ISO 9000 and Marketing in Europe: Should U.S.Manufacturers Be Concerned; European Quality System Standards*, Bus. Am., April 20, 1992, at 24.

145 Spizizen, *supra* note 114, at 334.

146 ISO 9001 regulates twenty elements including training, marketing, design, purchasing, contract review, corrective action and record keeping. Laree, *supra* note 125.

147 Revisions Being Considered to Current Good Manufacturing Practices (CGMP) for Medical Devices, 55 Fed. Reg. 24,544 (1990).

larity and not on consumer risk. In the European Community, products are considered "regulated" or "unregulated," depending upon whether there is a specific European Community Directive pertaining to the particular product group.[148] Regulated products, such as medical devices,[149] are those which affect health, safety or the environment.[150] All regulated devices are divided into three specific European Community Directives: (1) the Active Implantable Medical Devices Directive (AIMD)[151] which covers a small product area including pacemakers; (2) the Medical Device Directive (MDD)[152] which covers the majority of all active and non-active devices; and (3) the In Vitro Diagnostics Directive (IVD)[153] which covers reagents[154] and test kits.[155] The European Community's Active Implantable Medical Device Directive is the only category that has a corresponding American category, Class III. Both classifications regulate implant devices. The European Community's Medical Device Directive and In Vitro Device Directive have devices that are classified in Class I and Class II in the American system; however, since the systems are based on different schemes, these two sets of categories are not directly comparable.

Although there are some commonalities between the American approach and the European Community approach, there are substantial differences. First, in the United States, a product can go to market by demonstrating to the FDA that it is similar to another product on the market prior to the 1976 Amendments. This "piggy-backing"[156] process has proven dangerous because a new product with design flaws can be approved for consumer use just because it is similar to a product already on the market that may have the same design flaws. As previously stated, this process has already permitted the sixty thousand to eighty thousand defective jaw implants to enter the market and harm innocent consumers. However, in the European Commu-

148 Moses, *supra* note 116.

149 *Revisions Being Considered to Current Good Manufacturing Practices (CGMP) for Medical Devices, 55 Fed. Reg. 24,544, supra* note 147.

150 Spizizen, *supra* note 114.

151 The AIMD went into effect on Jan. 1, 1993 with a two year transition period. Michael Fuchs, *Medical and Dental Instruments and Supplies*, U.S. INDUS. OUTLOOK, Jan. 1993, at 3.

152 The MDD is likely to go onto effect in early 1995 and will have a three year transition period. *Id.*

153 Work has only begun on the IVD and it is likely to lag behind that of the MDD. *Id.*

154 A reagent, in chemistry, is a substance used to detect or measure another substance or to convert one substance into another by means of the reaction which it causes. *Id.*

155 U.S. Dep't of Commerce, *supra* note 118, at 1.

156 HUTT & MERRILL, *supra* note 41, at 775.

nity, in order to get a product in the market, the specific product or its manufacturing process must demonstrate that it is in conformity with European Community standards and must earn the "CE" mark. The European Community laws simply inform manufacturers that if a device does not earn the "CE" stamp, it cannot be sold in the European Community. Under either European Community method, every device or its processes are individually scrutinized and, unlike the United States, cannot rely on the data of similar devices to escape government scrutiny.

Second, although FDA is authorized to require the development of performance standards for Class II and Class III devices, such development is not mandatory and is left to the sole discretion of the FDA according to agency priorities and resources.[157] As of today, the FDA has virtually abandoned the idea of performance standards for most medical devices.[158] By sharp contrast, the European Community has offered device manufacturers a choice between two standards to prove that their device meets the essential requirements. Although the European Community standards seem superficially voluntary, they are, in fact, required. The government funds the preponderance of health care in Europe, therefore, conformity with standards are a precondition for reimbursement of expenditures for devices by publicly funded health care providers.[159] This makes compliance with standards virtually mandatory.[160] While the United States has merely empowered the FDA with the authority to protect consumers, the European Community has *required* that consumers are protected.

Third, there is a vast philosophical difference between the United States' and European Community's public health policies towards medical device consumers. Although the FDA finally conceded that the medical device GMP should mandate pre-production design controls to ensure quality devices and prevent consumer injuries, the recent proposal suggests that such design controls should not apply to all medical devices.[161] Reprehensibly, this is the same mistake that Con-

157 21 U.S.C. § 360(j)(1993).

