

Comments

An Undue Burden on an Otherwise Feasible Defense: California Courts' Burden on the Defendant Moving for Summary Judgment Based on Federal Preemption in Certain Medical Device Cases

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A YOUNG MAN COMPLETES endless days in class, hundreds of tests, limitless paperwork, and exhausting studies to graduate from college with his name affixed to a diploma representing his school's certification of accomplishment. With diploma in hand, a job comes his way with only one catch: the employer agrees to hire him if the young man can affirm that he has graduated from college. The employer, however, requires more than the diploma to establish that the graduation was obtained properly. This process will require the student to produce every test, attendance record, and classroom assignment for the employer to review. Without knowledge of these requirements, the recent graduate no longer has his tests and attendance records, much less proof that he was properly admitted based on his high school performance. Even if he had kept all of his records, there is no guarantee that this particular employer would grade his tests the same as his college professors: would that C- in Physics slip to a D under the grading style of the employer?

Without the necessary documents and with the employer's new grading style, the recent graduate does not get the job. This em-

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ployer's absurd requirement is similar to the burden California courts place on a defendant facing a state law tort claim who attempts to show that a new medical device has received approval by the Food and Drug Administration ("FDA") and that federal preemption therefore applies.

Currently, California courts will only allow a preemption defense to a motion for summary judgment if, in addition to the standard burden of showing that the FDA approved the product, the defendant also proves that its medical device has been *properly* approved by the FDA, and that the defendant has complied with all of the FDA's Medical Device Amendment¹ ("MDA") regulations both during and after the approval process.² California courts have adopted these additional requirements as a result of *Steele v. Collagen Corp.*,³ which places an undue burden on defendants who are properly moving for summary judgment based on federal preemption of state tort laws. Unable to show federal preemption without overcoming the burden requiring both the production of records and information they may not have and undergoing scrutiny on the propriety of the FDA's decision, FDA approval may not protect many companies in the way Congress intended when it included preemptive language in the MDA.

This Comment argues that the *Steele* standard is inconsistent with the liberal summary judgment standards recently adopted by California in *Aguilar v. Atlantic Richfield Co.*⁴ It further argues that the *Steele* standard cuts against the intent and purpose of federal preemption, improperly requires the judicial branch to perform legislative functions, and was read into a previous Supreme Court case that does not support its existence. These issues make it clear that the requirement should be replaced with a more relaxed burden-shifting standard that furthers the purposes of both summary judgment and federal preemption. Just as the employer should hire our graduate upon his presentation of a diploma, so too should the court grant summary judgment in favor of the moving defendant based on preemption where the defendant offers evidence that the FDA has approved the product, without regard to whether the FDA has *properly* approved and maintained approval of the product. Then, unless the plaintiff can proffer some evidence that would lead the court to think that the ap-

1. Pub. L. No. 94-295, 90 Stat. 539 (1976) (current version at 21 U.S.C. § 301 (2000)); H.R. REP. NO. 94-1090 (1976) (Conf. Rep.).

2. See *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 888-89 (Ct. App. 1997).

3. *Id.*

4. 24 P.3d 493, 512 (Cal. 2001).

proval was improper or non-existent, the court should grant the motion for summary judgment.

This Comment focuses on *Steele's* elevated burden on the moving defendant raising an MDA preemption defense related to medical devices. Part I examines the requirements for initial and continuing FDA approval of new medical devices, in particular Class III medical devices. It will continue to reveal the incredible hurdle that companies must leap in order to obtain and maintain FDA approval for such devices. This Part also illustrates the creation of the burdensome requirement applied by California courts. Part II details the errors and the lack of foundation of the *Steele* requirement and proposes a standard that simply requires a showing of FDA approval to shift the burden to the plaintiff to point out impropriety in the approval or compliance with the FDA requirements.

I. California's Creation of a Burdensome Requirement to Prove Preemption Based on the Medical Device Amendments

A. The Medical Device Amendments Subject Class III Medical Devices to a Rigorous Approval Process

Through the Food, Drug, and Cosmetic Act⁵ ("FDCA"), as amended by the Medical Device Amendments of 1976,⁶ Congress charges the FDA with ensuring that medical devices are safe and effective before they are placed on the market. Congress added the MDA to the FDCA as regulatory guidelines that divide devices into three classes depending on the degree of regulation necessary to ensure their safety and effectiveness.⁷ This Comment focuses on Class III devices.

Class III devices undergo the most stringent control of any of the devices under the MDA.⁸ This classification is reserved for those de-

5. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 301 (2000)).

6. Pub. L. No. 94-295, 90 Stat. 539 (1976) (current version at 21 U.S.C. § 301 (2000)); H.R. REP. NO. 94-1090 (1976) (Conf. Rep.).

7. 21 U.S.C. § 360c(a)(1)(A)-(C) (2000).

8. *Id.* § 360c(a)(1)(A). A small number of Class III devices can circumvent the PMA process. *Id.* § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (2005); *see also* 21 U.S.C. § 360e(b)(1)(B); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). This Comment does not address the law that should apply to products meeting the alternate approval methods. The first group of devices that can avoid the PMA process are pre-1976 devices that are "grandfathered" in until the FDA initiates and completes the PMA. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). The second group are those devices that are

vices used to support or sustain life and for devices that pose a potential unreasonable risk of illness or injury.⁹ To determine a device's classification, the FDA maintains a list of devices and their classifications.¹⁰ The list includes such Class III devices as artificial hearts,¹¹ implanted cerebellar stimulators,¹² and implantable pacemaker parts.¹³ If the device has not previously been classified, the FDA will classify the device as a Class III medical device if it finds that the device presents a potentially unreasonable risk of illness or injury, if the device is used in supporting or sustaining human life, or if it is of substantial importance in preventing impairment of human life.¹⁴

Before the FDA may approve such Class III devices, they must go through a rigorous pre-market approval process providing "reasonable assurance of safety and effectiveness of a device . . ." ¹⁵ The United States Supreme Court stated that "[d]espite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance,' which is known as the 'premarket approval,' or 'PMA' process, is a rigorous one."¹⁶

The pre-market approval ("PMA") process requires manufacturers to spend an average of 1200 hours on each submission, detailing information regarding the safety and efficacy of their devices.¹⁷ Manufacturers file an application that provides all information they know or reasonably should know about the design, manufacturing, use, and labeling of the device.¹⁸ The application is then reviewed through a four-step process.¹⁹ The "[a]pproval of a medical device through the PMA process can take months or even several years" in a process that

"substantially equivalent" to pre-existing devices that have avoided the PMA process due to the first exception. *Medtronic*, 518 U.S. at 478; see also 21 U.S.C. § 360e(b)(1)(B).

