# "LEFT TO OUR OWN DEVICES, WHAT DID WE GET WRONG?" THE MEDICAL DEVICE AMENDMENTS OF 1976 AS SEEN FROM THE INSIDER'S VIEW

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## ABSTRACT

In this article of historical commentary, veteran scholar Prof. James O'Reilly brings the reader back four decades into the turbulent climate which gave rise to the 1976 Medical Device Amendments. He and the other creators of the final text began their negotiations in 1975 with the conceptual framework which regulators and congressional staff had outlined, but they resisted any effort to follow the costs and complexities of the New Drug Application process. "Substantial equivalence" was a core gatekeeping step that was intended to be a temporary bridge for the comparison of newer devices with prior existing "predicate" devices. But a combination of urgent factors led to FDA staff's broadening of the norm of equivalence, into a mini-approval process that was new ("de novo") rather than predicated on existing devices. Other 1976 Act provisions, such as section 518 which failed in the tampon crisis of 1980, were the subject of unexpected problems. The reader will find a first-hand account of the very early roots underlying medical device law's several later statutory corrections.

## 1. THE HISTORICAL ROOTS OF MEDICAL DEVICES

This discussion builds upon the several eras of Food & Drug Administration history. Anyone can read the text of the Medical Device Amendments of 1976,[1] but it may help to know why some key decisions were made and why some of the decisions have failed in light of subsequent experience.

The 1906 Pure Food and Drugs Act, the ancient foundation of today's FDA, contained no mention of medical devices.[2] In 1917, the federal entity that later became FDA noted the difficulty of controlling "fraudulent mechanical devices used for therapeutic purposes."[3] By the time of the 1938 Act, a definition of medical devices

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1 Pub. L. 94-295, 90 Stat. 539 (1976).

2 Act of June 30, 1906, 59th Cong. 2d Sess. (1906)

3 This history is explained at length in JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD & DRUG ADMINISTRATION § 3 (4th ed. 2014-) [hereinafter "O'Reilly"] https://www.westlaw.com/Browse/

was added. Medical devices were treated in general as having the same functional roles as drugs, but with no chemical action that drugs have such as when metabolizing in the bloodstream or on the skin.[4] Senator Bennett Champ Clark of Missouri objected. He stated that regulating a mechanical item as if it were a drug "is the same thing as if Congress . . . should attempt to say by law that calling a sheep's tail a leg would make it a leg."[5]

During the 1930s, after FDA was created out of an office in the U.S. Department of Agriculture , were developing a slow awareness about this broad set of products, and they were aware of their inability to deal with fraud resulting from gaps in the "drug" regulatory system used for devices.[6] Some FDA Trade Correspondence defined specific items as devices,[7] but only when FDA was asked and when it cared to answer. Although the obviously fraudulent "quack" devices were a small problem, the government faced the legal challenges in the 1930s as it sought to conduct enforcement through criminal and litigated seizure remedies. Federal prosecutors had to prove each element of the offense, so the statute addressing "drugs" had to be construed to confer jurisdiction over the "machine" or "device" at issue. The operative definition of the 1906 Act for a "drug" was strictly construed in favor of the criminal defendant.[8]

During the 1960s, the dormant definition of a device from the 1938 Act was applied to a diagnostic product whose maker insisted that it was not a "drug." In 1969, when the Bacto-Unidisk diagnostic was treated as "drug," in an opinion by the U.S. Supreme Court,[9] stretching "drug-ness" was unsustainable. Accordingly, the Department of Health Education & Welfare (HEW) created a Medical Device Study Group headed by Dr. Ted Cooper, and in 1970, the resulting Cooper report recommended legislative reform to distinguish "device" definitions from the 1938 category of "drug-ness."[10] Critics said those new [Cooper proposals? Proposed amendments to the FD&C Act?] are too inclusive so that they would cover as a device "well nigh everything in Creation."[11]

## 2. WAS FDA READY TO WORK ON MEDICAL DEVICES?

As of 1970, only one professional within FDA's Bureau of Drugs dealt with all questions about this amorphous category of "devices."[12] FDA did not have a home-

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Home/SecondarySources/HealthLawSecondarySources/HealthLawTextsTreatises/FoodDrugAdministrationFourthEdition?contextData=(sc.Default)&transitionType=Default&VR=3.0&RS=cblt1.0.

4 21 USC 321(h) added by Act of June 25, 1938, ch. 675 §201, 52 Stat. 1040 (1938); *see* P. Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99 (1989).

5 O'Reilly *supra* note 3, § 18:1; *see* C. Dunn, Federal Food Drug & Cosmetic Act 287 (1938).

6 C. Dunn, Federal Food Drug & Cosmetic Act 287 (1938).

7 For a list see O'Reilly, *supra* note 4, at 18:2.

8 Richard Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996) [hereinafter "Merrill"].

9 United States v. An Article of Drug . . . Bacto-Unidisk . . . , 394 U.S. 784 (1969).

10 HEW Study Group on Medical Devices, Medical Devices: A Legislative Plan (1970).

11 Merrill, *supra* note 8, 1812 n. 189 (1996)

12 *Id.*

grown cadre of experts. In 1971, authority under the new Radiation Control for Health & Safety Act of 1968[13] had been assigned to FDA and much of that work [on characterizing devices? Laboratory analysis of devices? X-rays referred to below? Something else?] was conducted in Winchester, Massachusetts at the "WEAC" Laboratory. By 1973, FDA launched its "Center for Devices and Radiological Health" headed by John Villforth with ninety-five employees.[14] Major efforts continued on X-Rays and other radiological products at the WEAC laboratory. But to develop a flexible regulatory control system for other devices would require congressional action.

