I. INTRODUCTION

Consider this hypothetical scenario: In the early 1980s, Major Pharmaceutical & Medical Devices Company acquires Small Silicone Breast Implant Company, to function as a subsidiary. For several years, the acquired subsidiary manufactures and sells silicone gel breast implants at a substantial
profit. Then in 1988, the Food and Drug Administration ("FDA") informs the breast implant industry it will seek safety data from all manufacturers. The FDA relies on powers given to it 12 years earlier in the 1976 Medical Device Amendments. Silicone breast implants remain on the market while this data is gathered. Some data are eventually submitted by Major Pharmaceutical & Medical Devices Company and other companies in the industry. The FDA reviews the data and deems them inadequate. The FDA commissioner's announcement of the inadequacy of the data coupled with the decision on January 6, 1992, to call for a voluntary moratorium on the sale of breast implants remains on the market while this data is gathered.

1. A real-life example of this hypothetical scenario is MEC, Bristol-Myers's breast implant subsidiary. MEC was profitable every year between 1983 and 1990, increasing total sales from $14 million in 1983 to $65 million in 1990. In re Silicone Gel Breast Implants Prods. Liab. Litig., 887 F. Supp. 1447, 1451 (N.D. Ala. 1995).


4. See infra notes 128-57 and accompanying text.


The legal basis for the FDA's decision was straightforward. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act require that medical devices be shown by their manufacturers to be safe and effective before they may be distributed and used. . . . What many participants in this debate have failed to recognize is that under the law, "grandfathered" devices such as breast implants must eventually meet the same requirements as new devices: they must be shown to be safe.

Id. (emphasis added) (citation omitted). Kessler was appointed commissioner of the FDA in 1990. ANGELL, supra note 6, at 50.

8. Kessler, supra note 7, at 1713.
implants provokes an outcry that breast implants are dangerous. Tens of thousands of women with breast implants contact their lawyers and gather in an attempt to form a class. Some are featured on "The Connie Chung Show," causing near hysteria in some women, and starting an avalanche of products liability litigation against implant companies. By now, Major Pharmaceutical & Medical Devices Company's liability (potentially billions of dollars) far outweighs any profits Small Silicone Breast Implant Company could ever possibly have made.

Did the management of Major Pharmaceutical & Medical Devices Company improvidently acquire Small Silicone Breast Implant Company, thereby exposing Major Pharmaceutical & Medical Devices Company to these liabilities and legal bills? Or did management exercise sufficient "due diligence"? That is, was there a sufficient investigation of Small Silicone

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10. See infra notes 53-55 and accompanying text.


13. Id. at E6 (quoting then-CBS reporter Connie Chung declaring "a huge public health crisis might be looming").

14. See, e.g., William Bunch, Self-Surgery Woman in Hospital, NEWSDAY, Apr. 22, 1992, at 22; Claire Spiegel, Self Surgery on Breast Implants Stirs Warning, L.A. TIMES, Apr. 18, 1992, at A18. An extreme example of this hysteria is the case of a New Mexico woman who in desperation crafted a homemade scalpel from a disposable razor and, with valium as her sedative, slit her own breasts to squeeze out reconstructive implants from a double mastectomy. Id. Her desperation stemmed from not being insured for the operation, coupled with a doctor, with whom she appeared on "The Maury Povich Show," informing her she was infected. Bunch, supra, at 22.


16. In reality, breast implant manufacturers Bristol-Meyers, 3M, and Baxter initially agreed in 1994 to a massive class action settlement with approximately 440,000 women worth $4.25 billion. Id.

17. Cf. discussion supra note 1.

18. Black's Law Dictionary defines "due diligence" in general as "[t]he diligence reasonably expected from, and ordinarily exercised by, a person who seeks to satisfy a legal requirement or to discharge an obligation." BLACK'S LAW DICTIONARY 468 (7th ed. 1999). In the context of mergers and acquisitions, a more precise meaning is "[a] prospective buyer's . . . investigation and analysis of a target company." Id. See also In re Integrated Res., Inc.,
Breast Implant Company, including the regulatory status of its medical devices and its potential liabilities? Should Major Pharmaceutical & Medical Devices Company have known better?

While this hypothetical scenario may seem unlikely, it happened not once,

147 B.R. 650, 654 (S.D.N.Y. 1992) (referring to due diligence as "the detailed investigations necessary to informed decisions about [an] acquisition"). In this context, due diligence is essentially a business concept. Was sufficient investigation made? Was sufficient information uncovered to sensibly value the entity being acquired, taking into account its actual and potential liabilities?

This is separate and distinct from the meaning of "due diligence" in federal securities law. There, the term refers to a defense for virtually all involved except the issuer for material misstatements or omissions in a prospectus. See Helane L. Morrison, Sustaining the Due Diligence Defense for Underwriters Under Section 11 of the Securities Act of 1933, in SECURITIES LITIGATION 1992: STRATEGIES AND CURRENT DEVELOPMENTS, at 297, 304 (PLI Litig. & Admin. Practice Course, Handbook Series No. 443, 1992); William D. Sherman, The Due Diligence Defense, in MECHANICS OF UNDERWRITING, at 283, 286 (PLI Corporate Law & Practice Course, Handbook Series No. 670, 1990).

However, it is possible the securities-law concept could be relevant in a merger or acquisition and any resulting fallout (for example, shareholder derivative lawsuits). If an acquisition or merger involves stock purchases, the anti-fraud provisions of § 10(b) of the Securities Exchange Act of 1934 and, in particular, SEC Rule 10b-5 may be applicable. See Gould v. Ruefenacht, 471 U.S. 701, 702-04 (1985); Landreth Timber Co. v. Landreth, 471 U.S. 681, 683, 694 n.7 (1985). See generally Henry L. "Scott" Nearing, III, Note, Kahn v. Virginia Retirement System: The Impact of Rule 10b-5's Corporate Disclosure Requirements on the Williams Act's Tender Offer and Best Price Rules, 40 VILL. L. REV. 263 (1995) (discussing the issue of when general business developments must be disclosed under SEC Rule 10b-5).

The provisions of the Securities Act of 1933 (hereinafter the 1933 Act) may also be relevant in some mergers and acquisitions. For example, if the acquiring company uses its own shares or another security as consideration in an acquisition of a publicly held company, it represents a public offering of the acquiring company's shares. See Eric Luse et al., Structuring Mergers and Acquisitions of Savings Associations after FIRREA, in THE THRIFT INDUSTRY RESTRUCTURED: THE NEW REGULATORS AND OPPORTUNITIES FOR THE FUTURE, at 255, 273 (PLI Commercial Law & Practice Course, Handbook Series No. 508, 1989). As a result, registration under the 1933 Act would be required. Id. Similarly, a merger of two public companies with an exchange of corporate stock would also be a sale of securities and subject to registration. Id. at 276. Of course, if shares of the target corporation were purchased for cash, there would be no such implications under the 1933 Act. See id. at 273-74.

Additionally, in a shareholder derivative lawsuit alleging an acquisition was imprudent, the actions of the board of directors will be judged by the business judgment rule. See, e.g., Cede & Co. v. Technicolor, Inc., 634 A.2d 345, 360-61 (Del. 1993), modified, 636 A.2d 956 (Del. 1994); Smith v. Van Gorkom, 488 A.2d 858, 872-73 (Del. 1985). The business judgment rule is a presumption that "directors and officers from liability for unprofitable or harmful corporate transactions if the transactions were made in good faith, with due care, and within the directors' or officers' authority." BLACK'S LAW DICTIONARY 192 (7th ed. 1999). To invoke the rule, management must have reasonable basis for their decisions and show due care was exercised. See DENNIS J. BLOCK ET AL., THE BUSINESS JUDGMENT RULE: FIDUCIARY DUTIES OF CORPORATE DIRECTORS 20-41 (4th ed. 1993).

19. See infra Part V.


In 1982, after an extensive due diligence review that included information regarding capsular contracture, rupture, and gel bleed, Bristol-Myers, a Delaware corporation, purchased MEC's stock for $28 million through a series of mergers and corporate reorganizations. Bristol-Myers created a wholly-owned subsidiary, Lakeside Engineering, Inc., a Delaware corporation, which created MEC Acquisition Corporation, a Wisconsin corporation. After MEC merged into MEC Acquisition (extinguishing MEC Acquisition), it then merged into Lakeside, and the surviving corporation changed its name to Medical Engineering Corporation (MEC-2). Since this series of transactions in 1982, MEC, a Delaware corporation with a principal place of business in Racine, Wisconsin, has been a wholly-owned subsidiary of Bristol-Myers, operated by Bristol-Myers as part of its Health Care Group.

Silicone Gel Breast Implants Prods. Liab. Litig., 887 F. Supp. at 1450. Bristol-Myers conducted this due diligence review together with MEC. Id. The review pointed to potential hazards and possible liability concerning polyurethane-coated breast implants. Id. Polyurethane-coated implants were a "special case" because it was alleged polyurethane could degrade in the body, releasing toluenediamine (TDA), a substance that has been connected with cancer in animals. See Siu C. Chan et al., Detection of Toluenediamines in the Urine of a Patient with Polyurethane-Covered Breast Implants, 37 CLINICAL CHEMISTRY 756, 756 (1991). However, the FDA later determined the risk was minimal and did not warrant a recommendation of removal of such implants. See Rheinstein & Hoffman, supra note 5.


