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Comment: Surgically Implanted Medical Device Liability: Will the New Restatement Help the Unraveling Shield Created by Medtronic, Inc. v. Lohr?

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SURGICALLY IMPLANTED MEDICAL DEVICE LIABILITY: WILL THE NEW *RESTATEMENT* HELP THE UNRAVELING SHIELD CREATED BY *MEDTRONIC, INC. V. LOHR*?

I. INTRODUCTION

Representing a plaintiff in medical device litigation against the device manufacturer prior to 1996 probably felt like David preparing to meet Goliath.¹ The 1996 preemption analysis utilized by the United States Supreme Court in *Medtronic, Inc. v. Lohr*,² paved the way for various state actions to survive federal law preemption.³ However, questions remain regarding the reach of *Lohr*, which arguably dealt with only one aspect of a complex regulatory scheme.⁴

This Comment begins by guiding the reader through the rationale for device control, the various levels of control based upon the presumed risks of device use, and the specific statutory provisions that preempt state law.⁵ Knowledge of these concepts is essential to understanding device use liability implications as the various controls create the legal duties imposed under federal law and regulation—duties that are not to be preempted by state law.⁶

Medical devices are classified into three categories, Class I, Class II and Class III respectively, with each class subjected to greater regulatory control due to the potential risks associated with use.⁷ After briefly discussing Class I and II devices, the Comment focuses on Class III medical devices as they create the gravest risk of injury from failure, and are the class of devices most often utilized in surgical procedures.⁸

Subsequent to presenting the medical device preemption language, the Comment provides a brief history of preemption principles, and reviews how the Supreme Court originally analyzed similar statutory language.⁹ In addition, in this section, the Comment provides an overview of pre-*Lohr* Fourth Circuit preemption holdings, which essentially closed the door to seeking redress for device failure.¹⁰

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1. See *infra* note 171 and accompanying text for a discussion of the likelihood of preemptive claims prior to a landmark 1996 Supreme Court case.
 2. 518 U.S. 470 (1996).
 3. See *id.* at 489.
 4. See *infra* note 176.
 5. See *infra* Parts II.A-B.
 6. See *infra* note 82 and accompanying text for a discussion of the statutory preemption language.
 7. See *infra* Parts II.B.1-2.
 8. See *infra* Part II.B.2.
 9. See *infra* Part III.B.1.
 10. See *infra* Part III.B.2.

The Comment then exposes the new difficulties created in preemption analysis by providing a close, dissected look at *Lohr*.¹¹ In *Lohr*, the United States Supreme Court struggled to agree on the appropriate analysis, and deviated from precedent to reach a conclusion that provided the plaintiffs with a small opportunity for remedy.¹² Once presenting a framework for application of the *Lohr* opinion, the Comment individually examines the various causes of action related to surgically implanted medical device use.¹³ The Comment focuses on how courts within the Fourth Circuit handle claims of preemption post-*Lohr*, and liability analyses falling outside of the preemptive scope.¹⁴ Emphasis is placed upon manufacturing liability, although some interrelated discussions of downstream liability are presented.¹⁵

Legal principles advanced by the *Restatement (Third) of Torts: Products Liability*¹⁶ ("*Restatement (Third)*") are woven into this discussion.¹⁷ For the most part the new *Restatement* does not depart significantly from the principles applied in products liability litigation within the Fourth Circuit.¹⁸ However, the new standard raises the bar to attach strict liability for injury due to defective design or manufacturing, although pro-technology might render the harmed person without recourse if adopted.¹⁹

II. UNDERSTANDING THE INTRICATE MEDICAL DEVICE STATUTORY SCHEME

Because medical devices move through interstate commerce, the federal government has great latitude to exert statutory control.²⁰ As with any federally controlled industry, it is important to understand the reach of the specific statutory provisions and corresponding regulations.²¹

11. See *infra* Part III.C.

12. See *infra* Part III.C.3.

13. See *infra* Parts IV.A-D.

14. See *infra* Parts IV.A-F.

15. See *infra* Parts IV.

16. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (1998) [hereinafter RESTATEMENT (THIRD)].

17. See *infra* Part IV.D.

18. See *infra* Part III.

19. See *infra* Parts III.C-D.

20. *United States v. Depilation Epilator Model No. DP-206 Universal Tech., Inc.*, 473 F. Supp. 913, 915 (S.D.N.Y. 1979) (holding that Congress may regulate medical devices that are sold and distributed among the several states).

21. See, e.g., Merrit B. Fox, *Insider Trading Deterrence Versus Managerial Incentives: A Theory of Section 16(b)*, 92 MICH. L. REV. 2088, 2096 (1994) (discussing the importance of understanding the reach of statutes and regulations in securities law).

A. *The Federal Statutory Scheme: The Food and Drug Act of 1906 Through the Medical Device Amendments of 1976*

Since the early days of federalism, the several states have enjoyed significant latitude in regulating matters affecting the health and safety of their individual citizens.²² Under their policing power, states could legislate, as necessary, to protect the health, lives and limbs of all persons residing within their borders.²³ Industrialization and technological advances, however, opened the door for trade via interstate commerce, and therefore, the ability for the federal government to become increasingly involved in state affairs.²⁴

Although the role of Congress in regulating interstate commerce changed over the years,²⁵ Congress began to significantly impact the regulation of health matters by enacting the Food and Drug Act of 1906 ("1906 Act").²⁶ This legislation established a broad prohibition against the manufacture of any adulterated or misbranded food or drug placed in the stream of interstate commerce, or the actual shipment through interstate commerce of such an item.²⁷

As legitimate health-care entities competed against charlatans to promote their new "state-of-the-art" medical devices, Congress identified a need to expand the 1906 Act to offer additional protection from the sale of unsafe medical devices.²⁸ Consequently, Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), broadening the scope of protection to include misbranded or adulterated medical devices.²⁹

Meanwhile, within the health-care industry, technological advances were leading to an increase in the types and sophistication of health-care products entering the market.³⁰ These products had no govern-

22. Stanley E. Cox, *Garbage Out: Court Confusion About the Dormant Commerce Clause*, 50 OK. L. REV. 155, 220 (1997).

23. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (citing *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)).

24. See generally Richard A. Epstein, *The Proper Source of the Commerce Power*, 73 VA. L. REV. 1387, 1399-1454 (1987) (discussing the history of federal regulation of interstate commerce as society advanced through the years).

25. *Id.*

26. 34 Stat. 768 (1906).

27. See *id.*

28. See S. Rep. No. 94-33 (1975) (noting in section II that the 1930s reformers sought legislation to protect against "unsafe or quack devices").

29. 52 Stat. 1049-51 (1938).

30. In 1938, when the FDCA was enacted, most medical devices were relatively simplistic, employing basic scientific concepts. Trained medical personnel who utilized these devices could often detect if the device was malfunctioning. Legislative concern was focused upon truthful advertising resulting in an emphasis on labeling requirements. In the 1960s, the focus shifted from fraudulent devices to hazards associated with legitimate medical device use. This was prompted by the increased complexity of medical devices such as heart pacemakers, kidney dialysis units, and artificial heart valves. Because of the sophisticated technology utilized, skilled medical personnel were no

mental control beyond the parameters of misbranding or adulteration.³¹ Despite advantages to health-care advancements, the American public suffered harm resulting from these new sophisticated medical devices that were marketed as safe and effective for use.³²

In response to the mounting concern regarding public health and safety from consumer groups as well as legislators,³³ Congress enacted the Medical Devices Amendments of 1976 (MDA) to regulate device safety and effectiveness, including the entrance of medical devices into the stream of commerce.³⁴ Recognizing that medical devices, based upon their design and use, presented the potential for gradations of harm, the MDA provided a classification system subjecting each device class to increasingly stricter regulatory control.³⁵

B. Different Standards Based Upon Risk Potential

1. Classification System

Under the statute, Congress authorized the Secretary of Health and Human Services ("Secretary"),³⁶ in conjunction with expert panels,³⁷

longer able to determine if a device was defective or not. *See* S. Rep. No. 94-33, pt. II, at 1 (1975).

31. The FDCA additionally expanded public protection by providing for a premarket review process for new drugs. The statute required the submission of an application, including investigational reports, which became effective sixty days after filing. Once the drug became effective, it could be introduced into interstate commerce unless it was determined by the Secretary of Agriculture that the drug was unsafe for its intended use. Interestingly, these same protections were not implemented for new medical devices entering the market. *See* § 505, 52 Stat. 1052.
32. In 1969, Dr. Theodore Cooper, Director of the National Heart and Lung Institute, headed a panel that searched scientific literature and found a recorded 10,000 injuries including 731 deaths from medical devices. For example, heart valves caused 512 deaths and 300 injuries, pacemakers caused 89 deaths and 186 injuries, and intrauterine devices caused 10 deaths and 8,000 injuries. *See* S. Rep. No. 94-33, pt. II, at 6 (1975).
33. The Senate Labor and Public Welfare Committee held hearings over a two-day period in 1973 when previous medical device legislation was introduced. Testimony from various industrial, professional and consumer groups reflected agreement regarding the need for medical device legislation. *See* S. Rep. No. 94-33, pt. III, at 7 (1975) (providing a synopsis of the previous testimony).
34. Medical Device Amendments of 1976, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. (1976)).
35. *See* 21 U.S.C. § 360c (1994).
36. 21 U.S.C. § 321(d) (referring to the Secretary of Health and Human Services). The Commissioner of the Food and Drug Administration (FDA) was subsequently empowered to perform the "[f]unctions vested in the Secretary under the [FDCA]." 21 C.F.R. § 5.10(a)(1).
37. The FDA is charged to appoint experts to the panel who are qualified to evaluate device safety and effectiveness because of their experience in developing, manufacturing or utilizing such medical devices. The FDA is further required to ensure that there is a diverse range of expertise, such as

to classify devices into one of three categories.³⁸ Class I is reserved for medical devices that are not used to support or sustain human life and do not present an unreasonable risk of illness or injury.³⁹ For example, medical devices such as ice bags, examination gloves, patient scales, crutches, non-electric wheelchairs, and hand-crank hospital beds receive Class I status.⁴⁰

More complex devices such as diagnostic x-ray machines, magnetic resonance imaging machines, electrocardiograph equipment, electric heating pads, electric wheelchairs and electric hospital beds fall within Class II.⁴¹ These devices receive Class II designation because additional regulatory control⁴² is necessary to ensure device safety and effectiveness.⁴³

Finally, Class III is reserved for those devices that are life-supporting, life-sustaining or create a potentially unreasonable risk of harm.⁴⁴ Class III devices include hip prosthesis, pacemakers, intraocular lenses, pedicle screw fixation devices, inflatable penile prosthesis, heart valves, monitors to detect heart irregularities, anti-choking suction devices, silicone breast implants, and artificial knee joints.⁴⁵

2. Medical Device Controls

Each class is subjected to different regulatory controls designed to "provide reasonable assurance of the safety and effectiveness of the device."⁴⁶ Safety and effectiveness are determined by evaluating the intended user, the conditions of use, and by balancing the probable benefits against the probable risk of injury or illness.⁴⁷

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- within areas of medicine, engineering, biology, and physics. In addition, expert panels must include nonvoting members who represent the views of both consumers and the manufacturing industry. 21 U.S.C. § 360c(b)(2).
38. *See id.* § 360c(b)(1)(B) (providing power to classify all devices except those classified under subsection (f)).
39. *Id.* § 360c(a)(1)(A).
40. 21 C.F.R. §§ 880.6050 (ice bag), 880.6250 (examination gloves), 880.2720 (scale), 890.3150 (crutches), 890.3850 (wheelchair), 880.5120 (hospital bed).
41. 21 C.F.R. §§ 892.1680 (x-ray), 892.1000 (MRI), 870.2340 (EKG), 890.5740 (heating pad), 890.3860 (powered wheelchair), 880.5100 (adjustable bed).
42. *See infra* notes 53-54 and accompanying text.
43. *See* 21 U.S.C. § 360c(a)(1)(B).
44. *See id.* § 360c(a)(1)(C).
45. 21 C.F.R. §§ 870.3925 (valves), 870.1025 (heart arrhythmia detector), 874.5350 (suction device), 878.3530 (implant), 888.3480 (knee joint).
46. 21 U.S.C. § 360c(a)(1)(A)(i); *see also id.* § 360c(a)(1)(A)-(C) (addressing Class I devices in subsection (A), Class II devices in subsection (B), and Class III devices in subsection (C)).
47. *See id.* § 360c(a)(2)(A)-(C).

a. *General Controls*

All medical devices are subjected to "general controls."⁴⁸ These include specified good manufacturing practices (GMP), labeling requirements, and certain standards for registration, notification, record keeping and reporting.⁴⁹ In addition, federal statutes prohibit the manufacturing and introduction into interstate commerce of medical devices that are adulterated or misbranded.⁵⁰ Most Class I devices are exempt from additional regulatory controls because the "general controls" are adequate enough to ensure device safety and effectiveness.⁵¹

Some Class I⁵² and the remaining Class II and III devices are subjected to quality system GMP regulations that set forth quality control standards. These standards include requirements to control device design, monitor production processes, utilize sufficient numbers of trained personnel who adhere to certain health and cleanliness standards and perform quality audits.⁵³

b. *Special Controls*

In addition, Class II and III devices are subject to "special controls" because the general controls alone are deemed insufficient to reason-

48. *Id.* § 360c(a)(1)(A).