158 Adler, *supra* note 54, at 514-15.

159 Richard F. Kingham, *Regulation of Medical Devices in the European Community*, 47 FOOD AND DRUG L.J., 563, 564 (1992).

160 *Id.*

161 *Proposed Revisions to Current Good Manufacturing Practices (CGMP) for Medical Devices*, 58 Fed. Reg. 61,952 (1993) (to be codified at 21 C.F.R. § 820). The FDA did a cost/benefit analysis and declared that, "the benefits from subjecting all the device establishments. . .to the pre-production design elements were not great enough to justify the cost." The FDA is proposing to exempt ninety-five percent of Class I devices from design controls. *GMP Changes Add $84.5 Mil. to Annual Industry Costs; FDA Says Increase Would be Offset by Public Health and*

gress made when it passed the 1976 Medical Device Amendments which did not apply to all devices. Such gaping holes in the laws resulted in dangerous devices already on the market remaining there legally.

If the proposed GMP changes become law, there will still be marketable medical devices that are not required to demonstrate design validity. Such partial legislation lacks foresight. We are approaching the year 2000 when the modern technology of today will likely be archaic. The drafters of the Food, Drug and Cosmetic Law of 1938 did not anticipate such devices as breast implants and apnea monitors. Similarly, it is shortsighted not to anticipate the innovative technology of tomorrow. Therefore, it is critical that we place a standardized hurdle of safety for all future devices to jump over before they enter the market place. If the proposed regulations are approved it will just be another enormous legal loophole in the American device laws for injurious devices to once again be legally sold to innocent consumers.

By contrast, the European Community requires that manufacturers demonstrate that the design and materials of *all* medical devices are safe for consumers prior to the manufacturing stage. The European Community, in its efforts to protect the consumers from all dangerous devices, requires the product or its process to pass stringent third-party inspections in order to earn the "CE" mark of conformity to safety standards. This required symbol, which has no comparable American counterpart, makes it easy for European Community consumers to identify whether or not a device is legally on the market and safe for use. By requiring all medical devices to be subject to the same safety regulations, the European Community has quickly grasped a valuable lesson from American legislative mistakes. Unfortunately, the United States still does not comprehend the full message: No medical device should evade government scrutiny before it reaches consumers!

Lastly, the FDA's good manufacturing practice regulations for medical devices are so weak and vague that they could apply to a variety of industrial goods. The regulations do not specify what type of materials can or cannot be used for medical devices. Surprisingly, the regulations do not even apply to manufacturers of components, or parts of finished devices.[162] By contrast, the European Community

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Economic Benefits, THE GRAY SHEET, Nov. 22, 1993, at 3-4, *available in* LEXIS, GENMED Library, Gray Sheet File.

162 *Proposed Revisions to Current Good Manufacturing Practices (CGMP) for Medical Devices*, 58 Fed. Reg. 61,952, *supra* note 161.

has gone to great lengths to clearly and specifically state the "essential requirements" for the various medical devices. The essential requirements differ according to a device's intended use,[163] such as what materials may be used for various devices. However, the device's design and construction, including component parts, must be reviewed prior to its sale.[164] These key distinctions make the difference between the United States' vague and complicated approach, and the European Community's comprehensive and clear approach to medical device regulations. Unquestionably, these are life and death distinctions.

VI. FDA Regulations Should Emulate the European Community's Approach

A. Introduction

The European Community Directives are far more definitive and comprehensive in scope than the United States good manufacturing processes. The European Community Directives have set the stage for European consumers to purchase safer medical devices than American consumers. However, medical device legislation in the United States is well entrenched and cannot realistically be reformed with fresh legislation like that adopted by the European Community. To start over with a comprehensive new structure would have a monumental impact on the resources of hospitals, patients, physicians, manufacturers, legislators, FDA, Medicare, Medicaid and insurance companies. Therefore, the United States can realistically only add more "patchwork" regulations to the current laws. This section will recommend new device regulations for implementing an international standard within the current regulatory framework. The following section will examine its perceived drawbacks and potential benefits.

B. Recommendations for Implementing an International Standard

1. Adopt ISO Standard Verbatim

FDA should adopt the ISO 9001 standard verbatim. This internationally accepted standard includes a pre-production design validation requirement currently missing from American regulations. Additionally, such adoption would provide for harmony of the United States' and the European Community's standards. In turn, the European Community will allow American imports of medical devices. On the

163 Kingham, *supra* note 159, at 568.
164 Kingham, *supra* note 159, at 566.

other hand, if the United States does not adopt the European Community standards verbatim, the European Community will have reason to restrict imports from the United States.