The 1969-70 effort to design a regulatory system took the form of a study by the Cooper Study Group, whose 1970 report was very insightful.[15] HEW pondered deeply how to "ramp up" device oversight to implement the Cooper Report through legislation. The initial budget request allocated 228 positions to FDA for device work in fiscal 1975. HEW told Congress that FDA needed an additional $17 million appropriation for devices.[16]

Congress was typically slow because there seemed to be no health crisis. Lengthy subcommittee hearings began in 1973, but the several potential bills that had been introduced or considered were dormant amid the Watergate crisis of the 1974 Congress. After drafts were revised in winter 1974-75, there were four days of hearings in July 1975, and then the bills were marked up for eight subcommittee sessions. The near-final text of the Medical Device Amendments finally came out of committee for floor votes in January 1976.[17]

## 3. WHAT STIMULATED CONGRESS TO PASS LEGISLATION?

I was honored to be one of the keynote speakers on FDA's 100th birthday in 2006, and my talk concluded that the common element across the history of FDA has been a belated Congressional grant of powers and budgets to perform a "cleanup" role after health disasters had involved substandard food or substandard drugs. Crisis led to recognition of need, and that recognition led to positive regulatory empowerment.

How does a crisis come to be recognized as a basis for legislative reform? When the U.S. invaded Cuba and the Philippines during the 1898 war with Spain, disease and bad canned food killed more troops than did Spanish defenders. Congress heard from the public and from the "muckraking" press, especially following the publication of Upton Sinclair's exposé, the book "The Jungle." Congress eventually responded by passing the 1906 Pure Foods and Drugs Act.[18]

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[13] 42 USC 262 et seq. and 21 USC 360kk.

[14] Merrill, *supra* note 8, 1812 n. 189 (1996).

[15] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong. 2d Sess. (1976).

[16] *Id.*; H.R. REPT. NO. 94-853.

[17] *Id.*; *see also* S. Junod, *Commemorating the 40th Anniversary of the 1976 Medical Device Amendments*, 77 FOOD DRUG & COSM. L.J. 26 (2017).

[18] Act of June 30, 1906, 59th Cong. 2d Sess. (1906).

In 1901, the country needed a vaccine to address the St. Louis cholera outbreak. However, the vaccine that was produced was contaminated. Congress responded with adoption of a vaccine law.[19]

In 1937-1938, a novel untested drug, elixir sulfanilamide syrup, killed 104 people. Congress was outraged and revived a dormant legislative proposal which required submission of drug data and drug samples for the FDA's awareness of each new drug entering the market.[20]

Although the marketing of the European pregnancy drug thalidomide never really began in the U.S., experimental use of the drug [in 1962?] led to phocomelia deformity cases in seventeen American children.[21] This "morning sickness" relief drug was not approved for marketing in the U.S. because of the insistence on more detailed clinical safety data by an FDA drug reviewer, Dr. Frances Kelsey. Kelsey continued to resist during six rounds of debate with the drug's sponsor, which vigorously insisted on beginning U.S. distribution. Kelsey became a celebrated hero. Congress responded to news of the risky drug approval process with the 1962 Drug Amendments, which were adopted to establish the pre-approval stages of review of a drug's efficacy [and safety].[22]

So where were medical devices? By 1970, in contrast to the history of dangers arising from new drugs, there were only a few cases of medical device fraud, mostly involving false claims of cures A few fraud claims led to consumer-protection advocacy in the late 1960s and early 1970s,[23] but there had not yet been a safety crisis. Historically, FDA legislative changes often came after a crisis.

In 1970, officials of the Department of HEW had sent their Cooper Study Group Report to Congress and told Florida Democratic Representative Paul Rogers that legislative response to the device problem was needed. The Cooper Report found "10,000 injuries directly related to medical devices over a ten year period, of which 751 had proved fatal . . . "[24] Of particular interest were pacemakers, intrauterine devices, and heart valve implants.[25] HEW cautioned that FDA would need budget upgrades and extended powers and authorities to adequately oversee the newly expanded category of medical devices.[26]

Consider the situation before the 1976 device law was passed. Without any regulatory controls, electrical or mechanical products such as a heart pacemaker came on the market claiming benefits. It was generally not until a device failure that survivors might be able to sue the device maker. We can assume the tort liability system was not sufficient to recompense the survivors of those whose pacemakers

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[19] Eugene A. Timm, *75 Years Compliance with Biological Product Regulations*, 33 FOOD DRUG COSM. L. J. 225 (1978).

[20] C. Dunn, Federal Food Drug & Cosmetic Act (1938).

[21] *See* Comment, *The Food & Drug Administration: Law, Science and Politics in the Evaluation of New Drug Technology*, 67 NW. U. L. REV. 858, 868 (1973).

[22] Pub. L. 87-781, 76 Stat. 780 (1962).

[23] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong.2d Sess. at 7 (1976).

[24] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong.2d Sess. at 9 (1976).

[25] *Id.*

[26] Merrill, *supra* note 8.

failed.[27] The Dalkon Shield became another much-litigated device failure.[28] Before there was legislation requiring device approval, the victims could sue the device maker. Tort liability claims were one way to retrospectively punish a sloppy manufacturer, if it was not bankrupt by the time a lawsuit in the liability case was filed. Further, such a remedy was lengthy, uncertain, costly, and backward-looking (i.e., after the harm had occurred).

Accordingly, an efficiency value of regulatory consumer protection could be asserted. One could contrast reactive remedy for a device victim in private civil tort actions long after the harm occurred with the proactive the assurances afforded to patients by the FDA scientific assurance that drugs are safe and effective before patients receive them.

In 1973, lightning struck, or did NOT strike, as some of the electronic pacemaker leads marketed by General Electric (GE) health systems failed.[29] The pacemakers' failure came with allegations of insufficient warnings despite GE's knowledge of the risk. This had deadly consequences for some Florida cardiac patients. This GE pacemaker incident set the stage for Congressman to create new legislation to increase product scrutiny. Recognize the pattern: inaction by industry had a health consequence, and once again that resulted in calls for legislation.