22. McGhan Medical Corporation was incorporated in 1974, for the express purpose
Bristol-Myers, Baxter, and 3M were all major public companies with sophisticated management and both in-house and outside counsel.23 Furthermore, as major corporations in the medical devices industry, all three were on notice and well aware of the 1976 Medical Device Amendments and their provisions and implications.24 All three were well aware silicone breast implants had never been “approved” by the FDA, but were “grandfathered” under the 1976 Amendments.25 That is, they were temporarily excused from the full rigors of FDA approval. When the agency eventually decided to review the silicone gel breast implant market, only Dow Corning, Mentor Corporation Bioplasty, Inc., and McGhan Medical26 filed clinical data with the FDA in April 1991.27 However, this proffer of data was deemed inadequate,28 and the rest is history. Despite effectively 15 years’ notice, three major corporations were caught off guard and face potential liability ranging in the billions of dollars.

Perhaps the near hysterical reaction to then-FDA commissioner Kessler’s announcement29 and the avalanche of litigation30 could not have been foreseen by any degree of due diligence. However, given the provisions of the 1976 of marketing silicone breast implants. 3M Not Responsible for Plaintiffs’ Defective Implants, ANDREWS MED. DEVICES LITIG. REP., Jan. 26, 2001, at 6. In June 1977, 3M acquired the assets of McGhan and transferred them to a new subsidiary, also known as McGhan Medical Corp. (McGhan 2). Oregon Court Denies 3M’s Motion for Summary Judgment on Liability, MEALEY’S LITIG. REP.: BREAST IMPLANTS, Mar. 3, 1994, at 9. In 1980, McGhan 2 was merged into 3M, and operated as a department in 3M’s surgical products division. Id. In August 1984, 3M sold its breast implant business to a group of investors including the founders of the original McGhan Medical Corp. 3M Not Responsible for Plaintiffs’ Defective Implants, supra. They named the new company McGhan Medical Corp. (McGhan 3). Id. The following year, McGhan 3 was merged into a new company called Inamed Corporation. Id.

23. All three were Fortune 500 companies in the early 1980s. See Lucia Mouat, Minnesota’s Twin Cities: Partners in Quality Living, CHRISTIAN SCI. MONITOR, Aug. 5, 1982, at B6 (discussing 3M); Nancy L. Ross, The Corporate Score Card Takes to the Airwaves: Firms Commit Annual Reports of Videotape; And That’s the Way It Was... Annual Reports Take to the Airways, WASH. POST, May 2, 1982, at L1 (discussing Bristol-Myers); Ford S. Worthy, The Fortune Directory of the Largest U.S. Industrial Corporations, TIME, May 4, 1981, at 322 (discussing Baxter and Bristol-Myers).

24. See infra notes 128-49 and accompanying text.

25. See infra Part IV.B.


27. ANGELL, supra note 6, at 54.

28. See id. at 55; Kessler, supra note 7, at 1713.

29. See Kessler, supra note 7, at 1713.

Amendments, the necessity to conduct trials and gather data for FDA review at some point in the future was not only foreseeable but inevitable.  

This Article will explore the concept of due diligence in the context of mergers and acquisitions and the concept of successor liability, with particular reference to the medical device industry and products liability litigation. Following this introduction, the silicone breast implant litigation morass and the major players will be briefly outlined in Part II. Various theories of successor liability will then be described in Part III. Part IV will examine the FDA’s regulation of medical devices with particular focus on the grandfathering of all devices that were already on the market on May 28, 1976. Having set the scene, Part V will then examine due diligence in the context of the medical device industry following the 1976 Amendments. 

Despite its apparent age, the issues discussed herein are far from dead. As the Supreme Court has observed, most of the devices on the market today were grandfathered in 1976. Many have never received FDA approval, in the current sense of the word. Thus, acquirers of other medical device companies could end up in a position similar to that of Bristol-Myers, Baxter, and 3M. This situation is probably not going to change any time soon. There are still 

31. See discussion infra Part IV.B; Kessler, supra note 7, at 1713.
32. This grandfathering affected the entire medical-device industry, not just silicone breast implants. See discussion infra Part IV.B.
drugs on the market today that were grandfathered under the 1938 Food, Drug, and Cosmetics Act ("FDCA")\textsuperscript{35} and the 1962 Amendments to the FDCA which have also never been approved by the FDA, in the current sense of the word.\textsuperscript{36}

II. SILICONE GEL BREAST IMPLANTS AND THE LITIGATION INDUSTRY SURROUNDING THEM

Silicone breast implants are medical prostheses used in the augmentation or reconstruction of the breast.\textsuperscript{37} They consist essentially of a silicone elastomer bag containing silicone gel of a consistency approximately mimicking human breast tissue.\textsuperscript{38} Historically, about 80% of implants have been used for cosmetic breast augmentation and the remaining 20% in breast reconstruction, following, for example, a mastectomy.\textsuperscript{39} Following their development by Drs. Cronin and Gerow, they were first introduced to the United States market in the early 1960s.\textsuperscript{40}

The first medical report describing immunological and rheumatological problems allegedly attributed to silicone breast implants is generally considered to have been that of Dr. van Nunen and colleagues.\textsuperscript{41} The report came out in 1982,\textsuperscript{42} right around the time Bristol-Myers, Baxter, and 3M made their ill-fated acquisitions.\textsuperscript{43} It is these immunological, rheumatological, and

\textsuperscript{35} DONALD O. BEERS, GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS § 1.4[5] (4th ed. 1995). The FDCA’s “grandfather clause” provided that a drug would not be treated as a “new drug” (and therefore not be subject to the new regulations) if, “at any time prior to [the enactment of the FDCA], it was subject to the Food & Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.” 21 U.S.C. § 321(p)(1) (1994).

\textsuperscript{36} The 1962 Amendments to the FDCA also contained a grandfather clause, which permitted some drugs already on the market to avoid the new requirements. BEERS, supra note 35, at § 1.4[6] (citing Pub. L. No. 87-781, § 107(c)(4)).

\textsuperscript{37} See, e.g., Rheinstein & Hoffman, supra note 5, at 2227.


\textsuperscript{39} See ANGELL, supra note 6, at 19; Rheinstein & Hoffman, supra note 5, at 2227.

\textsuperscript{40} See Dow Corning Corp. v. Surgitek, Inc., 378 F. Supp. 1128, 1129 (E.D. Wis. 1974); Zuckerman, supra note 38, at 8; Mimi Swartz, Silicone City: The Rise and Fall of the Implant—Or How Houston Went from an Oil-Based Economy to a Breast-Based Economy, TEX. MONTHLY, Aug. 1, 1995, at 64 (1995).

\textsuperscript{41} See Sheryl A. van Nunen et al., Post-Mammoplasty Connective Tissue Disease, 25 ARTHRITIS & RHEUMATISM 694, 696 (1982) (reporting on a case series of three patients with implants and connective tissue diseases and making comparisons with the conditions previously reported in patients who had received direct injections of paraffin and processed petroleum for breast augmentation).

\textsuperscript{42} ANGELL, supra note 6, at 52; van Nunen, supra note 41, at 694.

\textsuperscript{43} See supra notes 20-22 and accompanying text.
autoimmune diseases that largely have formed the basis of plaintiffs' allegations in breast implant litigation. Various minor physical problems caused by implants were known from the early days of their use. As further case reports appeared in the literature and the FDA was made aware of the situation, a trickle of litigation began. This growing number of reports and litigation eventually led to the FDA's call for safety data.

Despite the seedy image of breast implants and absurd stories in the press, to this day most reputable medical studies have failed to show an increased incidence of disease in women who received breast implants over properly matched women who did not. Despite many suggestions to the contrary in the press, it is important to note that the FDA restricted, but did not ban, the use of implants. Furthermore, the FDA's decision in 1992 to restrict the availability of implants was based on the manufacturers' failure to gather and provide adequate information regarding the safety of implants, not on any known risk or hazard. That is much more than a mere semantic difference.

"Technically, what the panel said was that the safety of implants was not proven," Dr. Sergent said. "But in the public's mind, that was tantamount to saying they were unsafe. I do feel that the result of the moratorium was to fuel a lot of what I think borders on hysteria by the public."