2. *Mandate Pre-manufacturing Design Validation for All Medical Devices*

The United States should require all medical devices, regardless of risk category, to conform to the same regulations so that there are no loopholes for devices to slip through. The FDA should amend the current GMP regulations to mandate manufacturers to demonstrate that all devices presently on the market, regardless of class or level of risk, have safe designs. Such an amendment is essential as a clean-up effort for American devices to ensure that those devices already on the market are safe with regards to their design, materials and component parts. Since Congress started device legislation in the middle of the manufacturing process, it is critical that the FDA requires that manufacturers place pre-manufacturing controls not only on new devices but on those already in the marketplace. There should be a transition period whereby device manufacturers must establish that their device has been examined for design defects, and then they must submit a mandatory "Design Validation Report."

3. *Collect User Fees as a Source of Revenue*

User fees are the most efficient and equitable way to recover a portion of the private benefit that industry derives from federal regulation. There is a sound equitable rationale for user fees. Based upon equity principles, an identifiable beneficiary of a government service should at least pay the cost to the federal government of providing that service. Such fees are currently imposed on drug manufacturers seeking new drug approvals.[165] User fees are also employed in other arenas. For example, user fees are imposed on tollway users for repair expenses to keep the roads safe for travelers. Similarly, the profitable device industry must pay for the services they are requesting from the government. There are currently four untapped avenues for the FDA to assess.

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165 Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992). The FDA expects it will hire about six hundred new employees with the resources from the fees, which are expected to total more than $350 million over five years. Stuart L. Nightingale, M.D., *Prescription Drug User Fee Enacted*, 268 JAMA 3418 (1992).

a. Design Validation Report User Fee for Devices Currently on the Market

The FDA should require all manufacturers with devices currently on the market submit a Design Validation Report along with a one-time user fee. Like college or mortgage applications that require an application fee, the FDA should charge an application fee to offset the expenses incurred by additional reviewers.

b. Initiate User Fees for All New Medical Device Applications Which Include the Design Validation Report

The FDA should require that manufacturers submit all new medical device applications with a non-refundable fee to the FDA in order to pay for the time needed to review the general application, and specifically, the mandatory Design Validation Report.

c. Initiate User Fees for Medical Device Establishments

The FDA should require that all medical device establishments pay an annual fee to be registered with the government. Such a registration fee should be applied towards FDA services rendered, including consultations, reviews, inspectors, literature and other resources. As of June 30, 1990, approximately 13,000 domestic and 4,500 foreign medical device establishments were registered with FDA.[166] Therefore, an annual registration fee could result in valuable annual revenues which could be used to offset the costs of FDA activities to improve device safety.

d. Initiate User Fees on Medical Device Registrations

The FDA should require an annual registration fee for all FDA approved medical devices. Medical devices must be registered in case of recalls or safety alerts. The revenue from this fee should be directed to safety activities, including an annual evaluation of problematic devices reported under the Medical Device Reporting Regulations of 1984.

e. Spend User Fees Revenue on FDA Medical Device Sources Only

All revenues collected by the FDA from medical device companies should be directed towards FDA device-related activities, such as approvals, inspections, policy making and enforcement. Unless the

166 Hutt, *supra* note 156, at 785.

FDA channels the device revenues into making the industry a safer one for the public, there will be great resistance from medical device manufacturing associations.

f. Differential Fee Assessment for Small or New Medical Device Firms

Small and new medical device firms should be encouraged to access the market since innovative ideas and jobs are essential to the overall success of the program. Therefore, small and new firms should be granted a discount on their user fees.

The government would have to establish working definitions for the terms "small" and "new." The term "small" could either refer to the number of devices that a firm manufactures, or to the number of employees. A "new" firm could mean one that has been manufacturing devices for less than a fixed number of years.

4. Evaluate Recall Standards Annually

The FDA should annually evaluate those medical devices that cause injuries reported to the FDA under the Medical Device Reporting regulations of 1984.[167] This evaluation should include statistics about pre-manufacturing and manufacturing device problems, including the type of injuries sustained. The FDA should analyze this information in order to facilitate timely recalls of harmful devices.

