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## **FDCA MEDICAL DEVICE AMENDMENTS AND FEDERAL PREEMPTION:**

PUTTING THE SCREWS TO SPINAL **FUSION PATIENTS** 

J. Derrick Price

### INTRODUCTION

Dorothy Marie Reeves suffered a serious back injury in 1985.<sup>1</sup> Her injury required she undergo spinal fusion surgery.<sup>2</sup> To promote the fusion of her vertebrae, Reeves' doctor implanted two surgical devices into her back.<sup>3</sup> These surgical devices were manufactured by AcroMed Corporation.<sup>4</sup> Although Reeves' condition initially improved, within six months she experienced increasing pain that was not present prior to surgery.<sup>5</sup> In 1991, Reeves filed suit against AcroMed in a Fifth Circuit federal district court based primarily on a "failure to warn" claim.<sup>6</sup>

Nine years before Reeves' suit, the Food and Drug Administration (FDA) approved the manufacture and marketing of these two surgical devices by AcroMed Corporation.<sup>7</sup> These two devices, nested bone plates and cancellous bone screws, were actually the component parts of a device known as the Variable Placement Spinal Plate Fixation System (VSP).8 The FDA gave Acromed clearance to market these devices (the individual component parts of the VSP)

<sup>&</sup>lt;sup>1</sup> Reeves v. Acromed Corp., 44 F.3d 300, 302 (5th Cir. 1995).

<sup>2</sup> Id.

<sup>&</sup>lt;sup>3</sup> Id.

<sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> See Reeves, 44 F.3d at 302 (explaining Reeves' primary claim that AcroMed failed to warn her that the FDA had never approved the use of these devices for spinal fusion).

<sup>&</sup>lt;sup>7</sup> In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 820 (3rd Cir. 1998), rev'd sub. nom. Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001). <sup>8</sup> Id.

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for use in surgeries involving the long bones of the arms and legs.9 These devices were subsequently used in a vast amount of spinalfixation surgeries resulting in over 2300 civil causes of action.<sup>10</sup> Most of these cases involved traditional state law tort claims.

AcroMed contended that the Medical Devices Amendments (MDA) to the Food, Drug and Cosmetics Act (FDCA) pre-empted state law tort claims.<sup>11</sup> This contention led to a split between the federal circuit courts. For example, in the Reeves case the Fifth Circuit held that the MDA pre-empted Reeves' cause of action.<sup>12</sup> On the other hand, the Third Circuit held that the MDA would not preempt any state law claim.<sup>13</sup> In February of 2001, the United States Supreme Court resolved the split in the federal circuit courts with its decision in Buckman Co. v. Plaintiff's Legal Committee.14 In Buckman, the Court held that the "fraud on the FDA" claims as well as the various other state law tort claims advanced by the plaintiffs in these cases were pre-empted by the amendments to the FDCA.<sup>15</sup>

This decision has essentially left over two thousand injured plaintiffs with no remedy at law.<sup>16</sup> In addition, the decision may provide incentive to medical device manufacturers to misrepresent the purpose of proposed devices because they will not be held civilly liable. In addition to arguing for a change in FDA policy, this comment addresses the arguments for and against pre-emption in this field. This comment concludes that the United States Supreme Court misinterpreted the intent of Congress in implementing the FDCA and MDA; therefore, state law tort claims should not be preempted.

### I. BACKGROUND

Most of these cases make a fraud-on-the-FDA claim by stating that AcroMed Corporation misrepresented the "intended use" of the

84

12 Reeves, 44 F.3d at 307.

<sup>13</sup> Orthopedic Bone Screw Prods., 159 F.3d at 829.

14 531 U.S. 341, 348 (2001).

16 See id. at 346-47.

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bone plates and pedicle screws to the FDA.<sup>17</sup> To understand the substance of this claim, it is important to first understand how FDA marketing approval and labeling procedures work.

A. Getting Surgical Devices on the Market: The FDA Approval

The FDA provides three procedures for medical devices to reach the market.<sup>18</sup> A manufacturer wanting to get a medical device on the market may submit to premarket approval, ask for an investigational device exemption, or obtain § 510(k) clearance.<sup>19</sup>

## 1. Premarket Approval

Medical devices are separated into three categories by the MDA.<sup>20</sup> In Buckman, the Court explained the distinctions between

Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices "presen[t] a potential unreasonable risk of illness or injury" and therefore incur the FDA's strictest regulation.<sup>21</sup>

Under this statutory regime, the PMA process is available only for Class III devices.22

The PMA procedure, as governed by the statute, requires filing an application to obtain approval for the device.<sup>23</sup> The application requires that all pertinent information about the device be articu-

<sup>18</sup> James M. Beck & Elizabeth D. Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 FOOD & DRUG L.J. 71, 72 (1998). <sup>19</sup> See id. at 72-74.

<sup>20</sup> Buckman, 531 U.S. at 344.

<sup>21</sup> Id. (differentiating between Class I, II and III medical devices and enunciating guidelines for market approval of each); see also 21 U.S.C. § 360c (2000). <sup>22</sup> See 21 U.S.C. § 360c(a)(1)(C) (2000) (indicating that Class I and Class II devices will not be

subject to the premarket approval process outlined in § 360e).

<sup>23</sup> 21 U.S.C. § 360e(c)(1) (2000) (stating that anyone may file an application for premarket

<sup>9</sup> Id.

<sup>10</sup> Id. at 820.

<sup>&</sup>lt;sup>11</sup> Reeves, 44 F.3d at 301-02 (indicating that Acromed maintained that the failure-to-warn claim was pre-empted by the MDAs).

<sup>15</sup> Id.

<sup>&</sup>lt;sup>17</sup> James M. Beck & John A. Valentine, Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience, 55 FOOD & DRUG L.J. 389, 393-94 (2000)(declaring that most plaintiffs alleged that the initial FDA clearances for all these devices were obtained by deceiving the FDA and "that the 'intended use' (whether general, sacral, or anterior) for every screw was misrepresented to the FDA. . .").

lated.<sup>24</sup> In addition, the Code of Federal Regulations requires applicants to specify a medical device's "intended use" in the premarket notification submission.<sup>25</sup> Medical devices going through the PMA process will take much longer to reach the market than devices using the other two avenues. Indeed, the PMA process may take vears.<sup>26</sup> On average, the FDA spends 1200 hours researching and investigating each submission.<sup>27</sup> This process is also very costly to the manufacturers of medical devices.<sup>28</sup>

### 2. Investigational Device Exemption (IDE)

A second way for a manufacturer to get medical devices on the market is to obtain an exemption from the PMA process.<sup>29</sup> The IDE exemption allows for the use of unapproved medical devices in limited circumstances so the FDA may investigate their safety and effectiveness.<sup>30</sup> The FDA stringently oversees the IDE process.<sup>31</sup> Patients must volunteer to be treated with such devices.<sup>32</sup> In addition, manufacturers must obtain each patient's informed consent before they use the IDE device.<sup>33</sup> Devices available through the IDE

31 Id.

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are used only in clinical trials and remain unavailable to the general

## 3. Section 510(k) Clearance

The § 510(k) clearance process provides the most commonly used method to introduce a medical device to the market. Manufacturers must demonstrate that the medical device is the substantial equivalent of a device that was on the market prior to 1976.35

The passage of the MDA in 1976 gave rise to the § 510(k) process.<sup>36</sup> The MDA allowed for "... Class III devices that were in com-Grandfathering of devices already on the market created the

merce prior to its enactment to remain on the market until the FDA initiates and completes a premarket approval analysis for those 'predicate' devices."37 Congress allowed this because the medical devices already on the market "... could not be withdrawn ... while the FDA completed its PMA analysis for those devices."38 potential for market monopolization.<sup>39</sup> Thus, the MDA allows devices that are substantially equivalent to a predicate device to forgo the PMA process.<sup>40</sup> This procedure became known as the "Section 510(k) process," because that section outlined the procedure in the original MDA.<sup>41</sup> The manufacturer must show that the proposed device is as safe and effective as a device already legally on the market, and the proposed device will not "raise different questions of safety and effectiveness . . . . "42

Federal regulations require that "[a §] 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence."43 All § 510(k) summaries require an identification of the legally marketed device to which the

voluntary participation; and that the patient has the right to discontinue participation

<sup>&</sup>lt;sup>24</sup> Id. (mandating that the application include: (A) all information as to the safety and effectiveness of the device known or which should be reasonably known to the applicant; (B) a statement of components and materials used in the device and principles of operation; (C) a description of methods and facilities used in manufacturing, processing, and installation; (D) references to applicable performance standards under § 360d of the statute along with adequate information to show that the device meets those standards; (E) samples of the device and its components or complete information as to the location of such samples; (F) proposed labeling samples; and (G) any other information that the FDA may require).