44. See ANGELL, supra note 6, at 21-22.
45. Id. at 21.
46. See FDA to Require Safety Data on Breast Implants, supra note 3, at 2; U.S. Reviews Health Effect of Implants, supra note 3, at 1.
47. See, e.g., Klein v. Dow Corning Corp., 661 F.2d 998, 998 (2d Cir. 1981); Henderson v. Heyer-Schulte Corp., 600 S.W.2d 844, 845-46 (Tex. App. 1980); ANGELL, supra note 6, at 52-54.
48. In 1988, the FDA informed all silicone gel breast implant manufacturers of its intention to require premarket approval for implants, including full safety and efficacy data. Rheinstein & Hoffman, supra note 5, at 2227. On April 10, 1991, the FDA announced the deadline for submission of this data would be July 9, 1991. Id.
50. See, e.g., Sherine E. Gabriel et al., Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation, 330 NEW ENGL. J. MED. 1697, 1697-702 (1994) (reporting that a study showed no significant increase in the relative risk of connective-tissue disease among women with breast implants).
52. See Kessler, supra note 7, at 1713.
53. See ANGELL, supra note 6, at 54-56; Kessler, supra note 7, at 1713; Stine, supra note 15, at 491-92.
54. Gina Kolata, A Case of Justice, or a Total Travesty? How the Battle Over Breast Implants Took Dow Corning to Chapter II, N.Y. TIMES, June 13, 1995, at D1 (quoting Dr.
Potential liability from silicone breast implant litigation eventually led the major implant companies, Dow Corning, Baxter, Bristol-Myers Squibb, and 3M, to propose a $4.25 billion settlement, and subsequently drove Dow Corning to seek bankruptcy protection.\(^{55}\)

III. SUCCESSOR LIABILITY

One of the key concerns in any corporate merger or acquisition is successor liability.\(^{56}\) In addressing this issue, it is important to differentiate the three major forms of mergers or acquisitions and the differing effects these traditionally have. The three fundamental forms of mergers or acquisitions are a statutory merger,\(^{57}\) a stock acquisition,\(^{58}\) and an asset acquisition.\(^{59}\)

In a statutory merger, the surviving corporation is traditionally liable for the target company's liabilities.\(^{60}\) The corporation resulting from such a merger

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John Sergent, a well-known rheumatologist, who was a member of the committee convened by the FDA to examine the data in 1992, following then-FDA commissioner Kessler's call for a moratorium on the use of silicone gel breast implants except for research purposes).\(^{55}\)

\(^{55}\) Angell, supra note 6, at 22, 192-94; Stine, supra note 15, at 491; Kolata, supra note 54, at D1; Snyder, supra note 34, at 164-71. See also In re Dow Corning Corp., 212 B.R. 258 (E.D. Mich. 1997).


\(^{57}\) See, e.g., Lemelle v. Universal Mfg. Corp., 18 F.3d 1268, 1272 (5th Cir. 1994); PPG Indus., Inc. v. Guardian Indus. Corp., 597 F.2d 1090, 1091 (6th Cir. 1979); Lynda G. Wilson, Note, Corporate Successor Liability for Punitive Damages in Products Liability Litigation, 40 S.C. L. Rev. 509, 537 (1989). A merger can be defined as "[t]he absorption of one company... that ceases to exist into another that retains its own name and identity and acquires the assets and liabilities of the former." Black's Law Dictionary 1002 (7th ed. 1999). A statutory merger is one "provided by and conducted according to statutory requirements." Id. at 1003.

\(^{58}\) See, e.g., Phillips v. Cooper Labs., Inc., 264 Cal. Rptr. 311, 312-13 (1989); Citron v. E.I. DuPont de Nemours & Co., 584 A.2d 490, 492-98 (Del. 1990); Rogich, supra note 56, at 1119 & n.15.


\(^{60}\) See, e.g., Brotherton v. Celotex Corp., 493 A.2d 1337, 1339 (N.J. Super. Ct. Law Div. 1985) ("a survivor corporation is liable for all the obligations and liabilities of each of
assumes the liabilities of the corporation that was absorbed, at least to the extent of the assets acquired from that corporation. This is the result even if the merger is not accomplished in strict accordance with the statutory scheme. The *de facto* merger doctrine imposes liability when a transaction has the practical effect of a merger.

Stock acquisitions differ from statutory mergers primarily in the sense that they offer potential protection in the form of the corporate veil doctrine. If the acquired company is operated as a subsidiary, the parent or acquirer will ordinarily be insulated like any other shareholder. In such a transaction, the assets and liabilities of the two corporations remain separate and only the target's assets are, in principle at least, available to satisfy any such liabilities.

the corporations with which it has merged [so as to] impose liability on a successor corporation for any obligation incurred by its predecessor so long as a merger took place*; *Lockheed Martin Corp., 16 S.W.3d at 134 (citing James Ryan & Robert Beasley, *Asset Acquisitions: Caveat Emptor*, 53 TEX. B.J. 1221, 1221 (1990)).

61. See Shannon, 379 F. Supp. at 800; Brotherton, 493 A.2d at 1339.

62. Under the doctrine of *de facto* mergers, the legal consequences of a merger conducted in strict accordance with the statute will be applied to a merger conducted in a similar fashion although not *strictly* in accordance with the statute. See, e.g., Shannon, 379 F. Supp. at 800-03 (discussing the doctrine of *de facto* mergers); Richmond, *supra* note 56, at 558; 20 AM. JUR. 2D Corporations §§ 2680, 2681 (1986). The successor corporation in a *de facto* merger is liable for claims against the predecessor. Richmond, *supra* note 56, at 558.

The doctrine of *de facto* merger requires the showing of (1) continuity of the predecessor's physical assets and staff; (2) basic continuity of the predecessor's management and shareholders; (3) immediate dissolution of the predecessor following the transaction; and (4) assumption by the successor of those liabilities ordinarily necessary for the uninterrupted continuation of the predecessor's business. Shannon, 379 F. Supp. at 801. See also Richmond, *supra* note 56, at 558. For a somewhat different view, see Knapp v. North Am. Rockwell Corp., 506 F.2d 361 (3d Cir. 1974), cert. denied, 421 U.S. 965 (1975). The Knapp court imposed successor liability for a defective product even though the predecessor had not yet been dissolved. Id. at 368-70. The ruling in Knapp may be part of a movement away from the traditional rule of no successor liability in *de facto* mergers. See Howard L. Shecter, *Selected Risk Issues in Merger and Acquisition Transactions*, 51 U. MIAMI L. REV. 719, 722 (1997).


65. See, e.g., Walkovszky v. Carlton, 223 N.E.2d 6, 7 (N.Y. 1966). The corporate veil doctrine is a figurative term for the legal separation of a corporation and its shareholders. See id.

The acquirer is not liable for the target’s liabilities, unless the corporate veil is pierced.\(^6\)

In an asset acquisition or purchase, the acquirer traditionally is only liable for the specific liabilities assumed.\(^6\) Traditionally, the purchaser took the assets free of any liabilities not expressly assumed, including tort liabilities.\(^6\)

However, even this rule was subject to exceptions.\(^7\) The law continues to evolve in this area.\(^7\) Several courts have rejected the rule, and there are a series of exceptions to it.\(^7\) Exceptions to the general rule of non-liability have emerged in circumstances in which (1) the acquirer expressly or impliedly assumed liabilities;\(^7\) (2) the transaction amounted to a consolidation or a merger;\(^7\) (3) the acquirer was a continuation of the selling corporation;\(^7\) (4) the

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\(^6\) Under certain circumstances, such as to prevent fraud or when equity demands it, courts tend to pierce the corporate veil and hold shareholders liable for a corporation’s liabilities by disregarding their separate legal identities. See, e.g., Int’l Aircraft Trading Co. v. Mfrs. Trust Co., 79 N.E.2d 249, 252 (N.Y. 1948). "The doctrine [of piercing the corporate veil] holds that the corporate structure with its attendant limited liability of stockholders may be disregarded and personal liability imposed on the stockholders, officers and directors in the case of fraud or other wrongful acts done in name of [the] corporation." *Black’s Law Dictionary* 1148 (6th ed. 1990).


\(^10\) See generally Shecter, *supra* note 62, at 719-78 (discussing recent developments in the area of successor liability in de facto mergers and arguing courts have returned to favoring a general rule of non-liability with a few well-delineated exceptions).

\(^11\) Id. at 724.

\(^12\) See, e.g., Polius v. Clark Equip. Co., 802 F.2d 75, 78 (3d Cir. 1986); Kessinger v. Grefoe, Inc., 875 F.2d 153, 155 (7th Cir. 1989).


\(^14\) While the so-called continuity of enterprise doctrine offers no strict rule on how to determine whether a successor entity is a “mere continuation” of its predecessor, the
transaction was fraudulently entered into in an attempt to escape liability;\(^7\) (5) the transfer occurred without adequate consideration and no provisions were made for creditors of the selling corporation;\(^7\) (6) the purchasing corporation continued the seller’s product line;\(^7\) or (7) there was a duty to warn customers of defective products sold by the predecessor that the successor discovered or should have discovered.\(^7\)

Despite these traditional rules and the argument that corporations involved in a merger should be able to set the terms of their own deal, some courts have

following factors should be considered: whether there was a (1) transfer of corporate assets; (2) for inadequate consideration; (3) to a successor corporation which continued the predecessor’s business; (4) with shared management in the two corporations; and (5) inability on behalf of the predecessor to meet liabilities due to its dissolution. Jackson v. Diamond T. Trucking Co., 241 A.2d 471, 477 (N.J. Super. Ct. Law Div. 1968). See also Turner v. Bituminous Cas. Co., 244 N.W.2d 873, 881-82 (Mich. 1976); Cyr v. B. Offen & Co., 501 F.2d 1145, 1152 (1st Cir. 1974). But see Polius v. Clark Equip. Co., 802 F.2d 75, 80 (3d Cir. 1986) (criticizing the continuity of enterprise doctrine); Shecter, \textit{supra} note 62, at 723 

\& n.40 (noting that some jurisdictions had rejected the continuity of enterprise doctrine).\(^7\)

6. \textit{See}, \textit{e.g.}, Raytech Corp. v. White, 54 F.3d 187, 192 (3d Cir. 1995).