49. *See, e.g., id.* §§ 360j(f) (empowering the Secretary to prescribe regulations for pre-production design validation, manufacturing controls, packing, storage and installation of devices to assure safety and effectiveness), § 360(b), (c), (j) (requiring each medical device manufacturer to submit an initial and annual registration, including at the time of submission, a copy of the device label and packaging insert), § 360h(a)(2) (requiring health professionals to notify patients treated with a certain medical device of a risk presented by the device and the necessary action to reduce or eliminate the risk), § 360i(a)-(b) (requiring manufacturers to maintain records and reports with respect to safety and effectiveness, and more specifically, to report adverse medical device use consequences, such as malfunctioning likely to cause serious injury or death); 21 C.F.R. §§ 801.4, 801.15 (addressing labeling requirements such as stating the manufacturer's intended device use, labeling insufficiency such as inadequate information or space, and formatting limitations on print size, style, clarity and background contrast).

50. *See* 21 U.S.C. § 331(a), (g); *see also id.* § 351(g) (determining that a device banned from the market is deemed to be considered adulterated).

51. *See id.* § 360c(a)(1)(A)(i). Even if it is not possible to determine that the general controls are adequate to provide reasonable safety assurances, the device would still escape further scrutiny if it did not present an unreasonable risk of illness or injury and (1) was not intended to be used to support or sustain life, or (2) did not serve a substantial function in preventing impairment. *See id.* § 360c(a)(1)(A)(ii)(I).

52. *See, e.g.,* 21 C.F.R. § 820.30 (subjecting items such as surgeon's gloves and patient protective restraints to quality system design controls).

53. 21 C.F.R. §§ 820.1, .22, .25, .30, .70. In addition, manufacturers of surgically implanted devices likely to result in significant injury, should the device fail to perform as intended, are required to batch and distribute the device using a control system to facilitate corrective action. *Id.* § 820.65.

ably ensure device safety and effectiveness.⁵⁴ Special controls include requirements such as the establishment of patient registries, post-market surveillance, and designated performance standards.⁵⁵ Designated performance standards include specifications for device construction, device testing to ensure adherence to established standards, specific labeling content and restrictions on device sale and distribution.⁵⁶

c. Class III Designation—Premarket Approval Process

When neither the general nor the specific controls provide reasonable safety assurances of a device that either: (1) is intended to support or sustain life or is of substantial importance to prevent impairment; or (2) presents an unreasonable risk of illness, then a Class III designation is required.⁵⁷ As a result of the inherent dangers, these devices are subjected to a premarket approval (PMA) process.⁵⁸ Under the PMA process, the device manufacturer must submit an application to the FDA.⁵⁹ This application must contain full reports of investigations regarding device safety and effectiveness, a discussion of the device properties and mode of operation, a description of manufacturing and packaging methods, proposed labeling, and if required, device samples.⁶⁰ In addition, regulations require the application to include clinical indications for device use, a description regarding how the device functions, a listing of available alternative treatment interventions, and a description of the marketing history here and abroad, including any market withdrawals.⁶¹ Due to the level of scrutiny and

54. See 21 U.S.C. § 360c(a)(1)(B)-(C) (addressing Class II and Class III devices).

55. See *id.* §§ 360c(a)(1)(B), § 360d (providing examples of performance standards and discussing how standards are established and recognized); see, e.g., 21 C.F.R. § 888.3070(a)(2)(i)-(iv) (listing the “special controls” for a Class III pedicle screw spinal system, which include biocompatibility and mechanical testing standards, specific warning labeling and a precaution for use by specifically trained and experienced surgeons).

56. See 21 U.S.C. §§ 360c(a)(1)(B), § 360d.

57. *Id.* § 360c(a)(1)(C).

58. *Id.* § 360c(a)(1)(C)(ii)(II) (requiring adherence to the PMA process to reasonably ensure device safety and effectiveness).

59. *Id.* § 360e(c); see also 21 C.F.R. § 814.20(b)(3)(v).

60. 21 U.S.C. § 360e(c); see also 21 C.F.R. § 814.20(b)(3)(v) (delineating the application to include information on clinical investigations involving human subjects, as well as other nonclinical laboratory studies). Reports of clinical experimental studies must include information regarding human subject selection, study length, and results of statistical analysis, including adverse reactions and patient complaints. 21 C.F.R. § 814.20(b)(6)(ii). Nonclinical study reports contain information regarding biocompatibility, response to use and stress, and device shelf life. *Id.* § 814.20(b)(6)(i).

61. *Id.* § 814.20(b)(3)(i)-(iv).

attention to detail, the FDA spends an average of 1200 hours reviewing and approving a premarket device submission.⁶²

3. Alternatives to Place Class III Medical Devices on the Market

Although the PMA process provides a safety net to protect the public from unsafe medical devices entering the market, this statutory weapon has limited range due to the ability to place a Class III device into the stream of commerce by alternative methods. A minority of the Class III devices marketed today have undergone the rigorous PMA standards.⁶³

In adopting the Medical Device Amendments, Congress realized that devices falling into the Class III category, already in the stream of commerce, needed to remain on the market while the FDA completed the PMA analysis for those devices.⁶⁴ Market forces⁶⁵ further required that "substantially equivalent" devices to those already in the marketplace needed an easier entry than the cumbersome and lengthy PMA process.⁶⁶ In addition, to promote technological innovations, the MDA's scheme integrated an "[e]xemption for devices for investigational use" specifically applicable to experimental devices.⁶⁷

"Substantially equivalent" Class III devices do not enter the market in a completely unfettered fashion. Like new Class I and Class II devices, these Class III devices are subjected to a premarket notification submission,⁶⁸ also referred to as the "510(k) process."⁶⁹ The 510(k) submission for a Class III device must include the device name, pro-

62. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (citing the hearings before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce during the 1987 session); *see also* 21 U.S.C. § 360e(d)(1)(A) (providing the FDA with up to 180 days to decide to approve or deny the application).

63. *See Lohr*, 518 U.S. at 479 (relying upon House Reports estimating that 91% of Class III devices introduced between 1976-83 and 80% of devices introduced in 1990 entered the market as "substantially equivalent" therefore bypassing the premarket approval process).

64. *See id.* at 477-78 (explaining the rationale for the "grandfathering" provision for pre-1976 devices, but further adding in footnote 3 that the FDA had not yet initiated the process for most Class III devices).

65. Congress identified the two market influences behind the "substantially equivalent" exception as: (1) fear of market monopolization by manufacturers of pre-1976 devices, and (2) the desire to encourage the rapid entry of improved existing devices. *Id.* at 478.

66. *See* 21 U.S.C. § 360c(i)(1)(A) (defining "substantial equivalent" as a device that has the same intended use, and either (i) the same technological characteristics as an already marketed device; or (ii) different technological characteristics but information that demonstrates that the proposed device is as safe and effective as the legally marketed device); *see also Lohr*, 518 U.S. at 478 (referring to Congress' intention to permit these specific devices to avoid the PMA process).

67. 21 U.S.C. § 360j(g)(1).

68. *See id.* § 360(k) (requiring the submission of a report to the FDA at least ninety days before the device's market introduction).

posed labeling showing intended use, a statement with supporting data, indicating device similarities and differences from comparable devices already in commercial distribution, and a financial disclosure.⁷⁰ If the intended use differs from that of the legally marketed equivalent device, the FDA requires an explanation of why the differences do not affect device safety and effectiveness.⁷¹ Overall, the review required by the 510(k) process takes on average twenty hours to complete.⁷² Only if the FDA required the underlying pre-1976 device to submit to the rigors of the 510(k) process will the substantially equivalent device receive such scrutiny.⁷³

The "investigational device exemption" (IDE) allows limited market entry of new devices excluded from the rigorous PMA process.⁷⁴ Public health and safety concerns remain, but to encourage discovery and development of efficacious devices, Congress implemented this ex-

69. See *Lohr*, 518 U.S. at 478 (defining the "premarket notification" as the "[section] 510(k) process" because that was the section number in the original Act).

70. See 21 C.F.R. § 807.87 (requiring the comparative device summary to include problems related to safety and effectiveness based upon a reasonable search of information known or available).

71. See *id.* § 807.92(a)(5).

72. See *Lohr*, 518 U.S. at 479 (relying upon legislative reports of hearings before the House in 1987). The Court in *Lohr* quotes a journal commentator who stated that the "[section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Id.* (citation omitted); see also 21 C.F.R. § 807.100 (requiring the FDA to merely determine if the device is or is not substantially equivalent to a legally marketed device). But see *supra* note 62 and accompanying text for a discussion of the average 1200 hours the FDA requires to complete the PMA process.

73. See *Lohr*, 518 U.S. at 478; see also 64 Fed. Reg. 45,155 (Aug. 19, 1999). For example, final regulations published on August 19, 1999, require inflatable silicone breast implants to undergo the more vigorous PMA process. See 64 Fed. Reg. 45,155. It is interesting to note that although the FDA identified this medical device "as one of the high-priority devices that would be subject to [the] PMA [process]" on January 6, 1989, proposed regulations were not issued until January 8, 1993, and final regulations were not promulgated until August 19, 1999. See *id.*

74. See 21 U.S.C. § 360e(a)(2) (1994); see also 45 Fed. Reg. 3,732-33. In 1980 when the FDA published the final regulations governing the IDE exemption, they responded to comments from the industry concerning the "burdens" placed on manufacturers and investigators by the IDE regulations. See *id.* The FDA justified the regulations as "critical to [the] protection of [human] subjects in all investigations" by requiring, among other standards, "informed consent, institutional review, and reporting of unanticipated adverse device effects." *Id.*; see also, e.g., *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir. 1997) (recognizing that "[a]lthough investigational devices are not subject to the rigorous PMA process, they are subject to a different set of complex and comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective").

emption to provide optimal freedom to scientific investigators.⁷⁵ An IDE device is exempted from certain FDCA standards including requirements regarding misbranding, premarket notification, performance standards, and many of the GMPs.⁷⁶

Device entry does not, however, occur without any scrutiny. The initial IDE application must include, among other things, a description of the manufacturing methods and controls, and copies of all device labeling.⁷⁷ The applicant requesting an IDE must establish, maintain and submit reports of data obtained during the investigational study.⁷⁸ This data enables the FDA to determine compliance with investigational standards, review progress of clinical trials and evaluate device safety and effectiveness.⁷⁹ Throughout the investigational period, the investigators must personally supervise human studies and an informed consent from each subject must be obtained, except in certain life-threatening or life-saving situations.⁸⁰ IDE device approval is denied if the human risk outweighs the anticipated benefits to both specific individuals and the public as a whole.⁸¹

III. STATE OR LOCAL STATUTORY PROTECTION FROM MEDICAL DEVICE FAILURE—FACT OR FICTION

A. *Preemption Language of the MDA*

By enacting section 360(k), Congress preempted any requirements established by state and local law that related to a medical device's safety and effectiveness, or to any matter included within applicable federal requirements that differ from or are in addition to requirements under the MDA.⁸² Federal regulations sought to narrow this broad preemptive cloak by restricting preemption of state and local

75. 21 C.F.R. § 812.1(a) (allowing optimum freedom so long as it is consistent with public safety and ethical standards within the medical profession).

76. *Id.*

77. *Id.* § 812.20; *see also id.* § 812.5. Specific labeling regulations require not only a precautionary statement that the device is for "investigational use," but the label must indicate hazards and adverse effects and may not bear "false or misleading" statements or indicate that the device is "safe and effective." *See id.*

78. 21 U.S.C. § 360j(g)(2)(B)(ii) (1994).

79. *Id.*

80. *Id.* § 360j(g)(3)(C)-(D).

81. 21 C.F.R. § 812.30(b) (noting additional reasons for disapproval include fraudulent reporting, unsound scientific methodology, inadequate informed consent, or presumed lack of device efficacy).

82. Section 360k states:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

requirements only in situations where the FDA “has established *specific counterpart regulations* or there are other *specific requirements* applicable to a particular device.”⁸³

The regulations define “state or local requirements” as those having legal effect regardless of whether established through the legislative, administrative *or* judicial process.⁸⁴ State or local requirements that are not “applicable to a device” are not preempted merely because they might affect a medical device.⁸⁵ In addition, requirements equal to or substantially identical to federal requirements are not preempted.⁸⁶ Congress also empowered the Secretary, who then delegated the ability to the FDA, to exempt more stringent state and local requirements or those necessitated by local conditions if they did not violate federal requirements.⁸⁷ The federal requirements control ar-

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k (1994).

83. 21 C.F.R. § 808.1(d) (emphasis added). Language quoted from § 808.1(d) which states in part:

State or local requirements are preempted only when the Food and Drug Administration has established *specific counterpart regulations* or there are other *specific requirements* applicable to a *particular device* under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

Id. (emphasis added).

84. Relying on § 808.1(b) which states in part:

[As] a general rule [] after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

Id. § 808.1(b) (emphasis added). But see *infra* notes 86-87 and accompanying text for a discussion of the term “requirement” utilized in MDA as including specific statutory enactments and accompanying regulations, but not judicially applied common law.