9. See 21 U.S.C. § 360c(a)(1)(C)(ii).

10. U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Product Classification Database Search, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> [hereinafter Device Database Search] (last accessed Jan. 20, 2006).

11. Device Database Search, *supra* note 10 (search for "Product Code" = "LOX").

12. Device Database Search, *supra* note 10 (search for "Product Code" = "LOZ").

13. Device Database Search, *supra* note 10 (search for "Product Code" = "DXY").

14. 21 U.S.C. § 360c(a)(1)(C)(ii). Devices that fall within the latter two elements must also not be able to be classified as Class I or II devices to be classified as a Class III device. *Id.*

15. *Id.* § 360e(d)(1)(B)(iii).

16. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

17. *Id.*

18. Theresa J. Pulley Radwan, *Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments*, 10 J.L. & HEALTH 343, 346 (1995).

19. U.S. Food & Drug Admin. Ctr. for Devices and Radiological Health, Review Process, Overview, http://www.fda.gov/cdrh/devadvice/pma/review_process.html#steps [hereinafter FDA Review Process Overview] (last visited Jan. 9, 2006).

includes an outside panel of experts to make recommendations regarding the device.²⁰

The first step involves an administrative and limited scientific review by FDA staff to determine if an application is complete.²¹ Upon successful completion of the first step, the FDA files the application, making a threshold determination that it is “sufficiently complete to permit a substantive review.”²² This begins the 180-day period for review of the application.²³

The second step includes an in-depth scientific, regulatory, and quality systems review by FDA personnel.²⁴ During this review, the FDA will notify the applicant of any deficiency in the application, and the applicant may submit an amendment.²⁵ If any amendment contains significant updates, the review period may be extended to allow for thorough evaluation of the updates.²⁶

The third step includes a review and recommendations by an outside panel.²⁷ This step is not required, but in general, “all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel.”²⁸ PMAs that are referred to a panel must hold a public meeting to review the PMA and then submit a final report to the FDA that includes recommendations and the basis for such recommendations.²⁹

Finally, the FDA begins final deliberations, documentation, and notification of the FDA decision.³⁰ This occurs within 180 days of the filing in step one, and, if approved, the public will be notified and the applicant will then have to submit final labeling of the product before market.³¹

In addition to the rigorous PMA process, any subsequent changes to the product trigger the requirement that the manufacturer submit a PMA supplemental application.³² Furthermore, to maintain the continued validity of the FDA’s approval, the manufacturer must submit

20. Radwan, *supra* note 18, at 347.

21. 21 C.F.R. § 814.42 (2005); FDA Review Process Overview, *supra* note 19.

22. 21 C.F.R. § 814.42(a).

23. *Id.* § 814.42(b).

24. *Id.* § 814.44; FDA Review Process Overview, *supra* note 19.

25. FDA Review Process Overview, *supra* note 19.

26. *Id.*

27. 21 C.F.R. § 814.44; FDA Review Process Overview, *supra* note 19.

28. FDA Review Process Overview, *supra* note 19.

29. 21 C.F.R. § 814.44(b); FDA Review Process Overview, *supra* note 19.

30. 21 C.F.R. § 814.44(c); FDA Review Process Overview, *supra* note 19.

31. FDA Review Process Overview, *supra* note 19.

32. 21 C.F.R. § 814.39.

post-approval reports at yearly intervals to identify any changes in the device and the medical community's understanding of the device and its effects.³³ This extensive process, along with specific language in the MDA, leads to federal preemption of state law.

B. Federal Preemption and the Medical Device Amendments

1. Federal Preemption of State Law Provides Uniformity As Congress Intends

In our system of dual federal and state governments, Article VI of the Constitution creates order by providing that when Congress so intends, the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."³⁴ The doctrine of federal preemption implements this constitutional directive and creates a uniformity of law on matters regulated by federal law.³⁵ To this end, "it has been settled that state law that conflicts with federal law is 'without effect.'"³⁶ In determining whether a state law has been preempted, "the purpose of Congress is the ultimate touchstone,"³⁷ and "[c]onsideration . . . starts with the basic assumption that Congress did not intend to displace state law."³⁸

The intent of Congress may be "explicitly stated in the statute's language or implicitly contained in its structure or purpose."³⁹ This allows state law to be preempted in three ways: (1) through express language in the federal statute, (2) when the state law conflicts with the federal statute, or (3) when federal law occupies the field of law to such an extent that it is reasonable to infer that Congress intended to preempt any state law in that field.⁴⁰ If preemption is found through any of these methods, it is no longer necessary to search for preemption authority, and the focus shifts to the scope of the preemption.⁴¹

33. 21 U.S.C. § 360i (2000); *see also* Scott v. CIBA Vision Corp., 44 Cal. Rptr. 2d 902, 906 (Ct. App. 1995).

34. U.S. CONST. art. VI, § 1, cl. 2.

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

36. *Id.* (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).

37. *Id.* (quoting Malone v. White Corp., 435 U.S. 497, 504 (1978)).

38. Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

39. *See* Ray v. Atl. Richfield Co., 435 U.S. 151, 157 (1978); Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977).

40. *Cipollone*, 505 U.S. at 516; *see also* Brown v. Hotel & Rest. Employees & Bartenders Int'l Union, 468 U.S. 491, 501 (1984).

41. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996).

2. Congress Intends for the Medical Device Amendments to Preempt State Law Product Liability Claims for Class III Medical Devices

The Supreme Court has stated that Congress's intent regarding MDA's preemption of state law is clear.⁴² Most courts have found that the preemptive federal law binds products that go through the PMA process.⁴³ Furthermore, the MDA expressly states that federal law preempts any state law that seeks to impose different or additional requirements with respect to a medical device's safety or effectiveness.⁴⁴ When preemption is expressly stated in the statute, there is no need to look beyond the words of the statute.⁴⁵ Even with a minority of courts requiring the additional determination of exactly what common law claims Congress intended to preempt,⁴⁶ it is clear that the rigorous and detailed PMA process requirements preempt all state common law claims that impose different or additional standards.⁴⁷ Therefore, the only analysis of the state law claim is whether it imposes different or additional standards.

"Until 1996, nearly every court which had considered [the MDA's preemptive language] . . . had held that state tort law is a state 'requirement' under this provision because state tort law has the ability to require a manufacturer to endure additional testing or modification to prevent liability."⁴⁸ In 1996, the Supreme Court muddied the MDA's preemptive language by holding that "state law is only a 'requirement' if it is 'specific.'"⁴⁹ Nevertheless, California courts have uniformly stated that common law claims may apply such specific requirements as to be preempted by the MDA.⁵⁰

Steele also supports the premise that the MDA preempted state common law claims, explicitly stating, "a state common law tort claim relating to the safety and effectiveness of a device is preempted" by the

42. See 21 U.S.C. § 360k (2000); *Medtronic*, 518 U.S. at 484.

43. See, e.g., *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir. 1993); *Scott v. CIBA Vision Corp.*, 44 Cal. Rptr. 2d 902, 907 (Ct. App. 1995).

44. See 21 U.S.C. § 360k; *Medtronic*, 518 U.S. at 484.

45. See *Medtronic*, 518 U.S. at 483.

46. See *id.*

47. Although the MDA may not preempt all consumer claims, claims regarding devices subject to the MDA regulations, such as Class III medical devices, are preempted by federal law. See *King*, 983 F.2d at 1139.

48. Radwan, *supra* note 18, at 350.

49. *Medtronic*, 518 U.S. at 500; Radwan, *supra* note 18, at 350-51.

50. See *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 888 (Ct. App. 1997).

MDA.⁵¹ Furthermore, the court stated that “[t]he design, manufacture, and labeling of the device, as approved by the FDA as safe and effective after the device has undergone the PMA process, are the specific federal requirements giving rise to preemption.”⁵² Therefore, a state common law claim is preempted, as courts have properly held, if a manufacturer of a Class III medical device shows that the subject device underwent the FDA’s rigorous PMA process, and the plaintiff’s suit seeks to impose different or additional requirements.⁵³

Recently, in addition to a number of cases where courts have held that devices submitted to the PMA process are controlled by the preempted federal law,⁵⁴ the FDA stated in an amicus brief that the MDA preempts state product liability claims, which impose requirements that are different from or in addition to FDA requirements.⁵⁵ Moreover, the brief demonstrates that the FDA’s current position is that the preemption provision of the MDA specifically encompasses requirements imposed by state tort judgments.⁵⁶ The next issue is the requirements that a defendant must meet in order to receive summary judgment based on a preemption defense.

C. California’s Summary Judgment Standard and the Burden Courts Place on a Defendant Moving for a Summary Judgment on the Defense of Federal Preemption Based on the Medical Device Amendments

1. Modern Summary Judgment Standard in California

The California Supreme Court’s landmark authority on summary judgment, *Aguilar*, was decided after *Steele* and sets out the modern

51. *Id.* The court differentiates the preemptive power of the MDA when dealing with devices that underwent the less stringent substantial equivalence test, requiring only that the manufacturer show the device is substantially similar to a device already approved, as opposed to the full PMA process. *See generally id.* The court distinguished this scenario with that found not to be preemptive in *Medtronic. Id.* at 888.

52. *Id.*

53. *See, e.g.,* *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir. 1993); *Scott v. CIBA Vision Corp.*, 44 Cal. Rptr. 2d 902, 907 (Ct. App. 1995).

54. *See* *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Brooks v. Howmedica Inc.*, 273 F.3d 785, 799 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227–28 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *McMullen v. Medtronic, Inc.*, No. 2:03-cv-005-LJM-WGH, 2004 U.S. Dist. LEXIS 22819, at *29 (S.D. Ind. Sept. 15, 2004); *Davenport v. Medtronic, Inc.* 302 F. Supp. 2d 419, 430 (E.D. Pa. 2004).

55. *See generally* Brief for United States as Amicus Curiae Supporting Respondent/Petitioner at 30–31, *Horn v. Thoratec Corp.*, 376 F.3d 136 (3rd Cir. 2004) (No. 02-4597).

56. *See id.* at 18.

burden and procedure for summary judgment as interpreted from California Code.⁵⁷ The *Aguilar* court favorably described summary judgment as “a mechanism to cut through the parties’ pleadings in order to determine whether, despite their allegations, trial is in fact necessary to resolve their dispute.”⁵⁸ This mechanism is intended to “‘avoid a . . . trial’ rendered ‘useless’ by nonsuit or directed verdict or similar device.”⁵⁹ To that end, the *Aguilar* court made plain that summary judgment motions should be liberally granted.⁶⁰ The court held that a defendant moving for summary judgment does not bear the burden of negating an element of a plaintiff’s cause of action, but rather must show either that the plaintiff cannot establish an essential element or that there is a complete defense against the claim.⁶¹ Because preemption is a complete defense, the burden of showing preemption is on the defendant.⁶²

Therefore, to successfully move for summary judgment, a manufacturer of a Class III medical device must make a prima facie showing that the subject device underwent the FDA’s rigorous PMA process and that the plaintiff’s state tort lawsuit seeks to impose different or additional standards.⁶³ The burden then shifts to the plaintiff to show that his claim would not impose additional or different requirements, or that the manufacturer failed to comply with federal requirements imposed by the FDA.⁶⁴ This is the scheme applied to MDA preemption defenses.⁶⁵

2. The Court’s Exaggeration of the Defendant’s Burden in a Summary Judgment Motion

Although the burden that would be expected from the *Aguilar* standard appears innocuous, the California court in *Steele* raised the

57. See CAL. CIV. PROC. CODE § 437c (West 2005); *Aguilar v. Atl. Richfield Co.*, 24 P.3d 493, 505 (Cal. 2001).

58. *Aguilar*, 24 P.3d at 505.