<sup>25</sup> See 21 C.F.R. § 807.87(e)(2001) (indicating that "proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. ..." are required in a premarket notification submission).

<sup>&</sup>lt;sup>26</sup> See Beck & Azari, supra note 18, at 74.

<sup>27</sup> Orthopedic Bone Screw Prods., 159 F.3d at 819 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996)).

<sup>28</sup> See Beck & Azari, supra note 18, at 74.

<sup>29</sup> Id.

<sup>30</sup> Id.

<sup>&</sup>lt;sup>32</sup> See Beck & Azari, supra note 18, at 74 (explaining that volunteer patients have access to IDE devices only through doctors who volunteer to act as investigators for the FDA and agree to follow the FDA's protocols).

<sup>&</sup>lt;sup>33</sup> See id. at 75(reporting that IDE regulations require written informed consent documents that include statements that research is involved; descriptions of reasonably foreseeable benefits, risks, or discomforts to the patient; alternatives; confidentiality of the subject's medical records; an explanation of any compensation; available treatments for injuries possibly arising from the research that involve more than minimal risk; a statement of

<sup>&</sup>lt;sup>34</sup> Orthopedic Bone Screw Prods., 159 F.3d at 819.

<sup>&</sup>lt;sup>35</sup> Reeves, 44 F.3d at 303.

<sup>&</sup>lt;sup>36</sup> Id.

<sup>&</sup>lt;sup>37</sup> Orthopedic Bone Screw Prods., 159 F.3d at 819 (citing 21 U.S.C. §360e(b)(1)(A) (2000)).

<sup>38</sup> Id. (quoting Medtronics, Inc. v. Lohr, 518 U.S. 470, 478 (1996)). <sup>39</sup> Id.

<sup>40</sup> Id.

<sup>&</sup>lt;sup>41</sup> Id.

<sup>&</sup>lt;sup>42</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 820 n.1 (citing 21 U.S.C. § 360c(i)(1)(A) (2000)).

submitter claims equivalence.<sup>44</sup> The § 510(k) summary requirement must contain a statement of the device's "intended use."45 Finally, the § 510(k) summary must include a statement of the technological characteristics of the device in comparison with the predicate device.46

Additionally, the § 510(k) regulatory scheme anticipated modifications to devices themselves or modifications to the uses for these devices intended.<sup>47</sup> Thus, the regulations require a manufacturer that makes such a modification to the device or its intended use, to submit data showing that the modification will be safe and effective.48

Although these requirements seem to be stringent, the  $\S$  510(k) process is still the manufacturer's preferred route to the market because "review of a § 510(k) application by the FDA requires an average of only twenty hours of agency time, compared to the 1200 hours required for full market approval."49

### B. AcroMed's VSP Device

### 1. Spinal Fusion, How it Works

Spinal fusion is a surgical procedure used to treat severe back pain when no other medical remedy will suffice.<sup>50</sup> The physician

attempts to fuse, or connect, juxtaposed vertebrae "that have become unstable due to disease or injury."51 The mechanics of the fusion process are as follows: the doctor inserts bone chips (taken from the hip of the patient) between or around the affected vertebrae; these bone chips then fuse with the affected vertebrae, creating a mass of bone called an arthrodesis; this arthrodesis alleviates the patient's back pain by stabilizing the affected area.<sup>52</sup>

To encourage the fusion of the bone chips and vertebrae, and to provide stability during the fusion process, physicians sometimes use internal fixation devices.<sup>53</sup> These devices provide a splint to decrease "motion between segments of the spine to allow the bone fusion to knit together."54 These internal fixation devices may be removed once the bone chips form a solid fusion.55

If a physician uses an internal fixation device, several options are available.<sup>56</sup> This comment focuses on the use of orthopedic bone screws, also known as "pedicle screws."<sup>57</sup> These screws are implanted into the pedicles, which are the "two rear-ward facing bony arches on either side of the vertebral body that support the lamina."58 Surgeons implant these screws into the pedicles because "the pedicles face out and are more readily accessible to a surgeon than

## 2. Getting the VSP on the Market

AcroMed first attempted to get the VSP on the market in 1984.60 AcroMed sought § 510(k) clearance for the VSP indicating that the device's intended use was for spinal fusion and that the

<sup>44 21</sup> C.F.R. § 807.92(a)(3)(indicating that a device can claim "substantial equivalence" to a predicate device if it: (1) was legally marketed before May 28, 1976; (2) was originally classified as Class III but has since been reclassified to Class II or I; or (3) has been introduced into the market by a showing of substantial equivalence through the Section 510(k) process).

<sup>&</sup>lt;sup>45</sup> 21 C.F.R. § 807.92(a)(5) (2002). This section requires "a statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended." Id.

<sup>&</sup>lt;sup>46</sup> 21 C.F.R. § 807.92(a)(6) (indicating that the § 510(k) summary requires disclosure of the material, design, and composition of the new device; how such attributes of the new and predicate device are the same; and how these attributes compare with those of the predicate device).

<sup>47</sup> See 21 C.F.R. § 807.87(g).

<sup>&</sup>lt;sup>48</sup> 21 C.F.R. § 807.87 (declaring that when a person places a device into the stream of commerce that has been modified in a way that significantly effects its safety or effectiveness, or intends to market that device for a new use, the registrant must provide supporting data that the consequences and effects of this change have been considered).

<sup>&</sup>lt;sup>49</sup> Orthopedic Bone Screw Prods., 159 F.3d at 820 (quoting Medtronics, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996)).

<sup>&</sup>lt;sup>50</sup> See Beck & Valentine, supra note 17, at 392 (classifying spinal fusion surgery as a last resort for severe back pain).

<sup>&</sup>lt;sup>51</sup> Id.

<sup>&</sup>lt;sup>52</sup> Id.

<sup>&</sup>lt;sup>53</sup> Id.

<sup>&</sup>lt;sup>54</sup> Id.

<sup>&</sup>lt;sup>55</sup> Beck & Valentine, supra note 17, at 392.

<sup>&</sup>lt;sup>56</sup> Id. (explaining that not all spinal fusion surgeries utilize implants and that orthopedic bone screws, hooks or wires are other available options).

<sup>&</sup>lt;sup>57</sup> Id. (observing that "pedicle screws" is the name commonly used for orthopedic bone

<sup>&</sup>lt;sup>58</sup> Id; see also id. at 392 n.10 (citing Burton v. Danek Med. Inc., C.A. No. 95-5565, 1999 WL

<sup>&</sup>lt;sup>59</sup> Id. at 392 n.10 (citing Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at \*4 (Tex. Dist. Harris Co. June 7, 1999), aff d mem., No. 14-99-00616-CV, 2000 WL

<sup>&</sup>lt;sup>60</sup> Orthopedic Bone Screw Prods., 159 F.3d at 820.

device would be marketed as such.<sup>61</sup> The FDA denied this initial request for § 510(k) clearance.<sup>62</sup> The FDA determined that the VSP was a Class III device for purposes of the regulations and that no substantially equivalent predicate device existed on the market.<sup>63</sup>

The following year, AcroMed hired Buckman Company, Incorporated (Buckman) to help them clear the VSP through the FDA.<sup>64</sup> Buckman subsequently filed a second application for § 510(k) clearance on behalf of AcroMed.<sup>65</sup> Once again, the application indicated that the VSP device would be used and marketed for spinal fusion.<sup>66</sup> Although the application contained additional information about the device and its intended use, the FDA again denied  $\S 510(k)$ clearance for the VSP device.<sup>67</sup> This time, in addition to stating that the VSP had no predicate device to which it was substantially equivalent, the FDA also stated that the VSP device posed potential risks not exhibited by other spinal fixation systems.<sup>68</sup>

Two months later, in December of 1985, AcroMed and Buckman changed their strategy for introducing the VSP device to the market.<sup>69</sup> In the Buckman opinion, the Supreme Court explained the strategy employed by AcroMed and Buckman and its effectiveness.<sup>70</sup> At the urging of Buckman, AcroMed dissected the VSP device, splitting it into its component parts, renaming them "nested bone plates" and "[cancellous] bone screws."71 Buckman, on behalf of AcroMed, then filed separate § 510(k) applications for each individual component.<sup>72</sup> Both applications specified a new intended use for the devices.<sup>73</sup> In these new applications, AcroMed sought to market the separate component devices for use in long bones such

<sup>64</sup> See id. at 818 (stating that the appeal involved allegations made by plaintiffs that Buckman made misrepresentations to the FDA).