85. 21 C.F.R. § 808.1(d)(1), (3), (6)(ii) (including a laundry listing of examples ranging from requirements of general applicability such as electrical codes, to licensing requirements such as those of the medical board regulating the surgeon who dispenses the device, to requirements prohibiting the manufacture of adulterated devices).
86. *Id.* § 808.1(d)(2). The FDA has responsibility for determining whether a state or local requirement is equal to, different from, or in addition to a federal requirement. See *id.* § 808.1(e) (acknowledging the FDA decision is subject to judicial review); see also *id.* § 808.1(d) (qualifying the controlling nature of the federal regulations in case of a conflict).
87. Section 360k(b) states:
Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this sec-

as not covered by an exempted state or local requirement that are narrower in scope than the corresponding federal requirements.⁸⁸

B. Historic Preemption Analysis as Applied in Medical Device Litigation

1. Preemption Principles

Under the Supremacy Clause, state laws are superseded, or, preempted, to the extent that they conflict with federal legislation.⁸⁹ Caution must be taken, however, in a preemption analysis because finding a "clear and manifest" congressional intent is necessary before superseding the "historic police powers of the States."⁹⁰ Requiring this standard has a long history beginning with the 1912 Supreme Court case of *Savage v. Jones*.⁹¹ In *Savage*, the Court distinguished between express and implied preemption, finding either sufficient if the legislative intent was *clearly* manifest.⁹²

In 1947, the Supreme Court in *Rice v. Santa Fe Elevator*,⁹³ addressed the preemption scope where Congress provided express preemption language in the federal statute.⁹⁴ Despite the explicit statutory language, the *Rice* Court did not focus on the express language as the assessment of congressional intent.⁹⁵ The Court reasoned that even without the express language, congressional intent could be inferred, especially when the federal interest dominated state interest or the federal legislation was so comprehensive that it precluded the states' ability to supplement the legislation.⁹⁶

tion, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if -

- (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
- (2) the requirement -
 - (A) is required by compelling local conditions, and
 - (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(b).

88. 21 C.F.R. § 808.1(f).

89. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citations omitted).

90. *Id.* (citation omitted).

91. 225 U.S. 501 (1912).

92. See Susan Raeker-Jordan, *The Pre-emption that Never Was: Pre-Emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379, 1384-85 (1998) (tracing in Part II.B. the historical judicial preemption analysis).

93. 331 U.S. 218 (1947).

94. *Id.* at 222-23.

95. See *id.* at 230.

96. *Id.* (noting additionally that state exemption is appropriate when state policy is inconsistent with federal statutory objectives).

In 1977, the Supreme Court addressed federal law preemption of a state regulation in *Jones v. Rath Packing*.⁹⁷ This case addressed certain net-weight labeling requirements, an area “traditionally occupied by the States.”⁹⁸ The *Rath Packing* Court clarified once again that the preemption analysis “requires us to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written.”⁹⁹

A significant change in the historic preemption analysis occurred with the 1992 Supreme Court decision of *Cipollone v. Liggett*.¹⁰⁰ In *Cipollone*, the Court determined the scope of two statutory preemption provisions, the Federal Cigarette Labeling and Advertising Act of 1965 (“1965 Act”) and the Public Health Cigarette Smoking Act of 1969 (“1969 Act”).¹⁰¹ In its preemption analysis, the Court found that when Congress, by express language, includes a preemptive provision, and the written words reliably indicate congressional intent, no further inquiry of intent is necessary.¹⁰²

The 1965 Act expressly prevented “statements” related to “smoking and health” that differed from the labeling requirements of the federal statute.¹⁰³ A majority of the *Cipollone* Court concluded that “statement” referred to “only positive enactments by legislatures or administrative agencies that mandate particular warning labels.”¹⁰⁴ The 1969 Act amended the preemptive language of the 1965 Act by preempting not only “statements” but also “requirement[s] or prohibition[s] . . . imposed under State law.”¹⁰⁵ In concluding that the new

97. 430 U.S. 519 (1977).

98. *Id.* at 525.

99. *Id.* at 526 (reaffirming a finding of preemption as “explicitly stated in the statute’s language or implicitly contained in its structure and purpose”).

100. 505 U.S. 504 (1992).

101. *See id.* at 517.

102. *See Raeker-Jordan, supra* note 92, at 1407.

103. Under the 1965 Act, a section captioned “Preemption” stated in part:

(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be *required* on any cigarette package.

(b) No statement relating to smoking and health shall be *required* in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Cipollone, 505 U.S. at 514 (emphasis added).

104. *Id.* at 518-19. Justices Scalia and Thomas did not concur with the 1965 Act preemption analysis. *See id.* at 507.

105. *Id.* at 515. The 1969 Act modified subsection (b) of the 1965 Act’s preemption provision to state: “[n]o *requirement or prohibition* based on smoking and health shall be imposed *under State law* with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.” *Id.* (emphasis added).

language preempted some common-law actions, the Court no longer reached a majority opinion.¹⁰⁶

A plurality of the Court decided that federal labeling requirements preempted state common-law claims based upon state failure-to-warn negligence actions that created legal duties or "requirements" with respect to cigarette promotion.¹⁰⁷ The plurality acknowledged that even this expanded preemptive scope did not extend to express warranty or fraudulent misrepresentation claims.¹⁰⁸

Although stating that the new principle was to look only to express preemption language when provided, the Justices did not confine their discussion to the words of the statute alone. In the opinion, the Court placed emphasis upon the legislative purpose behind the 1969 Act, a purpose inferred based on substantive changes regarding labeling and advertising.¹⁰⁹ Despite this finding of an expanded legislative purpose, the Court acknowledged that: (1) Congress did not amend the express statutory purposes contained within the Act; and (2) the express purposes suggested congressional concern with "positive enactments, rather than common-law damages actions."¹¹⁰

2. Application in Medical Device Litigation

One year after the *Cipollone* holding, the Eastern Division of the District Court of Virginia, in *Flynn v. Biomet, Inc.*,¹¹¹ faced a complaint alleging strict liability, negligent design and manufacture, and breaches of express and implied warranties.¹¹² The device at issue was a hip prosthesis, a Class III medical device, which entered the market through the extensive PMA process.¹¹³ Based upon the analysis in *Cipollone*, the court acknowledged that the "express preemption provision in the MDA preclud[ed] any reliance upon the doctrine of implied preemption."¹¹⁴ Because of the extensive federal standards

106. *Id.* at 521-23. Only four Justices, Justices Stevens, Rehnquist, White and O'Connor, could agree on the preemptive analysis of the 1969 Act. *See id.* at 507.

107. *Id.* at 524.

108. *Id.* at 531. Express warranty claims do not create "requirements" as they are not state-imposed but rather "contractual commitment[s] voluntarily undertaken." *Id.* at 526. Fraudulent claims do not relate to "smoking and health" but rather to "the duty not to deceive." *Id.* at 528-29.

109. *Id.* at 520 (reasoning that these changes broadened the preemptive scope of section 5(b)).

110. *Id.* at 521 n.19. Section 2, created by the 1965 Act and unchanged by the 1969 Act, lists two statutory purposes: "(1) adequately informing the public that cigarette smoking may be hazardous to health, and (2) protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations." *Id.* at 514 n.9 (emphasis added).

111. No. CIV.A. 93-192, 1993 WL 540570 (E.D. Va. July 23, 1993).

112. *Id.* at *3.

113. *Id.* at *5; *see also supra* notes 57-62 and accompanying text.

114. *Flynn*, 1993 WL 540570, at *5.

regarding device design, manufacturing, and labeling under the PMA process, the court found that any state warranty laws or common-law tort actions based on negligence imposed "additional" or "different" requirements,¹¹⁵ and therefore were preempted by the MDA's express language.¹¹⁶ Summary judgment was granted for all of the claims,¹¹⁷ although the court noted that express warranties extending beyond required FDA labeling could survive preemption.¹¹⁸

Other courts addressed the issue of preemption for Class III medical devices entering the market under a PMA exception. Experimental devices were distinguished from those undergoing the PMA process by the California Court of Appeals in *Evracts v. Intermedics Intraocular, Inc.*¹¹⁹ The court found that IDE devices were not subjected to the "usual [FDA] safety and efficacy requirements," but to their own set of regulations "intended to encourage innovation" in device development, and therefore balanced the potential health risks of a product against its potential medical treatment benefits.¹²⁰ Following the lead of *Cipollone* and others, the court was concerned about the impact of tort liability actions placing *additional* "requirements" upon device manufacturers, serving to hamper innovation and frustrate the legislative purpose for creating this exception.¹²¹ But even more importantly, the court noted that strict liability and negligence claims are "predicated on the notion that a manufacturer has a duty to market a safe product," contrary to the IDE process recognizing the need for clinical trials to determine *if* the device is safe.¹²² Conversely, for the same reason these claims failed under a preemption analysis, warranty claims survived because "[a]ny guarantees of fitness as to investigational devices would not be imposed by the FDA but rather could only be provided directly to consumers by the manufacturer."¹²³

Even Class III devices entering the market through the less rigorous 510(k) "substantially equivalent" process were considered subject to

115. *Id.*

116. *Id.* at *5-*7. See *supra* note 82 for the preemption language within the MDA.

117. *Flynn*, 1993 WL 540570, at *10.

118. *Id.* at *7 (quoting *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993)). The court announced in dicta that even the strict liability claim would be preempted. *Id.* at *6. Virginia law, however, prohibited strict liability recovery, thus, the court could not rule on that claim. *Id.*

119. 29 Cal. App. 4th 779, 34 Cal. Rptr. 2d 852 (1994).

120. *Id.* at 785, 34 Cal. Rptr. 2d at 855; see also *supra* Part II.B.

121. *Evracts*, 29 Cal. App. 4th at 786-87, 34 Cal. Rptr. 2d at 855-56.

122. *Id.* at 787, 34 Cal. Rptr. 2d at 856.

123. *Id.* at 789, 34 Cal. Rptr. 2d at 857 (concluding that their reasoning is analogous to how the *Cipollone* Court handled the express preemption claim). In addition, the *Evracts*' court found that a medical device manufacturer could not "claim the shield of preemption" when it had knowingly misled the FDA to obtain approval. *Id.* at 790-91, 34 Cal. Rptr. 2d at 858. The court also upheld claims based upon the manufacturer's failure to adhere to federal regulations. *Id.* at 794, 34 Cal. Rptr. 2d at 860.

federal requirements capable of exerting preemptive effect. In *Duwall v. Bristol-Myers-Squibb Co.*,¹²⁴ (“*Duwall I*”), the United States Court of Appeals for the Fourth Circuit concluded that the plaintiff’s claims for breach of implied warranty, breach of express warranty based on FDA-mandated requirements, defective design and manufacturing and failure to warn were preempted.¹²⁵ The court determined that because the 510(k) “notification process” required manufacturers to indicate, upon application, proposed labeling, design and manufacturing processes, and to continue adherence to those standards, the “notification process” imposed requirements on the particular medical device.¹²⁶ Therefore, self-created manufacturing standards, reported to the FDA through the “notification process” created binding federal requirements capable of preempting state requirements.¹²⁷

With few claims surviving preemption because of the extensive federal medical device regulatory scheme,¹²⁸ some courts did not even find the need to discuss how the device entered the market. In *Martin v. American Medical Systems, Inc.*,¹²⁹ the plaintiff alleged strict liability, negligence and breach of warranty claims.¹³⁰ The court granted summary judgment to the defendant based upon precedent,¹³¹ without any discussion of the specific federal requirements applicable to this particular medical device.¹³²

C. *Stirring the Waters: The Supreme Court’s Preemption Analysis In Deciding Medtronic, Inc. v. Lohr*

Simply identifying the express preemptive language in the statute and accompanying regulations and relying upon previous Supreme Court rationale is insufficient to resolve questions regarding MDA preemptive scope. Debate regarding this issue is easily found and reaches beyond the language in the statutes and regulations. In 1996, the Supreme Court struggled to determine the prospective standard for a preemption analysis of state claims related to federally controlled

124. 65 F.3d 392, 398 (4th Cir. 1995), *cert. granted, vacated*, 518 U.S. 1030 (1996), *and remanded*, 103 F.3d 324 (4th Cir. 1996) [hereinafter “*Duwall I*”].

125. *Id.* at 401. Once again, the court did not find preemption of express warranties regarding device performance made voluntarily by the manufacturer instead of by state law. *Id.* (relying on the *Cipollone* reasoning).

126. *Id.* at 399-400.

127. *Id.*

128. *See, e.g.*, *Griffin v. Medtronic, Inc.*, 840 F. Supp. 396, 397 (D. Md. 1994) *aff’d in part rev’d in part*, 82 F.3d 79 (4th Cir. 1996) (citing cases both prior and subsequent to *Cipollone* finding MDA preemption of “state-law based causes of action”).

129. 923 F. Supp. 89 (E.D. Va. 1996).

130. *Id.* at 90.

131. *Id.* at 91 (citing *Duwall I* for the holding that the MDA preempts state law when state law imposes requirements on a medical device that are different or additional to those imposed under the MDA).

132. *See id.*

medical devices. Although reaching majority and even unanimous conclusions, the Court was unable to agree beyond a plurality opinion on the rationale to guide a preemption analysis.