59. *Id.* at 514 (quoting *Guz v. Bechtel Nat’l, Inc.*, 8 P.3d 1089, 1109 (2000) (Chin, J., concurring)).

60. See *id.* (modern California summary judgment law now largely conforms to its “liberalized” “federal counterpart”).

61. *Id.* at 512.

62. *Marshall v. Bankers Life & Cas. Co.*, 10 Cal. Rptr. 2d 72, 76 (Ct. App. 1992); see also *Aguilar*, 24 P.3d at 513.

63. See *supra* Part I.B.2.

64. *Aguilar*, 24 P.3d at 513 (holding that once the defendant makes the necessary showing, the burden shifts to the plaintiff to present admissible evidence establishing that there is a triable issue of material fact).

65. See generally *Brooks v. Medtronic Corp.*, 273 F.3d 785 (8th Cir. 2001).

burden for the defendant to make a prima facie showing that the device underwent the FDA's PMA process.

In *Steele*, plaintiff Patricia Steele filed a civil suit for damages against defendant Collagen Corporation, when Steele developed an autoimmune disorder after receiving a test injection of Collagen Corporation's Zyderm.⁶⁶ Zyderm is classified as a Class III device,⁶⁷ which did not go through the FDA's substantial equivalence approval process ("SEAP")—an approval process that does not always lead to preemption—but went through the full PMA certification process that preempts state law.⁶⁸

At the trial level, Collagen Corporation moved for summary judgment, asserting that Steele's causes of action were preempted by the MDA because the FDA had approved Zyderm.⁶⁹ It asserted in its statement of undisputed facts that it had submitted Zyderm to the FDA for the PMA process and that Zyderm had ultimately been approved by the FDA as being "safe and effective for use."⁷⁰ The trial court agreed with Collagen Corporation and found that Steele's causes of action were preempted.⁷¹ It granted the motion and entered judgment in favor of Collagen Corporation.⁷² Steele appealed to the Third District Court of Appeal in California, leading to the decision that is the subject of this Comment.⁷³

In the appeal to the California Court of Appeal, the plaintiff contended that the trial court had erred in granting summary judgment based on federal preemption.⁷⁴ The plaintiff argued this contention on the grounds that no state common law action is ever preempted under the MDA.⁷⁵ The court conducted an exhaustive analysis of the United States Supreme Court's decision in *Medtronic, Inc. v. Lohr*⁷⁶ to determine whether state common law claims are preempted under the MDA after the product has gone through the PMA process.⁷⁷

Medtronic, decided in 1996, was a case involving a Class III medical device that underwent the SEAP, the less rigorous test under the

66. *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 880–81 (Ct. App. 1997).

67. *Id.* at 882.

68. *Id.* at 889.

69. *Id.* at 881.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *See id.* at 885.

75. *See id.*

76. 518 U.S. 470 (1996).

77. *See Steele*, 63 Cal. Rptr. 2d at 882–86.

MDA.⁷⁸ In *Medtronic*, the Court determined that there was no preemption under the MDA when the product underwent the SEAP.⁷⁹ The court in *Steele*, however, found that based on *Medtronic*, a state claim is preempted when: “(1) . . . [the] state damages award on the claim would establish a state requirement applicable to the device which is different from or in addition to a federal requirement and (2) . . . the FDA has established a specific counterpart requirement for the device.”⁸⁰ In this case, “specific counterpart requirement[s]” include the PMA process requirements that Class III medical devices undergo when they do not undergo the SEAP.⁸¹ Additionally, the court noted that where the manufacturer violates the FDA requirements, preemption does not apply.⁸²

The court in *Steele* then addressed whether the state common law establishes a requirement applicable to the device that is different than or in addition to the federal requirements.⁸³ Finding that “common law standards of care and behavior impose specific requirements”⁸⁴ and that those requirements are different than the FDA standards,⁸⁵ the court was left with the final task of determining whether Zyderm was “designed, manufactured, and labeled according to the specifications approved by the FDA.”⁸⁶ Or otherwise stated, whether Collagen Corporation had met its prima facie showing that the FDA approved its device.

In determining whether Collagen Corporation followed the FDA requirements, the court required that Collagen Corporation prove compliance. To do this, the court required Collagen Corporation to show not only evidence that the product had gone through the rigorous PMA process and ultimately been approved, but additionally that the product complied with all the requirements of the FDA and PMA process.⁸⁷ Because the Court of Appeal could not determine from the record whether Collagen Corporation met the federal standard of care emanating from the PMA process, considering that determina-

78. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

79. *Id.* at 501.

80. *Steele*, 63 Cal. Rptr. 2d at 886.

81. *Id.*

82. See *id.*

83. See *id.* at 886–87.

84. *Id.* at 887.

85. *Id.* at 887–88.

86. *Id.* at 889.