8. This exception was created in 1977 by extending the strict-liability concept that manufacturers who benefit by putting products into the market should bear the costs of injuries caused by defective products, at least in part, because they are in the best position to spread those costs to all consumers by purchasing insurance and charging a correspondingly higher price for their products. Ray v. Alad Corp., 560 P.2d 3, 7-11 (Cal. 1977). The test established in \textit{Ray} requires the following justifications to be considered: (1) the virtual removal of the plaintiff’s remedies against the predecessor manufacturer because of the acquisition; (2) the successor’s ability to take over the predecessor manufacturer’s risk-spreading role; and (3) the fairness in requiring the successor to assume responsibility for defective products, in light of the fact this burden is part and parcel of the predecessor manufacturer’s good will, which the successor enjoys by virtue of its continued operation of the predecessor’s product line. \textit{Id.} at 8-9. \textit{Accord} Ramirez v. Amsted Indus. Inc., 431 A.2d 811, 825 (N.J. 1981) (holding that continuation of the product line following an asset acquisition was sufficient to impose strict corporate successor liability). \textit{See also} Chrysler Corp. v. Alumbaugh, 342 N.E.2d 908, 916 (Ind. Ct. App.), \textit{modified}, 348 N.E.2d 654 (Ind. Ct. App. 1976) (discussing in general the justifications for imposing strict products liability under § 402A); \textit{Assumption of Products Liability in Corporate Acquisitions}, 55 B.U. L. REV. 86, 107 (1975).

9. \textit{See}, \textit{e.g.}, Gee v. Tenneco, Inc., 615 F.2d 857, 866 (9th Cir. 1980) (listing cases in which a duty to warn was found); Polius v. Clark Equip. Co., 802 F.2d 75, 84 (3d Cir. 1986) (discussing successor corporations’ duty to warn of defects in products manufactured by predecessors, but ultimately holding that, because the successor corporation in question had no actual knowledge of the alleged defect, and because it had no business relationship with the plaintiff, there was no duty to warn); Florom v. Elliott Mfg., 867 F.2d 570, 576-77 (10th Cir. 1989) (pointing out that succession alone does not create a duty to warn; rather, it requires a relationship between the successor corporation and the customers of the predecessor); Richmond, \textit{supra} note 56, at 553-75; Shecter, \textit{supra} note 62, at 727-28.
taken an expansive view of successor liability, especially in suits involving physically injured plaintiffs. Of course, this is usually the case in medical device matters. In fact, especially in product liability cases, courts have gone beyond the traditional rules and have sought to impose successor liability on the acquiring company, regardless of the form of the transaction. This is done essentially as a matter of public policy.

Courts have adopted several themes in their development of a reasonable rule for products liability litigation arising out of corporate mergers and acquisitions. Some have simply expanded the traditional merger and continuation exceptions to allow recovery against the acquirer in an asset acquisition. Other courts have analyzed the issue in terms of continuity of

80. See generally Friedrich K. Juenger & Stephen H. Schulman, Assets Sales and Products Liability, 22 WAYNE L. REV. 39 (1975) (discussing a series of products liability cases in which injured parties have been allowed to recover against successor corporations even though the merger transaction was at arms length and for adequate consideration).


To the injured person the problem of recovery is substantially the same, no matter what corporate process led to transfer of the first corporation and/or its assets. Whether the corporate transaction was (1) a traditional merger accompanied by exchange of stock of the two corporations, or (2) a de facto [sic] merger brought about by the purchase of one corporation’s assets by part of the stock of the second, or (3) a purchase of corporate assets for cash, the injured person has the same problem, so long as the first corporation in each case legally and/or practically becomes defunct. The injured person has no place to turn for relief except to the second corporation. Therefore, as to the injured person, distinctions between types of corporate transfers are wholly unmeaningful.

Id. See also Henry Hansmann & Reinier Kraakman, Toward Unlimited Shareholder Liability for Corporate Torts, 100 YALE L.J. 1879, 1931-32 (1991) (critically discussing the movement to increase the number of cases in which liability is imposed by piercing the corporate veil); Juenger & Schulman, supra note 80, at 60.

84. See Turner, 244 N.W.2d at 878-84.

85. See cases cited supra notes 74-75.

86. See, e.g., Knapp, 506 F.2d at 367-70 (predicting an expansion of the merger
ownership and have required that the stockholders of the selling corporation also be stockholders of the purchasing corporation before successor liability can be attached. 87

Although some courts have extended, bent, broken, or rewritten the rules to assist injured plaintiffs in seeking redress, the traditional rules are still the law in many states. 88 Perhaps the split in jurisdictions is not surprising because there are plausible arguments on both sides of the divide. 89 A strong argument in favor of imposing successor liability, regardless of the form of the transaction, is to protect public interests. Companies producing defective products should not be able to avoid liability simply by, for example, carrying out an asset sale and distributing the proceeds to their shareholders. 90 A counter argument is that business and public interests are also served by a well-functioning market in corporate assets. 91 Any such market will be inhibited if purchasers acquiring assets also (potentially) acquire unknown liabilities. 92 Until recently, the latter argument was overwhelmingly accepted in common law analysis. 93 However, as discussed in this section, and indicated by at least

87. See, e.g., Dayton v. Peck, Stow & Wilcox Co. ("Pexto"), 739 F.2d 690, 693 (1st Cir. 1984) (pointing out that a merger traditionally requires continuity of shareholders, which is at hand when the purchasing corporation uses its own stock as consideration for the seller corporation's assets, so that shareholders of the selling corporation become part of the purchasing corporation); Bud Antle, Inc. v. Eastern Foods, Inc., 758 F.2d 1451, 1458-59 (11th Cir. 1985) (reasoning that common identity of officers, directors, and shareholders in the selling and purchasing corporations is a key element to a finding of continuity).

88. See Bernard v. Kee Mfg. Co., 409 So.2d 1047, 1049 (Fla. 1982) ("The vast majority of jurisdictions follow the traditional corporate law rule which does not impose the liabilities of the selling predecessor upon the buying successor company unless (1) the successor expressly or impliedly assumes obligations of the predecessor, (2) the transaction is a de facto merger, (3) the successor is a mere continuation of the predecessor, or (4) the transaction is a fraudulent effort to avoid liabilities of the predecessor."); David R. Langdon, Note, Ohio Upholds Traditional Exception to General Rule of Corporate Successor Nonliability, 28 AKRON L. REV. 333 (1995) (discussing Welco Industries, Inc. v. Applied Companies, 617 N.E.2d 1129 (Ohio 1993) and the refusal by the Ohio Supreme Court to further expand successor liability).

89. See EEOC v. Vucitech, 842 F.2d 936, 944 (7th Cir. 1988).


91. See Yamin, supra note 59, at 206-07.

92. See id. at 207-08.

one commentator,\textsuperscript{94} perhaps courts are moving toward the other end of the continuum where side stepping the corporate legal form to award product-liability damages on public-policy grounds is the norm instead of the exception.

IV. REGULATION OF MEDICAL DEVICES

A. History of Medical-Device Regulation

While the FDA's regulation of drugs,\textsuperscript{95} which began with the Pure Food and Drugs Act of 1906,\textsuperscript{96} is considered by many to be one of the most stringent in the world,\textsuperscript{97} the FDA's regulation of medical devices is another story.\textsuperscript{98} Indeed, the legislative history of the 1906 Act does not even mention medical devices, although the subject had been discussed at the time.\textsuperscript{99} A medical device is now defined as any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and


\textsuperscript{94} Shecter, \textit{supra} note 62, at 722.

\textsuperscript{95} \textit{See generally} Dixie Farley, \textit{Benefit vs. Risk: How FDA Approves New Drugs}, FDA CONSUMER, Dec. 1987-Jan. 1988, at 7 (discussing in general terms the FDA review process for new drugs to be introduced into the market).

\textsuperscript{96} Pub. L. No. 59-384, 34 Stat. 768 (1906).

\textsuperscript{97} \textit{But see} David A. Kessler et al., \textit{Approval of New Drugs in the United States: Comparison with the United Kingdom, Germany, and Japan}, 276 J. AM. MED. ASS'N 1826, 1826, 1829 (1996) (noting the FDA was no slower than the United Kingdom, and actually faster than Germany and Japan, in approving important new drugs). \textit{See also} S. REP. NO. 94-33, at 2 (1975), \textit{reprinted in} 1976 U.S.C.C.A.N. 1070, 1071.

\textsuperscript{98} \textit{See generally} Rodney R. Munsey, \textit{Trends and Events in FDA Regulation of Medical Devices over the Last 50 Years}, 50 FOOD & DRUG L.J. 163 (1995) (discussing the history of FDA regulation of medical devices, focusing on the last half of the 20th century).