1. The Beginning of the Debate: Background Facts

In *Medtronic, Inc. v. Lohr*,¹³³ the Supreme Court granted *certiorari* to determine which, if any, of the cross-petitioner's claims against the manufacturer were preempted by the MDA provisions.¹³⁴ The initial complaint filed by the Lohrs in 1993 alleged common-law negligence claims for defective design and manufacture and failure to warn, and strict liability claims for unreasonably dangerous design and defective manufacture.¹³⁵

Lora Lohr required the surgical implantation of a cardiac pacemaker in 1987 to ensure proper heart functioning.¹³⁶ The device selected for implantation was a Medtronic pacemaker equipped with a Model 4011 lead.¹³⁷ Ms. Lohr required emergency surgery on December 30, 1990 due to pacemaker failure allegedly causing a "complete heart block."¹³⁸ Her doctor presumed the lead caused the device failure.¹³⁹

The initiation into the market of the Model 4011 pacemaker's lead began in October 1982, when Medtronic notified the FDA that they were seeking an exemption to the premarket approval process under the "substantially equivalent" 510(k) process.¹⁴⁰ Medtronic was granted approval to market the device on November 30, 1982, following the FDA concurrence that the device was substantially equivalent to a pre-1976 device.¹⁴¹ In their letter to Medtronic, however, the FDA emphasized that FDA approval to market should not be considered a safety endorsement of Medtronic's product.¹⁴²

133. 518 U.S. 470 (1996).

134. *Id.* at 484 & n.6 (justifying their decision by citing a string of cases demonstrating the discrepancy of holdings by various circuits).

135. *Id.* at 481 (noting breach of warranty theory alleged in the complaint was dismissed for failure to state a claim); *see also* *Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988) (noting the abolishment of a common-law implied warranty claim for personal injury with the adoption of the strict liability doctrine).

136. *Lohr*, 518 U.S. at 480.

137. *Id.* (discussing the lead function to transmit an electronic signal from the pacemaker generator to the heart, thereby controlling the heartbeat).

138. *Id.* at 481.

139. *Id.*

140. *Id.* at 480.

141. *Id.*

142. The FDA also noted that the Medtronic device would be subjected only to the general controls for Class III devices marketed under the "substantially equivalent" exemption. *Id.* For a discussion of the controls applicable to all medical devices and specific information related to the section 510(k) process for "substantially equivalent" devices, *see supra* Part II.B.

2. Unanimity Among the Justices

Faced with express preemptive language, the Court had to determine the intended legislative MDA preemptive scope: defective design claims.¹⁴³ Despite the differing opinions regarding preemption analysis principles, the *Lohr* Court reached unanimous agreement on two of the Lohrs' claims.¹⁴⁴

The Lohrs presented a persuasive argument that manufacturers of devices entering the market under the 510(k) process were not subjected to federally imposed design requirements.¹⁴⁵ Without federal standards there could be no preemption of the state defective design claims.¹⁴⁶

In addition, negligent manufacturing and labeling claims, insofar as they allege a statutory violation or a regulatory requirement violation, are not preempted.¹⁴⁷ The Court acknowledged that a state cause of action seeking to enforce federal standards, whether imposed by the MDA or the underlying FDA regulations, does not impose a requirement "different from, or in addition to" federal requirements.¹⁴⁸

3. The Majority Opines

Recognizing that the preemption analysis began with the express statutory language, the Court majority quickly identified the need to review the language within the context of two underlying presumptions regarding preemption.¹⁴⁹ First, when Congress legislated in domains traditionally occupied by the several states, there was an assumption that state power usurpation did not occur unless there was

143. See *Lohr*, 518 U.S. at 484 (identifying that their task was similar to the that of the Court in *Cipollone*).

144. *Id.* at 513.

145. *Id.* at 492-93 (agreeing that the section 510(k) process requirements are "not sufficiently concrete to constitute a pre-empting" and noting that the design of the Model 4011 pacemaker lead was never analyzed from a safety or efficacious perspective). The majority further reasoned that because Congress intended the section 510(k) process to "maintain the status quo" and equalize competition for marketing equivalent devices, manufacturers of post-1976 equivalent devices would be subject to the status quo of defending against common-law claims for defective design. *Id.* at 494 & n.14. The dissent took an even stronger position that the section 510(k) process "places no 'requirements' on a device." *Id.* at 513; see also *supra* note 50 for a discussion of the focus of the 510(k) process on equivalence—providing a comparative analysis.

146. See *Lohr*, 518 U.S. at 494, 513 (declaring the majority and dissenting opinions).

147. *Id.* at 497, 513 (declaring the majority and dissenting opinions). Throughout this Comment, references to "labeling" or "failure-to-warn" claims are utilized interchangeably to reflect the differing language used in case opinions.

148. *Id.* at 495-97, 513 (stating the majority and dissenting reasoning).

149. *Id.* at 484-85 (citing *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992)).

a “clear and manifest” congressional intent.¹⁵⁰ Second, to determine congressional intent, the Court looked not only at the preemption provision and “the structure and purpose of the statute as a whole,” but also performed a reasoned analysis of how Congress intended the federal act to impact upon business, consumers and the law.¹⁵¹ The *Lohr* Court majority agreed that state common-law negligent manufacturing and failure-to-warn claims were not preempted.¹⁵² Under the federal regulations, medical device manufacturers needed to adhere to good manufacturing practices and comply with labeling requirements.¹⁵³

The *Lohrs* argued that the general nature of these requirements carry no preemptive effect over duties imposed by state common law for the manufacture¹⁵⁴ of a specific device because section 360k(a)(1) expressly referenced a requirement “applicable to the device” not to devices in general.¹⁵⁵ They also relied upon the statutory language of section 360k(a)(2), preempting only those requirements relating to the device safety and effectiveness or a matter included in a device-specific requirement.¹⁵⁶

The majority conceded that federal requirements must apply to a specific device to preempt counterpart state requirements and that general state requirements would only be preempted where they place

150. *Id.* at 485 (discussing several Supreme Court cases supporting this proposition, but noting dissenting opinions that hold that the presumption should only apply when deciding if preemption is intended at all, not when analyzing preemptive scope).

151. *Id.* at 485-86 (citing several cases supporting this presumption). *But see* discussion *supra* Part III.B.2. The *Lohr* Court, like many before, utilized the often quoted *Rice v. Santa Fe Elevator*, 331 U.S. 218 (1947), opinion requiring a “clear and manifest” Congressional purpose to supersede the historic state police powers. *Lohr*, 518 U.S. at 485. After tracing a thorough history of preemption analysis, including implied preemption considerations, Susan Raeker-Jordan questions the *Lohr* stretch to look at the impact on businesses and consumers reasoning that going to such lengths raises questions as to how “clear and manifest” is Congressional intent. *See* Raeker-Jordan, *supra* note 92, at 1419.

152. *Lohr*, 518 U.S. at 502.

153. *See supra* note 49 and accompanying text.

154. *Lohr*, 518 U.S. at 501 (noting that the manufacturer’s general duties are to use due care, to avoid foreseeable danger, and to inform users of risks involved in the use of potentially dangerous items). *But see Duvall I*, 65 F.3d at 399 (finding the GMPs involving manufacturing facility standards, quality assurance program, mandatory device failure reporting and federal labeling regulations create requirements giving rise to federal preemptive effect). In addition, the *Duvall I* court held that the 510(k) notification process, which requires manufacturers to include proposed labeling and maintain the device design and manufacture as represented, has preemptive effect. *See id.* at 399-400.

155. *Lohr*, 518 U.S. at 498; *see also* 21 U.S.C. § 360k.

156. *Lohr*, 518 U.S. at 498; *see also* 21 U.S.C. § 360k.

a substantive requirement on a particular device.¹⁵⁷ Thus, the state common-law manufacturing and warning duties escaped preemption because their generality placed such requirements outside the scope envisioned by the government.¹⁵⁸

4. Plurality Rationale for Limiting the Scope

From this point forward the Justices became very fractured in their preemption analysis.¹⁵⁹ Justices Stevens, Kennedy, Souter and Ginsberg ("Four Justices") focused attention on the congressional intent behind the selection and use of the word "requirement."¹⁶⁰

These Justices addressed the *Cipollone* opinion as that case determined, in part, the meaning behind the word "requirement" used in a preemptive statutory context.¹⁶¹ Broad interpretation of "requirement" to include judicial decisions by the Court in *Cipollone*¹⁶² was considered distinguishable, as the narrowly focused preemptive statute had minimal impact upon state sovereignty.¹⁶³ The *Lohr* case was

157. *Lohr*, 518 U.S. at 500. Utilizing statutory construction, the dissent might have found preemption of all the *Lohr*'s common-law negligent manufacturing and failure-to-warn claims. The dissent views the GMPs and labeling regulations as quite extensive and certainly specific enough to meet the preemptive terms of section 360k(a). *Id.* at 513-14.

158. *See id.* at 501-02 (noting general common-law duties are not the type of "requirements" Congress or the FDA feared would impact the enforcement of specific federal standards). Additional understanding of this conclusion may be gleaned from the Court's discussion in Part IV of the opinion, when Medtronic advanced the argument that all common-law causes of action create a "requirement" that imposes duties "different from, or in addition to" the federal standards. *Id.* at 486. Four Justices responded that Medtronic's statutory construction could result in complete immunity to manufacturers for defective devices. In addition to closing the state door by barring common-law claims, the MDA provides no express and probably no implied private right of action to persons injured by defective devices thereby closing the federal door. Aside from a general doubt that Congress intended to protect an industry that it determined required more stringent regulation, these four Justices found no support for Medtronic's argument in the statutes, plain language, or accompanying legislative history. *Id.* at 487.

159. *See id.* at 503-05.

160. *Id.* at 486 (referring to the preemption language in 21 U.S.C. § 360k(a) (1994) that says, "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement"). For complete statutory language, *see supra* note 82.

161. *See id.* at 488 & n.8.

162. *Cipollone v. Liggett*, 505 U.S. 504, 521-22 (1992) (discussing the "requirement" definition of the case and how such a definition "sweeps broadly" and encompasses statutory enactments, regulatory interpretations, and judicial decisions).

163. *See Lohr*, 518 U.S. at 488; *see also* *Montoya v. Mentor Corp.*, 919 P.2d 410, 414 (1996) (contrasting the broad MDA statute to the narrowly focused cigarette labeling statutes construed in *Cipollone*). For a discussion of pre-*Lohr* cases extending "requirement" as used in the MDA to encompass common-law claim, *see supra* note 111-32 and accompanying text. The *Lohr*

further distinguished because “requirements” was utilized throughout section 360k of the MDA in a context suggesting targeting at specific positive law enactments versus judicially applied common law.¹⁶⁴ Furthermore, the Four Justices reasoned that if such a broad preemptive scope was envisioned, the legislators would have chosen more precise language.¹⁶⁵

Court did not attempt to rewrite history but merely employed a *stare decisis* analysis to follow other announced preemption principles. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). In discussing congressional intent to preclude state common-law remedies, the *Silkwood* Court found it “difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.” *Id.* at 251; *see also Cipollone*, 505 U.S. at 541 (Blackmun, J., dissenting) (citing *Silkwood* and noting that even the *Silkwood* dissent agreed with this concept). Other courts have interpreted *Silkwood* to require “a presumption against preemption if it would deny an injured party all judicial remedies, especially in the face of congressional silence.” *Montoya*, 919 P.2d at 412 (deciding the MDA preemptive scope between the time the *Lohr* case was argued and the Court announced the result). *But see Flynn v. Biomet, Inc.*, No. CIV.A. 93-192, 1993 WL 540570, at *10 (E.D. Va. July 23, 1993) (finding congressional “failure to provide a federal remedy will not defeat [Congress’s] intent to preempt state law”). Furthermore, the Court majority determined that even if the MDA statutory language was found to be ambiguous, deference to the FDA interpretation would be appropriate, yielding the same result. *See Lohr*, 518 U.S. at 496 (relying on *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

164. *See Lohr*, 518 U.S. at 489-90 & n.11 (emphasizing section 360k(a)(2) preempting state statutory enactments and regulations “pursuant to the MDA” and section 360k(b) and the corresponding regulations at 21 C.F.R. §§ 808.53-808.101 providing the exceptions to preemption, none of which include common-law claims). *See also* 21 U.S.C. § 360.
165. *Lohr*, 518 U.S. at 487. It is worth noting the differing opinions among the Justices regarding the frequency, or lack thereof, of common-law duty preemption by the MDA as well as the differing analyses of the remaining Justices. The Four Justices considered it rare that a common-law duty would be preempted, as the Court’s judgment would most likely not result in the imposition of a device-specific substantive requirement. *Id.* at 502-03. Justice Breyer provided a slightly different analysis concluding that preemption of common-law claims may not be so rare as stated by the plurality. *Id.* at 508. He cautioned that a court must not be granted greater power than state officials to establish state requirements “different from, or in addition to” federal requirements. *Id.* Justice Breyer highlighted the similarity between state regulatory standards and standards of care established in state tort actions and notes that a similar analysis should be utilized to determine preemptive effect. *Id.* He provided, hypothetically, a federal standard requiring the use of a two-inch hearing aid wire and argued that such a federal requirement should preempt not only a state regulation setting a one-inch standard but also prevent a court from finding liability based upon expert testimony that use of greater than a one-inch wire would be negligent. *Id.* at 504. The dissent, focusing on the express statutory preemption language, found the language to be unambiguous and admonished the Court’s, including Justice Breyer’s, deference to the narrowly focused agency interpretation. *See id.* at 512. Determining that state common-law actions operate to require compliance with common-law duties and therefore impose “requirements,” the dissent concluded that preemption should occur where the requirements differed from federal standards. *Id.* at 509.