<sup>65</sup> Orthopedic Bone Screw Prods., 159 F.3d at 820.

67 Id.

68 Id.

<sup>69</sup> See Reeves, 44 F.3d at 303 (noting that the December 1985 § 510(k) application submitted by AcroMed contained no statements identifying spinal fusion as an intended use of the devices).

<sup>70</sup> Buckman, 531 U.S. at 346 (quoting Orthopedic Bone Screw Prods., 159 F.3d at 820).

- 71 Id.
- 72 Id.

73 Id.

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as arm and leg bones.<sup>74</sup> The application made no mention of using the devices in spinal fusion.<sup>75</sup> Buckman and AcroMed claimed that predicate devices used in long bone surgery existed and that these component parts were substantially equivalent.76

The FDA subsequently granted approval of these devices in February 1986.77 Despite the intended use of the components of the VSP device as recited by the § 510(k) applications, these devices were used in Dorothy Reeves' spinal surgery in 1986-the same year they were approved by the FDA for other purposes.<sup>78</sup>

AcroMed opened the door for other VSP manufacturers of similar devices who copied AcroMed's application strategy.79 After the VSP components received § 510(k) clearance, the FDA cleared AcroMed's competitors' products either as general orthopedic devices or as anterior spinal or sacral indications relating to other predicate devices.<sup>80</sup> Some manufacturers even received IDE clearance for use of the screws in pedicle fixation, but no devices were cleared through the PMA process.<sup>81</sup> However, physicians were able to use these devices for pedicle fixation as an off-label use of the devices.<sup>82</sup>

## C. "Intended Use"

Much of the ensuing litigation over the pedicle screw systems focused on the manufacturers' intended use of the screws as represented to the FDA.<sup>83</sup> Federal regulations define intended use as the "objective intent of the persons legally responsible for the labeling of

### <sup>74</sup> Id.

<sup>76</sup> Id.

77 Id.

<sup>78</sup> See Reeves, 44 F.3d at 302 (indicating Acromed manufactured the plates and screws used in

<sup>79</sup> See Beck & Valentine, supra note 17, at 393. <sup>80</sup> See id.

<sup>81</sup> Id

<sup>82</sup> Id. (defining "off-label" use as "a term used to indicate that a particular medical device being used was not cleared by FDA for marketing for that use." Id.).

<sup>83</sup> Id. at 393-94 (relating that plaintiffs alleged that the FDA labeling clearances were obtained by the manufacturers by fraudulently representing the intended use of the pedicle screws, and that the manufacturers actually intended for every screw (general, sacral or anterior) to be used for pedicle fixation in spinal fusion surgeries). <sup>84</sup> See Edward M. Basile et. al., Medical Device Labeling and Advertising: An Overview, 54 Food

& DRUG L.J. 519, 523 (1999) (citing 21 C.F.R. § 801.4 (1998)).

<sup>&</sup>lt;sup>61</sup> Id.

<sup>62</sup> Id.

<sup>63</sup> Id.

<sup>66</sup> Id.

<sup>75</sup> Buckman, 531 U.S. at 346.

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Edward Basile further explained the regulatory provisions for intended use in Medical Device Labeling and Advertising: An Overview by stating:

Intent is determined by "such persons' expressions" or "by the circumstances surrounding the distribution of the article." [The] FDA provides examples of how objective intent may be shown by stating that "[t]his objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." The regulations further provide that intended use may be shown "if the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised . . . . [I]f a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.<sup>85</sup>

The Plaintiffs believed they had a viable argument for liability because the intended use of the pedicle screws as represented to the FDA did not include spinal fixation. The plaintiffs believed they had a viable argument for liability.86

### D. "Off-label" Use of Medical Devices

Unfortunately for the plaintiffs in the pedicle screw cases, the FDA and MDA provided a loophole for the intended use argument with the "practice of medicine" exception.<sup>87</sup> This exception gives doctors the authority to prescribe any device that has been cleared by the FDA for any purpose that the doctor deems safe and necessary.88 Thus, this section allows for off-label use of medical devices.89

<sup>87</sup> See Basile et al., supra note 84, at 524.

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The medical community widely accepts off-label use of drugs and medical devices.<sup>90</sup> Considering current FDA labeling and product approval procedures, there are several policy justifications for allowing such use. Quite often, such off-label use represents the cutting edge of medical treatment techniques.<sup>91</sup> Therefore, restrictions on off-label use would not only handicap the medical profession in their ability to treat and cure patients, but it would also have the effect of prohibiting the advancement of medical science.<sup>92</sup> Considerable evidence supports the proposition that off-label use is common, necessary and important for continued advancement in treatment techniques.93 James Beck noted in 1998 that off-label use prescriptions comprise approximately twenty-five percent of over 1.6 billion prescriptions written annually, some recent estimates run as high as sixty percent.94 Physicians extensively use prescription drugs off-label in the treatment of cancer, heart and circulatory disease, Acquired Immune Deficiency Syndrome (AIDS), kidney diseases requiring dialysis, osteoporosis, spinal fusion surgery, uncommon diseases and most pediatric uses.95 Thus, the medical community has strong arguments justifying the practice of using off-label drugs and medical devices.<sup>96</sup>

Furthermore, the FDA itself recognizes the value and need for off-label use of medical devices.97 The FDA stated this policy in a 1982 FDA Drug Bulletin.98 Once approved by the FDA for marketing, physicians may prescribe any drugs or product for uses and

<sup>95</sup> See Beck & Azari, supra note 18, at 80.

<sup>96</sup> Id.

<sup>85</sup> Id. at 523-24. See also id. at 523-24 nn. 43-46 (citing 21 C.F.R. § 801.4; V.E. Irons v. United States, 244 F.2d 34, 44 (1st Cir. 1957); United States v. El Rancho Adolphus Prods., 243 F.2d 367 (3rd Cir. 1952); United States v. 3 Cartons, More or Less, No. 26 Formula GM, 132 F.Supp. 569, 574 (S.D. Cal. 1952)).

<sup>&</sup>lt;sup>86</sup> See Beck & Valentine, supra note 17, at 394. The plaintiffs contended that none of the devices should have been marketed, and therefore, all clearances of pedicle screws by the FDA should be invalidated under theories of negligence, liability per se and fraud-on-the-FDA. Id.

<sup>&</sup>lt;sup>88</sup> See 21 U.S.C. § 396 (West 1999) (declaring "[n]othing 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 or disease within a legitimate health care practitioner-patient relationship.").

<sup>&</sup>lt;sup>89</sup> See Beck & Valentine, supra note 17, at 398 (indicating that doctors are not restricted by labels in prescribing the use of medical devices and that the "FDA permits doctors to

prescribe drugs for 'off-label' uses" (quoting Ortho Pharm. Corp. v. Cosprohar, Inc. 32 F.3d 690, 692 (2nd Cir. 1994)).

<sup>&</sup>lt;sup>90</sup> See Beck & Azari, supra note 18, at 79 (observing that off-label use is both a common and integral practice of the medical community).

<sup>&</sup>lt;sup>91</sup> See id. (noting that "the pace of medical discovery invariably runs far ahead of FDA regulatory machinery, and off-label use is frequently state-of-the-art treatment.").

<sup>&</sup>lt;sup>92</sup> See id. (acknowledging that new uses for drugs and devices are often discovered after companies put them on the market, and restrictions on physicians in this regard creates

<sup>93</sup> Id. at 80.

<sup>&</sup>lt;sup>94</sup> Id. (quoting Lars A. Noah, Constraints on Off-Label Uses, 16(2) J. PROD. & TOXICS LIAB. 139,

<sup>&</sup>lt;sup>97</sup> Id. at 77 (acknowledging that the FDA recognizes both the value of and propriety of off-

<sup>98</sup> Id. (citing 12 FDA DRUG BULLETIN 4-5 (1982)(cited in 59 Fed. Reg. 59,820, 59,821 (Nov. 18,

treatments not included in approved labeling.99 The FDA reasoned that such use of devices is often necessary for the advancement of medical science and treatment techniques.<sup>100</sup>

More specifically, the FDA addressed the off-label use of bone screws in 1993.<sup>101</sup> The FDA stated that "in practice, surgeons often use orthopedic screws which [the] FDA has cleared for other purposes . . . as pedicle screws. Such use of medical devices for nonapproved purposes has traditionally been regulated by the hospitals in which the physicians practice and not by the FDA."<sup>102</sup> Such a specific statement suggests that the FDA rejected the prospect of regulating the off-label use of orthopedic screws.