\textsuperscript{99} \textit{See} Peter Barton Hutt, \textit{A History of Government Regulation of Adulteration and Misbranding of Medical Devices}, 44 FOOD DRUG COSM. L.J. 99, 100-01 (1989).
which is not dependent upon being metabolized for the achievement of its primary intended purposes.\textsuperscript{100}

Effectively, this means any health-related item except drugs\textsuperscript{101} and biologics, (including vaccines).\textsuperscript{102} The range of items that can be considered a medical device has been described as anything "[f]rom bedpans to brainscans."\textsuperscript{103}

A major update of the 1906 Act was attempted in 1933\textsuperscript{104} as part of the New Deal.\textsuperscript{105} After five years, medical devices were regulated for the first time under the Food, Drug, and Cosmetics Act of 1938.\textsuperscript{106} In practice, however,

\begin{itemize}
    \item \textsuperscript{100} 21 U.S.C. § 321(h) (1994).
    \item \textsuperscript{101} For purposes of FDA administration [t]he term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).
    \item A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.
    \item \textsuperscript{103} STAFF OF SUBCOMM. ON OVERSIGHT & INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY & COMMERCE, 98TH CONG., REPORT ON MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 1 (Comm. Print 1983). See generally Robert B. Leflar, Public Accountability and Medical Device Regulation, 2 HARV. J.L. & TECH. 1 (1989) (arguing the FDA has gone far beyond its congressional mandate in its medical-device regulation).
    \item \textsuperscript{105} See generally Stephen Gardbaum, New Deal Constitutionalism and the Unshackling of the States, 64 U. CHI. L. REV. 483 (1997) (discussing the expansion of federal powers under the commerce clause during the New Deal).
    \item \textsuperscript{106} Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. IV 1999)). Medical devices were regulated under the adulteration and misbranding provisions. §§ 301, 304, 52 Stat. at 1042, 1044. A possible reason for this was that at the time, it was considered that physicians and surgeons could separate the good from the bad ("quack" devices) and the FDA's primary
medical devices were not really covered by the 1938 Act. Congress separated drugs from devices with regard to the FDA approval process. Specifically, devices were not required to obtain FDA approval prior to marketing, whereas drugs were. It should be remembered that this premarket notification for drugs was actually an afterthought. It was added only because of the elixir sulfanilamide tragedy which occurred during 1937 while Congress was considering the 1938 Act. As a result, a premarket notification provision for drugs, but not for devices, was added to the legislation then pending in Congress.

Following the thalidomide disaster in Europe and the early stages of one in the United States, Congress reacted by enacting the Drug Amendments of concern was truthful labeling and misbranding. For an insight on the public’s view of quack devices in the mid- to early '30s, see Morris Fishbein, Fads and Quackery in Healing (1932); Arthur Kallet & F. J. Schlink, 100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics (1933); Ruth DeForest Lamb, American Chamber of Horrors: The Truth About Food and Drugs (Arno Press 1976); Arthur J. Cramp, Nostums and Quackery and Pseudo-Medicine (1936). After implementation of the 1938 Act, much of the FDA’s energy was directed at ridding the market of quack devices, including several celebrated examples. See, e.g., United States v. One Article of Device Labeled Spectrochrome, 66 F. Supp. 754 (D. Or. 1946), rev’d sub nom. United States v. Olsen, 161 F.2d 669 (9th Cir. 1947) (involving a lamp claimed to cure various ailments via the use of differently colored bulbs); United States v. Diapulse Mfg. Corp. of Am., 389 F.2d 612 (2d Cir. 1968) (involving a device claimed to cure some 121 different diseases). For further details of these and many other amazing devices from this period, visit the Museum of Questionable Medical Devices in Minneapolis, MN, or the museum’s web page at http://www.mtn.org/quack (last visited Apr. 10, 2001).


109. See generally Phillip Knightley ET AL., SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE (1979) (discussing the impact the thalidomide disaster had on legal, social, and political systems across the world, and arguing the issues raised due to this tragedy will reverberate for a long time); Max Sherman & Steven Strauss, Thalidomide: A Twenty-Five Year Perspective, 41 FOOD DRUG COSM. L.J. 458 (1986) (arguing this unprecedented medical disaster led to the strengthening of drug regulation in numerous countries, even leading to the initiation of drug regulation in some); Helen B. Taussig, A Study of the German Outbreak of Phocomelia: The Thalidomide Syndrome, 180 J. AM. MED. ASS’N 1106 (1962) (reporting on a German outbreak of the clinical syndrome Phocomelia, which is a condition in which the bones between the hand and shoulder are deformed or missing, with the suspected cause being thalidomide sleeping tablets).

110. Despite the thalidomide disaster frequently being used as a justification for the FDA’s supposedly uncompromising standards, it should not be forgotten that fortuity played a large part in how the United States escaped thebulk of the thalidomide tragedy. Richard E. McFadyen, Thalidomide in America: A Brush with Tragedy, 11 CLIO MEDICA 79, 80-82 (1976). The birth defects for which the drug became infamous began to become apparent
1962. However, despite a 1955 report calling for more power to be given to the FDA in regulating medical devices, all mention of devices was dropped from the 1962 Amendments. Nevertheless, device regulation continued to be discussed and recommended throughout the rest of the 1960s, but nothing concrete resulted.

The medical-device industry and Congress got another rude awakening in 1970 from the publication of a major report detailing serious problems with medical devices. A committee chaired by Dr. Theodore Cooper reported on an extensive survey of 731 deaths and some 10,000 injuries attributed to medical devices in the previous ten-year period. The Cooper committee recommended substantial changes in device regulation, but in a very different way.

during 1960, while an FDA reviewer was investigating previously published reports of peripheral nerve damage allegedly caused by thalidomide. Id. at 82. What is not widely remembered in connection with this story is that thalidomide was already in clinical trials in the US at that point, with the FDA’s blessing. Id. at 84. These trials led to a small outbreak of birth defects in some children whose mothers had taken the drug during pregnancy. Id. at 86. See also KNIGHTLEY ET AL., supra note 109, at 1; Sherman & Strauss, supra note 109, at 458.


114. See, e.g., Excerpts and Summary of a National Conference on Medical Devices, supra note 111, at 1750.

115. It is noteworthy, however, that there was some blurring of the line between “drug” and “device,” and a deliberate attempt by the FDA to expand the definition of “drug” during the 1960s. Two important cases supported the FDA’s ever-broadening view of what was a “drug.” The Second Circuit Court of Appeals held that a product used to ligate blood vessels in surgery was essentially a suture and therefore a drug, because sutures generally were listed in the official compendia of drugs. AMP, Inc. v. Gardner, 389 F.2d 825, 830 (2d Cir. 1968). The following year, the Supreme Court agreed with the FDA’s determination that an antibiotic sensitivity disk used to screen for antibiotic-resistant bacteria was also a drug. United States v. An Article of Drug . . . Bacto-Unidisk . . ., 394 U.S. 784, 787, 800 (1969).


way to the one developed by the FDA for drugs.119 The committee recommended a scheme in which devices and their regulation would be classified by risk.120 This scheme eventually became the law in the form of the 1976 Medical Device Amendments and survives basically intact to this day.121

It has been said that the legislative history of the 1976 Medical Device Amendments "reads like a remake of an old movie—same lines, same characters, same message [as in the 1930s], only different actors."122 After much debate throughout the six years following the Cooper report, spurred on by the Dalkon Shield disaster,123 the 1976 Amendments resulted.124 Despite the six-year gestation period and the Dalkon Shield being fresh in everybody's mind,125 some critics argued the 1976 Amendments were not particularly well

119. Compare Link, supra note 117, at 625-28 (describing the activities and recommendations of the Cooper Committee), with Farley, supra note 95, at 7-13 (describing the FDA review process for new drugs).

120. Link, supra note 117, at 626.


123. See Laura K. Jortberg, Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments Under Slater v. Optical Radiation Corp., 43 DEPAUL L. REV. 963, 978 (1994). The Dalkon Shield was an intrauterine contraceptive device that caused infections and infertility due to scarring in many women who used it. See Miller v. A.H. Robins Co., 766 F.2d 1102, 1103 (7th Cir. 1985); Duigan v. A.H. Robins Co., 559 P.2d 750, 751 (Idaho 1977); Ravin v. A.H. Robins Co., 538 N.E.2d 164, 169-70 (Ill. App. Ct. 1989). The Shield had been placed on the market in the early 1970s and was linked to miscarriages, various injuries, and even deaths. Georgene M. Vairo, The Dalkon Shield Claimants Trust: Paradigm Lost (or Found)?, 61 FORDHAM L. REV. 617, 624-25 (1992). There were many lawsuits and millions of dollars were awarded in damages; the litigation eventually forced A.H. Robins, the manufacturer of the Shield, into bankruptcy in 1985. Id. at 626. See generally SHELDON ENGELMAYER & ROBERT WAGMAN, LUST'S JUSTICE (1985) (describing the Dalkon Shield litigation from the perspective of one judge's efforts to resolve the dispute); Mary G. Boguslaski, Classification and Performance Standards Under the 1976 Medical Device Amendments, 40 FOOD DRUG COSM. L.J. 421 (1985) (discussing the political and regulatory background to the 1976 Medical Device Amendments).


125. See Food and Drug Administration Practice and Procedure, 1975: Joint Hearings
thought-out and caused yet more regulatory problems. However, the Amendments did effectively track the recommendations of the Cooper report, at least as far as the classification of devices was concerned.