Turning to the legislative history, Medtronic cited language in a House report to argue that MDA preemption extends to common-law claims because a corollary purpose of enactment was to prevent stifling of technological innovations through “unnecessary restriction.”¹⁶⁶ The Four Justices rejected this argument. Recognizing that legislators were “acutely aware” of ongoing products liability litigation, these Justices relied upon the absence of any decision in the legislative history expressing concern that “product liability actions would hamper” technology and language acknowledging that “at least some common-law claims” survived MDA preemption to reach their conclusion.¹⁶⁷

The majority agreed with the Lohrs’ argument that even if “requirements” included state common-law claims, those “requirements” are not preempted unless they are “different from, or in addition to” the federal standards.¹⁶⁸ Although recognizing that a claim based upon a state common-law violation may require proof of certain elements, these additional “state requirements,” though technically “different from,” merely made the state requirements narrower.¹⁶⁹ Their position was supported by FDA regulations that limit preemption to situations where there are “specific” counterpart regulations or “specific”

The dissent relied on the *Cipollone* majority conclusion that state common-law damages actions did impose “requirements,” finding no distinction between enacted law and judicially established duties. *Id.* at 510. The dissent further rejected the plurality emphasis on device-specific requirements pointing to the absence within the statute of any reference to specificity. *Id.* at 511-12; *see also* 21 U.S.C. § 360k.

166. *Lohr*, 518 U.S. at 490 (explaining that H.R. Rep. No. 94-853, at 12, was cited in petitioner’s supporting brief). Although acknowledging that an objective was to encourage innovation, the Four Justices focused on what they believed to be the key purpose of the MDA, which was “to provide for the safety and effectiveness of medical devices.” *Id.* (relying on the MDA express statutory language). Susan Raeker-Jordan raises the question regarding what conclusions the plurality would have made if they had focused on Medtronic’s argument that the MDA intended to protect technological innovations “from being stifled by unnecessary restrictions, and that this interest extended to the pre-emption of common-law claims.” Raeker-Jordan, *supra* note 92, at 1421.
167. *Lohr*, 518 U.S. at 490-91 (referring to records of the “hearings, the Committee Reports, [and] debates”). The Four Justices instead interpreted “restrictions” to indicate fear of additional regulatory burdens rather than imposition of common-law duties upon manufacturers. *Id.* at 490. Additional support was gleaned from the lack of contemporary commentary viewing the MDA as having a broad sweeping preemption of common-law claims. *Id.* at 491 n.13.
168. *Id.* at 495 (referring to statutory language in section 360k(a)(1)); *see also* 21 U.S.C. § 360k.
169. *Lohr*, 518 U.S. at 495 (distinguishing from state requirements that broaden federal standards and thus refusing to extend the preemptive scope by providing a literal interpretation of “different from”). The Court further noted that a damages remedy merely provides an impetus to comply with overlapping state and federal law. *Id.*

requirements for a particular device.¹⁷⁰ Because Congress empowered the FDA to promulgate regulations consistent with the MDA and to interpret the scope of preemption under section 360k, congressional deference required substantial weight to be given to the agency's interpretation.¹⁷¹

D. The Aftermath: Attempts to Explain and Apply the Lohr Analysis

Prior to *Lohr*, most courts analyzing the preemptive scope of section 360k(a) found broad preemption of state common-law claims.¹⁷² The *Lohr* Court upset this stability in an analysis that deviated from the road map provided by *Cipollone*.¹⁷³ In addition, the *Lohr* dissent argued that the Court deviated from the Court's analysis in *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*¹⁷⁴ The "fractured holding"¹⁷⁵ in *Lohr* has left the legal community grappling to find clear language to guide future preemption analysis.¹⁷⁶ As a result, courts

170. *Id.*; see also *supra* note 60 and accompanying text.

171. *Lohr*, 518 U.S. at 496 (relying especially on delegated duties that require the FDA to analyze the preemptive effect of the federal standards upon state laws i.e. section 360k(b) providing statutory authority for the FDA to exempt state regulations from preemption and 21 C.F.R. § 808.5 allowing the issuance of advisory opinions regarding preemption of a state requirement); see also *supra* note 83 and accompanying text. The *Lohr* majority acknowledged that it is both the congressional delegation of power to the FDA and the ambiguity in the statute that supports deference to the agency's interpretation. *Lohr*, 518 U.S. at 496 (relying on the standard established in *Chevron USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) and *Flynn v. Biomet, Inc.*, No. CIV.A. 93-192, 1993 WL 540570 (E.D. Va. July 23, 1993)). The dissent argued that the statutory language is clear and therefore "resort[ing] to the agency's interpretation is improper." *Lohr*, 518 U.S. at 512 (citing *Chevron*, 467 U.S. at 842-43).

172. See Scott W. Saylor & Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After Medtronic, Inc. v. Lohr*, 6 ANNALS HEALTH L. 185, 186 (1997); see, e.g., *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 327 (4th Cir. 1996) (noting the initial holding pre-*Lohr* that the plaintiff's common-law claims for breach of implied warranty, breach of express warranty based on FDA-mandated requirements, defective design and manufacturing and failure to warn were preempted by the express statutory language of section 360k(a)) [hereinafter "*Duvall II*"]; see also *supra* Part III.B.

173. See *supra* note 145 and accompanying text. But see *supra* note 143 and accompanying text.

174. The dissent suggested that the majority denied deferring to the regulations, but merely utilized the regulations to "inform" them on the meaning of the preemptive statute. *Lohr*, 518 U.S. at 512 (O'Connor, J., dissenting).

175. Saylor & Thomas, *supra* note 172, at 185 (referring to the four separately written opinions).

176. See, e.g., *Mitchell v. Collagen Corp.*, 126 F.3d 902, 910 (7th Cir. 1997) (recognizing its obligation to adhere to Supreme Court holdings but adding that the "holding in [*Lohr*] contains several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to follow").

apply different standards to determine preemption, citing *Lohr* for support.

1. A Simplistic Two-Prong Inquiry

The United States Court of Appeals for the Tenth Circuit in *Oja v. Howmedica, Inc.*¹⁷⁷ interpreted the *Lohr* opinion to require a two-prong inquiry to determine state-law preemption.¹⁷⁸ The first prong of the inquiry focused on the federal requirement, allowing preemption only if the federal requirement is device-specific.¹⁷⁹ The second prong focused on the state requirement, allowing preemption only if the state requirement is (1) device specific or a general standard that establishes substantive requirements for a specific device, and (2) “‘different from, or in addition to’ a federal requirement.”¹⁸⁰

Applying the two-prong inquiry to the facts, the *Oja* court determined that the FDA “requirement” restricting marketing for non-cemented use satisfied the first prong inquiry of a federal device-specific requirement.¹⁸¹ Despite finding a device-specific federal requirement, the court found that the state common law survived preemption because the elements of the second-prong inquiry were not satisfied.¹⁸²

177. 111 F.3d 782 (10th Cir. 1997).

178. *Id.* at 788. On appeal, the court addressed three claims—negligence, negligent failure to warn and strict liability—against Howmedica, Inc., the manufacturer of the Porous-Coated Anatomic One-Piece Acetabular Component hip (PCA hip) surgically implanted into Maureen Oja on July 2, 1984. *Id.* at 784-85. Upon removal of the PCA hip on July 29, 1992, necessitated by Oja’s severe pain, the surgeon discovered that the PCA hip staking peg was missing, the polyethylene liner had separated from the metal cap, and debris from the disintegrating lining was scattered throughout Oja’s hip joint. *Id.* at 785.

179. *Id.* at 788 (recognizing that the *Lohr* Court’s analysis relied on both the statutory language of section 360k and regulatory language of § 808.1(d)).

180. *Id.*

181. *Id.* at 789. The PCA hip entered the stream of commerce initially under the 510(k) process after Howmedica, Inc., submitted a premarket notification to the FDA on April 25, 1983. *Id.* at 786-87. The FDA granted final approval on August 10, 1983, conditioned on marketing and promotion of the PCA hip for use only in conjunction with low-viscosity cement. *Id.* at 787. The federal “requirement” was therefore not restricted to standards established through legislative enactment or regulatory rule making but was viewed by this court to encompass administrative policy decisions, including those provided in private letters to specific manufacturers. *Id.* at 789.

182. *Id.* (adopting the reasoning of the *Lohr* Court that the general duty to warn purchasers of potentially dangerous items is not the type of state “requirement” that would interfere with the federal interest advanced by the MDA). In addressing the defective manufacturing claim based upon a strict liability theory, the *Oja* court reversed the directed verdict for Howmedica, Inc. *Id.* at 793. Although not required to apply the two-prong inquiry to reach this decision, the holding indicates that the claim most likely survives preemption, otherwise there existed no reason for reversal.

2. A Three-Condition Test

An unpublished Fifth Circuit opinion discussed in *Lewis v. Intermedics Intraocular, Inc.*¹⁸³ provided a different test, based upon the *Lohr* analysis, for determining when preemption exists.¹⁸⁴ *Lewis* required a finding of three conditions for state-law preemption to occur: (1) a federal device-specific requirement, usually in the form of a regulation, (2) a state safety and effectiveness requirement or any other federal requirement applicable to the device, with "requirement" referring to statutes, regulations, ordinances, or common-law duties, and (3) "the state requirement is different from, or in addition to, the federal requirement."¹⁸⁵ In addition, this test is to be applied to any medical device regardless of the mechanism utilized to enter the market.¹⁸⁶ Applying the test, the only claim to survive preemption was the argument that Intermedics violated FDA regulations.¹⁸⁷ Finding that a judgment regarding the state-law defective design claim could impose "requirements" different from the detailed regulations governing the design process for IDE devices, the court determined that preemption was appropriate.¹⁸⁸

183. 19 F. Supp. 2d 625 (E.D. La. 1998) [hereinafter "*Lewis II*"].

184. *Id.* at 626 (determining that any Fifth Circuit MDA preemption analysis must not only occur within the context provided by *Lohr* but also as that opinion was interpreted by *Lewis v. Intermedics*, No. 95-31080, slip op., 114 F.3d 1182 (5th Cir. 1997) [hereinafter "*Lewis I*"].)

185. *Id.* at 628.

186. *Id.* at 628-29 (noting that *Lewis I* demands application of the test for devices undergoing premarket approval or entering through the exceptions created by the 510(k) and IDE processes); see also 62 Fed. Reg. 65384 (Dec. 12, 1997) (proposing an interpretive rule to clarify the FDA's "longstanding" position regarding preemption in light of the confusion created when the *Lohr* Court did not "definitively decide" the preemptive scope for devices entering the market via the PMA or IDE paths). These proposed FDA regulations may have influenced courts like *Lewis I* because, in the discussion supporting the need for the regulation, the FDA explicitly stated that the preemption analysis in *Lohr* is applicable to any device, regardless of how the device entered the market. See *Lewis II*, 19 F. Supp. 2d at 628 (noting that state common-law claims generally are not preempted by the MDA). *But see supra* note 150.

187. See *Lewis II*, 19 F. Supp. 2d at 629. In this case, five plaintiffs alleged defective design, failure to warn and breach of warranty for severe eye damage, including blindness in one case, from surgically implanted intraocular lenses manufactured by Intermedics. *Id.* at 626. The particular 44B lens is a Class III medical device that entered the market through the IDE process. *Id.* at 627. *Lewis I* interpreted *Lohr* to unequivocally find no preemptive effect of claims based upon violations of FDA regulations, and the record reflected that Intermedics failed to notify investigators that the "44B design was under attack" and failed to warn of potential problems experienced during the investigational study. *Id.* at 629-30.

188. *Id.* at 630 (reviewing the congressional purpose of the IDE process to encourage research and development, recognizing the need for experimentation because of the inherent lack of a known safe and effective designs as well as other court holdings that common-law claims impose requirements different from IDE regulations).

3. A Complex Two-Prong Analysis

In addition to courts grabbing to create a clear and objective preemption analysis consistent with *Lohr*, various commentators have attempted the same task. In one publication worth noting, authors Scott Sayler and Steven Thomas utilize key language to fashion yet another test.¹⁸⁹ Their test, in essence, is a more detailed two-prong analysis. Federal requirements will typically have a preemptive effect provided that they: (1) are device specific, and (2) “constitute ‘specific counterpart regulations’ to state law”¹⁹⁰ State requirements will typically be preempted if they: (1) are “developed ‘with respect to medical devices;’” (2) have specific applicability; (3) are “different from or in addition to federal requirements;” and (4) are “concerned with safety, efficacy, or any other matter included in a federal requirement that applies to the device.”¹⁹¹ Although not in a situation to apply the test, Sayler and Thomas believe that a careful analysis between the state and federal requirements in question would find the preemption defense viable for devices entering the market through either the PMA or IDE processes.¹⁹² Defining the “regulation-intensive” “device-specific” PMA and IDE processes as “safety-oriented mechanisms,” state common-law claims would likely create “requirements” that conflict with the specific federal interests articulated through regulatory standards.¹⁹³ The authors also caution that future cases dealing with devices entering the market through the 510(k) process need to include an analysis of any changes to the labeling and GMP regulations made after the *Lohr* decision, as well as, any changes to the 510(k) process, especially the adoption of regulations focusing on safety.¹⁹⁴

189. See Sayler & Thomas, *supra* note 172, at 185.

190. *Id.* at 190.