VII. The Drawbacks vs. The Benefits

A. Overview of the Tension Between the Drawbacks and the Benefits of Harmonized Device Standards

It is difficult to quarrel with government statistics that illustrate the vast number of unsafe medical devices on the American market. Device manufacturers admit that design validation is a healthy focus for the industry. Yet, they argue the drawbacks outweigh the benefits. However, the advantage of having safe and effective medical devices on the market is not only economically favorable but is a just and humane social policy. Additionally, harmony with European Community device standards will not only afford American manufacturers greater profits from exporting opportunities but will positively impact other social and economic structures.

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[167] The most recent analysis of quality problems covers 1983-88 and the report was not available until 1990. *Recalls, supra* note 79.

B. The Critics

1. More Regulations are Too Expensive

Critics of additional device legislation allege expenditures to comply with any new regulations are too costly for manufacturers. However, this is shortsighted. Device manufacturers have many secondary costs associated with defectively designed devices which result in voluntary recalls, mandatory FDA seizures and exorbitant litigation expenses. Moreover, if after a seizure or recall, the manufacturer wants to keep its product on the market, it will inevitably need to return to the drawing board to recreate a new design for the device or replace it with better materials or components. Even the FDA concedes benefits to the public health will easily exceed the cost of compliance to new regulations. FDA calculated a manufacturers savings of five million dollars per fatality avoided.[168]

Initially, these recall or seizure costs include on-site inspections, user notifications, and shipping or medical waste disposal expenses. There are also re-manufacturing costs associated with redesigning the device, purchasing new materials, re-tooling the factory, retraining factory workers, re-educating salesmen, creating new sales literature and discarding old inventory. The health care industry is a small world, and the negative publicity of a recall adversely impacts sales and the goodwill of the company. Further, those consumers seriously injured from a device and unable to work become the financial responsibility of the taxpayers under the Social Security Disability program. Most importantly, the company pays enormous litigation expenses to defend a negligence or products liability lawsuit. Many multi-million dollar awards and settlements[169] result from defectively designed devices. Additionally, courts may give plaintiffs punitive monetary awards as high as three times the cost of the original jury award if manufacturers market defective devices.[170]

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168 *GMP Changes Add $84.5 Mil. to Annual Industry Costs; FDA Says Increase Would be Offset by Public Health and Economic Benefits*, THE GRAY SHEET, Nov. 22, 1993, at 3-4, *available in* LEXIS, GENMED Library, Gray Sheet File.

169 There is a proposed $4.75 billion settlement fund for silicone gel-filled breast implant recipients and individual settlements would range from $150,000 to $2 million. THE GRAY SHEET, Sept. 13, 1993 at 1-3, *available in* LEXIS, GENMED Library, Gray Sheet File.

170 Currently, there are more than five hundred lawsuits seeking compensatory and punitive damages totally more than four hundred million dollars against the manufacturer of the intrauterine device, Dalkon Shield. HUTT AND MERRILL, *supra* note 41, at 743; *see generally* Morton Mintz, *The Dangers Insurance Companies Hide; Insurers Don't Have to Tell You When they Know You Are About To Be Killed*, Wash. Monthly, Jan. 1991 (discussing the Dalkon Shield).

Initial costs of adapting to the proposed legislation are only short-term expenses; the manufacturer will eventually prosper from the long-term benefits. New standards can increase manufacturers' financial growth, because once their product is in harmony with the European Community standards, they can market it to the European Community which is a nineteen billion dollar medical products market, the second largest market behind the United States.[171] Industry analysts contend that the European Community is a "virtual hotbed" for medical device sales.[172] Finally, a decrease in defective products may result in substantially lower product liability rates for the manufacturer. Manufacturers who look only at today's costs foolishly miss tomorrow sales.

Clearly, taking the time to validate a device's design will be a more efficient use of resources. There will not only be a great deal of financial savings with design controls, but such a policy will spare manufacturers and consumers a great deal of pain and suffering.

2. *New Standards are Burdensome to Implement*

Manufacturers also claim that to comply with the ISO 9001 standards would be a "major effort."[173] However, American device manufacturers already comply with the ISO 9002 standards which begin from the manufacturing phase of production.[174] Manufacturers would not have to design a totally new system of manufacturing in order to comply with the next standard, because ISO 9002 is a subset of ISO 9001.