87. See *id.*

tion is best made by the FDA during the process, the court reversed summary judgment.⁸⁸

Much like the recent graduate was unable to meet the burden of proof required by the demanding potential employer, Collagen Corporation was unable to meet the unexpected requirement of proving that the FDA acted properly in approving the product and that there was full compliance. This requirement, set by *Steele*, serves as a difficult hurdle for defendants arguing federal preemption based on a Class III medical device undergoing the PMA process.⁸⁹

For example, in *Robinson v. Sultz Orthopedics*,⁹⁰ the defendant Sultz Orthopedics brought a motion for summary judgment based on federal preemption stemming from its product undergoing the full PMA process.⁹¹ Sultz asserted that it had complied with the FDA requirements and that the plaintiff's cause of action created different and additional requirements: the two elements necessary for preemption to apply.⁹²

The plaintiff responded by stating that Sultz's "attempt to establish . . . [that the device was manufactured in compliance with FDA requirements] is inadequate."⁹³ The plaintiff then analogized the case with *Steele* asserting that Sultz had not met its burden of proving compliance and therefore preemption did not apply.⁹⁴

Following the *Steele* court's precedent, the *Robinson* court denied the motion for summary judgment.⁹⁵ In its denial, the court discussed Sultz's inability to meet the burden necessary to show that it had complied with the FDA requirements.⁹⁶ The *Robinson* decision further illustrates the continuing onerous burden emanating from *Steele* by stating that the plaintiff has no burden of showing non-compliance with FDA requirements to avoid the preemption defense when the

88. *See id.*

89. *See Robinson v. Sultz Orthopedics, Ltd.*, No. 2001-029190 (Cal. Super. Ct. Alameda County Aug. 20, 2004) (order denying motion for summary judgment).

90. *Id.*

91. *See* Defendant's Memorandum of Points and Authorities in Support of Motion for Summary Adjudication, *Robinson v. Sultz Orthopedics, Ltd.*, No. 2001-029190 (Cal. Sup. Ct. Alameda County June 4, 2004).

92. *See id.*

93. *See* Plaintiff's Memorandum of Points and Authorities in Opposition to Motion for Summary Judgment, or in the Alternative, for Summary Adjudication at 8, *Robinson v. Sultz Orthopedics, Ltd.*, No. 2001-029190 (Cal. Sup. Ct. of Alameda County Aug. 4, 2004).

94. *See id.* at 9.

95. *See Robinson v. Sultz Orthopedics, Ltd.*, No. 2001-029190, at 2 (Cal. Super. Ct. Alameda County Aug. 20, 2004) (order denying motion for summary judgment).

96. *See id.* at 3-4.

defendant's evidence is inadequate to show compliance.⁹⁷ This burden is too great on the moving defendant and should be reduced.

II. The Burden Should Be Reduced to Stay in Line with the Purpose of Summary Judgment and the Intention of Federal Preemption

The court in *Steele* properly stated that the MDA preempts state law when the state law has requirements that are different from or in addition to the requirements of the MDA.⁹⁸ These are the proper considerations for determining preemption under the MDA and would have led to the court finding that federal law did, in fact, preempt *Steele's* claims.⁹⁹

The court, however, never addressed the issues as it should have. Instead, it placed an impenetrable wall in the path of the moving defendant, requiring it to show that it complied with all FDA regulations and that the FDA properly approved the product before considering the possibility of federal preemption.¹⁰⁰ In light of the later refinement of the summary judgment standard in *Aguilar*, it is evident that the hurdle is an unreasonable burden on the moving defendant.¹⁰¹ Furthermore, this additional hurdle cuts sharply against the intent and purpose of federal preemption and requires the courts to improperly perform legislative duties.¹⁰² The proper initial burden should be to require the defendant to show evidence that the FDA approved the device through the PMA process, which shifts the burden to the plaintiff to bring evidence that the device was improperly approved or that the FDA's requirements were not followed.

97. See *id.* at 4.

98. See *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 886 (Ct. App. 1997).

99. See *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1138-39 (1st Cir. 1993); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771 (Ct. App. 1996).

100. See *Steele*, 63 Cal. Rptr. 2d at 886.

101. See *Aguilar v. Atl. Richfield Co.*, 24 P.3d 493, 510 (Cal. 2001).

102. *Id.* at 505 (quoting *Guz v. Bechtel Nat'l, Inc.*, 100 Cal. Rptr. 2d 352, 393 (Ct. App. 2000) (Chin, J., concurring)); see *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

A. Modern Summary Judgment Standards Do Not Comport with the *Steele* Court's Burden

1. The California Summary Judgment Standard Has Become Less Restrictive Than the Standard Applied in *Steele*

The court in *Aguilar* declared that “[t]he purpose of the law of summary judgment is to provide courts with a mechanism to cut through the parties’ pleadings in order to determine whether, despite their allegations, trial is in fact necessary to resolve their dispute.”¹⁰³ Although this purpose of summary judgment has not changed over the years, the law regarding summary judgment in California has changed dramatically.¹⁰⁴ Amendments in 1992 and 1993 to California’s Code of Civil Procedure set the drastic change in motion.¹⁰⁵ The amendments, however, were not completely interpreted by the courts until the California Supreme Court handed down the *Aguilar* decision in 2001.¹⁰⁶ *Steele* was decided in 1997, during this period of change.¹⁰⁷

Before the amendments, summary judgment was more restrictive in granting motions than the current law.¹⁰⁸ The comparatively increased restrictiveness came from a number of various burdens on the moving parties that were decreased by the *Aguilar* court’s interpretation of the amendments.¹⁰⁹ For example, a defendant moving for summary judgment had to present evidence to conclusively negate an element of the plaintiff’s action.¹¹⁰ The modern post-*Aguilar* standard only requires the defendant to point out that the plaintiff does not possess, and cannot reasonably obtain, needed evidence.¹¹¹ Although some of these changes were implied in the amendment, none became solidified in California law until 2001 when the court in *Aguilar* interpreted the amendments to intend to bring state law more in line with federal summary judgment standards.¹¹²

103. *Aguilar*, 24 P.3d at 505; see also FED. R. CIV. P. 56; 28 U.S.C. app. at R.56, Notes of Advisory Committee on Rules, 1963 amend. to rule 56(e) (2000).

104. See *Aguilar*, 24 P.3d at 508–09.

105. *Id.*

106. See generally *id.* at 504 (granting review to allow the court to clarify the law that must apply to rulings on summary judgment).