The congressman from Tampa began seeking to fix that process, but it was not a rapid congressional response. Paul Rogers' subcommittee took on the role of investigating what GE knew and when GE knew it.[30] GE soon departed the pacemaker business. What Congress saw was a contrast in safety: that proposed new drugs were reviewed by FDA, but new devices had no screening or pre-approval. In the 1973 congressional hearings, the instances of the known product failures were highlighted as support for giving FDA "good manufacturing practice" authority over medical devices.[31]

Subcommittee hearings by the House Health Subcommittee diagnosed the risk of medical device products' lack of regulatory oversight, by contrast to FDA scrutiny of drugs. One could look back to where the new drug approval system stood in 1973, before adoption of FDA User Fees legislation and its congressionally-mandated deadlines for decisions[32]. Drug approval by FDA for a new drug entering the drug marketplace at that time was slow, expensive, and secretive—aspects which industry felt should be avoided in a new structure of regulatory controls for medical devices.

Accordingly, FDA's new drug approval process was an unattractive paradigm for medical device industry innovators. However, in addition to very close scrutiny of novel drug innovator formulations, there had been developed a classification alternative for familiar "generally recognized" drugs, an approach that could be copied in new device law.[33] FDA lawyers under Chief Counsel Peter Hutt had bypassed the

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[27] *See e.g.*, Dreiling v. General Elec. Co., 511 F.2d 768 (5th Cir. 1975).

[28] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong. 2d Sess. at 9 (1976).

[29] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong. 2d Sess. at 9 (1976).

[30] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong. 2d Sess. at 9 (1976).

[31] H.R. REPT. NO. 94-853; Medical Device Amendments of 1976, 94th Cong. 2d Sess. at 9 (1976).

[32] Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250 (2002).

[33] 21 C.F.R. § 330.

new drug apparatus and invented the OTC Drug Monograph system in 1972,[34] and the system utilized expert panels which continued into the late 1980's.[35] This "OTC Drug Review" set one standard for all non-prescription drugs for a particular class of use, like dental cavities: several active ingredients were allowed, some classes of inactive ingredients were allowed, and the benefit claims were restrained.[36] Co-existence here was a novel legal creation; the FD&C Act did not offer an easier classification track for non-prescription drugs, but Peter Hutt had invented one.

So the time was (unfortunately) right, when the GE pacemaker electrical failure incidents came to Rep. Rogers' attention. His district around Tampa had many retirees, and so the local news media alarm among the voters set the stage for legislation to progress from early drafts of statutory proposals. Some change would need to occur, supported by a wave of reformers in support. A parallel Senate bill had not drawn much attention.[37] The device industry faced significant shifts of regulatory power toward FDA, and a team was assembled to work on the legislation.

## 4. THE ACCIDENTAL TOURIST

I joined the device industry drafting team's discussion in 1975 as its youngest and junior member. My employer, Procter & Gamble, had started selling a line of hospital disposable drapes made with heavy absorbent paper, which P&G sold in kits along with disposable patient care gear for hospital use when delivering a baby or managing enteric feeding.[38] P&G had paid its small membership fee to the Health Industry Manufacturers Association, which later became AdvaMed. They solicited team members, and my time was expendable as the junior lawyer for the company. It helped that I understood most of the FDA issues because I had studied in the first law school class offered by a full time faculty member on FDA law and procedure, Dick Merrill, at the University of Virginia School of Law before Dick became FDA's Chief Counsel in 1975.

I learned early that some strong characters were engaged in this debate. I was in awe of Captain John Villforth, the FDA's radiation device expert, and I learned a lot from House and Senate career staffers. However, I was dubious about some of the large pharma/device/diagnostics companies and their Washington counsel. The large companies often had drug subsidiaries that had mastered the FDA's new drug processes. They saw the new legislation as a vehicle to avoid replicating the slow process of drug approvals in their device subsidiaries. These large companies wanted to use the device legislation to smooth their launch or upgrading of new medical product technologies with minimal FDA interference.

Separately, some participants in the debate also sought to hijack the reform train. They wanted to abolish the recent *Park* doctrine establishing individual criminal liability of corporate executives, which the Supreme Court had recognized in a 1974

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[34] *Id.*

[35] For detailed background on the OTC Drug Review, *see* O'Reilly, *supra* note 3, at ch. 13.

[36] Daniel F. O'Keefe, Jr., *The Over-the-Counter Drug Review – Helping the Client Make Decisions*, 29 FOOD DRUG COSM. L.J. 262 (1974).

[37] S. 510, 94th Cong. (2d Sess. (1975).

[38] Views expressed are solely those of the author, who retired from Procter & Gamble in 1998; factual items herein are a matter of public record.

appeal of an FDA prosecution.[39] FDA disagreed and questioned the "unanimity" among the affected industries to weaken this form of deterrence; that proposed change did not make it into the legislative draft consensus.[40]

## 5. STRUCTURE OF PRODUCT APPROVALS

The device law's proposed route for new products to enter the market was a three-level structure, based on the suggested routes in the 1970 HEW Cooper Report.[41] Each proposal made its way into the legislation, though with adjustments along the way. These include:

> (1) Preclearance of a new device via the premarket approval application in section 515[42] is an aspect of this device framework most similar to the drug NDA.[43] This more risky device receives detailed review by FDA and a panel of experts,[44] and the approval may impose specific conditions. The process is expensive and time consuming, and the industry group and the congressional staffers agreed that it should be reserved only for the highest risk devices, like heart and lung implants. The Cooper Study Group Report called on FDA to "issue guidelines to define the scientific content of applications to permit assessment of safety and performance characteristics and effectiveness."[45] HEW insisted that premarket approval should only be tied to a criterion of unreasonable risk; this generated the statutory approval standard allowing approval of a Class III device if experts could "fairly and reasonably" conclude the device would be effective.[46]
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> (2) Our industry group expected that classification and reclassification decisions would be the primary vehicle for most all devices entering the market. Petitions for reclassification[47] were to be frequent and efficient. This followed Peter Hutt's model of the less intensive OTC monograph pathway,[48] similar to the approach for devices. We did not expect what actually followed. Sadly, the Carter Administration's HEW budget for 1977 did not adequately address FDA fiscal needs for rolling out the new law, while HEW was under pressure

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39 United States v. Park, 421 U.S. 658 (1975).