3. *Standards Should Remain Voluntary*

Device manufacturers assert that the government should not mandate quality.[175] They want design validation activities to remain

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171 The United States has the largest medical device market size, followed by the European Community, Japan, and Canada. Mexico, Taiwan, Korea and Australia tied in market size after Canada. Fuchs, *supra* note 151.

172 Gomez, *supra* note 135.

173 THE GRAY SHEET, June 3, 1991, at 12-14, *available in* LEXIS, GENMED Library, Gray Sheet File.

174 This includes manufacturing process controls, packaging process controls, equipment maintenance, reprocessing controls, manufacturing material removal, environmental control, finished device storage, and problems attributable to employee error.

175 *Silicone Implant Ruling not Popular with Industry*, CHEM. MARKETING REP., Jan. 13, 1992, at 4.

voluntary and left to their own discretion.[176] Unfortunately, that mind set created today's catastrophic situation.

Historically, the FDA counted on device manufacturing companies to carry out the necessary testing themselves, in an honest manner.[177] Although the FDA scrutinized the results of the manufacturers research, it rarely demanded the raw data and instead, relied upon the analyses and conclusions drawn by the company.[178] The validity of data submitted by medical device companies to the FDA has been increasingly questioned.[179]

Clearly the "honor system" is a sham. It has left the United States with injured consumers, bankrupt businesses and over-burdened courts. There have been more than 1,300 deaths, and thousands of serious injuries in the last decade alone resulting from the use of FDA-approved drugs and medical devices.[180] Manufacturers are often blinded by ambiguous clinical data. It is easier for manufacturers to focus only on the good aspects of the device, especially when there is no impartial agency checking the results.

Lax regulation is still the far greatest danger to the public's safety.[181] Regulation, after all, protects consumers from unscrupulous business practices.[182] Therefore, design validation regulations must be mandatory in order to compel compliance. Additionally, third-party inspections, required under the ISO 9000 Series, will put an objective police force at the plant.

4. There Should Be No Punitive Enforcement

Manufacturers not only want voluntary policy implementation, but, if regulations are created, they do not want to be subject to punitive actions.[183] The American device industry is a profitable market,

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176 *GMP Revision that Adopts ISO Standards Poses Some Problems, HIMA Says; Association Recommends Development of "Approach" for Using ISO 9000*, THE GRAY SHEET, Mar. 11, 1991, at 9-11, *available in* LEXIS, GENMED Library, Gray Sheet File.

177 Christine Gorman, *Special Report: Drug Safety; Can Drug Firms Be Trusted?*, TIME, Feb. 10, 1992.

178 *Id.*

179 Drug Approval Speedup Called Threat by HRG; Public Citizen Health Group, CHEM. MARKETING REP., March 23, 1992, at 3.

180 *Consumerists Say Approvals No Product Safety Guarantee*, CHEM. MARKETING REP., May 21, 1990, at 9.

181 Barnaby J. Feder, *F.D.A. to Investigate Safety of 5 More Medical Devices*, N.Y. TIMES, March 23, 1992, at D1.

182 Julie Kosterlitz, *High-Wire Act*, 22 NAT'L J. 1289 (1992).

183 *GMP Revision that Adopts ISO Standards Poses Some Problems, HIMA Says; Association Recommends Development of "Approach" for Using ISO 9000*, THE GRAY SHEET, Mar. 11, 1991, at 9-11, *available in* LEXIS, GENMED Library, Gray Sheet File.

generating more than thirty billion dollars in sales a year.[184] During the early 1990's, the United States was the largest producer, consumer and exporter of medical devices.[185] Yet, there have been unprecedented reports of criminal or negligent activities by drug manufacturers seeking approval for new medical devices.[186]

Clearly, the industry does not have a clean record and the honor system is a governmental disgrace. Consumers need to be protected from the profit-motivated elements of manufacturers who do not want to be punished for injuring the innocent consumer. Between the enormous profits and the intense competition to bring new devices to the $70.9 billion global market, there will be dirty hands unless there is strict enforcement of device validation regulations.[187] Congress must implement such regulations with powerful enforcement tools such as seizure, criminal contempt and treble damage awards.

C. Major Benefits of Additional Legislation

1. Safer Devices on the Market

The first step in producing a safe and effective medical device begins in the design phase. Thoughtfulness paid to the plan and materials of a medical device will increase the safety of that device's design. The FDA concedes that if it implemented mandatory design validation it would result in fifty-three fewer deaths and approximately 1,149 fewer serious injuries annually.[188] This is an unequivocal benefit to public health.