In addition, Congress indirectly approved off-label use.<sup>103</sup> Beck notes that had Congress not allowed for off-label use, it would have:

created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting new drugs to new uses. Thus Congress exempted the practice of medicine from the [FDCA] so as not to limit a physician's ability to treat his patients.<sup>104</sup>

Congress codified this policy in the MDA where it stated that nothing in the legislation should be construed to interfere with a physician's authority to use FDA approved medical devices for any purpose that the physician deems necessary.<sup>105</sup>

### II. SETTING THE STAGE FOR BUCKMAN - IN RE: ORTHOPEDIC **BONE SCREW PRODUCTS**

As noted previously, by 1994 some 2300 civil causes of action had been filed against AcroMed, Buckman, and various other manufacturers of the spinal fixation/orthopedic bone screw devices used in spinal fusion surgeries.<sup>106</sup> That same year, the Judicial Panel on Multidistrict Litigation decided to designate the United States Federal Court for the Eastern District of Pennsylvania as the designated court for In re: Orthopedic Bone Screws Products Liability Litiga-

<sup>101</sup> Id. (quoting Food and Drug Admin., Update on Pedicle Screws (1993)). 102 Id.

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tion.<sup>107</sup> In 1995, with over 2300 claims transferred, the district court granted a motion by AcroMed to dismiss the plaintiffs' fraud-onthe-FDA claims.<sup>108</sup> The district court reasoned that: (1) the MDA pre-empted those claims and (2) such claims impermissibly implied a private right of action for violation of the FDCA.<sup>109</sup> In granting this motion, the district court relied on the Third Circuit's decision in Michael v. Shiley, Inc.110 In that case, plaintiff Nina Michael brought similar state law causes of action against Shiley Inc. for injuries she received from a defective heart valve implant.111 The Third Circuit held that § 360k pre-empted Michael's fraud-on-the-

In June of 1996, the Bone Screw plaintiffs amended their claims and reasserted their fraud-on-the-FDA complaints basing them on the 1996 United States Supreme Court decision in Medtronic, Inc. v. Lohr.<sup>113</sup> In Lohr, the plaintiff brought suit for a defective lead in a pacemaker that failed and required emergency surgery.<sup>114</sup> Medtronic, like Shiley, contended that Lohr's state law tort claims were pre-epmted by § 360k(a).<sup>115</sup> The Court in Lohr rejected Medtronic's claims and held that § 360k(a) did not pre-empt Lohr's claims because Congress did not intend for that statute to pre-empt such

AcroMed and Buckman filed their own motions to reaffirm the District Court's dismissal prior to Lohr.<sup>117</sup> The district court, while conceding that "Lohr likely invalidated one of the two grounds for

## 107 See id. at 817, 820.

<sup>109</sup> Id.

<sup>111</sup> See Michael v. Shiley, Inc., 46 F.3d 1316, 1319-21 (3d Cir. 1995) (explaining that defects of the Shiley heart valve produced a potentially fatal condition necessitating the replacement of

Michael's heart valve, and also caused the deaths of several other implantees). <sup>112</sup> Id. at 1319; see also 21 U.S.C. § 360k (1999) (stating that no state may make additional requirements for medical devices which are different from, or in addition to, any requirement imposed by the FDA, or any requirement that relates to the safety or effectiveness of

<sup>113</sup> Orthopedic Bone Screw Prods., 159 F.3d at 821.

<sup>114</sup> Medtronic Inc. v. Lohr, 518 U.S. 470, 480-81 (1996). <sup>115</sup> Id. at 481.

<sup>116</sup> Id. at 499 (holding that in general § 360k(a) does not pre-empt state or local requirements which prohibit the manufacture of devices that are misbranded or adulterated unless the effect of such a prohibition would be to establish "a substantive requirement for a specific

<sup>99</sup> Id.

<sup>&</sup>lt;sup>100</sup> See Beck & Azari, supra note 18, at 77 (noting the similarity to the rationale of the medical community for off-label use).

<sup>&</sup>lt;sup>103</sup> See Beck & Valentine, supra note 17, at 398. 104 Id

<sup>105</sup> See 21 U.S.C. § 396 (1999).

<sup>&</sup>lt;sup>106</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 820.

<sup>&</sup>lt;sup>108</sup> Id. at 821.

<sup>&</sup>lt;sup>110</sup> Id. (citing Michael v. Shiley Inc., 46 F.3d 1316 (3d Cir. 1995)).

<sup>&</sup>lt;sup>117</sup> Orthopedic Bone Screw Prods., 159 F.3d at 821.

its prior decision," granted AcroMed's motion for dismissal.<sup>118</sup> The Court reasoned that Lohr did not address claims of fraud-on-the-FDA with respect to the absence of a private right of action for violations of the FDCA.<sup>119</sup>

Plaintiffs subsequently appealed this decision to the Third Circuit.<sup>120</sup> Relying on the Supreme Court's decision in Lohr, the court held that the plaintiffs' claims were not pre-empted by the MDA.<sup>121</sup> In arriving at this conclusion, the Third Circuit explained the fraudon-the-FDA theory of liability:122

(1)[i]n response to the FDA's inquiry concerning the intended use of the bone plates and bone screws, . . . Buckman, acting as representative of AcroMed . . . intentionally and falsely represented to the FDA that .... [they were] 'intended for use in appropriate fractures of long bones of both the upper and lower extremity and other flat bones; (2) Buckman intended for the FDA to clear the VSP device components based on this misrepresentation;" (3) [i]n reliance on this express misrepresentation, the FDA determined . . . that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed . . . prior to May 28, 1976 for the intended use represented by AcroMed and issued a § 510(k) clearance; (4) the VSP device was intended exclusively for use in the spine; (5) the only purpose for which AcroMed's plates and screws were sold was for use in the spine; (6) [t]he FDA was ignorant of the fact that these devices and device components were intended by AcroMed to be used as pedicle fixation devices; (7) [w]ere it not for these fraudulent acts and statements, the FDA would not have issued § 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in Plaintiff's spine; and (8) [a]s a direct and proximate result of the wrongful conduct alleged in Count I of this Complaint, Plaintiff has suffered, and will continue to suffer, severe physical harm, including injury to Plaintiff's spine.<sup>123</sup>

Having identified the claim in contention, the Third Circuit then addressed the "the issue of whether federal law forecloses re-

120 See id.

122 Id. at 821-822.

123 Id. (internal footnotes omitted).

sort to state law . . . . " and examined § 360k of the MDA.<sup>124</sup> The court began by examining FDA regulations interpreting the scope of § 360k's preemption clause.<sup>125</sup> For example, the text of 21 CFR § 808.1 (d) explains that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations . . . 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

Of greater interest to the Third Circuit were §§ 808.1(d)(1) and (2), which provide that § 360k does not pre-empt state or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices, or to unfair trade practices in which the requirements are not limited to devices, and does not pre-empt state or local requirements that are equal to, or substantially identical to, requirements imposed under the act.<sup>127</sup> The Third Circuit noted that those were the same provisions cited by the U.S. Supreme Court in its decision to give § 360k a narrow reading in Lohr. 128

The interpretation of the scope of § 360k's pre-emptive effect given by the Supreme Court in Lohr is narrow indeed.<sup>129</sup> In Lohr, the Court outlined four specific requirements before preemption under § 360k can occur.<sup>130</sup> First, the Court instructs that state requirements must be specific to medical devices and should either differ from or supplement federal requirements.<sup>131</sup> Second, the Court explains that state requirements must relate to the safety or effectiveness of devices.<sup>132</sup> Third, generally applicable state requirements will prevail over Federal requirements unless they effectively establish substantive requirements for specific devices.<sup>133</sup> Finally, the pre-empting

<sup>118</sup> Id.

<sup>&</sup>lt;sup>119</sup> Id. (explaining the District Court's opinion that allowing such a claim would create a private right of action for violation of the FDCA and "would be contrary to the letter and spirit of the statute.").

<sup>&</sup>lt;sup>121</sup> See Orthopedic Bone Screw Prods., 159 F. 3d at 829 (holding that if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be pre-empted by the MDA).

<sup>&</sup>lt;sup>124</sup> Orthopedic Bone Screw Prods., 159 F.3d at 822.

<sup>&</sup>lt;sup>125</sup> Id. at 822-23 (citing 21 CFR § 808.1(d) (2002)).

<sup>126 21</sup> CFR § 808.1(d) (2002).

<sup>&</sup>lt;sup>127</sup> 21 CFR §§ 808.1(d)(1), (2) (2002).