40 Legislative action to reverse the Park liability was strongly opposed by HEW. H.R. Rep. No. 94-853, at 60 (1976).

41 *See generally* Theodore Cooper, Device Legislation, 26 FOOD DRUG COSM. L.J. 165 (1971).

42 21 U.S.C. § 360c (2017).

43 21 U.S.C § 355 (2017).

44 This portion of 21 U.S.C. § 360e(c)(2) (2017) mandates an advisory panel review, and by contrast the Panel review for new drugs had been an FDA practice but was not mandated by 21 U.S.C. § 355. An insightful review is Ellen J. Flannery, *The Safe Medical Device Act of 1990: An Overview*, 46 FOOD DRUG COSM. L.J. 129 (1991) [hereinafter "Flannery"].

45 HEW Study Group on Medical Devices, *supra* note 10, at 15.

46 21 U.S.C. § 360c(a)(3) (2017); *see also* O'Reilly, *supra* note 3, §18:61.

47 21 U.S.C. § 360c(e) (2017).

48 21 C.F.R. § 330 (2017).

> for constraints on the FDA's existing programs. The cuts in the requests for spending on devices in the inaugural HEW fiscal year 1977 budget showed how devices were struggling as the "new kid on the block" at the end of the line, sitting in a partially used rental building in Silver Spring MD, about 20 minutes' drive away from FDA offices in Rockville MD.
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> (3) General Controls is the base line for all devices of any type, if they "do not present potential risk."[49] About 30% of devices were given this classification by FDA in 1976-1984.[50] This general FDA oversight status includes good manufacturing practices, records and reports, etc. The new law recognized the ability of any company with a low-risk Class I device to come on the market easily after a mere notification. The class I device maker would assert its easy adoption of this lowest classified status, by simply drawing comparisons to already-marketed low risk devices, doing so through the 510(k) "substantial equivalence" comparative analysis.[51] The nursing home supply of elderly incontinent persons' diapers are a favorite example of a class I device with general controls.[52]

Much of the device industry team's 1975-76 jawboning during debates and hearings was related to Class III device statutory language concerning premarket approval applications.[53] The focus was on what device clearance would NOT be—it was NOT to replicate the vastly complex NDA process for approval of new drugs. This effort led the industry team to draft its desired wording for the 515 premarket approval process, in a way that favored the experienced and best-funded applicants.[54] FDA would later need to expand upon its 515 discretion.[55] Although consumer activist groups existed, they did not, at that time seem to care greatly about the nuances of medical device approvals.

Another failing of the drafting team was the weak provision for FDA to scrutinize on the "old" pre-1976 risky devices. No deadline for review of those existing devices was included.[56] Only ten of the 1,200 Class III devices were subjected to intense scrutiny between 1976 and 1990.[57] The process of supplementing a premarket approval was largely ignored until 1990.[58]

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[49] 21 U.S.C. § 360c(a) (2017).

[50] U.S. Congress, Office of Technology Assessment, Federal Policies & The Medical Device Industry 105 (1984).

[51] 21 U.S.C. § 360(k) (2017).

[52] H.R. Rep. No. 94-853, at 34 (1976).

[53] *See id.*, at 42; *see also* 21 U.S.C. § 360c(e).

[54] The key players on the industry side tended to have long experience of the NDA review stages; one can speculate that their sales would likely have been diminished by a competitor's quick entry into the market with a competing device.

[55] The 1990 amendments expanded provisions on device review. *See* Flannery, *supra* note 44.

[56] Merrill, *supra* note 8, at 1813.

[57] Howard M. Holstein, *The Safe Medical Devices Act of 1990: Product Approval Changes and Access to PMS Data*, 46 FOOD DRUG COSM. L.J. 153, 154 n. 8 (1991).

[58] Merrill, *supra* note 8, at 1813.

In addition, not all of the innovations included in the statute were practical. For example, the Product Development Protocol was a concept from our industry team that remained dormant for twenty-two years, with the first use of this provision in a device approval in 1998.[59]

## 6. SUBSTANTIAL EQUIVALENCE

The draft legislation's 1975 negotiators had agreed to three levels of market entry, based upon risk. As a result, the operative question became: If the device being launched is not a new high tech Class III approval project, how should FDA review it as it enters the device marketplace? What should sponsors of the more ordinary devices need to show?

The choices were either "similarity" to an existing "predicate" device, or screening applicants for some measure of safety and efficacy. Industry preferred the "similarity" approach, which entailed a straight comparison of old and new products.

I do not recall why we negotiators during that busy period chose the term of premarket "substantial equivalence,"[60] but I suspect it was a term borrowed from patent law. FDA was told to look at the predicate device that the applicant firm chose, and if the FDA reviewers saw the same set of characteristics, and if they did not act for 90 days, the device would be deemed to be cleared.[61]

Soon after enactment, however, the patent lawyers awoke to our team's "poaching" of their term from the patent law doctrine of equivalents, with their words' special meaning. Patent lawyers were concerned that those words in arcane patent jargon would undercut the patent applicant's element of originality.[62] Accordingly, they insisted that Rep. Rogers send a letter to the FDA Commissioner stating Rogers' intent that the new law's use of "substantially equivalent" was only so much "equivalence" as in medical device terms, and that a company filing such a notification was not conceding that its patented device was "substantially equivalent" to an older device, as that term of art is used in patent law. Chairman Rogers did, in fact, send that letter to the FDA. Our "oops moment" was saved!