107. *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Ct. App. 1997).

108. *Aguilar*, 24 P.3d at 508.

109. See *id.* at 507–09.

110. *Id.* at 508.

111. *Id.* at 507.

112. *Id.* at 508.

2. Under the Modern and More Lenient *Aguilar* Standard the Burden Emanating from *Steele* Is Too Great

Reviewing the decision in *Steele* with the understanding of summary judgment law provided by *Aguilar* amplifies the flaw in the court's burden. The great burden placed on the moving defendant, by requiring the proof of compliance with the MDA, would no doubt be considered a restrictive—if not a prohibitive—requirement that is far more than the prima facie showing that *Aguilar* requires.¹¹³ This is not in line with the *Aguilar* court's opinion that summary judgment motions should be liberally granted.¹¹⁴

It is necessary to limit or abolish the additional MDA compliance requirement to bring the holding of *Steele* more in line with the modern liberalized summary judgment standards. Many federal courts have applied a limited and more reasonable version of this standard and require that the defendant only prove that the device underwent, and was approved through, the PMA process.¹¹⁵ This reinterpretation through the lens of *Aguilar* would not only bring the summary judgment procedure more in line with the liberal modern standard, but would also maintain the important purpose that prompted Congress to explicitly provide for MDA preemption.

*Davenport v. Medtronic, Inc.*¹¹⁶ presents an example of the modern standards generally applied to a motion for summary judgment based on federal preemption by the MDA.¹¹⁷ In *Davenport*, the plaintiff alleged that there was no preemption because of the defendant's non-compliance with the FDA's PMA standards.¹¹⁸ The court decided the summary judgment issue based on the federal summary judgment standards in line with California's post-*Aguilar* summary judgment standard.¹¹⁹ The court stated that “[i]t is clear that ‘when the non-moving party bears the burden at trial and the movant meets its burden of directing the court to items demonstrating the absence of a genuine issue of material fact, the non-moving party must produce

113. See *supra* Part I.C.1.

114. *Aguilar*, 24 P.3d at 512 (stating that California summary judgment has been “liberalized” and now largely conforms to its “federal counterpart”).

115. See, e.g., *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir. 1993); *Scott v. CIBA Vision Corp.*, 44 Cal. Rptr. 2d 902, 907 (Ct. App. 1995).

116. 302 F. Supp. 2d 419 (E.D. Pa. 2004).

117. See generally *id.*

118. *Id.* at 433.

119. See *id.* at 435; *Aguilar*, 24 P.3d at 512.

evidence sufficient to create a genuine issue.’”¹²⁰ The court continued by stating that the “non-moving party cannot sustain this burden through unsupported assertions, conclusory allegations or mere suspicions in attempting to survive a summary judgment motion.”¹²¹ Medtronic provided evidence that it had complied with the FDA’s MDA requirements, and the court found that, absent evidence by the non-moving party to the contrary, the summary judgment motion would be granted.¹²²

Although Davenport produced some evidence on the issue, he was unable to provide the quantity of reliable evidence necessary to establish a genuine issue of material fact, and the summary judgment motion was granted.¹²³ This is just one of a number of examples where the court granted a summary judgment motion for preemption based on the non-moving party’s inability to point out specific instances of non-compliance by the defendant.¹²⁴

Courts following the federal summary judgment standard do not require such a great burden to prevail on summary judgment. Now that, after *Aguilar*, California’s summary judgment procedures are in line with federal procedures, the burden for showing that state tort law is preempted by the MDA must be reinterpreted. The onerous burden that California courts place on the moving defendant does not fit with the modern, more liberal, standard illustrated above. The burden on the movant should be amended to require only the proof of approval and compliance with the FDA’s MDA requirements. This standard properly leaves the plaintiff to point out specific instances of non-compliance or error to avoid summary judgment, holding true to the procedures and burdens the *Aguilar* court intended to create.

B. The *Steele* Court’s Requirement Cuts Against the Intent and Purpose of Preemption

Federal preemption provides order and protection for an even-handed standard.¹²⁵ “Instead of having 50 or more standards with respect to a given human pursuit, there is one.”¹²⁶ Moreover, “[t]he

120. *Davenport*, 302 F. Supp. 2d at 435 (quoting *Kozma v. Medtronic, Inc.*, 925 F. Supp. 602, 609 (N.D. Ind. 1996)).

121. *Id.* (citing *Williams v. Borough of W. Chester*, 891 F.2d 458, 460 (3d Cir. 1989)).

122. *Id.*

123. *Id.* at 435–38.

124. *See, e.g.*, *Brooks v. Howmedica, Inc.* 273 F.3d 785, 799 (8th Cir. 2001) (affirming trial court’s grant of summary judgment for the defendant’s device manufacturer).

125. *See Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 880 (Ct. App. 1997).

126. *Id.*

purpose of Congress is the ultimate touchstone' in every pre-emption case."¹²⁷

The intent of Congress appears clear from the language of the MDA. The MDA provides:

[N]o 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

(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.¹²⁸

These statements demonstrate that Congress intended the MDA to preempt state law. Nevertheless, to understand the purpose for the preemption one must look further.

The MDA promotes public health by encouraging the development of new and much needed medical devices. Congress explained:

As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development.¹²⁹

Congress intended preemption of state law claims to ensure that "innovations in medical device technology are not stifled by unnecessary restrictions."¹³⁰ Congress explained that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the federal government, interstate commerce will be unduly burdened."¹³¹ Additionally, an amicus brief filed by the FDA demonstrates that the FDA currently contends that the preemption provision of the MDA encompasses requirements imposed by state tort judgments.¹³² From both Congress's explanation and the subsequent interpretations by the congressionally empowered FDA, the MDA is intended to preempt state and local law in order to provide one unified standard, making it less burdensome on manufacturers to produce new devices.

127. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

128. 21 U.S.C. § 360k(a) (2000).