Logically, manufacturers examining a device under close scrutiny discover problems that will occur during the everyday use of the product. In order to insure that a design will be safe, its blueprint and material must be tested in the setting in which it will be used. Had the breathing device, mentioned at the beginning of this Comment, been tested for flaws with the devices design, it would not have electrocuted the eleven day-old healthy baby.[189]

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184 Feder, *supra* note 181.

185 Gomez, *supra* note 135.

186 Drug Approval Speedup Called Threat by HRG; Public Citizen Health Group, CHEM. MARKETING REP., March 23, 1992, at 3.

187 Fuchs, *supra* note 151.

188 *GMP Changes Add $84.5 Mil. to Annual Industry Costs; FDA Says Increase Would be Offset by Public Health and Economic Benefits*, THE GRAY SHEET, Nov. 22, 1993, at 3-4, *available in* LEXIS, GENMED Library, Gray Sheet File.

189 The shortcoming with the blueprint for the breathing devices that caused so many infants to be electrocuted involved its connecting wires, called leads. Correctly used, a lead is attached to the baby's chest and connected to the apnea monitor. Another lead is attached to a different opening in the monitor and plugged directly into the electrical wall socket. The fatal design flaw

The jaw implant device highlights the other area, where design defects occur with regard to the material selected. The manufacturer selected inferior material for use between the jaw and the skull which could not withstand the constant use and pressure of the motions of the mouth. Eventually, the material fragmented and migrated to the skull, causing the user ceaseless, excruciating pain. This, in turn, required patients to undergo numerous surgeries to remove the device and repair the joint. Disturbingly, the device's expected failure rate is one hundred percent![190] The substance selected for the TMJ device could have effortlessly and inexpensively been examined by putting the device in the TMJ joint of a test skull, and motorizing the jaw to move and grind under the same pressure. Eventually, the material would have fragmented in the laboratory without having to fragment the lives of sixty thousand to eighty thousand consumers.

By contrast, the European Community's approach recognizes the significance of ensuring that manufacturers design a device that is compatible with its environment before production. The European Community mandates that pre-production design validation must occur before the device gets to the manufacturing process, or to the consumer. Although the European Community is still passing the laws into effect, European consumers will no doubt benefit from the prior experience of American legislative blunders.

Furthermore, the European Community has essentially barricaded itself against disastrous American devices because no device can be sold on the European Community market without design validation and the CE seal of compliance. Additionally, the European Community has mandated its safety requirements, instead of wasting time and lives with a ludicrous voluntary system like that utilized in the United States.

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manifested itself when a busy or untrained user connected the two leads together without connecting them to the monitor. The plugs fit directly and easily together. Thus, the lead from the baby's chest could be connected into the lead going directly into the electric outlet. This resulted in a direct surge of electricity into the baby's body. This scenario is what an electric chair is designed to accomplish. Ultimately, such an erroneous design begged for accidents.

This design flaw could have been readily detected if natural use investigations were mandated. If, in a pseudo-hospital or home setting, an experimenter was asked to use the device in as many ways as possible, this defect would have inevitably surfaced. The answer, while still in the pre-manufacturing stage, would have been to make the input/output connection incompatible so that no direct attachment could possible be made. This is exactly what the manufacturer did after tragically discovering the design defect during in vitro use. However, another fatal mistake was made when the original leads were never taken off the market after the new ones were manufactured. THE GRAY SHEET, Sept. 6, 1993, at 7, *available in* LEXIS, GENMED Library, Gray Sheet File.

190 *20/20: After The Cure* (ABC television broadcast, Oct. 8, 1993).

2. *Greater Exporting Opportunities to the European Community*

The European Community is a significant player in the medical device industry. Accordingly, American device manufacturers, with foresight, can benefit from its presence. The mid-1990's represents an opportunity for non-European companies to do business within the European Community which has 345 million consumers and a $6.2 trillion market.[191] Compliance with the ISO 9000 Series would make it easier and quicker for American manufacturers to export their medical devices to countries in the European Community. Manufacturers will no longer need to alter products to meet a multiple set of local standards,[192] and instead will deal with one market rather than with twelve.[193] European Community physical barriers such as custom controls and border formalities cost companies six billion dollars in delays and red tape.[194] This will decrease with the integration of European Community member countries,[195] and ISO registration of American products.