<sup>&</sup>lt;sup>128</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 823.

<sup>&</sup>lt;sup>129</sup> See Lohr, 518 U.S. at 500 (noting that although this regulatory language does not preclude federal requirements from pre-empting state requirements, § 360k will have the affect of pre-empting a state requirement only where such a requirement "threatens to interfere 130 Id.

<sup>&</sup>lt;sup>131</sup> Id.

<sup>&</sup>lt;sup>132</sup> Id.

<sup>&</sup>lt;sup>133</sup> Id.

federal requirement must also apply to the device in question, and it will pre-empt state regulations only where "they are 'specific counterpart regulations' or 'specific' to a 'particular device.'"<sup>134</sup> According to the Court, this analysis therefore requires a detailed comparison between the supposedly pre-empting federal requirement and the pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.135

Having established this analytical framework, the Court concluded that federal labeling and manufacturing regulations did not pre-empt the common law tort claims advanced by it.136 The Court reasoned that although the federal regulations reflected important concerns, such concerns were generic rather than specific to any particular device.<sup>137</sup> Based on this analysis, the Court concluded that § 360k was not intended to pre-empt this type of state regulation.138

Following the holding in Lohr, the Third Circuit concluded that § 360k likewise did not pre-empt the claims of plaintiffs against Buckman and AcroMed.<sup>139</sup> The court stated that § 360k imposes no federal requirement applicable to the device at issue here; nor does a state requirement apply.<sup>140</sup> Further, state common law that the plaintiffs relied upon was not inconsistent with federal law.141 In support of this argument, the court pointed to 18 U.S.C. § 1001 and 21 C.F.R. § 807.87(k).142 Under 18 U.S.C. § 1001, fraudulent misrepresentations made to federal agencies are criminal offenses punishable by fines and imprisonment.143 Within 21 C.F.R. § 807.87(k), the

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statute requires that every premarket notification application must contain a statement to the effect that all information contained in the application is believed by the submitter to be truthful.<sup>144</sup> In reference to these statutes, the court demonstrated that no conflict existed between the state common law claims and federal regulations.<sup>145</sup> At the same time, the court seemed to imply that state common law claims served to augment the aims of the federal regulations.<sup>146</sup>

Having found no pre-emption, the Third Circuit Court then considered the district court's second ground for dismissing the plaintiffs' case: Lohr had no effect on the fact that Congress failed to create express or implied private rights of action under the FDCA or MDA.<sup>147</sup> The district court pointed to the Third Circuit's holding in Michael v. Shiley, to support the dismissal of the plaintiffs' bone screw claims.<sup>148</sup> Disagreeing with the district court, the Third Circuit explained that its decision in Michael was based on the preemption doctrine, and that absent a pre-empting federal law, a district court with the requisite jurisdiction must not refuse to impose liability established by state common law.<sup>149</sup> The court then restated that "the ultimate touchstone in every pre-emption case" is congressional intent.<sup>150</sup> In Lohr, the Supreme Court reiterated its position stated in Gade that the intent of Congress can be discerned from the pre-emption statute language and the "statutory framework" sur-

In Michael, the Third Circuit acknowledged the fact that neither the FDCA nor the MDA created private rights of action for violation thereof and inferred that Congress intended to eliminate the possi-

<sup>145</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 823. <sup>146</sup> See id.

<sup>147</sup> Id. at 824.

<sup>148</sup> Id. (citing Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3d Cir. 1995) (indicating that the Third Circuit relied on the absence of such a cause of action as a significant factor in holding that the FDCA pre-empted common law fraud claims)).

<sup>149</sup> Id.

<sup>134</sup> Lohr, 518 U.S. at 500.

<sup>135</sup> Id.

<sup>136</sup> Id. at 501.

<sup>&</sup>lt;sup>137</sup> Id. (stating that the federal regulations did not reflect concerns "regarding a specific device or field of device regulation . . .").

<sup>&</sup>lt;sup>138</sup> Id. (explaining that the concerns raised by the federal requirements were "not the sort of concerns . . . that the statute or regulations were designed to protect from potentially contradictory state requirements.").

<sup>&</sup>lt;sup>139</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 823.

<sup>140</sup> Id.

<sup>&</sup>lt;sup>141</sup> Id.

<sup>142</sup> Id.

<sup>143 18</sup> U.S.C. § 1001 (1994) (stating: "(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly or willfully-(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious,

or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement

<sup>144 21</sup> C.F.R. § 807.87(k) (2002).

<sup>&</sup>lt;sup>150</sup> Orthopedic Bone Screw Prods., 159 F.3d at 824 (citing Medtronic v. Lohr, 518 U.S. 470, 485

<sup>&</sup>lt;sup>151</sup> Lohr, 518 U.S. at 486 (quoting Gade v. Nat'l Solid Waste Mgmt. Assn., 505 U.S. 88, 111

or entry; shall be fined under this title or imprisoned not more than five years, or both.").

bility of suits based on state common law grounds.<sup>152</sup> However, Lohr specifically rejected this notion.<sup>153</sup> By dismissing the plaintiffs' bone screw claims, the district court seemed to accept the same construction of § 360k that the Supreme Court rejected in Lohr.<sup>154</sup>

Under that reasoning, Medtronic argued that Congress' intent was to preclude all state law causes of action by consumers for injuries caused by medical devices.<sup>155</sup> Such a construction of § 360k grants immunity to all medical device manufacturers for any injury resulting to patients.<sup>156</sup> The Supreme Court stated that such a result was contrary to congressional intent.<sup>157</sup> "It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result."158

Further, the Court reasoned that the language of § 360k was inappropriate to effectuate such a result.<sup>159</sup> Based upon its reading of the statute, the Court concluded that Congress "was primarily concerned with the problem of specific, conflicting state statutes and regulations, rather than the general duties enforced by common . . .[ ] law actions."<sup>160</sup> Indeed, the Court went so far as to say that the use of the word "requirements" in § 360k of the MDA referred "only to statutory and regulatory law that exists pursuant to the MDA itself, suggesting that the pre-empted 'requirements' established or continued by States also refer primarily to positive enactments of state law."<sup>161</sup>

156 Id.

<sup>158</sup> Id. (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984)).

160 Id. at 489.

<sup>161</sup> Id.

The Court also addressed Congress' intent in enacting § 360k.<sup>162</sup> The Court noted that the enactment of the MDA provided consumers with safe and effective medical devices.<sup>163</sup> Indeed, the legislature drafted the 1976 MDA with this underlying assumption.<sup>164</sup> The Court noted that the concerns Congress addressed with the enactment of § 360k focused more on the possibility of additional federal and state regulation rather than the danger of preexisting duties under the common law.<sup>165</sup> The Court further asserted that in the legislative history of § 360k, nothing indicated that Congress intended this statute to pre-empt all state common law

Based on these findings by the Supreme Court, the Third Circuit overruled the dismissal of the Bone Screw plaintiffs' claims.<sup>167</sup> The court further concluded that the dismissal of plaintiffs' claims of fraudulent misrepresentation against Buckman based only on the fact that the FDCA provides for no private causes of action "would be the equivalent of finding pre-emption of state law claims contrary to the clear holding of Lohr."168 Thus, the Third Circuit remanded the case for trial.<sup>169</sup>

## III. BUCKMAN

As a result of the Third Circuit's ruling, AcroMed promptly settled, and Buckman appealed the Third Circuit's decision to the Supreme Court.<sup>170</sup> Prompted by the circuit split, the Supreme Court

<sup>164</sup> See John J. Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications under the Federal Food, Drug, and Cosmetic Act, 55 FOOD & DRUG L.J. 245, 245-46 (2000) (chronicling the explosion of medical technology during the 1960s which led to the expansion of the FDCA to allow for new medical devices to reach the market as quickly as possible, with the least possible risk to patients).

<sup>165</sup> Lohr, 518 U.S. at 490.

<sup>166</sup> Id. at 491. "There is . . . nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common . . . []law remedies against manufacturers and distributors of defec-

<sup>152</sup> Orthopedic Bone Screw Products, 159 F.3d at 824 (citing Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3d Cir. 1995)).

<sup>&</sup>lt;sup>153</sup> Id. at 825. "Ironically, a plurality of the Supreme Court in Lohr drew a diametrically opposed inference from the same fact." Id.

<sup>&</sup>lt;sup>154</sup> See Lohr, 518 U.S. at 487 (concluding that Medtronic's argument is neither believable nor persuasive).