The 1976 Amendments required for the first time that effectiveness be determined by investigations, including clinical trials, if appropriate. The FDA is to look for "valid scientific evidence" of efficacy, which effectively means controlled trials. In addition, the 1976 Amendments require device manufacturers to notify the FDA of their intent to market a device at least 90 days in advance of such marketing.

The extent and degree of FDA regulation depends on the classification of the device. This in turn depends on the risk associated with the device. Devices are accordingly divided into three classes, depending on the degree of risk involved.

The 1976 Medical Device Amendments established panels of experts to classify existing and future devices. In fact, the FDA had actually begun classifying devices back in 1973, in anticipation of the legislation, and has been doing so ever since. Class I devices are considered to pose the least risk

on Examination of the History of Food and Drug Administration's Regulatory Efforts with the Dalkon Shield and the Procedures They Use in Considering Various Drugs Given to Animals that May be Consumed by the American People Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong. 1 (1975).


128. See Kessler et al., supra note 124, at 357-66. 129. 21 C.F.R. § 860.7(c)(2) (2000).


132. See id.


135. See Medical Device Classification Procedures, Notice to Manufacturers, 40 Fed. Reg. 21,848 (May 19, 1975).

136. See 21 U.S.C. § 360c(b) (requiring the FDA to set up and use the panels of experts when classifying medical devices).
to patient health and are subjected to the least amount of scrutiny.\footnote{See 21 U.S.C. § 360c(a)(1)(A) (1994).} However, even class I devices have to comply with the general requirements of being safe, effective, and truthfully labeled.\footnote{Id.; Javitt, supra note 116, at 559. A typical example of a device that would fall into class I is a tongue depressor. Id.} Class II devices are considered to present higher risks and are therefore required to comply with not only the general requirements, but also other applicable standards.\footnote{21 U.S.C. § 360c(a)(1)(B) (1994). These additional standards include performance standards, postmarket surveillance, patient registries, and other actions deemed necessary to assure safety. Id. This class of devices includes items such as tampons and diagnostic devices, such as CT and MRI scanners. John J. Smith & Anne M. Shyjan, \textit{Defining \"Least Burdensome Means\" Under the Food and Drug Administration Modernization Act of 1997}, 55 FOOD & DRUG L.J. 435, 436 (2000).} Class III devices are life-sustaining devices or devices implanted in the body and deemed to pose the highest degree of risk.\footnote{21 U.S.C. § 360c(a)(1)(C) (1994). Examples of items falling into this class are heart valves, pacemakers, and other implantable medical devices, such as breast implants. Teich v. Food & Drug Admin., 751 F. Supp. 243, 250 (D.D.C. 1990); Javitt, supra note 116, at 560.} They are therefore required to obtain premarket approval ("PMA"), unless they are substantially similar to a device that was in medical use before the Amendments, \textit{i.e.}, before May 28, 1976.\footnote{21 U.S.C. § 360e(b)(1) (1994). \textit{See also} Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).} This has become known as the 510(k) route.\footnote{Patricia C. Kuszler, \textit{Financing Clinical Research and Experimental Therapies: Payment Due, but from Whom?}, 3 DEPAUL J. HEALTH CARE L. 441, 450 (2000). This name stems from the section designation, 510(k), in the session law. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.}

The PMA process requires a device manufacturer to submit summaries of clinical data, a description of the device and its functional components, and the facilities and controls used in manufacturing it.\footnote{21 U.S.C. § 360e(c)(1) (1994); 21 C.F.R. § 814.20 (2000).} This information has to be provided in a manner analogous to the New Drug Application ("NDA") process for drugs.\footnote{See James M. Beck & Elizabeth D. Azari, \textit{FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions}, 53 FOOD & DRUG L.J. 71, 75 (1998).} As the Supreme Court has observed, the PMA process is extremely rigorous and often involves up to 1,200 hours of FDA review.\footnote{\textit{Medtronic}, 518 U.S. at 478-79.} In contrast, devices submitted via the 510(k) route may receive as little as 20 hours of review to determine substantial equivalence to a pre-amendment device.\footnote{Id. at 479.} New devices, introduced after May 28, 1976, are generally automatically placed in
Most of these devices can then be reclassified. However, this option is not available for those devices intended for use in sustaining human life, unless the manufacturer can show class III classification (and, therefore, regulation) is unnecessary to ensure safety and efficacy.

B. The 1976 Grandfathering of Existing Medical Devices

The requirement to demonstrate efficacy presented a problem in terms of those devices that were already on the market when the 1976 Amendments were adopted. Having never been required to gather this form of data, no manufacturer of medical devices would have been able to meet this requirement. As a result, the entire medical devices industry would have been shut down overnight. Congress therefore delayed the implementation of the provisions for devices already on the market by “grandfathering,” that is, temporarily exempting those devices. Specifically, those class III devices on the market on May 28, 1976, and subsequently introduced devices deemed “substantially equivalent” to a pre-amendment one, could be marketed under the 510(k) notification procedure instead of the PMA procedure. A similar procedure had been implemented with regard to drugs on the market before the Food,

151. To establish substantial equivalence, a new device must have the same intended use and technological characteristics as one or more predicate devices. In addition, the safety and efficiency questions must also be substantially the same. 21 U.S.C. § 360c(i) (1994 & Supp. IV 1998). Given the pace of technology in the last 20 years, claiming a device developed today is substantially equivalent to anything from before May 28, 1976, is increasingly tenuous.
152. Section 510(k), codified at 21 U.S.C. § 360(k), requires a device manufacturer to notify the FDA of which class the device falls into (or on what basis the manufacturer concludes the device should not be classified) and how the manufacturer has complied with the performance standards under section 360d and the premarket approval provisions of section 360e at least 90 days in advance of marketing the device. See also Jonathan S. Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 FOOD DRUG COSM. L.J. 510, 514-24 (1984).
Drug, and Cosmetics Act of 1938 and to drugs on the market before the 1962 Drug Amendments.154

Crucially for the subject of this Article, Congress required that, even though they were grandfathered, every pre-amendment class III device undergo the PMA process at some point in the future when the FDA called for manufacturers to submit the necessary safety and effectiveness data.155 Silicone gel breast implants were grandfathered in this way. Thus, any company that had acquired breast implant manufacturers was arguably on notice since May 28, 1976 that safety data would be required at some undetermined point in the future. Twelve years later, in 1988, the FDA informed the industry of its intention to seek safety data.156 On January 6, 1992, then-FDA commissioner Kessler announced the agency was calling for a voluntary moratorium on the sale of implants because inadequate safety data had been supplied.157 Although the acquirers had been on notice for over a decade that this very thing might happen, they were all caught off guard.

V. DUE DILIGENCE

A. “Due Diligence” in the Context of Mergers and Acquisitions

Corporate managers and officers are required to exercise due diligence in the management of corporate affairs.158 In the context of a merger or acquisition, due diligence refers to the analysis and investigation of the target company managers of the prospective acquirer are expected to carry out.159 In other words, due diligence is the research and analysis the acquirer must conduct to obtain all relevant information necessary to make an informed and reasoned decision about the desirability of the acquisition. This includes on

154. See Rutherford v. United States, 542 F.2d 1137, 1141-42 (10th Cir. 1976), rev’d, 442 U.S. 544 (1979) (discussing the drug grandfathering provisions); supra notes 35, 36 and accompanying text.
155. Kessler, supra note 7, at 1713.
156. See FDA to Require Safety Data on Breast Implants, supra note 3, at 2.
157. See Kessler, supra note 7, at 1713-15; Fisher, supra note 9, at 1696-98; Kolata, supra note 54, at D1.
159. See supra note 18.
what basis it should occur, such as the price, terms, and other conditions. Interestingly enough, although corporate leaders are expected to exercise it, due diligence is not statutorily defined. Rather, it is a relative concept, depending greatly on the parties involved in a transaction, the circumstances, the businesses, the scale of the transaction, and the budget. While the undertaking of due diligence as applied to a particular transaction is not always viewed with pleasure by attorneys, paralegals, and others involved, it is crucially important. Furthermore, as one commentator has pointed out, this process allows for virtually no mistakes, since the determination of whether due diligence was exercised is made with the benefit of hindsight. Although, hindsight is not the test. Essentially, proper due diligence research enables the acquirer to assess the “value,” in the broadest sense, of the target business.

