

Predicate Creep: The Danger of Multiple Predicate  
Devices

Arianne Freeman\*

I. INTRODUCTION

Before a company can begin marketing a new medical device in the United States, the device must first be approved by the Federal Drug Administration (FDA).<sup>1</sup> Device manufacturers must submit a Premarket Approval (PMA) application or a §510(k) premarket notification to gain FDA approval.<sup>2</sup> A PMA application is the most stringent FDA review, requiring manufacturers to use clinical trials and scientific evidence to establish a device's safety and efficacy for its intended use.<sup>3</sup> Conversely, a manufacturer seeking clearance through §510(k) is only required to show that the device is substantially equivalent to a predicate device, a device already legally marketed in the United States.<sup>4</sup> The FDA can approve a new medical device as substantially equivalent even if the device combines different functional

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\*Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2010. Ms. Freeman is a staff member of Annals of Health Law.

1. See *Overview of Device Regulation*, FDA (Mar. 5, 2013), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>; *Premarket Notification (510k)*, FDA (Jan. 3, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>; *Medical Device Exemptions 510(k) and GMP Requirements*, FDA (Mar. 31, 2014), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>. Low risk medical devices, such as Class I devices, may be exempt from a formal review process so long as the manufacturer register with the FDA and comply with good manufacturing practices. *Id.*

2. *Overview of Device Regulation*, *supra* note 1.

3. *Premarket Approval (PMA)*, FDA (Jan. 24, 2012), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>.

4. *Premarket Notification (510k)*, FDA (Jan. 3, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

components of multiple predicate devices.<sup>5</sup> The use of multiple predicates is now scrutinized because of the recent DePuy metal-on-metal hip implant litigation.<sup>6</sup>

Using multiple predicate devices in the §510(k) pathway creates a potential danger called the Predicate Creep. The predicate creep emerges from the repeated cycle of slight component changes from predicate device to predicate device, which leads to uncertainty in the clinical risks and benefits of the device.<sup>7</sup> The danger is most severe in high-risk, life-saving medical devices.<sup>8</sup> Allowing such devices to bypass the PMA application process shifts device testing from the clinical trial setting to the public marketplace, thus unethically veering potential risks to patients.<sup>9</sup> This paper advocates for legislative reform to minimize the use of multiple predicate devices. Part II examines the federal landscape of medical device regulation. Part III illustrates the flaws of the §510(k) program in light of the recalled DePuy ASR XL Metal-on-Metal Hip Replacements.<sup>10</sup> Part IV provides recommen-

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5. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMIN., MEDICAL DEVICE REPORTING (MDR) RATE IN 510(K) CLEARED DEVICES USING MULTIPLE PREDICATES (Oct. 14, 2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM275631.pdf> [hereinafter MDR RATE IN 510(K) DEVICES].

6. See Complaint at ¶17, *Kransky v. DePuy Orthopaedics, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011).

7. FDA & HHS, REVIEW OF THE REGEN MENAFLEX®: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION 1, 3 (Sept. 2009), <http://www.fda.gov/downloads/newsevents/publichealthfocus/ucm183642.pdf>

8. See *Classify Your Medical Device*, FDA (Dec. 3, 2012), <http://www.fda.gov/20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>

9. See Deborah Cohen, *How safe are metal-on-metal hip implants?*, BRIT. MED. J. 1, 4 (Feb. 28, 2012), <http://www.bmj.com/content/344/bmj.e1410.pdf%2Bhtml> [hereinafter *How safe are metal-on-metal hip implants?*].

10. The DePuy ASR XL litigation was based in the design flaws of a metal-on-metal hip implant cleared through the §510(k) process. See generally Complaint at ¶17, *Kransky v. DePuy, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011). DePuy lawfully received clearance by citing to multiple predicate devices to prove substantial equivalence. *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 N. ENGL. J. MED. 97-98 (2013) [hereinafter *510(k) Ancestry*], available at <http://www.nejm.org/doi/full/10.1056/NEJMp1211581>. Without clinical testing to establish safety and effectiveness, the DePuy entered the market despite having a significantly higher rate of revision, four times the average 5-year revision rate. *Id.*

datations to encourage both innovative and safe medical devices.