191. *Id.* (noting the specific applicability requirement acts as a savings clause for requirements of “general applicability”).

192. *Id.* at 208; see also *supra* notes 60-62, 77-81 and accompanying text.

193. See Sayler & Thomas, *supra* note 172, at 200. Although admitting that the *Lohr* Court never directly announced that the holding was applicable only to devices that enter the market through the 510(k) process, the authors find the *Lohr* Court’s lengthy attention to the 510(k) process indicative of a narrow holding. See *id.* at 195-96. Furthermore, they caution against extending the holding to factually dissimilar cases such as situations in which devices entered the market through the PMA or IDE processes. *Id.* at 195. But see *id.* at 204 & nn.89, 101, 206 (acknowledging various cases, including a Fourth Circuit case decided post-*Lohr*, in which the courts reached different conclusions regarding devices entering the market through the PMA and IDE processes).

194. *Id.* at 201. Speculating that future federal requirements would most likely not dictate product design, the authors surmise that defective design claims would escape preemption. *Id.* at 208. They immediately noted, however, the likelihood of other defenses available to manufacturers including the proposed draft of the *Restatement (Third) of Torts: Products Liability* (“*Restatement (Third)*”). *Id.* Compare *Weiland v. Telectronics Pacing Sys., Inc.*, 721

IV. EXPLORING VARIOUS CAUSES OF ACTION: FACTORS TO CONSIDER

The complexity of Class III medical device litigation is exacerbated when plaintiffs allege multiple causes of action against manufacturers.¹⁹⁵ At times, court opinions combine claims or utilize different nomenclature to discuss specific claims, thus creating obstacles to understanding the court's reasoning for their conclusions. As a result, a better understanding of preemption and medical device litigation can be achieved by exploring each cause of action separately.¹⁹⁶

Although emphasis is placed on preemption, the reader should not lose sight of other hurdles facing the injured plaintiff. Proving causation is not an easy task for plaintiffs.¹⁹⁷ With delay in identifying the cause as proximately related to the medical device, and the potential for class action litigation, there also exists statute of limitation problems.¹⁹⁸ Furthermore, because medical devices reach the ultimate consumer in a somewhat unusual manner, additional considerations need to be explored before initiation of an action against others in the distribution chain.¹⁹⁹

N.E.2d 1149, 1152 (Ill. 1999) (holding that the PMA process does not impose device specific design requirements because the design "originate[s] solely with the manufacturer of the device, not the FDA"), *with Salazar v. Medtronic, Inc.*, No. CIV.A. C-96-425, 1997 WL 1704284, at *4 (S.D. Tex. Aug. 8, 1997) (deciding "any claim challenging the design" would be preempted because the PMA process contains specific federal device design requirements). See discussion *infra* Part IV.D.

195. See *Medtronic Inc. v. Lohr*, 518 U.S. 470, 481 (1996) (alleging negligence and strict liability); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 156 (4th Cir. 1999) (alleging breach of express and implied warranties, fraud and negligence) [hereinafter "*Talley II*"]; *Duwall II*, 103 F.3d at 326 (alleging breach of express warranties, breach of implied warranties of merchantability and fitness for a particular purpose, strict liability for defective design, defective manufacture, and failure to warn, and negligent design, manufacture, promotion, and sale); *Flynn v. Biomet, Inc.*, No. CIV.A. 93-192, 1993 WL 540570, at *3 (E.D. Va. July 23, 1993) (alleging breach of implied warranty of merchantability, negligent design and manufacture, breach of the implied warranty of fitness for a particular purpose, breach of express warranty, strict liability, negligence per se, and negligent infliction of emotional distress).

196. See *infra* Part IV.A-D.

197. See generally *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 126 (4th Cir. 1995) (holding that there was no breach of implied warranty under which plaintiff could recover damages for injuries sustained using disinfectant manufactured by the defendant); *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 644, 647 (4th Cir. 1981) (holding that the plaintiff failed to demonstrate that defendant's failure to warn plaintiff's doctor of alleged risk of Guillain-Barre Syndrome associated with its product was the cause-in-fact of her injury); Lawrence W. Kessler, *Alternative Liability in Litigation Malpractice Actions: Eradicating the Last Resort of Scoundrels*, 37 SAN DIEGO L. REV. 401, 466-82 (2000) (discussing various alternative tort causation doctrines and their applicability to the medical malpractice claims).

198. See *infra* Part IV.F.

199. See *infra* notes 218-23 and accompanying text.

A. *Common-Law Breach of Duty and Negligence Per Se*

Negligence claims relating to design, manufacture, and failure to warn against the medical device manufacturer for devices that reach the market through the 510(k) process are currently not preempted based on the *Lohr* Court's analysis and its outcome.²⁰⁰ Breach of duty creates a cause of action that may constitute a "requirement" that is preempted when there is a conflict between the state requirement and a device-specific federal regulation or statutory requirement.²⁰¹ State common-law claims pertaining to 510(k) devices currently survive preemption because these devices are subjected only to "general" federal manufacturing and labeling requirements.²⁰²

Even though broad preemption of many negligence claims occurred prior to *Lohr*,²⁰³ there remained some remedies available to the plaintiff.²⁰⁴ A claim of negligent contamination of a medical device was likely to survive preemption.²⁰⁵ In addition, negligent surgical implantation or removal claims fall outside the preemptive scope, although these are medical malpractice and not products liability claims.²⁰⁶

To defend a negligence claim based upon unreasonably dangerous design, the manufacturer must prove that prevailing safety standards were met, not that the "safest conceivable design" was utilized.²⁰⁷ Although issues of defective design are usually determined by a jury, if a plaintiff fails to show a safety standard violation the defendant is entitled to judgment as a matter of law.²⁰⁸

Although uninsulated by the preemptive cloak of section 360k(a) for negligent failure-to-warn claims, manufacturers receive some protection through the "learned intermediary" doctrine.²⁰⁹ This doctrine provides an exception to the manufacturer's general duty to warn

200. See *Duvall II*, 103 F.3d at 330 (finding "little difficulty" concluding, based upon the *Lohr* reasoning, that the state-law claims advanced by *Duvall* regarding negligent design and manufacture and failure to warn were not preempted by section 360k(a)).

201. See *id.* (developing the rule to utilize from a summation of the *Lohr* analysis).

202. See *id.* (referring to the GMPs and labeling requirements contained in 21 C.F.R. §§ 801, 820 (1996)).

203. See, e.g., *Griffin v. Medtronic, Inc.*, 82 F.3d 79, 82 (4th Cir. 1996); *Duvall I*, 65 F.3d at 401; *Flynn v. Biomet, Inc.*, No. CIV.A. 93-192, 1993 WL 540570, at *6 (E.D. Va. July 23, 1993).

204. See *supra* notes 147-48 and accompanying text.

205. See *Flynn*, 1993 WL 540570, at *10; see also *infra* note 239.

206. See *Flynn*, 1993 WL 540570, at *10.

207. *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998), *aff'd by*, 179 F.3d 154 (4th Cir. 1999) (relying on *Redman v. John D. Brush & Co.*, 111 F.3d 1174 (4th Cir. 1997)) [hereinafter "*Talley I*"].

208. *Id.*

209. See *Talley II*, 179 F.3d at 162 (relying on *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

consumers about risks associated with product use.²¹⁰ The doctrine's scope may be limited to warning of potential risks and, therefore, may not extend to situations where the manufacturer fails to inform the consumer that a new and improved device has entered the market.²¹¹

Under the doctrine, for products requiring surgical implantation by the physician, the manufacturer owes a duty to warn the physician only and not the ultimate consumer.²¹² The doctrine is based on sound policy reasons identifying that the learned professional is in the best position to provide an assessment of the benefits and risks to each patient for the various medical products available to treat their condition.²¹³ Support is gathered from the practical reality that it is virtually impossible for manufacturers to provide adequate patient warnings.²¹⁴

In order for the learned intermediary doctrine to be applied, the physician must indeed be an intermediary, which is described as "an intervening and independent party between patient and drug manufacturer."²¹⁵ When there is an existing relationship between the physician and the manufacturer, whether the physician falls within the category of intermediary is determined by exploring the nature of the relationship.²¹⁶ Particular emphasis is placed on the extent to which

210. *Id.*

211. In determining the validity of a strict liability claim, the Fourth Circuit noted that strict liability focuses on a failure to disclose risks associated with the particular device in question making discussion of alternative options irrelevant. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1233 (4th Cir. 1984). Although not deciding a negligence claim, the court articulated that a negligence claim based upon failure to inform of an alternative might be sustained. *Id.*

212. *Talley II*, 179 F.3d at 162. Hospitals also receive protection from the "learned intermediary doctrine" because the hospital personnel do not select the device to be utilized and the manufacturer's warnings are directed only to the physician using the device. See *Pleasant v. Dow Corning Corp.*, No. CIV. A. 92-3180-17, 1993 WL 1156110, at *6 (D.S.C. Jan. 7, 1993) (determining that the hospital was a "sham defendant" for purposes of diversity).

213. See *Talley II*, 179 F.3d at 162-64 (quoting *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 644 n.2 (4th Cir. 1981)).

214. See *id.* (citing *Hill v. Searle Laboratories, Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989) to note that (1) inclusion of written warnings within the product packaging could not ensure receipt by the patient because the product is applied by the physician, and (2) even if able to provide written warnings to each product user, the warnings are often too technical for an informed decision regarding product use).

215. *Id.* (quoting *Hill*, 884 F.2d at 1070). *Talley* advanced the argument that as a consultant to Danek, the financial connection rendered Dr. Mathews, her surgeon, incapable of independence from Danek thus eliminating the doctrine as a defense. See *id.*

216. *Id.* at 163-64. The consultative services provided to Danek by Dr. Mathews consisted of designing and facilitating FDA approval of endoscopes and serving as an instructor for surgical techniques utilizing products manufactured by Danek and others. *Id.* at 157. Annual compensation included an income of \$250,000, certain paid research and travel expenses, and receipt

the physician is allowed to make independent medical decisions regarding device use.²¹⁷ The learned intermediary doctrine may provide no protection if the physician is too closely related, such as being an agent, to the manufacturer.²¹⁸

In *Talley v. Danek Medical, Inc.*,²¹⁹ ("Talley II") the United States Court of Appeals for the Fourth Circuit determined that committing an FDA violation by marketing a device for off-label use does not constitute negligence *per se*.²²⁰ The court first acknowledged the difference between statutory violations that amount to a breach of tort duty supporting a negligence *per se* claim and statutory violations of administrative requirements that do not support such a claim.²²¹ Although determining that some FDA violations create negligence *per se* claims,²²² obtaining FDA medical device approval is viewed as an administrative requirement setting no substantive standard, and therefore negating a negligence *per se* claim.²²³ The *Talley II* court gathered

of 25,000 shares of Danek company stock. *Id.* Dr. Mathews explained that his decision to utilize the Dyna-Lok Device was based upon the individual patient circumstances, further noting his preference for the device because of its predictability, ease of application and of use in surgical teaching, and cost effectiveness. *Id.* The record reflected Dr. Mathews' use of other spinal fixation devices or no device at all when performing spinal fusions. *Id.* at 157, 164.

217. *Talley II*, 179 F.3d at 163-64.

218. *Id.* at 163.

219. 179 F.3d 154 (4th Cir. 1999).

220. *Id.* at 161. After two prior failed back surgeries, Talley agreed to a third operation consisting of a spinal fusion through the use of a Dyna-Lok Device, a medical device marketed by Danek Medical. *Id.* at 156. This particular device was recommended by Dr. Mathews, who intended to attach the device to the spine pedicles to enhance Talley's potential for a successful spinal fusion. *Id.* At the time of her surgery, although approved as a Class II device, the Dyna-Lok was not FDA-approved for use as a spinal fixation device. *Id.* at 160. Other pedicle screw fixation devices were Class III devices according to the FDA. *Id.* Talley argued that committing an FDA violation by marketing a device for an unapproved use constitutes negligence *per se* under Virginia law. *Id.* at 156, 160. Finding the negligence *per se* doctrine inapplicable is consistent with the principles established in the newly published products liability *Restatement*, articulating that statutory or regulatory noncompliance is a factor to be considered but not automatically decided as a matter of law. *See* RESTATEMENT (THIRD) § 4(b).

221. *Talley II*, 179 F.3d at 161. The court provides some conceptual illustration of the difference by comparing a duty to abide by the standard of care requirement, established through enactment of a speed-limit law with administrative requirements, such as obtaining a license or filing a report, that do not create tort duties. *Id.* at 158-59.

222. *Id.* at 161 (citing the decision in *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) that a substantive care standard, similar to the standard created by a speed-limit law, was created by the FDA requirement to correctly label the size of a surgical nail).