American medical device manufacturers with foresight are taking advantage of the European Community changes by setting global financial goals.[196] United States exports to the European Community reached $3.4 billion in 1991, about sixty-one percent of total medical device imports to that region.[197] The European medical device market presents tremendous opportunities for American companies to maximize growth.[198] Clearly, registration with ISO 9000 is a cost of admission for doing business in Europe.[199] Therefore, ISO registration will be a must for any American company seeking the benefits of

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191 Don Linville, *Doing Business in the Single Market*, BUS. AM., Mar. 8, 1993, at 20.

192 Elkes, *supra* note 16, at 563.

193 Steven M. Schneebaum, *Products Liability in the European Community: What Does it Mean for U.S. Companies?*, 44 FOOD DRUG COSM. L.J., at 283 (1989).

194 Elkes, *supra* note 16, at 570.

195 Elkes, *supra* note 16, at 563.

196 Mary Wagner, *The New Era in the European Marketplace*, MOD. HEALTHCARE, Oct. 1, 1990, at 26.

197 Gomez, *supra* note 135.

198 Wagner, *supra* note 196. The European Commmunity has a large aging population with corresponding medical problems. Medical device manufacturers who concentrate on the needs of the elderly in America could benefit the elderly in the European Community as well as providing devices such as canes, hearing aids, and pacemakers. James M. Gomez, *Medical Device Companies Await Marketing Breakthrough in Europe; Sales: The Plan by 12 European Nations to Create Closer Economic Ties May Provide a Bonanza for Local Firms*, L.A. TIMES, Aug. 9, 1992, at D1.

199 Spizizen, *supra* note 114, at 331.

the European marketplace.[200] In competing against European suppliers in the post 1992 European Community environment, an American manufacturer who has not upgraded its system to ISO 9000 standards will be at a competitive disadvantage.[201] A more consistent dedication to standards development would improve the United States position in the international medical device arena .[202] Medical devices regulated by stringent European Community standards will almost certainly be marketable anywhere else in the world.[203] Therefore, changes in the American standards will not only open the door to the European Community, but to Japan,[204] Canada,[205] and other countries.[206] The prospects for exporting sales are enormous.

Additionally, such growth will correspond with creating new jobs which will benefit the American economy. Employees will be needed at all levels of manufacturing from the factory to the sales force. New factories and office buildings will be needed which will boost the construction business. Therefore, the new legislation will be a win-win situation, not only for device manufacturers, but also for the labor force and consumers.

Lastly, there is a beneficial domestic by-product of focusing on international harmonization of device standards. Although many companies still see the standards as a prerequisite for international trade, more and more are discovering that, in fact, ISO compliance is a factor in their United States business.[207] Using ISO standards can improve a company's marketing position because registration has become a de facto marketing requirement in its particular industry.[208] Where high product reliability is crucial, and two suppliers are com-

200 Jonathan B. Levine, *Want EC Business? You Have Two Choices*, BUS. WK., Oct. 19, 1992, at 58.

201 Moses, *supra* note 116.

202 THE GRAY SHEET, Mar. 18, 1991, at 11-12, *available in* LEXIS, GENMED Library, Gray Sheet File.

203 James Callari, *EC'92: Boon or Bust for U.S. Processors; Europe in 1992*, PLASTICS WORLD, Jan. 1992, at 36.

204 Japan has the largest single-nation market for medical products outside the United States. Fuchs, *supra* note 151.

205 Canada has the second largest single-nation market, behind Japan, for medical products outside the United States. Fuchs, *supra* note 151.

206 Mexico, Taiwan, Korea, and Australia share an identical market share behind Canada. Fuchs, *supra* note 151.

207 Laree, *supra* note 125.

208 Laree, *supra* note 125.

peting for the same contract, the one with the ISO 9000 registration may provide the needed competitive edge.[209]

D. Further Beneficial Effects of New Legislation

1. International Exchange of Medical Technology

Another benefit of ISO 9000 registration is the international exchange of scientific information with foreign governments.[210] As scientists and physicians work together to develop harmonized device standards, they will create an environment to share and relate new medical information. As universal diseases become more complex, the sharing of device technology will be even more critical to doctors and their patients. This proposal will expedite scientific discoveries, make better use of expertise and avoid duplication of work.