129. S. REP. NO. 94-33, at 2 (1975).

130. H.R. REP. NO. 94-853, at 12 (1976) (Conf. Rep.).

131. *Id.*

132. See Brief for United States as Amicus Curiae Supporting Respondent/Petitioner, *supra* note 55, at 18.

Congress's decision to have the MDA preempt state law was based on the recognized impediments that state law claims would have on the development of new medical devices.¹³³ It recognized that requiring manufacturers, such as Collagen Corporation, to comply with "50 or more standards" would greatly burden the companies' ability to develop a product that can be sold in multiple markets and to maintain compliance with multiple changing standards.¹³⁴ Ultimately, not only would this requirement retard the development of new beneficial devices, but it would also increase the design, production, and marketing costs of products, thus increasing the cost to the end consumer. The court in *Steele* recognized these matters in its analysis when it concluded that the MDA does preempt state law imposing different or additional requirements; however, it ignored the need when it created a requirement so great that few defendants could receive the benefits Congress intended it to provide.¹³⁵

By requiring the moving defendant to show not only that the product was approved through the PMA process, but also that it abided by federal requirements emanating from the PMA process, the *Steele* court raised the necessary burden to a degree bordering on removing the availability of preemption.¹³⁶ By simply elevating a burden required in summary judgment and thus removing preemption, the court defeated Congress's intent to protect medical device manufacturers from varying and burdensome state standards.

The requirement that is more reasonable and more closely aligned with the intent of Congress is to allow the defendant to create the presumption of compliance by showing that the product received approval by the FDA through the PMA process. This requirement would allow the device manufacturer the opportunity to access preemption by gaining approval through the PMA process and abiding by the emanating requirements. Thus, the manufacturer could avoid the undue burden of proving approval and conformity with the requirements in order to avoid a failed preemption defense and necessitate compliance with fifty or more individual state standards.

133. H.R. REP. NO. 94-853, at 12.

134. *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 880 (Ct. App. 1997).

135. *Id.* at 880, 888-89.

136. *Id.* at 889.

C. The Summary Judgment Burden Improperly Requires the Courts to Perform Legislative Duties

A jury resolving a state tort claim regarding a medical device approved by the FDA under its comprehensive PMA process would be forced to second-guess and reexamine the FDA's approval process and, having done so, leave the defendant open to state tort liability for having sold an FDA approved product in the manner the FDA intended.

In *Buckman Co. v. Plaintiffs' Legal Committee*,¹³⁷ the United States Supreme Court considered whether a conflict between the FDA's comprehensive regulatory scheme and state tort claims could give rise to implied preemption.¹³⁸ The *Buckman* plaintiff charged that the defendant had defrauded the FDA in its PMA submissions and that the FDA would have required a different warning or imposed different safety requirements had it known the truth.¹³⁹ Because these allegations necessarily would require a jury to second-guess the FDA's regulatory actions and adopt safety requirements the FDA never imposed, the Supreme Court concluded that the tort claim posed an unacceptable threat to the medical device regulation and undermined congressional intent in establishing a comprehensive regulatory scheme.¹⁴⁰ As a result, the plaintiff's fraud-on-the-FDA claim was impliedly preempted.¹⁴¹

The idea that the courts should not oversee the jobs delegated to administrators by Congress is evident in a number of cases. For example, in *Papas v. Upjohn Co.*,¹⁴² the court stated, "it is for . . . Administrator[s], not a jury, to determine whether" there has been compliance with the demonstration's requirements.¹⁴³ The plaintiff in *Papas* alleged that because there was a violation of the federal requirements on the product, federal preemption would not apply, just as the plaintiff in *Steele* successfully argued.¹⁴⁴ Disagreeing with *Steele*, the *Papas* court denied that compliance was a requirement and declared that states "may not interfere with the methods designed by Congress to

137. 531 U.S. 341 (2001).

138. *See id.* at 347.

139. *See id.* at 343.

140. *See id.* at 350–53.

141. *See id.* at 348.

142. 985 F.2d 516, 519 (11th Cir. 1993).

143. *Id.* at 519.

144. *Id.* at 518–19.

achieve" federal goals.¹⁴⁵ This rule is more closely aligned with the intent of Congress in creating MDA preemption.¹⁴⁶

As the *Buckman* Court noted, if a claim that effectively reviewed the decisions made by the FDA were allowed to proceed and liability ensued, "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes [would] dramatically increase the burdens facing" manufacturers, who might then decline to seek regulatory approval of new devices out of fear of "unpredictable civil liability."¹⁴⁷ This result would defeat the federal goal of ensuring the availability of efficacious medical devices.¹⁴⁸ This unfavorable situation can be avoided by limiting the court's oversight of whether the FDA has properly approved the device and focusing it only on whether the FDA has approved the device.

D. Inclusion of the Requirement Is Inappropriate and Is Unjustified in *Steele*

The inclusion of a requirement that the manufacturer has complied with the MDA for preemption to be available is suspect. It is a unique requirement that originated in *Steele* where the court appears to have read the requirement into a previous case without any analysis of the difficult issues it presents.¹⁴⁹

1. The Proof Requirement Was Unjustified and Inaccurately Read into a Previous Case

In stating the requirement that a manufacturer must comply with the FDA's requirements, the *Steele* court cites to the United States Supreme Court case *Medtronic*.¹⁵⁰ The Court in *Medtronic*, however, does not address the requirement of proof of compliance with the MDA for preemption to apply.¹⁵¹ The Eleventh Circuit Court of Appeals did address the issue when deciding *Lohr v. Medtronic, Inc.*,¹⁵² the same case at the appellate level.

That court stated, "[P]reemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory

145. *Id.* at 519.

146. H.R. CONF. REP. NO. 94-853, at 1, 12 (1976).

147. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

148. *See id.* at 350-51.

149. *See Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 886 (Ct. App. 1997).

150. 518 U.S. 470 (1996); *see also Steele*, 63 Cal. Rptr. 2d at 886.

151. *Medtronic*, 518 U.S. at 470.

152. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995).