## 7. WAS OUR MISSION LEFT INCOMPLETE?

The special mission for our industry negotiating team was easy: promote greater speed from development to marketing; determine the amount of premarket scrutiny based on degree of risk; place fewer constraints on innovation, with less cost; and show an awareness of limits of clinical experimentation in light of the nature of some devices. Like Hippocrates' "first do no harm," our team's mission was to avoid the

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[59] 21 U.S.C. § 369e(f) (2017); *compare* William F. Weigel & Charles J. Raubicheck, *How to Comply with the New Medical Device Law*, 31 FOOD DRUG COSM. L.J. 320, 323 (1976) *with* Bradley M. Thompson, *Resurrecting the Product Development Protocol for Medical Devices*, 46 FOOD DRUG COSM. L.J. 187, 203 (1991).

[60] 21 U.S.C. § 360c(f) (2017); 21 C.F.R. § 807.

[61] 21 U.S.C. § 360(k) (2017).

[62] In brief summary, a claim is not "original" in a patent application if the patent owner admits the invention is substantially equivalent to an existing product. Many patent texts offer extensive background on these issues.

lessons learned through the NDA route for new drugs[63] with its delay and costs, as we sped up market entry for lower risk products. In drafting legislation, much work needed to be done to differentiate these processes to avoid the easier route of Congress replicating the existing NDA new drug model[64] as the channel for new medical devices.

We also had to recognize that 1976 was a presidential election year for the surprising post-Nixon president, Gerald Ford. To keep this much-deliberated draft of life-saving legislation away from presidential politics, we in the industry team were eager to have the bill pass in early 1976. By May, the bill was signed into law.

How did that timing tie in to a clearance process? Remember that the new law would perhaps pressure the makers of newly launching medical devices to avoid delays in clearances by reaching marketing status before the new law's effective date, and the law's set of "grandfathering" provisions served as a protection for the future of that product. Accordingly, there was a strong incentive for device companies to ship as much medical device inventory as possible, across state lines, for that device to be deemed "old,", that is, deemed to travel in interstate commerce before the effective date of May 28, 1976.[65] The incentive was lawful, and certainly legitimate, for differentiating pre-existing devices from "new" device products.

I still have on my desk the marble paperweight commemorating the sudden rush of activity that May. Our factory in Memphis shipped a small number of cases of our medical device hospital disposable gowns, drapes, and gear to a local warehouse customer just thirty-eight minutes away, across the Tennessee/Mississippi border. The decorative paperweight reproduces, in miniature form, the actual shipping receipt, a remembrance to those of us making these devices officially "old." It was our client's "thank you" for arranging to send each of the hospital kits, e.g. plastic tubes for patients with needs for tube feeding, south across that state line, to make them "old" devices for which pre-clearance processes would not be needed, then or in the future. Although this process was lawful, some device makers did not realize this pathway was an option until after May 28, when they began to face their duty to submit to FDA certain information to be able to market their "new" and modified devices.

## 8. THE OPTIONAL ADDITIONAL PROVISIONS

The draft legislation also included a mixed bag of additional powers, including current good manufacturing practice requirements (borrowed from the drug provisions);[66] and adverse event reporting,[67] and the non-judicial removal from the market of a risky device was the goal of §518's "death penalty."[68]

Willingness of industry to allow more reporting of adverse experiences post-market was important, but there was a twist. Yes, industry would receive a complaint from a provider, such as a hospital. Yes, FDA wants to monitor these adverse events to look

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[63] 21 U.S.C. § 355 (2017).

[64] 21 U.S.C. § 355 (2017).

[65] A "pre-enactment" (prior to the effective date of May 28, 1976) device was not required to report to or seek permission from FDA.

[66] *See* 21 U.S.C. § 360j(f) (2018).

[67] *See* 21 U.S.C. § 360i(a) (2018).

[68] *See* 21 U.S.C. § 360h(b) (2018).

for trends. The FDA form for reporting these adverse events associated with devices was the Form FDA-3500A. Those, such as myself, who were designated as an "Official Correspondent" would sign and submit the form when serious injury related to use of our device was alleged to have occurred. The devices that were associated with the adverse event were to be identified on the form. However, we can speculate that FDA employees who drafted the official reporting form overlooked the legal consequences of the following choice. Only one of two distinct causes of harm had to be chosen by the person filled Block B-1 on that form and needed to determine whether this adverse event was caused by a **User Error** or **Product Problem**.

Consider the product liability consequence of the company representative signing the official form and making such an "admission against interest." No prudent company would ever check the FDA form's box indicating that the company's medical device product was the cause of the patient's injury. In retrospect, there may often have been two dueling reports filed on the same incident; the product maker filled in the "user error" field, blaming the doctor or nurse, while the hospital provider filled in the "product defect" field, blaming the designer. This issue of rival defect reports was not one that industry had chosen to create, but we can speculate that these dueling claims about causation were the result of a design-of-forms error by someone inside FDA.

In retrospect, our industry team effort missed a big opportunity. Because there had not been real consideration of the products liability issues at the outset, we did not think ahead to install an express escape valve for those who comply with standards. The industry could have put into the package a "get out of jail free" card for the better-behaved Class II or III device marketers. It cost years of effort from layers and millions of dollars of legal fees in litigation and to win a special immunity status for the Class III devices, which could have sailed through in spring 1976.[69]

## 9. WHAT WAS FDA MISSING?

In 1981, five years after he led the congressional effort to adopt the 1976 Medical Device Amendments, Chairman Paul Rogers said the law's philosophy "was to be so specific in language that less discretion was left to the agency – a first step in the trend in the Congress to make clear that Congress wanted the agencies to follow the Congressional mandate more carefully and not go off on bureaucratic binges pursuing bureaucratic whims."[70] Industry, of course, concurred.

What was missing at FDA on Day One for Devices, May 29, 1976? First and foremost was the shortfall of the funds and personnel that would be needed to actively study and classify new incoming devices. Our drafting team had been considering the model of FDA's successful OTC drug review process,[71] which was well organized with outside panels that created sets of well-defined and straightforward criteria for each class of use of the non-prescription drugs. These criteria contrasted the contents

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[69] *See e.g.,* Medtronic v. Lohr, 518 U.S. 470 (1996) (finding victory for the device innovators after three years of litigation).