<sup>&</sup>lt;sup>155</sup> Id. (explaining that such a construction of the statute would bar many, if not all, avenues of compensation for those injured by defective medical devices).

<sup>&</sup>lt;sup>157</sup> Id. (indicating that Congress intended more, not less, stringent regulation of medical devices in order to protect consumers).

<sup>&</sup>lt;sup>159</sup> See Lohr, 518 U.S. at 487-88 (reading the word "requirement" to mean a state-imposed specific duty placed on the manufacturer, rather than a common law cause of action, and stating that the word "remedy" in place of "requirement" foreclose such claims).

<sup>&</sup>lt;sup>162</sup> Id. at 490. (opining that the congressional intent behind § 360k supports the Court's rejec-

<sup>&</sup>lt;sup>167</sup> See Orthopedic Bone Screw Prods., 159 F.3d at 825.

<sup>&</sup>lt;sup>169</sup> Id. at 829.

<sup>&</sup>lt;sup>170</sup> Daniel W. Sigelman, Is Fraud-on-the-FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?, 2 ATLA-CLE 2483 (2001); Buckman, 531 U.S. at 352-53.

granted certiorari to determine whether or not the MDA preempted the plaintiffs' fraud-on-the-FDA claims.<sup>171</sup> In a unanimous decision, the Supreme Court reversed the Third Circuit's holding and concluded that the MDA did pre-empt plaintiffs' fraud-on-the-FDA claims.172

Beginning its pre-emption analysis, the Court noted that the states' traditional abstention from policing fraud against federal agencies did not warrant federal pre-emption of a state law cause of action.<sup>173</sup> The Court found no such presumption in this case relying on the fact that federal statutes empower the FDA itself to police such fraud.<sup>174</sup> Furthermore, this power of the FDA conflicts with such fraud-on-the-FDA claims.175

The Court noted the effect that such claims would have on offlabel use of medical devices.<sup>176</sup> Reiterating that off-label usage is an accepted practice protected by the practice of medicine doctrine, the Court recognized the FDA's unenviable position.<sup>177</sup> The FDA regulates the marketing and distribution of medical devices without intruding upon the statutorily protected discretion of health care professionals.<sup>178</sup>

The Court also expressed concern that allowing such claims would defeat the purpose of the § 510(k) process.<sup>179</sup> The Court argued that the "unpredictable civil liability" that allowing such claims would impose would discourage many potential § 510(k) applicants from filing applications for approval.<sup>180</sup> This would effec-

175 Buckman, 531 U.S. at 352-53.

176 See id. at 352-53.

177 Id. (citing 21 U.S.C. § 396) (1994).

179 Id.

180 Buckman, 531 U.S. at 352-53

tively exclude many potentially helpful devices (as well as their possible off-label uses) from the market.<sup>181</sup> The Court further asserted that such a state of affairs would deter off-label use of medical devices, which would be contrary to the policy of the FDCA, the MDA and the medical community in general.<sup>182</sup>

The Court argued further that allowing fraud-on-the-FDA claims would create apprehension among applicants that their disclosures to the FDA may be adjudged insufficient by state courts even when the FDA deemed them appropriate.<sup>183</sup> The Court argued that in response to these apprehensions, applicants would submit a vast amount of un-required information further complicating and delaying the § 510(k) process, which would ultimately frustrate the timeliness of the approval process.184

The Court then addressed the contention of the Bone Screw plaintiffs that the Silkwood opinion created a "virtually irrefutable presumption against implied pre-emption of private damage remedies predicated on an alleged conflict with a federal remedial scheme."185 In Silkwood, the Court concluded that federal law did not pre-empt an award of punitive damages for injuries to a plaintiff caused by exposure to plutonium at a Kerr-McGee nuclear facility.<sup>186</sup> The Court distinguished this case from Silkwood on several

First, Silkwood's claim was based on Kerr-McGee Corporation's violation of the duty of care owed to its employees, a principle of traditional state tort law.<sup>188</sup> The plaintiffs' claims in this case, however, were based on fraud on a federal agency with exclusive authority to police such fraud.<sup>189</sup> Second, the Silkwood decision "turned on specific statutory evidence that Congress 'disclaimed any interest in promoting . . . atomic energy by means that fail to

<sup>181</sup> Id.

<sup>182</sup> Id. (predicting that fraud on the FDA claims would have the effect of deterring off-label use, despite the federal codification of the practice of medicine doctrine). <sup>183</sup> Id. at 351.

<sup>184</sup> Id. (noting that the flood of information would result in further burdening the FDA, and would therefore slow down the approval process and would hinder physicians' discretion

<sup>185</sup> Buckman, 351 U.S. at 352 (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)).

<sup>186</sup> See Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 258 (1984).

<sup>187</sup> Buckman, 531 U.S. at 352-53 (relating that "Silkwoood is different from the present case, <sup>188</sup> Id.

<sup>189</sup> Id.

<sup>171</sup> See Buckman, 531 U.S. at 352-53 (citing Kemp v. Medtronic Inc., 231 F. 3d 216, 233-236 (6th Cir. 2000) (identifying the split in the circuits and holding that such claims are pre-empted expressly by § 360k)).

<sup>172</sup> Id.

<sup>173</sup> Id. at 1017.

<sup>174</sup> Id. (emphasizing that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives."); see also 21 U.S.C. § 372 (1994) (allowing FDA investigation of suspected fraud); 18 U.S.C. § 1001 (1994) (criminalizing the making of false statements to a federal agency); 21 U.S. § 333 (2000) (giving the FDA authority to impose civil penalties and to seek criminal prosecution for fraud); 21 U.S.C. § 332 (2000) (authorizing the FDA to seek injunctive relief for fraud); 21 U.S.C. § 334 (2000) (approving FDA seizure of devices as a valid response to fraud).

<sup>178</sup> Id.

provide adequate remedies for those who are injured by exposure to hazardous nuclear materials."190 That statutory scheme differed from the MDA, which provides for exclusive enforcement by the federal government.191

Having dispensed with Silkwood, the Court then addressed Lohr, disposing of it with much less analysis than that accorded to it by the Third Circuit.<sup>192</sup> The Bone Screw plaintiffs attempted to analogize their claims to those advanced in Lohr as "claims arising from violations of FDCA requirements."193 The Court rejected this analogy by noting that Lohr addressed express, rather than implied, preemption.<sup>194</sup> Moreover, the claims in Lohr arose from an alleged failure to use reasonable care during production rather than from FDCA violations.<sup>195</sup> Based on this analysis, the Court asserted that while Lohr does allow some state law tort claims that parallel federal safety requirements, it does not follow that all violations of the FDCA will support a state law claim.<sup>196</sup>

The Court concluded that fraud-on-the FDA claims are not traditional state tort claims because federal enactments comprise critical elements of the case.<sup>197</sup> In choosing to hold that the fraudon-the-FDA claims here asserted were pre-empted, the Court narrowed the scope of Lohr and widened the scope of the MDA's preemption provisions.<sup>198</sup>

### IV. ANALYSIS

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By holding that fraud-on-the-FDA claims are pre-empted by the MDA, the Court in Buckman insulated medical device manufacturers from civil liability for fraudulent misrepresentations made to the FDA, while simultaneously precluding individuals injured by

192 Compare Buckman, 531 U.S. at 352-53, with Orthopedic Bone Screw Prods., 159 F.3d at 819-20.

<sup>195</sup> Id.

197 Id.

198 See id

the effects of such fraud from any avenue of compensation.<sup>199</sup> In many instances, this may mean that manufacturers who follow the example set by AcroMed and Buckman will not face any penalties. Indeed, although the FDA has the authority to police fraud, seldom does it use that authority.<sup>200</sup> Even if the FDA did regularly exercise this authority, such action provides little comfort to a patient injured by a device that found its way to the market because of fraudulent misrepresentations made by a manufacturer to the FDA.<sup>201</sup>

## A. The FDA's Enforcement Record

In Buckman, the Court argued that fraud-on-the FDA claims were implicitly pre-empted by federal regulations because such regulations give the FDA exclusive authority to enforce violations of the FDCA and MDA.<sup>202</sup> In so concluding, the Court places responsibility for protecting patients against fraud solely on an agency with a questionable track record for enforcement.<sup>203</sup> Contemporary legal scholars recognize that when companies violate FDA regulatory standards "the FDA has neither the resources nor the will to enforce the FDCA in every circumstance. . . [and that] [t]he agency issues hundreds of warning letters each year alleging violations of the act

Specifically, "the agency seems determined to ignore allegations of company misconduct."205 Even when the FDA acknowledges claims of fraud and conducts investigations internally, they focus primarily on prevention of future incidents.206 The FDA's handling of complaints relating to the Bone Screw litigation supports

<sup>190</sup> Id. (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 257 (1984)).