B. The Due Diligence Review

It is critically important that the due diligence review be customized to the specific circumstances of the targeted enterprise. In a negotiated deal, the acquirer should ensure the target company provides it with the information necessary to enable the acquirer to determine the assets (current and projected), liabilities, and potential liabilities of the resulting entity. As far as possible,
this information should be verified from independent third parties.\footnote{\textsuperscript{167}}

Several benefits flow from a well-conducted due diligence research. Specifically, it can limit professional liability,\footnote{\textsuperscript{168}} identify areas of weakness in the target company,\footnote{\textsuperscript{169}} identify possible synergies following the transaction,\footnote{\textsuperscript{170}} and generally provide relevant information for the management of the new entity, should the deal go ahead.\footnote{\textsuperscript{171}}

While there is no one definition and no one set of rules or guidelines a potential acquirer must follow, there are many sources of advice and lists of factors to be considered. Securities and Exchange Commission ("SEC") Rule 176 lists some that are useful in evaluating whether an investigation was sufficient and appropriate for due diligence purposes.\footnote{\textsuperscript{172}} In 1973, the National

\begin{itemize}
\item [\textsuperscript{167}] Cf. infra notes 192-201 and accompanying text.
\item [\textsuperscript{168}] See supra note 18.
\item [\textsuperscript{171}] Cf. Ing & Sullivan, supra note 170, at 908.
\item [\textsuperscript{172}] Although SEC Rule 176 applies directly to due-diligence reviews under section 11 of the Securities Act of 1933, its provisions can be applied indirectly to the mergers and acquisitions arena. The provisions of SEC Rule 176 are as follows:

\begin{itemize}
\item (a) The type of issuer;
\item (b) The type of security;
\item (c) The type of person;
\item (d) The office held when the person is an officer;
\item (e) The presence or absence of another relationship to the issuer when the person is a director or proposed director;
\item (f) Reasonable reliance on officers, employees, and others whose duties should have given them knowledge of the particular facts (in the light of the functions and responsibilities of the particular person with respect to the issuer and the filing);
\item (g) When the person is an underwriter, the type of underwriting arrangement, the role of the particular person as an underwriter and the availability of information with respect to the registrant; and
\item (h) Whether, with respect to a fact or document incorporated by reference, the particular person had any responsibility for the fact or document at the time of the filing from which it was incorporated.
\end{itemize}
Association of Securities Dealers ("NASD") proposed a rule for the due
diligence to be conducted by an underwriter in connection with the issuance of
securities. Although the rule was not adopted, it provides a useful checklist
of fifteen non-exclusive factors to be considered in a merger or acquisition.

One of the leading cases in the field is Escott v. BarChris Construction
Corporation. While it analyzed due diligence only in the context of liability
under section 11 of the Securities Act of 1933, its teachings have been
applied more broadly. BarChris was a company involved in the building of
bowling alleys. The company offered convertible debentures in an
underwritten offering, which was registered under the 1933 Act. As a result
of a decline in the profits of the bowling alley operators who were still indebted
to it, BarChris found itself in a worsening financial situation and soon filed for
bankruptcy protection. Subsequently, BarChris failed to pay the interest due
on the debentures. Investors who had purchased them approximately eighteen

17 C.F.R. § 230.176 (2000); SEC Rule 176, reprinted in Selected Statutes, Rules and
eds., 1989).

173. Lawrance, supra note 162, at § 1.04. NASD proposed the rule following a request
of the SEC. Short Form for Registration of Securities, 43 Fed. Reg. 56,053, 56,056 n.19
(proposed Nov. 30, 1978).


175. To paraphrase the proposed rule, the fifteen non-exclusive factors are (1) review
of the target corporation's charter, bylaws and minutes; (2) examination of the financial
reports for the preceding 10 years; (3) review of any changes in auditors during the preceding
10 years; (4) review, with the target's auditors, of the targets financial statements; (5) review
of budgets and orders; (6) review of internal projects, including the proposed use of the funds
raised; (7) review of all pertinent studies or reports concerning the target in the preceding 10
years; (8) possibly third-party review, if the target is a promotional organization or engaged
in marketing high technology or previously unmarketed products; (9) investigation of the
target's current and past relations with banks, creditors, suppliers, etc.; (10) communication
with key personnel at the target regarding the nature of the business and role(s) of the key
personnel; (11) inspection of plant and property; (12) examination of the intellectual property
portfolio; (13) review of information regarding the company's position within its industry;
(14) review of management organization and of the backgrounds of key personnel; and (15)
preparation and maintenance of memoranda pertaining to meetings and conversations
regarding the target. See Lawrance, supra note 162, at §1.04[1].

176. See Auspitz & Levy, supra, note 163, at 367; Glassman v. Computervision Corp.,
90 F.3d 617, 628 (1st Cir. 1996) (commenting on how few cases there are concerning due
diligence).


178. Id. at 652.

179. See Absher, supra note 160, at 740; Katz, supra note 160, at 474-75.


181. Id. at 652.

182. Id. at 654.

183. Id.
months earlier sued the officers and directors who had signed the registration documents, BarChris’ investment bankers, including the underwriters, and BarChris’ accountants. The suit was brought under Section 11 of the 1933 Act and alleged materially false statements and omissions in the registration statement.

The court listed several misstatements in the registration statement concerning BarChris’ statement of sales, net operating income, earnings per share, contingent liabilities, backlog of orders, customer delinquencies, use of the proceeds, improper characterization of assets, BarChris’ precarious financial situation, and even in the nature of its business. The court further noted the underwriters had no reasonable ground for their belief that many of the statements in the prospectus were accurate. Drexel & Co., the lead underwriter, had conducted some investigation and had met with BarChris officials. However, it seems generally vague and nondescript information was given at these meetings. Drexel’s attorneys had not sufficiently reviewed minutes of BarChris’ executive committee of the board of directors; these would have revealed some of the misstatements. Additionally, the lawyers had failed to thoroughly examine BarChris’ major contracts. The court held that

[i]n order to make the underwriters’ participation in this enterprise of any value to the investors, the underwriters must make some reasonable attempt to verify the data submitted to them. They may not rely solely on the company’s officers or on the company’s counsel. A prudent [person] in the management of his [or her] own property would not rely on them.

Another important case in the field of due diligence is Feit v. Leasco Data Processing Equipment Corp., which also arose out of section 11 liability and defenses. Specifically, Feit involved a class action by shareholders of Reliance Insurance Company, the target of Leasco’s tender offer, against Leasco and its directors, as well as the dealer-managers of the tender offer.

184. Id. at 652.
186. Id. at 655-82.
187. Id. at 697.
188. Id. at 692-93.
189. Id. at 692-94.
191. Id.
192. Id. at 697 (emphasis added).
194. Id.
The suit sought to recover damages caused by alleged material omissions from the registration statement and prospectus. Reliance had accepted Leasco's tender offer to exchange Leasco stock for Reliance stock. Leasco sought to acquire Reliance chiefly because it had some $100 million of "surplus surplus" which is an insurance industry term-of-art for cash reserves over and above that required to continue the business. Leasco planned on paying for a large part of the acquisition with this money, once it gained control of Reliance. Counsel for the dealer-managers thoroughly reviewed all available financial data, independently examined audit and actuary reports, made inquiries of Leasco's major bank, and studied corporate minutes, records, and major agreements.

The court found that the dealer-managers had "just barely established that they reasonably investigated the surplus surplus concept." Although one cannot expect dealer-managers to have the same intimate knowledge of corporate affairs as that enjoyed by the corporation's directors, they are nevertheless "expected to exercise a high degree of care in investigation and independent verification of the company's representations. Tacit reliance on management assertions is unacceptable; the underwriters must play devil's advocate."

At the very least, BarChris and Feit reveal that due diligence standards require independent investigation on the part of the acquiring company's managers and directors. That seemingly means going beyond that which is provided the acquirer by the target and obtaining independently verifiable data from third parties. That is probably of utmost importance when the due diligence review moves into the areas of contingent liabilities of the target, particularly future exposure to suits based on defective products manufactured or sold by the target prior to the merger or acquisition.

C. Contingent Liabilities

As part of a properly conducted due diligence review, a potential acquirer would have to make some assessment of the target's actual and contingent liabilities and some estimate of the likelihood of the events in question.

195. Id. at 549-50.
196. Id.
197. Id. at 551.
199. Id. at 582.
200. Id.
201. Id.
occurring. A contingent liability is one "that depends on the occurrence of a future and uncertain event."\textsuperscript{202} Pending or threatened litigation—for example, products liability litigation—would be such a contingent liability.\textsuperscript{203}

In any merger or acquisition of a manufacturing company, products liability issues should be considered in the due diligence review. This is perhaps even more important if the company manufactures medical devices which, as discussed above, tend to result in physical injury and resultant willingness on the part of courts to extend the traditional scope of successor liability.\textsuperscript{204} Products liability refers to a "manufacturer's or seller's tort liability for any damages or injuries suffered by a buyer, user, or bystander as a result of a defective product."\textsuperscript{205} In the medical device context, with injured plaintiffs and courts willing to break traditional rules and impose successor liability regardless of the form of the transaction, the potential acquirer should be especially wary.

Contingent liabilities have two main effects on a specific acquisition or merger: price and apportionment of liabilities. Probably the most obvious is price. The probability of a given liability occurring and having to be paid, and its potential dollar amount, will cause the suitor to adjust the price or possibly reconsider whether the deal should go ahead at all. Alternatively, the parties may seek to apportion the liabilities or ensure they remain with the target company, if the deal is to continue.

D. How Much Diligence is Due?

Since corporate managers are bound to engage in acquisitions and mergers using due diligence, it naturally presents the question of how much diligence is due. A workable answer is as much diligence as is required for the acquiring company's management to make "informed decisions" about the acquisition in a manner that a prudent person in the management of his or her own property would.\textsuperscript{206} In the medical device industry, the due diligence review should always include potential products-liability lawsuits, regardless of grandfathering. Indeed, after the Dalkon Shield disaster,\textsuperscript{207} Shiley heart valves,\textsuperscript{208} penile

\textsuperscript{202} BLACK’S LAW DICTIONARY 926 (7th ed. 1999).