[70] Paul Rogers, *Medical Device Law – Intent and Implementation*, 36 FOOD DRUG COSM. L.J. 4 (1981).

[71] 21 C.F.R. § 330 (2018).

and claims of each newly entered OTC drug to a standard active ingredient in dose and potency.[72]

For devices, however, Class II product classification standards needed to be written. We expected that Congressional funding would follow the adoption of the new product clearance structure. FDA now had the legal authority, but it needed technical expertise and staff to give a baseline of comparisons for those newly marketed products. Regrettably, Congress failed to deliver the funding; it was about twelve years, aroud 1988, before the device classification standards were all in place.[73] FDA still has a reclassification process,[74] like a dinosaur in a museum, while the 510(k) has morphed into a front line tool, just by virtue of some creative efforts to "make do."

## 10. HOW THE GATEKEEPER BECAME THE COMPARITIVE MONITOR

The absence of funds to open a robust safety and efficacy classification model for new device products led to dependence on "predicate" devices as the primary product benchmark. This meant that applicants relied heavily upon the "me, too!" analysis rather than the review of safety and efficacy established based on models such as the OTC Drug review standards.[75] The 510(k) "substantial equivalence" evaluations for FDA review teams in 1977 were not required to judge the device's safety and effectiveness, a significant retreat from the scope of the OTC drug review decisions.[76] FDA veteran Robert Temple was critical of the limitations in the 510(k) review in a 1993 retrospective.[77]

Comparison is not qualitative evaluation. Such an analysis as a gatekeeper of devices was flawed because it began with the flawed contrast to the 'old" devices—artificially pegged before the effective date of May 28, 1976. This includes, for example, like my client's kits of hospital drapes, which moved across state lines to become "old" at whatever time the product had been launched.

The second flaw in the original 510(k) was the ninety-day "default" timing provision.[78] FDA could act on the notification within 90 days, but if it did not, the product would be deemed to be cleared for marketing.[79] This echoed the problem drugs had faced before the 1962 amendments; if the drug product's category was deemed to be "generally recognized" as safe and effective, it would enter the market. This enabled to slip through the system drugs that would later be found to have serious deficiencies. Because of this, FDA reviewers had a quandary. For fourteen years from 1976 to 1990, FDA knew that if it failed to stop the device within ninety days of premarket notification, then it would automatically be deemed sufficiently safe and effective to

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[72] *See* 1 J. O'Reilly, *supra* note 3, § 13:22.

[73] *See* 21 U.S.C. § 360g (2018).

[74] *See* 1 J. O'Reilly, *supra* note 3, § 18:10 (detailed analysis of process).

[75] 21 C.F.R. § 330. (2018).

[76] *See id.* (detailing the panel review of "old drug" nonprescription products, which was not required of the medical devices entering the market).

[77] *See* FINAL REPORT OF THE COMMITTEE FOR CLINICAL REVIEW (1993)115, 128-29 (1993), *as reprinted in* LESS THAN THE SUM OF ITS PARTS (1993).

[78] *See* H.R. REP. NO. 94-853, at 31 (1976).

[79] *See* 21 U.S.C. § 360(k) (2018).

enter the market on day ninety-one. In 1990, the law was amended to require an FDA decision to clear the device,[80] and inaction by FDA was no longer deemed to be a substitute for approval.

The politics of the device premarket clearance situation, although unusual in 1976, became bizarre in 2012. Focusing on the 510(k) process, the Institute of Medicine recommended a set of changes. FDA incorporated those changes into a non-binding guidance document, but the device industry heavily lobbied for Congressional action against the IOM recommendations. In 2012, Congress stated that FDA "shall withdraw" its guidance and that the IOM views shall not be part of any FDA medical device decisions or actions.[81] That slap heard 'round the FDA showed the political power of device makers.

But let's look at the big picture of the Act as a whole: §510 is a registration and listing paperwork section of the Act; it does not require FDA decision-making as does §505 and §515.[82] This widespread use of notifications under 510(k) assumes that the sponsor of a modified or new device had stayed close to that device's original design, because the sponsor wanted to avoid undertaking the huge burden of the full §513 PMAA.

How did the drafters fail? If our intent had been to let only the truly safe and effective devices pass through the gatekeeper's scrutiny, we sadly failed. That is because "equivalence" simply did not follow criteria of safety or of effectiveness, and "equivalence" was just a sponsor's claim based on mechanically contrasting the new device product, down the line of one product being matched to another. Is it equivalent because it is red vinyl? Is it six inches like its "predicate"? Is there a twenty degree curve? If so, it is substantially equivalent by the contrast method, but not the safety comparison. FDA device reviewers found, as public health reviewers, it to be a dissatisfying chore.

Soon after the May 1976 kickoff, we began to see reports of 510(k) clearance in which the FDA device reviewers were accepting more recent products as predicates, and we saw only 2% of the 510(k) submissions rejected for lack of clinical data to support the products' claims.[83] Most of the premarket notifications sailed through the review process.[84] FDA would eventually request that Congress revise certain provisions of the approval process, like those made in the 1990 device amendments. The eventual creation of a fictional "de novo" or new non-comparative category is a result of this odd comparison.

The logic of the 1976 premarket clearance language meant that a device with no "predicate" product to which it could be compared could not be substantially equivalent. Logically, equivalence requires some existing known medical device to which the new item can be compared. The equivalence standard of §510(k) was never intended to be a good fit for the newer design or newer benefit claims, which we expected to routinely proceed through reclassification or to undergo the full premarket approval process.

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[80] *See* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 16(a)(2), 104 Stat. 4526 (1990).

[81] 18:23.50

[82] *Compare* 21 U.S.C. § 355 (2018) *with* 21 U.S.C. § 360c (2018).

[83] *See* Merrill, *supra* note 8, at 1820.

[84] *See id.* at 1819.