<sup>&</sup>lt;sup>191</sup> Id. (citing 21 U.S.C. § 337(a)).

<sup>193</sup> Buckman, 531 U.S. at 352 (citing Brief for Respondents at 38, 2000 WL 1591271 (No. 98-1768)).

<sup>194</sup> Buckman, 531 U.S. at 352.

<sup>196</sup> Id. at 353.

<sup>&</sup>lt;sup>199</sup> See Buckman, 531 U.S. at 355 (Stevens, J., concurring) (stating that "Under the pre-emption analysis the Court offers today, ... parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process.").

<sup>&</sup>lt;sup>200</sup> See Lohr, 518 U.S. at 487 n.7 (explaining that the FDA rarely, if ever, invokes its authority to

<sup>&</sup>lt;sup>201</sup> See id. (explaining that "[t]he FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs. . . . ").

<sup>&</sup>lt;sup>202</sup> Buckman, 531 U.S. at 348 (holding that state-law fraud-on the-FDA claims conflict with the FDA's authority to police fraud, and are thus impliedly pre-empted by federal law).

<sup>&</sup>lt;sup>203</sup> See Edward J. Parr Jr., How to Buck Preemption In Drug Cases, 37-Nov Trial 35, 35 (2001) <sup>204</sup> Id. at 40.

<sup>&</sup>lt;sup>205</sup> Parr, *supra* note 203, at 36. <sup>206</sup> Id

this conclusion.<sup>207</sup> In response to those complaints, the FDA decided that the claims of misconduct by the company, agency, employees and advisory committee member were irrelevant to their decision to reclassify pedicle screw devices.<sup>208</sup>

Moreover, device manufacturers exploit opportunities to commit fraud-on-the-FDA after the pre-market approval process.<sup>209</sup> The post-marketing period is ripe with opportunities for fraud as well, and the FDA's track record for enforcement during this period is suspect.<sup>210</sup> The FDA's lack of resources may be to blame for its failure to adequately enforce these regulations.<sup>211</sup> With their limited resources, the FDA simply cannot identify every manufacturer who engages in misconduct such as misleading advertising or encouraging off-label uses.<sup>212</sup> Evidence suggests that drug industry advertising has been inaccurate and nothing indicates more stringent monitoring for medical device advertising either.<sup>213</sup> Additionally, the FDA does not require pre-advertising clearance; rather, it relies on voluntary pre-advertising submissions by manufacturers.<sup>214</sup> This, taken together with the fact that the FDA simply lacks the resources needed to monitor all of the advertising in the various media, limits the FDA's ability to prevent misleading information provided voluntarily by manufacturers from reaching the public.<sup>215</sup> Consequently, the actions of a manufacturer who intends to engage in misleading advertising, and in fact does so, will go undetected by the FDA. This state of affairs results in greater risks for patients.<sup>216</sup> Thus, the Court's holding in Buckman, which eliminates a private citizen's ability to sue for damages resulting from fraud committed on the FDA, treads one step further in reducing punishment and

<sup>210</sup> See id. (acknowledging that the FDA's ability to control the post-marketing is questionable).

<sup>211</sup> See id.

212 Id. at 2142-43.

<sup>213</sup> Id. at 2144.

<sup>214</sup> See Green, supra note 209, at 2144.

<sup>215</sup> See id.

<sup>216</sup> Id. at 2142.

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deterrence of manufacturers who engage in making fraudulent misrepresentations to the FDA.217

B. Pre-emption Analysis: The Case for No Federal Pre-emption The Court's holding in Buckman that the FDCA and MDA preempt state-law tort claims contradicts its holding in Lohr and the Third Circuit's holding in Orthopedic Bone Screw Products.<sup>218</sup>

## 1. Meaning of "Requirements"

In Lohr, the Court addressed the meaning of the word "requirements" as used in § 360k of the MDA.<sup>219</sup> The Court concluded that "requirements," as used in § 360k, applied to positive enactments of state law rather than common law tort claims.<sup>220</sup> Indeed, the Court expressly stated that "when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations, rather than the general duties enforced by common. . .[] law actions."221 The Court further cited legislative history to support their conclusion that Congress did not intend for § 360(k) to pre-empt most common law duties enforced by actions for

To arrive at this conclusion, the Court relied on its holding in Cipollone v. Liggett Group, Inc..<sup>223</sup> In Cippolone, the Court addressed a similar question with respect to the Public Health Cigarette Smoking Act of 1969 and fraudulent misrepresentation claims brought by plaintiffs.<sup>224</sup> There, the Court determined that the plaintiffs' claims were not pre-empted because of their basis on the common law

<sup>222</sup> Id. at 491.

<sup>&</sup>lt;sup>207</sup> See id.

<sup>&</sup>lt;sup>208</sup> Id.

<sup>&</sup>lt;sup>209</sup> See Michael D. Green & William B. Schultz, Tort Law Deference to FDA Regulation of Medical Devices, 88 GEO. L.J. 2119, 2142 (2000) (noting that the post-marketing period, including advertising, off-label uses, and labeling revisions to reflect newly-emergent risks, is important for risk management involving drugs).

<sup>&</sup>lt;sup>217</sup> See Mary A. Zendran, Medical Devices: Food, Drug, and Cosmetics Act Preempts State Law Fraud Claims — Buckman Co. v. Plaintiffs' Legal Comm., 27 Am. J.L. & MED. 351, 352 (2001) (indicating that Buckman precludes patients' lawsuits "under state tort law for

<sup>&</sup>lt;sup>218</sup> Compare Buckman, 531 U.S. at 353 (holding that state law fraud-on-the-FDA claims are preempted by federal statutes), with Lohr, 518 U.S. at 501 (concluding that "common-law claims are not pre-empted by federal labeling and manufacturing requirements."), and Orthopedic Bone Screw Prods., 159 F.3d at 829 (stating that "the plaintiffs" 'fraud-on-the-FDA' theory is not so at odds with traditional principles of tort law that Buckman is entitled to a

<sup>&</sup>lt;sup>219</sup> See Lohr, 518 U.S. at 486-89.

<sup>&</sup>lt;sup>220</sup> Id. at 489.

<sup>&</sup>lt;sup>221</sup> Id.

<sup>&</sup>lt;sup>223</sup> See id. at 500 n.19. (citing Cipillone v. Liggett Group, Inc., 505 U.S. 504, 528-29 (1992)). <sup>224</sup> See Cipollone v. Leggitt Group, Inc., 505 U.S. 504, 515 (1992).

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duty to not make fraudulent statements, as well as the absence of that duty in the state laws specifically pre-empted by the federal statutes.<sup>225</sup> The Court concluded that "the language of the MDA's pre-emption statute and its counterpart regulations require an even more searching inquiry into the relationship between the federal requirement and the state requirement at issue than was true under the statute in Cipollone."226 The Court then concluded that the comparison mandated by this framework of analysis required the conclusion that the common law claims advanced by Medtronic were not pre-empted by § 360k.227

However, the Buckman opinion distinguished Lohr, stating that the claims advanced by Medtronic "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements."228 Thus, the Court made a distinction between claims based on traditional state tort law predating the federal enactments, which seem not to be pre-empted, and those claims based solely on the FDCA disclosure requirements which are pre-empted.<sup>229</sup>

In analyzing this distinction, the Court only offers presumptions to support its conclusion that "this sort of litigation would exert an extraneous pull on the scheme established by Congress, and is therefore pre-empted by that scheme."230 Note that fraud-on-the-FDA claims have all the elements of traditional common law causes of action based on fraudulent misrepresentations.<sup>231</sup> Arguably, fraud-on-the-FDA claims, such as those based on the misrepresentations made by Buckman and AcroMed to the FDA, fall into the category of claims not pre-empted under the Court's interpretation of Lohr.<sup>232</sup> Consequently, the presumed greater effect of fraud-on-the-FDA claims on the federal scheme over that of traditional state law tort claims remains ambiguous. Moreover, in similar contexts,

<sup>230</sup> Id. at 351, 353 (arguing that applicants will submit a deluge of information if fraud-on-the-FDA claims were permitted).

<sup>231</sup> See Orthopedic Bone Screw Prods. 159 F. 3d at 821-22.