223. *Id.* (noting that approval alone does not create a substantive requirement but rather functions as "a tool to facilitate administration of the underlying regulatory scheme"); *see also* *Hartwell v. Danek Med., Inc.*, 47 F. Supp. 2d 703, 705 (W.D. Va. 1999) (citing comments in a final FDA rule, 63 Fed.

additional support for its decision by concluding that FDA approval is analogous to a licensing requirement to sell a medical device.²²⁴ Further, the trend among Virginia courts is to resolve licensing infringements by demonstrating a lack of causation.²²⁵

Because of the type of FDA violation alleged, the *Talley II* court never directly opined about preemption of claims based upon FDA violations.²²⁶ Through one unpublished opinion and dicta in *Duwall II*, the Fourth Circuit acknowledged that *Lohr* required a finding that claims alleging violation of state-law duties that parallel FDA requirements are not preempted.²²⁷

B. Breach of Warranty

Breach of warranty claims fall within one of several categories: breach of implied warranty, breach of express warranty based upon FDA-mandated labeling and promotion requirements, and breach of express warranty based upon the manufacturer's voluntary representation of their product.²²⁸ The breach of warranty claims could be based upon statutory duties under language similar to Article II of the Uniform Commercial Code (UCC) or obligations created under common law.²²⁹ The *Lohr* Court's analysis is controlling, at least with respect to devices entering the market through the 510(k) process, despite the fact that the *Lohr* Court did not have to address breach of warranty claims.²³⁰

The FDA requires certain statements be utilized in the promotion of medical devices.²³¹ For a device entering the market through the 510(k) process, manufacturers must submit proposed labeling and advertising information to the FDA.²³² If the device meets the "substan-

Reg. 40026, 40036-37 (July 27, 1998), acknowledging off-label use of pedicle fixation devices as an appropriate standard of care used by many surgeons).

224. *Talley II*, 179 F.3d at 159-60. The *Talley II* court cautioned against trivializing an FDA violation because causation might be determined for infringement of a regulation controlling medical device quality or proper labeling. *Id.* at 161.

225. *Id.* at 159-60.

226. See generally *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498 (1996).

227. *Sanders v. Optical Radiation Corp.*, No. 95-1967, 1996 WL 423124, at *1-*2 (4th Cir. July 30, 1996) (per curiam) (noting that even the *Lohr* dissent agreed with this position); *Duwall II*, 103 F.3d at 330 n.4 (acknowledging that it was not necessary to decide the issue because any claim based upon an FDA violation was waived when not presented to the district court).

228. See *infra* text accompanying notes 231-46.

229. See *infra* text accompanying notes 231-46.

230. *Duwall II*, 103 F.3d at 330 & n.5.

231. 21 C.F.R. § 801 (noting general labeling provisions); see also *supra* note 70 and accompanying text for a discussion of labeling requirements.

232. 21 C.F.R. § 807.87(e).

tially equivalent" criteria, the green light to market creates FDA-mandated labeling and promotion requirements.²³³

In *Duwall v. Bristol-Myers-Squibb Co.*,²³⁴ the court quickly found that express warranty claims based upon FDA-mandated statements required for "substantially equivalent" devices are not preempted because neither the 510(k) notification process nor the general labeling requirements carry preemptive effect.²³⁵ Although not having to rule on the merits of the express warranty claim based on oral representations, the court affirmed the decision that such claims are not preempted.²³⁶ Even prior to *Lohr*, under the broader preemptive cloak, the Fourth Circuit concluded that an express warranty claim based upon promises voluntarily offered by the manufacturer were not preempted under section section 360k(a).²³⁷ The contractual "requirements" of an express warranty are self-imposed by the manufacturer, not "imposed under State law."²³⁸

Likewise, the *Duwall II* court determined that breach of implied warranty claims survive preemption, relying on the rationale in *Lohr*.²³⁹ Similarly, the court in *Martin v. American Medical Systems, Inc.*,²⁴⁰ based their decision on *Lohr's* reasoning that the 510(k) process does not eliminate common-law liability in part because nothing in the 510(k)

233. *Duwall II*, 103 F.3d at 332. To create an FDA labeling requirement through the issuance of a private letter to the manufacturer see *supra* note 194 and accompanying text.

234. 103 F.3d 324 (4th Cir. 1996).

235. *Duwall II*, 103 F.3d at 332 (determining the *Lohr* decision as explicitly dictating such a position although not having to rule on the merits, and thus finding no error in the district court's granting of summary judgment in favor of Bristol-Myers-Squibb). In 1990 *Duwall* had an inflatable penile prosthesis manufactured by Bristol-Myers-Squibb implanted, however, malfunctioning of the prosthesis required subsequent surgical removal. *Id.* at 326. This particular prosthetic device entered the market through the section 510(k) process after successfully completing clinical trials under the IDE exception for Class III devices. *Id.* at 328. Bristol-Myers-Squibb argued that *Lohr* was not controlling because this device was tested under the rigorous IDE regulations prior to requesting section 510(k) status. *Id.* at 330. The court was unpersuaded because nothing in the MDA statutory scheme indicated that IDE requirements remain in effect after the experimentation exception expires. *Id.* *Duwall II* dealt with an express warranty claim, based on information contained in a promotional brochure utilized by Bristol-Myers-Squibb, to advertise their product. *Id.* at 331.

236. *Id.*

237. *Griffin v. Medtronic, Inc.*, 82 F.3d 79, 82 (4th Cir. 1996); *Duwall I*, 65 F.3d at 400-01.

238. *Duwall I*, 65 F.3d at 400 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525-26 (1992)).

239. *Duwall II*, 103 F.3d at 329-30. Although the *Lohr* Court did not address a claim for breach of implied warranty, the Court referenced an FDA regulation listing the UCC warranty of fitness as a type of state regulation that survives section 360k(a) preemption. *Id.* at 330 n.5.

240. 116 F.3d 102 (4th Cir. 1997).

process connotes an FDA endorsement regarding device safety and efficacy.²⁴¹

In deciding *Martin*, the court addressed a breach of warranty claim based upon a Virginia statute limiting, as a defense, lack of privity in an action for breach of express or implied warranty.²⁴² In *Martin*, the manufacturer extended a limited warranty to the physician responsible for medical device surgical implantation.²⁴³ The Fourth Circuit determined that this express warranty claim survived preemption thus allowing *Martin* to rely upon the Virginia statute to determine the manufacturer's warranty scope and validity.²⁴⁴ The court also held that the warranty formed the basis of the bargain even though the plaintiff was unaware of the express limited warranty prior to the litigation.²⁴⁵ Regulatory language demonstrates the FDA position that

241. *Id.* at 103-04 (vacating the district court's decision and remanding for further proceedings consistent with the opinion that the breach of implied warranty claim is not preempted by the MDA). After suffering from erectile dysfunction, John Martin agreed to surgical implantation on June 2, 1993, of the Dynaflex inflatable prosthesis manufactured by American Medical Systems. *Id.* at 103. The Dynaflex is a Class III device that entered the market through the 510(k) process. *Id.* at 103-04. After sustaining an infection that did not respond to conventional treatment, Martin had the prosthesis surgically removed. *Id.* Continued complications from the infection necessitated five hospitalizations for various surgical interventions leaving Martin with a shortened and disfigured penis. *Id.* at 103. Martin based the implied warranty claim on the premise that the Dynaflex would be distributed in a sterile condition safe for implantation. *Id.* at 103-04.

242. *Id.* at 104-05. The Virginia statute at issue states:

Lack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods

VA. CODE ANN. § 8.2-318 (Michie 1950). See generally Richard E. Speidel, *The Virginia "Anti-Privity" Statute: Strict Products Liability Under the Commercial Code*, 51 VA. L. REV. 804, 813-41 (1965) (discussing privity through the interface of the *Restatement (Second) of Torts* ("Restatement (Second)") § 402A and the Uniform Commercial Code in products liability suits). See also U.C.C. § 2-318 cmt. 2 (explaining that rule of privity does not preclude certain beneficiaries from receiving the same benefit of warranty that the buyer received in the contract of sale).

243. *Martin*, 116 F.3d at 103 n.1 (referencing the warranty, "the AMS Dynaflex Penile Prosthesis . . . [is] delivered to the hospital prefilled and sterile").

244. *Id.* at 104. The court relied on *Lohr* to overturn the district court's holding. See *id.* The district court determined that although the claim was not preempted *per se* because *Martin* was unaware of the AMS limited warranty, any judgment in his favor would be based solely on Virginia state law thus failing under the preemption analysis. *Id.*

245. *Id.* at 105 (citing *Daughtrey v. Ashe*, 413 S.E.2d 336 (Va. 1992) to support factual findings that: (1) an awareness that the physician or hospital is not the ultimate user prevents American Medical Systems from relying on their limited warranty language, and (2) "Martin surely did rely on and expect the fact warranted to be true: i.e. the implant was sterile").

warranty claims based upon obligations articulated in the UCC are untouchable by section 360k(a) preemptive scope.²⁴⁶

The Supreme Court of South Carolina refused to extend liability to a health-care provider based upon breach of warranty claims under the UCC as it applies to transactions in goods and not to services.²⁴⁷ Under a similar analysis, a hospital providing services, including the use of a surgical suite and the purchasing of a medical device for the surgeon, escaped liability under a UCC warranty claim.²⁴⁸

C. *Fraud*

Fraud claims take many forms and in a competitive market as the temptation to commit fraud lurks at every corner. For example, manufacturers can make fraudulent misrepresentations during the FDA application and approval process including false statements and fraud through active concealment.²⁴⁹ Regardless of the FDA status of their device, the potential exists to utilize fraudulent marketing and promotional techniques. For example, manufacturers could overstate the performance or clinical uses of a device, or fail to inform users of risks identified with device use. Although not specifically requested to analyze a fraudulent misrepresentation claim, the *Lohr* Court opined that fraud claims would most likely survive preemption.²⁵⁰

246. The MDA "does not preempt State or local requirements of general applicability where the purpose of the requirement relates to products other than devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices." 21 C.F.R. § 808.1 (d)(1).

247. *See In re Breast Implant Prod. Liab. Litig.*, 503 S.E.2d 445, 452 (S.C. 1998) (supporting their holding with lower court and other jurisdictional decisions and statements in learned treatises). It is worth noting that this case was heard under writ of *certiorari* finding the issues to be both novel legal questions and issues of great public interest. *Id.* at 447 & n.2.

248. *See Pleasant v. Dow Corning Corp.*, No. CIV.A.92-3180-17, 1993 WL 1156110, at *7 (D.S.C. Jan. 7, 1993) (determining that the hospital was "sham defendant" for purposes of diversity jurisdiction). Here, the court determined that the plaintiff could not recover against an in-state hospital for strict liability and breach of implied warranties because the hospital was not engaged in the sale of goods, therefore, the South Carolina Commercial Code was inapplicable. *Id.* at *4-*6. Because the court found the in-state hospital a "sham defendant," removal of the case against the hospital and manufacturer to federal court did not destroy complete diversity. *Id.* at *1.

249. 21 U.S.C.A. § 360e(c)(1)(A)-(G) (West Supp. 1999) (listing information that should be included in an application for premarket approval of Class III devices). In practice, fraud may occur by a failure to disclose information required by sub-sections (A) through (G) or by making misleading statements about this information.

250. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 500 n.19 (1996).

The potential also exists for manufacturers to conspire with others within the industry to enhance success of market penetration.²⁵¹ Conspiracy objectives may include: (1) placing medical devices into interstate commerce without proper FDA approval, (2) promotion of a medical device marketed under the IDE exception as safe and efficacious, and (3) device promotion through deceptive and misleading conduct.²⁵²

In *Wade v. Danek Medical, Inc.*,²⁵³ although the Eastern District of Virginia did not have to consider conspiracy claims, the court noted its intention to follow the court's analysis in *Coleman v. Danek Medical Inc.*²⁵⁴ The dismissal of a claim based solely on a theory of conspiracy to violate the MDA is warranted because the statute creates no private right of action.²⁵⁵ But promotion of a non-FDA-approved, Class III device through unlawful means, such as through active concealment, would create a fraud claim recognized by most states.²⁵⁶ Furthermore, the medical associations remain unshielded by the protection afforded physicians because a seminar presenter, who happens to be a physician, is not practicing medicine.²⁵⁷

251. See *In re Orthopedic Bone Screw Prod. Liab. Litig.*, No. MDL 1014, 1997 WL 186325, at *3 (E.D. Pa. Apr. 16, 1997) (including a discussion of conspiracy theories, differentiating between a vertical conspiracy among the defendant and consulting engineers or surgeons from a horizontal conspiracy among the defendant and similar manufacturers or medical associations).

252. See *Coleman v. Danek Med., Inc.*, 43 F. Supp. 2d 629, 630-31 (S.D. Miss. 1998) (citing *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1997 WL 186325, at *3).

253. 5 F. Supp. 2d 379 (E.D. Va. 1998).

254. *Id.* at 383 (referring to the analysis in *Coleman v. Danek Medical, Inc.*, 43 F. Supp. 2d 629 (S.D. Miss. 1998)). The complaint in *Wade* named as defendants a number of medical associations claiming that they unlawfully conspired with the device manufacturers in the promotion of pedicle screw fixation devices to medical providers. *Id.* at 381 & n.1. The court never reached the conspiracy issue because the case was dismissed as untimely. *Id.* at 382.

255. See *Coleman*, 43 F. Supp. 2d at 632; see also *Osburn v. Danek Med., Inc.*, 520 S.E.2d 88, 93 (N.C. Ct. App. 1999) (cautioning against interpreting *Lohr* as creating an implied private cause of action for MDA violations).