Dissatisfaction inside the FDA with the comparison role was soon evident. From outside the Office of Device Evaluation's review team, those who followed devices sensed a desire for review to become more qualitative and less routinely comparative, though the design of the 1976 statute left qualitative review within the provisions for Class III devices and section 515 reviews. What was happening behind the scenes? Creative reviewers inside FDA began to expand their authority by calling some 510(k) products "de novo," Latin for "new," even though it was illogical to stretch the concept of equivalency to encompass newness. Flying a new device into CDRH without having a predicate would mean a mini-PMAA review would occur; this would contravene the statutory language. Remember what Chairman Paul Rogers had said about the 1976 Act: "Congress wanted the agencies to follow the Congressional mandate more carefully and not go off on bureaucratic binges pursuing bureaucratic whims." Years later, the Congress accepted the FDA's view of the "de novo" 510(k) process.

The result of informally allowing device review teams to apply lesser comparisons and more evaluative roles in 510(k) clearance reviews was that fewer devices were sent into Class III. The FDA did not often insist on Class III premarket approval, the statutory "gold standard," but accepted a less stringent showing of support for a de novo 510(k) clearance.[85] Was FDA engaging in what Rogers had called a "binge" and a "whim," or was the de novo 510(k) an appropriate bureaucratic response to public health needs? Reasonable minds can differ.

## 11. WHAT DID WE GET WRONG IN 1975-76?

First and foremost, the industry team assumed that FDA's classification decision makers would be lined up in the Agency's Silver Spring headquarters, with inboxes full of petitions for classification of the newer innovative Class II devices that would be submitted under §514. We had assumed that a temporary bridge would carry across the mere registering of any new device; so Congress included that notification provision in the registration and listing requirements of the Act, §510.[86]

Unfortunately, FDA ran short of funding, the ninety-day clearance waiting times increased, and the device industry ran short of viable predicates within the pre-1976 universe of devices. Accordingly, that seemingly simple §510 bridge for notices of new product comparison changes to existing devices was swamped, and reviewers insisted that an "improved" version of a product would not be accepted as equivalent if the marketing claims about product benefits were expanded.[87]

Looking back at 1975-76: Could legislators have simply put in a "de novo" option from the outset? Could our industry negotiating team have convinced device companies and the Congress to install a two-tier clearance procedure, if we proposed having two qualitative evaluation paths drawn in parallel, one easy and one hard, for device companies that applied?

No. If the drafters had put into the law a "de novo" provision for market entry in the 1976 legislation, such a move probably would have confused the small handful of

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[85] *See* 21 C.F.R. § 807 (2018); Ethicon, Inc. v. Food & Drug Admin., 762 F. Supp. 382, 389 (D.D.C. 1991).

[86] *See* 21 U.S.C. § 360(k)(2) (2018); *see generally* U.S. GOV'T ACCOUNTABILITY OFF., PEMD-88-14,FDA's 510(k) Operations Could Be Improved (1988); Alan H. Kaplan, *Through the Maze of 510(k)'s*, 39 FOOD DRUG COSM. L.J. 160 (1984).

[87] *See* Merrill, *supra* note 8, at 1817-19.

congressional staff members for whom device safety was a priority. From the industry side, we would not have won acceptance of the full PMAA in section 515. The drafters saw the distinction and wrote the PMAA and 510(k) routes of market entry as distinct routes. There was never an intention to have created a type of 510(k) de novo as a form of "515 approval light." But looking back, that seems to be what clearance for a "de novo" has turned out to be. Congress returned to the issue years later and allowed this approach to "equivalence" in the amended statute.

Second, as mentioned briefly above, our team failed to touch upon product liability defenses. We could have imposed product liabilities on device firms or equipped them with tort immunities, but the 1976 law was silent. Our mistake was in not determining the parameters of the product liability defense. If the industry participants in 1976 could have foreseen the advocacy work that led to the 1996 Supreme Court's *Lohr* decision[88] and subsequent rulings, it would have been much less expensive for industry to have placed product liability wording expressly into the statute in 1976.

Sadly, devices sometimes fail, patients sometimes die, and lawyers embrace loopholes. Accordingly, millions of dollars have been spent on lawyers' creativity in litigation, in which they often seek an elusive implicit legislative intent to have shielded some class III devices from liability. The rationalization is that no civil trial juror could find a device maker liable for a defect in design if the FDA Class III device reviewer had not anticipated and rejected that attribute of design. We were realists, and such a rationalized excuse for risky design flaws would not have passed the "laugh test" in 1976.

Third, the drafters looked for a way to address FDA's desire to halt the marketing of bad devices more quickly without awaiting court proceedings. We debated how to do this and then borrowed from the 1966 Radiation Control Act remedies section.[89] Section 518 was ultimately a compromise.[90] The device industry sought a balance to constrain FDA's desire for access to that recall authority by expanding the procedural safeguard system through the steps that must precede the use of new mandatory product recall powers.

There's a "story inside a story" on the failure of these 518 administrative remedies.

## 12. THE OVER-BURDENED SECTION 518

FDA's then-Chief Counsel Nancy Buc was an energetic pioneer who expected to use new enforcement tools like §518 when the tampon cases, discussed below, arose in September 1980. FDA had used this tool once, on a hair-growth product, as part of an unreported court case in Buffalo in 1978. However, in those cases, section 518 failed for FDA because too much administrative process was required.

A very small percentage of women have a certain biochemical variant of staph aureus in their menstrual fluid, which can generate a toxin under certain conditions of heat and time. As the technology of cellulose absorbent materials increased, it became possible to create and sell an overnight tampon that would capture and prevent leaks of menses into clothing or bedding. Three major designs were launched by three competing companies, and each was registered as a medical device manufacturer.

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88 Medtronic, Inc. v. Lohr, 518 U.S. 407 (1996).

89 21 U.S.C. 360pp (2018); 21 C.F.R. § 1020. (2018).

90 *See* H.R. REP. NO. 94-853, at 73 (1976).