[MDA] standards.”¹⁵³ Although the Supreme Court disagreed with the finding of preemption in the *Medtronic* case, the Court did not address the issue of whether a violation of the MDA removes the preemption ability when a product does undergo the full PMA process because the product had been approved only through SEAP.¹⁵⁴

The *Steele* court’s conclusion that non-compliance could defeat preemption was, therefore, relying on a Supreme Court case that did not address, and may have implicitly denied, the issue. In an attempt to buttress this flawed foundation, the *Steele* court cites to *Marshall v. Bankers Life & Casualty Co.*¹⁵⁵

In *Marshall*, an insurance company and health plan administrator claimed that an insured employee’s actions were preempted by the Employee Retirement Income Security Act of 1974¹⁵⁶ (“ERISA”). ERISA preemption, however, differs drastically from preemption under the MDA. Unlike the MDA’s PMA process that serves as guidelines for the FDA’s approval or denial of medical devices, ERISA is simply a body of law designed to promote the interests of employees and their beneficiaries in employee pension and benefit plans.¹⁵⁷ Although compliance with ERISA or the PMA process may be required for preemption, compliance with ERISA is a question of fact to be determined by a jury, whereas compliance with the PMA process is determined by the FDA.¹⁵⁸ Therefore, in *Marshall*, compliance with ERISA was properly determined by the court, but the FDA, not the court, properly determines compliance with the MDA. The *Steele* court did not recognize this important difference when it burdened the moving defendant with the proof of compliance, ignoring the government agency set up for the purpose of determining compliance, extending *Marshall* well beyond its original scope.¹⁵⁹

It is evident that the *Steele* court cited *Medtronic* for the proposition that compliance with the FDA approval requirements is necessary, although the Court never addresses the issue at the Supreme Court level and denied the requirement in the circuit court. It is also evident that the *Steele* court cited *Marshall* to determine the degree of proof required to meet the burden of proving approval and compli-

153. *Id.* at 1343.

154. *Medtronic*, 518 U.S. at 470.

155. 832 P.2d 573 (Cal. 1992).

156. *Id.* at 575; Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended in scattered sections of 26 U.S.C. and 29 U.S.C.).

157. *See id.* at 576; *see also* FDA Review Process Overview, *supra* note 19.

158. *Marshall*, 832 P.2d at 577; FDA Review Process Overview, *supra* note 19.

159. *See Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 889 (Ct. App. 1997).

ance, although the *Marshall* court dealt with a preemptive law that requires courts to determine compliance unlike the MDA, where compliance is determined by the FDA. This analysis of *Steele's* authority makes it evident that the court read these two requirements into prior cases and had no foundation for their creation.

2. The Proof Requirement Is Inappropriate

In addition to the fact that the requirement derives from a case that did not support its existence, and may have even implicitly denied the requirement and another case with highly distinguishable facts, every circuit court decision addressing this issue has declined to uphold the requirement.¹⁶⁰

It follows logically from Congress's intent to allow the FDA to develop preemptive regulatory schemes regarding Class III medical devices that non-compliance with the federal regulations does not preclude the possibility of preemption, making it understandable that every circuit court to address the issue found that preemption was, in fact, not precluded by non-compliance.¹⁶¹ Class III devices undergo the most stringent control of any of the devices under the MDA.¹⁶² The control includes both pre-market requirements and continuing post-market approval requirements.¹⁶³ The pre-market requirements, focused on safety and effectiveness of the device, require the applicant to undergo the PMA process, which forces the manufacturer to spend an average of 1200 hours on each submission detailing information regarding the safety and efficacy of the device.¹⁶⁴ The post-approval requirements include resubmission to the PMA process when any subsequent change is made to the product and the submission of detailed approval reports on a yearly basis.¹⁶⁵ These MDA requirements are extremely taxing on the company; however, they are far less taxing and likely more effective than requiring the company to comply with fifty or more similar yet slightly different requirements that would be

160. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1328–29 (3rd Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir. 1995); *Nat'l Bank of Commerce of El Dorado v. Kimberly Clark Corp.*, 38 F.3d 988, 992 n.2 (8th Cir. 1994); *Papas v. Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir. 1993) (Aldrich, J., concurring).

161. *Michael*, 46 F.3d at 1328–29; *Reeves*, 44 F.3d at 307; *Nat'l Bank of Commerce of El Dorado*, 38 F.3d at 992 n.2; *Papas*, 985 F.2d at 519; *King*, 983 F.2d at 1140.

162. 21 U.S.C. § 360c (2000).

163. *Id.* § 360e.

164. *Id.*; see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

165. 21 U.S.C. § 360i; 21 C.F.R. § 814.39 (2005); see also *Scott v. CIBA Vision Corp.*, 44 Cal. Rptr. 2d 902, 905–06 (Ct. App. 1995).

imposed if state law were not preempted. The result of such requirements on top of the already extensive federal requirement would hinder progress in the field of medical devices and greatly increase the cost born by the end consumer, two interests that Congress was explicitly attempting to protect.¹⁶⁶

Conclusion

The court in *Steele* properly stated that the PMA process may preempt state law tort claims.¹⁶⁷ However, the burden *Steele* places on the moving defendant to show preemption is far too great. By imposing this great burden, the court has effectively removed the ability to move for summary judgment based on federal preemption. The proper burden should require a moving defendant to assert that it has been properly certified through the FDA's PMA process and that the certification was valid throughout the time in question. This should be all that is required to meet its prima facie showing for preemption to apply. The burden should then shift to the non-moving party to point out specific instances of non-compliance or improper certification. Absence of this showing by the non-moving party should be equated with the absence of a genuine issue of material fact and the case should be dismissed due to federal preemption of the law. Just as this standard would give our recent graduate employment, it would allow manufacturers to abide by the federal standards emanating from the MDA as Congress intended without fear of being tried based on any of fifty different or additional standards of each state.

166. H.R. CONF. REP. NO. 853, 94th Cong. 1, 12 (1976).

167. *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 888 (Ct. App. 1997).