232 See Id.

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courts have allowed claims based on misrepresentations made to other federal agencies.233

## 2. Congressional Intent

The overriding intent of Congress in passing the MDA to the FDCA sought to protect patients.<sup>234</sup> The Court in Lohr made two relevant observations about the intent of Congress in passing the MDA.235 First, "[t]he MDA was enacted 'to provide for the safety and effectiveness of medical devices intended for human use."236

Indeed, nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices. To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision; furthermore, any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices.237

Thus, the Court previously concluded that this type of litigation was not what Congress intended to pre-empt by its enactment of the MDA.238 Buckman certainly does not advance the intent of Congress to provide safety and protection to patients who use medical devices.<sup>239</sup> Justice Stevens provides a clear summary in his con-

Under the pre[-]emption analysis the Court offers today, however, parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process. I do not believe . . . that Congress intended

<sup>233</sup> Id. at 826 (citing Learjet Corp v. Spenlinhauer, 190 F.2d 198, 202-03 (1st Cir. 1990) (allowing claims based on fraudulent misrepresentations to the Federal Aviation Administration) and Stanton by Brooks v. Astra Pharmaceutical Products, 718 F.2d 553, 568-69 (3d Cir. 1983) (allowing claims against a drug manufacturer based on misrepresentations to the FDA)). <sup>234</sup> See Lohr 518 U.S. at 490-91.

<sup>235</sup> Id.

<sup>236</sup> Id. at 490.

237 Id. at 490-91

238 See id. at 490.

<sup>239</sup> See Green, supra note 206, at 2142 (stating "the FDA's failure to act because of a lack of resources or to negotiate informally with a manufacturer to avoid the need to take a recalcitrant manufacturer to court results in greater, not lesser, risks being imposed on

240 Buckman, 531 U.S. at 355 (Stevens, J., concurring).

<sup>&</sup>lt;sup>225</sup> Id. at 528-29.

<sup>&</sup>lt;sup>226</sup> Lohr, 518 U.S. at 500 n.19.

<sup>&</sup>lt;sup>227</sup> Id. at 501.

<sup>&</sup>lt;sup>228</sup> Buckman, 531 U.S. at 352.

<sup>&</sup>lt;sup>229</sup> Id. at 353.

### C. Implications

Initially, Buckman seems to deny any compensation to consumers injured by device manufacturers that make fraudulent misrepresentations to the FDA.<sup>241</sup> However, the effects of this decision reach much further. With respect to medical device manufacturers, this decision provides less deterrence from making fraudulent misrepresentations to the FDA than before Buckman because now no question of civil liability arising from resulting injuries remains.<sup>242</sup>

In another context, defendants may cite this case to bar tort claims arising from fraudulent misrepresentations to other federal agencies.<sup>243</sup> "A broad reading of the case suggests that it might 'stop suits against the oil industry for defrauding the Environmental Protection Agency; against the recreational boating industry for defrauding the U.S. Coast Gaurd regarding boat safety; against the automobile industry challenging submissions to the National Highway Traffic Safety Administration, and so on."244

Further, the Court's ruling has already shown that it is subject to ambiguous interpretations by lower courts.<sup>245</sup> In Globetti v. Sandoz Pharmaceutical Corp., for example, defense attorneys attempted to use the Buckman holding to dismiss not only the fraud-on-the-FDA claims asserted by Globetti, but all of the other claims advanced by Globetti as well.246 The defense asserted that Buckman precludes the claims because the claims included communications between the defendant and the FDA.<sup>247</sup>

While the court hearing this case conceded that Buckman barred the fraud-on-the-FDA claim, it reasoned that the other claims were not pre-empted, and it allowed those other claims to proceed.<sup>248</sup> The Court reasoned that while the plaintiff's claims were based in part on a violation of the FDCA requirements by Sandoz, they were not solely based on those violations.<sup>249</sup> The court argued:

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Defendant owed separate duties beyond simply full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts needed by physicians and consumers to assess the safety of the product, and to adequately warn of known risks associated with it. These duties existed irrespective of the FDCA. Thus, while plaintiff cannot recover simply because defendant defrauded the federal agency, nothing in Buckman suggests that she cannot recover where the misrepresentations or suppression were directed at her (through her physician) or when the warning given (even though FDA approved) inadequately disclosed the hazards of the product.<sup>250</sup>

This holding could spark controversy over the scope of the Buckman decision. Specifically, a party could argue that such a holding conflicts with Buckman because the Court did not find that Buck-

## V. CONCLUSION

The Buckman holding raises some perplexing questions. Whether this holding applies only to medical devices and the FDA or to other federal agencies as well remains unclear.<sup>252</sup> However, "[r]egardless of how broadly Buckman is interpreted by future courts . . . at least some plaintiffs have lost the right to sue federally regulated industries under state common law."253

In addition to the fact that the Court closed off all avenues of compensation to plaintiffs injured by AcroMed's and Buckman's misrepresentations, it also closed avenues of recovery for future plaintiffs with meritorious claims.<sup>254</sup> The Court must address the scope of Buckman and answer the questions raised by the Northern District of Alabama's holding in *Globetti*.<sup>255</sup> Furthermore, the Court not only provided a blueprint to those who wish to follow the example set by AcroMed and Buckman, but it also essentially eliminated any deterrence to such manufacturers. Now such manufacturers know how to do this, and they know that their only punishment will come from the FDA, if any comes at all.

Finally, Congress should address the question of legislative intent with respect to pre-emption: which is more important, fostering

<sup>252</sup> Lan, *supra* note 242 at 235.

<sup>&</sup>lt;sup>241</sup> See Parr, supra note 203 at 40.

<sup>242</sup> Id.

<sup>&</sup>lt;sup>243</sup> See Iris Lan, Fraud: Tort Claims Against FDA Preempted by Federal Law, 29 J.L. MED. & ETHICS 233, 235 (2001).

<sup>244</sup> Id.

<sup>245</sup> See Globetti v. Sandoz Pharmaceutical Corp., No. CV98-TMP-2649-S, 2001 WL 419160 (N.D. Ala. Mar. 5, 2001)).

<sup>&</sup>lt;sup>246</sup> Id. at 1. <sup>247</sup> Id. <sup>248</sup> Id. at 1-2.

<sup>&</sup>lt;sup>249</sup> Id. at 2.

<sup>&</sup>lt;sup>250</sup> Globetti, 2001 WL 419160 at 2.

<sup>&</sup>lt;sup>251</sup> See Parr, supra note 203, at 40.

<sup>&</sup>lt;sup>253</sup> Id.

<sup>&</sup>lt;sup>254</sup> But see Globetti, 2001 WL 419160 at 2 (holding claims of misrepresentation directed at the

victim through a physician or a warning are not pre-empted). <sup>255</sup> See id. at 1.

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the development of medical science in a liability free environment or the protection of the patients into whose bodies these devices are being implanted? Hopefully, Congress will recognize the injustices and dangers to patients in allowing such an interpretation of preemption. If it does not, the possibility of more people in the position of Dorothy Marie Reeves, innocent, injured, and uncompensated, will loom larger than ever.

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# THE POLICY AND POLITICS OF ILLEGAL IMMIGRANT HEALTH CARE IN TEXAS

Kristalee Guerra

## INTRODUCTION

This comment will focus on the July 2001 Texas Attorney General advisory decision that barred Texas county hospital districts The author advocates that this decision is a technically correct

from providing preventive health services to undocumented immigrants.<sup>1</sup> Although illegal immigrants can still receive medical care for emergency conditions, immunizations, and communicable diseases, the Attorney General's decision precludes unqualified immigrants from receiving other government-provided medical benefits.<sup>2</sup> interpretation of state and federal regulations. Under current law, illegal immigrants are not entitled to preventive health care services provided by the government.3

The current law, however, also gives states the opportunity to circumvent this limitation of benefits.<sup>4</sup> State legislatures can pass affirmative legislation providing state funded (not federally funded) services to illegal immigrants.<sup>5</sup> The Texas Legislature should utilize this capability to fund limited preventive health care services to illegal immigrants in Texas. The issue of providing health care to illegal immigrants is clearly one for the legislature to grapple with not the court system or the Attorney General. The legislature can more appropriately weigh the ethical and economic consequences of an ill immigrant population.

Part II of this comment will focus on the background of the Texas Attorney General's advisory opinion regarding illegal immigrant health care. In particular, this section will discuss Title IV of the Personal Responsibility and Work Opportunity Reconciliation

<sup>&</sup>lt;sup>1</sup> Op. Tex. Att'y Gen. No. JC-0394 (2001). <sup>2</sup> Id. at 2. <sup>3</sup> 8 U.S.C. §1621 (2000). <sup>4</sup>8 U.S.C. §1621(d) (2000). <sup>5</sup> 8 U.S.C. §1621(d).