2. Decrease in Products Liability Litigation

The United States is a litigious society whose citizens are ready, willing, and able to file suit against anybody and everybody who causes injury. Medical device litigation grew by seventy percent from the 1960's through the 1970's, and continues to grow.[211] During the 1990's, American judges and juries have awarded multi-million dollar damage verdicts to medical device implant recipients.[212] Additionally, experts contend that legal costs would be in excess of one hundred thousand dollars per case if each of the TMJ cases proceed through the courts individually.[213]

Currently, there are 1,800 devices on the market, and with estimates of over 90,000 new and improved devices coming into commerce by the year 2000, product liability litigation will explode unless manufacturers pay attention to device designs. The chain reaction will be devastating. Manufacturers will continue to purchase costly insur-

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209 Mary Saunders, *ISO 9000 and Marketing in Europe: Should U.S. Manufacturers Be Concerned; European Quality System Standards*, BUS. AM., Apr. 20, 1992, at 24.

210 THE GRAY SHEET, Jan. 25, 1993, at 6-7, *available in* LEXIS, GENMED Library, Gray Sheet File.

211 John Agar, *Labeling of Prescription Devices for the Food and Drug Administration and Product Liability: A Primer-Part I*, 45 FOOD DRUG COSM. L.J., 447 (1990).

212 A jury awarded a forty-eight-year-old woman $8.6 million in damages because she developed connective cell disease when one of her breast implants ruptured. Some attorneys estimate one thousand lawsuits pending against breast implant manufacturers. D'arcy Jenish et al., *Beauty and the Breast; Thousands of Canadian Women have Implants, and Many Now Fear the Effects*, MACLEAN HUNTER LIMITED, Mar. 9, 1992, at 38.

213 *Judge Approves Plan for Paying Vitek Tort Liability Claims*, UPI, Oct. 22, 1989, *available in* LEXIS, News Library, UPI File.

ance, thus driving up the device price. This, in turn, hits the American citizen, both as a consumer and taxpayer.

By contrast, if manufacturers scrutinize products in the design phase for defects and alternative designs, there will be a natural decrease in injuries because less defective devices will be placed on the market. Such activities will have a beneficial impact on decreasing products liability in our society. Thus, the costs of devices will either stabilize or decrease, benefitting consumers.

3. *Manufacturing Benefits*

There are also numerous documented manufacturing benefits from adopting the European Community's ISO approach to medical device legislation. Cost savings as a result of standardization will be enormous.[214] By consistently reviewing the entire manufacturing chain, from pre-production through market use, actual production costs are reduced as processes are refined.[215] This review will ultimately result in safer, less expensive products coming off the manufacturing line. Additionally, increased consistency in production processes, especially from shift to shift, will also reduce process deviations and variability.[216] Manufacturers consistently providing higher quality products will result in less rework, less customer returns, and less time spent solving customer problems.[217] This will also reduce costly inspections and warranty costs.[218] Moreover, such reviews will increase manufacturing yields.[219] Finally, it will allow for better on-time delivery resulting in more business[220] and bigger profits. Quality consultants estimate that seventy percent of American companies, including medical device companies, could improve by implementing a quality system along the lines of the ISO standards.[221] It is difficult to argue with such success.

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214 Elkes, *supra* note 16, at 572.

215 Spizizen, *supra* note 114, at 337.

216 Spizizen, *supra* note 114, at 337.

217 Spizizen, *supra* note 114, at 337.

218 Spizizen, *supra* note 114, at 337.

219 Spizizen, *supra* note 114, at 337.

220 Cyndee Miller, *U.S. Firms Lag in Meeting Global Quality Standards*, MARKETING NEWS, Feb. 15, 1993, at 1.

221 Laree, *supra* note 125.

VIII. CONCLUSION

The medical device industry and the FDA cannot permanently improve that which they cannot control.[222] Lax legislation followed by insufficient regulations of medical devices has actually harmed consumers in numerous instances and, more importantly, has left consumers vulnerable to potential injury in the future. As a result, the federal government should require device firms to prove that a design is safe before it is sold. Additionally, the United States government must remedy previous mistakes by requiring medical devices currently in the stream of commerce to submit design validation reports. It would be a repeat mistake for the United States to treat certain medical devices differently from others and to allow some to circumvent the proposed design validation requirements.[223] Once again, the United States has an opportunity to sew up the hole in medical device legislation. Hopefully, this will be the last repair.

222 March J. Laree, *The Best & Worst of ISO 9000*, CORP. REP. WIS., Aug. 1992, at 10.
223 58 Fed. Reg. 61,952, *supra* note 76.