The weekend of Labor Day of 1980, three physicians at the Centers for Disease Control and Prevention engaged in phone interviews with approximately seventy-one women who had, according to CDC, been treated for the newly recognized condition known as "toxic shock syndrome." One of the questions posed during the interview asked what tampon the woman had been using when she became ill.

The phone interviews indicated that users of Procter & Gamble's Rely tampons appeared to show a statistically greater propensity for toxic shock syndrome than the users of Playtex or Johnson & Johnson's O.B. Over the months preceding the phone interviews, thirteen million free sample boxes of Rely had been distributed. We will never know which of the women had used Rely and which saw the free sample box of Rely tampons when the caller from CDC invited them to look for their bathroom supply. CDC privacy rules prevented tampon companies from interviewing the TSS patients. So we will never be able to reconstruct the sequence of events.

My phone rang at mid-day on September 16, 1980, when section 518 of the recent Medical Device Amendments got its first major use. Procter & Gamble, maker of Rely, was told to withdraw the tampons from sale nationwide, pursuant to FDA's section 518 authority. FDA asked P&G to meet with the Deputy Commissioner, the director of the Center for Device and Radiological Health, and then-Chief Counsel Nancy Buc. Buc prepared a very strong document titled "Settlement of Charges under §518"and demanded we sign. I stated that FDA had not followed the statutory requirements for action. FDA had not made a finding under § 518(a), had held no hearing under § 518(b), and had issued no order under § 518(c). As a result, FDA recognized that the product recall power in the four-year-old Medical Device Amendments was not as easy to use as some had thought.

Instead, FDA accepted the voluntary withdrawal from the market proposed by P&G. Agreeing to withdraw its product from the market instead of fighting made commercial sense. It also made logical sense, even though the price was huge.

However, the general counsel of the PhARMA trade association told me in a bitter tone that "[a] lot of people in this town are sticking pins in your doll over that one!" Translated, the large drug companies that are members of PhARMA wished that P&G had not agreed to conduct a product withdrawal; they would have preferred that the company confront FDA in court. To this day, I am convinced that the long term trust of women consumers for corporate responsibility mattered more that the PhARMA lawyer's bravado about scoring points against FDA.

Accordingly, Rely was removed. FDA was pleased with follow-up visits that showed 100% retrieval from the market, Playtex was spending years bitterly fighting against adding a warning to its product labeling, and those 2.2 billion Rely tampons had been burned for electric energy at an energy facility. But apart from the FDA issues, P&G had zero punitive damages from the many toxic shock syndrome cases, while its competing tampon makers who remained in the marketplace were required to pay, according to jury verdicts, about $80 million to plaintiffs. We delivered the company's special testing machine, the "synthetic vagina," to the FDA labs. The tampon warning rules have been in effect since 1982.[91]

You can study section 518 without much difficulty. It is short and associated with only two court decisions. The 1990 and 1992 amendments made it somewhat more clear; but the tool FDA thought it had been given proved to be much more procedurally

[91] *See* 21 C.F.R. § 801.430 (2018); 47 Fed. Reg. 26989, (June 22, 1982).

challenging than FDA had thought. Building process into legislation can affect administrability.

## 13. HOW FAILURE OF 1976 CHANGES BRED LATER AMENDMENTS

The device industry saw what was not working well during the 1980's. It successfully sought the de-regulatory 1990 Safe Medical Devices Act[92]. This reflected industry's attempt to "fine tune" the deficiencies in the 510(k) substantial equivalence system. By 1990, both industry and FDA wanted to be relieved of the classification process for Class II devices, and FDA wanted to be rid of the automatic "deemed approved" status that takes effect ninety days after the premarket notification was filed. FDA wanted to be rid of this constraint because of time pressures arising from the shortage of review personnel. The smarter industry players knew that FDA enforcement officials would be able to retract any automatic "deemed clearance" in case of trouble, so all sides were better served by having an affirmative decision. A an authority that was not granted in the 1976 law was subsequently granted in 1990: the power for device reviewers to require clinical data, but at a level of intensity less than that which is required for the submissions for §515 premarket approval.[93]

Yet, the desire to routinely make a decision about a device in 510(k) often stumbled because the FDA to readily interpreted a modification in an existing device to be "significant," and the result was a constipation of the system. By 1993, there were nearly 2,000 backlogged 510(k)s, and the review time for a Class III device had risen to 21.5 months. There were 6,434 510(k) devices submitted in 1994, and 5,498 were cleared after an average review time of 184 days. Premarket approval delays reached 649 days in 1994.[94] Does this reflect the simple quick system that was intended?

Let me step back and clearly say, NO! If we drafters in 1975-76 had known the budgets would be so low that it would take more than six months to clear a 510(k) device and more than twenty-one months to clear a class III device, the industry team would have resisted the 1976 amendments. The HEW budget for 1977 and 1978 was the X factor, causing a backlog and delays that none of us had anticipated. It was the much later MDUFA user fee legislation that has made the difference.

## 14. CONCLUSION

History will judge that the 1976 work product was imperfect. Were the imperfections of the 1976 Act going to be the basis for the 1990, 1992, 1997 and later changes? My answer is "probably yes," but each section and each revision deserves its own attention. If the post-1976 FDA had been blessed with user fee money like MDUFA[95] provides today, some of the outcomes would have been different. But that's the fun of legislative retrospection; we will never know.

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92 Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4526 (1990).

93 *See id.* at § 5(a)(2).

94 *See* Merrill, *supra*, note 8, at 1832.

95 *Medical Device User Fee*__Amendments (MDUFA), U.S. FOOD & DRUG ADMIN., https://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/default.htm [https://perma.cc/98SB-UHHB].

Historians warn policy makers: "Those who do not learn from history are condemned to repeat it." Now at age 71, I appreciate the opportunity to talk with my students about these policy choices and errors in the 1976 statute, all of which form the roots of today's device regulation. I urge future students of medical device law to learn from these experiences.