256. See *Coleman*, 43 F. Supp. 2d at 632-33 (quoting *In re Orthopedic Bone Screws Prods. Liab. Litig.*, 1997 WL 186325, at *11 and noting that the record contained allegations of several material facts actively concealed at medical association seminars, that some of the instructors had financial incentives to promote the pedicle screw fixation devices carrying the potential for relaying biased or inaccurate information, and that the lack of FDA approval for the specific use of this device was withheld).

257. See *id.* at 633-34 (referring to 21 U.S.C. § 396 exempting the practice of medicine from the MDA). Section 396 provides: "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition of disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (1994 & Supp. IV 1999).

D. Liability Without Fault

Strict liability claims for unreasonably dangerous products or defective designs are likely to survive preemption unless the FDA decides to dictate specific medical device design standards.²⁵⁸ The initial fear raised by *Lohr* is surely lessened by the learned legal community's adoption of liability principals in the *Restatement (Third)*.²⁵⁹ The new *Restatement* raises the bar for finding manufacturer liability for harm resulting from the sale or distribution of legally sold and medically prescribed defective medical devices.²⁶⁰

The standard requires the medical device to have "so little merit" that a reasonable health-care provider would not prescribe the medical device because the defective design renders the device unsafe or ineffective to any class of patients.²⁶¹ The design is not considered defective even if certain groups of patients would sustain harm by us-

258. *See supra* note 186.

259. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (1998).

260. *See id.* § 6. Section 6, entitled "Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices," states:

- (a) A manufacturer of a . . . medical device who sells or otherwise distributes a defective . . . medical device is subject to liability for harm to persons caused by the defect. A . . . medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
- (b) For purposes of liability under subsection (a), a . . . medical device is defective if at the time of sale or other distribution the . . . medical device:
 - (1) contains a manufacturing defect as defined in § 2(a); or
 - (2) is not reasonably safe due to defective design as defined in Subsection (c); or
 - (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
- (c) A . . . medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the . . . medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the . . . medical device for any class of patients.
- (d) A . . . medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
 - (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
 - (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warning.

Id.

261. *See id.* § 6 cmt. b. Section 6(b)(1) refers to a manufacturing defect as defined in Section 2(a). The text of section 2(a) appears in its entirety at *infra* note 265.

ing the medical device.²⁶² By providing adequate warnings of unavoidable risks to medical personnel, the manufacturer is protected. Patients, through discussion with their physician, are assumed to be able to make an informed choice as to whether to accept the risk or seek alternative treatment.²⁶³

In order for a manufacturer to prevail in a liability action, it must only prove that an informed and reasonable health-care provider would recommend the particular medical device to at least *one* patient.²⁶⁴ Should the manufacturer be unable to meet this minimum burden, the plaintiff may prevail under a strict liability theory.²⁶⁵ Strict liability is used based on the theory that plaintiffs have difficulty proving device defects and negligent manufacturing, and the manufacturer is in a better position to absorb the cost of injury.²⁶⁶

The Supreme Court of South Carolina found that strict liability for defective design does not apply to health-care providers who utilize these products while rendering medical treatment.²⁶⁷ Under the South Carolina statute, “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer”²⁶⁸ The decision turned on whether health-care providers were considered “sellers of products” or “providers of services” when utilizing devices in the course of rendering medical treatment.²⁶⁹ Although the health-care provider recommended the device and surgical procedure, the product and professional services were a package deal to the ultimate consumer.²⁷⁰ The consumer was

262. See RESTATEMENT (THIRD) § 6 cmt. b.

263. See *id.* § 6 cmt. d.

264. *Id.* § 6 cmt. f. (emphasis added).

265. Section 2(a) states as follows:

§ 2. CATEGORIES OF PRODUCT DEFECT

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

- (a) contains a manufacturing defect when the product departs from its intended design *even though all possible care was exercised* in the preparation and marketing of the product;

Id. § 2(a) (emphasis added).

266. See *id.* § 2 cmt. a.

267. See *In re Breast Implant Prods. Liab. Litig.*, 503 S.E.2d 448, 451 (S.C. 1998). Although finding little opposition to their position, the court cited a Missouri Court of Appeals decision holding that strict liability attaches to anyone, including a hospital, placing the product in the stream of commerce by sale or any other means. See *id.* at 450 & n.5.

268. *Id.* at 447 (quoting S.C. CODE ANN. § 15-73-10 codifying almost verbatim, *Restatement (Second)* § 402A).

269. *Id.* at 448 (acknowledging that prior case law found “providers of services” not strictly liable under the South Carolina Code).

270. *Id.* at 449 (following their analysis with a number of supportive leading cases from other jurisdictions).

incapable of purchasing the product independent of the surgical service.²⁷¹ Likewise, hospitals are insulated from strict liability claims.²⁷²

E. Causation Issues

The use of expert testimony to prove causation is essential to avoiding summary judgment for many medical device liability claims.²⁷³ Choosing a qualified expert is of utmost importance.²⁷⁴ In granting summary judgment the court in *Hartwell v. Danek Medical, Inc.*,²⁷⁵ determined that expert testimony of two physicians was sufficiently unreliable and therefore inadmissible.²⁷⁶ This decision was based on the fact that the expert was not versed in the surgical procedure at issue.²⁷⁷ In addition, the expert did not personally examine the plaintiff, did not interview the surgeons who performed the procedures and did not review the radiographic studies.²⁷⁸ One physician, testifying about an orthopedic procedure, was not even board-certified as an orthopedic surgeon.²⁷⁹

Further, the court opined that expert testimony needed to state proximate causation in terms of reasonable probability.²⁸⁰ It is insufficient to merely testify that the surgery "did not achieve the desired results."²⁸¹ The expert must discuss other potential causes that were considered and determined to not feasibly be the proximate cause.²⁸²

Even claims that do not require expert testimony require proof of causation to sustain the claim.²⁸³ In *Coleman v. Danek Medical Inc.*, the plaintiff claimed that a defective pedicle screw fixation device attached to the pedicle of her spine caused her physical injuries.²⁸⁴ In addition, the plaintiff claimed that the defendants conspired with the manufacturers to promote, market, and sell the devices to medical providers. The court granted summary judgment on the fraudulent

271. *Id.*

272. *Pleasant v. Dow Corning Corp.*, No. CIV.A.92-3180-17, 1993 WL 1156110, at *2 (D.S.C. Jan. 7, 1993).

273. *See* Darrell L. Keith, *Medical Expert Testimony in Texas*, 43 BAYLOR L. REV. 1, 5-6 (1991).

274. *See* *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260-61 (4th Cir. 1999) (indicating the power of medical expert testimony to prove causation); *Friendship Heights Assoc. v. Koubek*, 785 F.2d 1154, 1156-57 (4th Cir. 1986); *Fitzgerald v. Manning*, 679 F.2d 341, 347 (4th Cir. 1982) (stating that expert testimony is required to establish a standard of medical care and a violation of that standard).

275. 47 F. Supp. 2d 703 (W.D. Va. 1999).

276. *Id.* at 716.

277. *Id.* at 708.

278. *Id.* at 708, 712.

279. *Id.* at 713.

280. *Id.* at 707.

281. *Id.* at 709.

282. *Id.*

283. *See* 63 AM. JUR. 2D *Products Liability* § 47 (1996).

284. *Coleman v. Danek Medical Inc.*, 43 F. Supp. 2d 629, 630 (S.D. Miss. 1998).

concealment claim because the plaintiff failed to produce evidence to show causation.²⁸⁵

F. Statute of Limitation Concerns

Often, a surgically implanted medical device is utilized after the patient sustains an injury or disabling disease. For instance, a hip prosthesis may be utilized for a fracture or a pacemaker because of a slowed heart rate.²⁸⁶ Even with surgical interventions, symptoms may not immediately be relieved.²⁸⁷ It may be some time before the patient realizes that their continued symptoms may be due to a defective device.²⁸⁸ In *Smith v. Danek Medical, Inc.*,²⁸⁹ the plaintiff alleged design defect and argued that the cause of action began to accrue when the device became dislodged.²⁹⁰ Following Virginia law, the court determined that the statute of limitations begins to run when the initial injury is sustained.²⁹¹ This fixes the accrual for dangerous design to begin at the time of surgical implantation, even if more serious resultant device injury occurs at a later date.²⁹²

Moreover, an allegation of defective device raises the potential for class action litigation thus creating some additional statute of limitation concerns. In *Wade v. Danek Medical, Inc.*,²⁹³ the court, hearing a diversity action, decided whether to apply federal or state law regarding equitable tolling of the statute of limitation during the pendency of federal products liability litigation.²⁹⁴ Acknowledging that many states allow equitable tolling during the pendency of a class action suit in their own state, the court indicated that few states have addressed, and even fewer have allowed "cross-jurisdictional" equitable tolling.²⁹⁵ Finding that Virginia has no interest in furthering the efficiency of another jurisdiction's class action procedures, and expressing concern

285. *Id.* at 635.

286. See JOYCE M. BLACK ET. AL., *MEDICAL-SURGICAL NURSING CLINICAL MANAGEMENT FOR CONTINUITY OF CARE* 2110-12 (5th ed. 1997).

287. *Id.*

288. *Id.*

289. 47 F. Supp. 2d 698 (W.D. Va. 1998).

290. *Id.* at 701. The plaintiff, a forty-seven-year-old former mechanic, initially injured his back in 1983 and sustained a re-injury in 1991. *Id.* at 699. In 1992 at the recommendation of his physician, Mr. Smith underwent spinal fusion with a Texas Scottish Rites Hospital (TSRH) spinal fixation device, a device not FDA-approved for use by attachment to the spine pedicles. *Id.* at 699-700. Although receiving some relief, the surgery was not a complete success, and in 1994 Mr. Smith began experiencing extreme pain. *Id.* at 700. A radiographic examination revealed that the TSRH device was no longer attached to the spine and surgery to remove the device was performed the next day. *Id.*

291. *Id.* at 701.

292. See *id.*

293. 182 F.3d 281 (4th Cir. 1999).

294. *Id.* at 286.

295. *Id.* at 287.

about the potential flood of litigation following class action dismissal, the court determined that Virginia would not adopt a cross-jurisdictional tolling rule.²⁹⁶ Thus, under an *Erie* analysis, plaintiffs' claims were time barred following Virginia's "adopted" rule against equitable tolling.²⁹⁷

V. CONCLUSION

Certainly, *Lohr* provided a divergent path from the previously settled case law regarding preemption of many common-law liability claims for injuries sustained from medical devices.²⁹⁸ As with most legal concepts where intelligent minds differ, the *Lohr* Court plurality based their preemption analysis on principles announced by the Supreme Court in prior cases.²⁹⁹ Within their own analysis, however, the Court neglected to seriously consider all articulated legislative purposes behind the MDA enactment.³⁰⁰

The history of food and drug regulation from 1906 to the present indicates increased legislative concern to control medical device standards to ensure safety. Indeed, safety concerns are the foundation upon which the *Lohr* Court based its support for the legislative intent to provide a remedy to those negatively impacted from device failure.³⁰¹ The other legislative goal, to foster innovation, however, should not be lost in the analysis.³⁰² The age of computers and artificial materials development provides an opportunity to create an ever-increasing number of sophisticated medical devices; devices that may be more prone to malfunction by virtue of their complexity. The public has the right to expect innovation, and development efforts should not be unduly hampered by litigation threats. There needs to be a correct balancing of the risks and benefits, requiring courts to analyze the federal intent to balance the goal of patient protection against the need for innovation.³⁰³

Perhaps even more unsettling is the legal community's response to such a landmark case.³⁰⁴ Among the cases that follow *Lohr*, although acknowledging the differing paths for medical device market entry, there is little attention to whether the *Lohr* "2-prong" or "3-condition" test is the correct analysis for devices entering through the IDE excep-

296. *Id.*

297. *Id.* at 290.

298. See discussion *supra* Part III.B.

299. See discussion *supra* Part III.B.1.

300. See *supra* notes 151, 157 and accompanying text.

301. See *supra* Part II.A.

302. See *supra* note 166 and accompanying text.

303. This is especially important for devices under the IDE exception, where Congress specifically recognizes that experimentation would not be needed if the safest and most effective devices were already available on the market. See *supra* notes 74-81 and accompanying text.

304. See *supra* Part III.D.

tion or the PMA process. Both IDE and PMA devices traverse a route far different from the 510(k) process examined in *Lohr*. Courts need to consciously decide if extension is appropriate. Even with claims involving a device marketed through the 510(k) process, the discussion is void of analysis as to regulatory changes, since the *Lohr* decision, that might impact the outcome.

Specifically, within the Fourth Circuit, the history post-*Lohr* is devoid of cases regarding devices that have completed the rigorous PMA process. This result was not unexpected because so few devices fall outside of one of the PMA exceptions. Courts required to address liability claims resulting from PMA devices should tread lightly before applying the *Lohr* analysis.

Lastly, attention should focus on the response to the principals espoused in the new *Restatement*. Certainly, many lives are saved by technological advances from medical devices that are more sophisticated. The increased complexity, however, is often accompanied by graver consequences when failure occurs. Will the green light provided by the *Restatement (Third)* enhance scientific technology by providing a safety net for the manufacturers to become creative, or will the desire to protect consumers guide the courts to ensure remedies exist unless *expressly* removed by Congress?

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