\textsuperscript{203} See generally Katz, supra note 160, at 484, 488-89; Shecter, supra note 62, at 719-36 (discussing the development of successor liability in the context of products liability litigation).

\textsuperscript{204} See supra notes 80-83 and accompanying text.

\textsuperscript{205} BLACK’S LAW DICTIONARY 1225 (7th ed. 1999).


\textsuperscript{207} See supra note 123.

\textsuperscript{208} See, e.g., Michael Schroeder, Mechanical Heart Valve Problems May Lead to a
implants,\textsuperscript{209} and breast implants,\textsuperscript{210} to name just a few examples, nobody could be unaware of such liabilities. Additionally, combining the Supreme Court’s statement on the large number of grandfathered devices still on the market\textsuperscript{211} with the litigation and public outcry over silicone breast implants,\textsuperscript{212} acquirers of medical device manufacturers are by no means safe or out of the woods.

Given the breast-implant morass, it seems two new factors should be added to the checklist for due diligence as applied to transactions in the medical device industry. First, corporate managers should determine whether a particular device was grandfathered under the 1976 Amendments. Second, each medical device company should evaluate whether it is gathering adequate safety data for the FDA when that agency inevitably decides to seek this information. Arguably, these factors should be at the top of the list. In addition to the checklists provided by the SEC,\textsuperscript{213} the NASD,\textsuperscript{214} and others,\textsuperscript{215} which can be adopted and adapted as needed for due diligence reviews, the following non-exclusive list should be kept in mind by any potential acquirer of a medical device manufacturer and any advisor of such party:

1. Were the devices manufactured by the target corporation grandfathered under the 1976 Amendments to the Food Drug & Cosmetic Act?\textsuperscript{216}
2. Has the FDA given notice of its intent to require PMA submissions from the industry?\textsuperscript{217}
3. Has a PMA been prepared or even filed?
4. Does the target company have adequate clinical data demonstrating the safety and efficacy of its devices?\textsuperscript{218}
5. Is the target company gathering such data?
6. Has the potential acquirer scoured the various medical databases for


\textsuperscript{210} See supra notes 10-15, 20-22 and accompanying text.

\textsuperscript{211} See supra note 34.

\textsuperscript{212} See supra notes 10-15 and accompanying text.


\textsuperscript{214} LAWRENCE, \textit{supra} note 162, § 1.04[1] (quoting the NASD’s proposed rule for determining due diligence standards for underwriters).


\textsuperscript{216} \textit{See supra} Part IV.B.

\textsuperscript{217} Cf. \textit{supra} notes 3, 49 and accompanying text.

\textsuperscript{218} Cf. \textit{supra} note 53 and accompanying text.
anything remotely related to the device\textsuperscript{219} that could conceivably become a products liability suit in the hands of a creative lawyer?\textsuperscript{220}

7. In addition to checking for published papers in various databases, has the potential acquirer examined abstracts from recent meetings of professional societies, members of which are likely to be involved in the use or study of the device(s) and any conditions possibly associated with the device(s)?\textsuperscript{221}

8. Has the potential acquirer retained consultants who attend such professional meetings and work in the relevant medical or scientific fields, and whose ears are close to the ground and know what is going on in the field?\textsuperscript{222}

In short, in addition to all the traditional commercial and accounting details, any potential acquirer of a medical device company should learn a great deal about the device(s) in question and the regulatory and medical context in which the target operates.

\textsuperscript{219} There is no excuse for not doing so, now that Medline, the National Library of Medicine's database of scientific publications, is freely available on the Internet via http://www.medscape.com. An experienced searcher should readily be able to locate all relevant publications. Additionally, Medline and other databases are available via Westlaw, Lexis, and Dialog.

\textsuperscript{220} For example, with silicone breast implants, there was a history of problems associated with injections of silicone (probably not medical grade) and other liquids for cosmetic purposes. See, e.g., Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 913 (Mass. 1998) (referring to animal studies demonstrating problems following injection of silicone); Stander v. Orentreich, 627 N.Y.S.2d 879, 880-81 (N.Y. Sup. Ct. 1995) (concerning injections of liquid silicone into face); Anderson v. Am. Soc'y of Plastic & Reconstructive Surgeons, 807 P.2d 825, 826 (Utah 1997) (same as previous case); Yasuo Kumagai et al., Scleroderma After Cosmetic Surgery: Four Cases of Human Adjuvant Disease, 22 Arthritis & Rheumatism 532, 532 (1979). However, there were also several instances of safe use of silicone devices. See, e.g., Jack C. Fisher, The Silicone Controversy—When Will Science Prevail?, 326 N. ENG. J. MED. 1696, 1696-97 (1992).

\textsuperscript{221} For example, preliminary results from many of the breast implant studies may have been first published as abstracts at meetings of the American College of Rheumatology, the Society for Biomaterials, and the American Society for Aesthetic Plastic Surgery.

\textsuperscript{222} For example, the medical report by Dr. van Nunen and colleagues was published in 1982, but it is possible that preliminary results were being discussed in the field earlier than that. See van Nunen et al., supra note 41, at 694. Despite the strict duty of non-disclosure under which all peer reviewers of scientific and medical journal articles supposedly operate, people in the field generally know in advance that important papers are about to be published. The grapevine is alive and well, and doubtless facilitated by e-mail, the Internet, and frequent travel to scientific conferences and meetings.
VI. CONCLUSION

Potential acquirers of companies in the medical device industry should be aware of the dangers involved. As the Supreme Court has observed, many of the medical devices on the market today have not been FDA approved, in the current sense of the word. As then-FDA commissioner Kessler stated, it is the law that sooner or later all grandfathered devices will have to undergo the PMA process and prove their safety and efficacy, or be removed from the market. If any of the studies had actually shown truly negative data, things would certainly have been much worse. While it seems unlikely anything quite like the breast implant fiasco could be repeated for other medical devices, a potential acquirer should keep it in mind when evaluating what due diligence requires. The acquirer must examine whether the devices manufactured by the target corporation were on the market, and therefore grandfathered in 1976; whether they were introduced into the market after 1976 but are substantially equivalent to devices on the market prior to 1976; whether the FDA has yet to seek PMA submissions from the industry; whether data suitable for a PMA has been collected by the target; whether PMA documents have been prepared; and whether such studies have been planned, completed, or are in progress.

Bristol-Myers, 3M, and Baxter were all caught off guard when they improvidently acquired the breast implant companies, not because they should have known scientifically that implants might cause immunological problems, as the plaintiffs have since alleged, but because the requirement to submit a PMA was inevitable. At the time they were acquired, none of the implant companies had data appropriate for a PMA. It should be noted that, when they

223. See supra note 33.
224. See Kessler, supra note 7, at 1713-14.
225. See supra notes 53-55 and accompanying text.
226. A key difference between breast implants and most medical devices was that 80% of implants were implanted in healthy women for purely cosmetic purposes. See Kathy A. King-Cameron, Comment, Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation, 68 Tul. L. Rev. 937, 960 (1994); Kristin B. Meyer, Comment, Silicone Breast Implants and Hospital Liability: A New Forum for Hybrid Transactions, 99 Dick. L. Rev. 429, 475 (1995); Sarah Glazer, Women’s Health; Battle over Breast Implants; Fewer Women Are Seeking Cosmetic Enlargements, Plastic Surgeons Say, WASH. POST, Jan. 14, 1992, at Z07. Thus, almost any risk of adverse effects in healthy women was probably unacceptable. This reasoning was likely factored into the FDA’s decisions. Clearly, the risk-benefit analysis is rather different for other medical devices, such as a cardiac pacemaker, without which the patient will die.
227. See Kessler, supra note 7.
were acquired in 1981, each of the breast implant manufacturers had over five years' notice that a PMA eventually would be sought. Indeed, they still lacked this data years later, when the FDA finally sought PMAs.

Since the turmoil in the 1980s, it has become scientifically apparent there was nothing to know. To this day, studies have failed to show implants cause immunological or rheumatological problems. However, Bristol-Myers, 3M, and Baxter can surely be faulted for not having conducted or funded such epidemiological studies earlier to demonstrate safety. Perhaps if they had done so, they would have had adequate data available when the FDA called for it.

In conclusion, a potential acquirer of a medical device company should keep in mind the expansive view of successor liability expressed by some courts in the products-liability arena. Successor companies have been held liable regardless of the form of the merger or acquisition. Suitors would also do well to dig deeply into the regulatory status of the devices in question and any reports in the medical and scientific literature. Assessment of the costs of obtaining PMA data and filing a PMA is another critical element. Additionally, the danger of being caught without adequate PMA data should be considered. It was, after all, the inadequacy of safety data, not the presence of any hazard that sparked the whole breast implant furor. The acquirer should then factor all of this information into the price, or reconsider whether to go ahead with the deal at all. In the end, had Bristol-Myers, Baxter, and 3M done so, they probably would have escaped the exposure to liability and negative press that followed from their acquisitions of breast implant manufacturers in the early 1980s.

228. See supra Part IV.B.
229. See supra note 7 and accompanying text.
230. See supra note 50.
231. See supra notes 80-95 and accompanying text.
232. See supra notes 49-55 and accompanying text.