## II. DEVELOPMENT OF MEDICAL DEVICE REGULATION & §510(K) CLEARANCE

For most of the twentieth century, medical devices were largely unregulated and not required to undergo a premarket review.<sup>11</sup> The massive Dalkon Shield failure demonstrated the American tort system's inability to manage the dangers arising from defective devices.<sup>12</sup> The Dalkon Shield Intrauterine Device entered the market without any federal oversight or premarket testing and was linked with serious complications such as pelvic inflammatory disease, ectopic pregnancies, sterility, and in some cases, death.<sup>13</sup> In response, Congress passed the Medical Device Amendments of 1976 (MDA) to provide additional protection to patients and enacted a regime of detailed federal oversight by the FDA.<sup>14</sup> The MDA imposed different safeguards depending on the device's classification,<sup>15</sup> determined by a risk-based approach and the type of controls required to ensure its safety and effectiveness.<sup>16</sup> Class I devices present the least risk of illness or injury,

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11. See Jordan Bauman, *The "Déjà Vu Effect:" Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program*, 67 FOOD & DRUG L.J. 337, 340-41 (2012) (Noting the significant premarket reviews for new drugs and the obvious lack of specific premarket requirements for medical devices).

12. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008) (noting that the IUD litigation showcased the inability of the tort system); See generally, John M. Van Dyke, *THE DALKON SHIELD: A "Primer" in IUD Liability*, 40 W. St. U. L. Rev. 1, 7 (2012); Gina Kolata, *The Sad Legacy of the Dalkon Shield*, N.Y. TIMES, (May 2, 2013). The IUD was attached to a multi-filament string that created a pathway for bacteria to travel from the vagina to the uterus. *Id.* Over 200,000 claimed injuries and years of litigation concluded with a 2.4 billion dollar compensation fund and the bankruptcy of the manufacturer. *Id.*

13. *Id.*

14. See *Riegel*, 552 U.S. at 316.

15. See 21 U.S.C. § 360c (2014); *Classify Your Medical Device*, FDA (Dec. 3, 2012), <http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>.

16. *Regulatory Controls*, FDA (April 11, 2013) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm>. Class I devices are required to comply with general controls such as registering the device with the FDA and conforming with good manufacturing practices. 21 U.S.C. § 360c (2014). In addition to general controls, Class II devices must also comport with special controls such as creating patient registries, conducting post-market surveillance,

Class II devices are intermediary risk devices, and Class III devices support or sustain human life, thus presenting the highest risk of illness and injury.<sup>17</sup>

Today, manufacturers are required to submit either a PMA application or §510(k) premarket notification submission.<sup>18</sup> A PMA review is rigorous, requiring all clinical study reports and investigative documents of the device's safety and effectiveness, FDA facility inspections, manufacturing controls, labeling proposals, and a full description of the investigational methods.<sup>19</sup> The FDA spends an average of 1,200 hours<sup>20</sup> reviewing each PMA application, granting PMA approval only when a device demonstrates a reasonable assurance of safety and effectiveness.<sup>21</sup>

Devices that satisfy substantial equivalence to a predicate device enjoy significantly easier FDA clearance<sup>22</sup> through the §510(k) premarket notifi-

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and meeting FDA promulgated performance standards. *Id.* Because Class III devices may present a potential unreasonable risk of illness or injury, more than general and special controls are required to provide a reasonable assurance of safety and effectiveness. *Regulatory Controls*, FDA (April 11, 2013) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm>. Therefore, devices used in supporting or sustaining human life are classified under Class III and must submit a PMA application. *Id.*

17. *Regulatory Controls*, supra note 15.

18. *Overview of Device Regulations*, supra note 1. Some devices are also exempt from all review so long as they comply with good manufacturing practices such as quality inspection of materials, meeting specific requirements for the building which houses the manufacturing, and labeling specifications. *See Class III Exemptions*, FDA (Dec. 12, 2012), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm>; *Quality System Regulation Labeling Requirements*, FDA (Dec. 6, 2012) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/QualitySystemRegulationLabelingRequirements/default.htm>.

19. MARK HERMANN & DAVID B. ALDEN, *DRUG AND DEVICE PRODUCT LIABILITY LITIGATION STRATEGY* 13 (2012).

20. *Riegel*, 552 U.S. at 315.

21. 21 U.S.C. § 360c (2014). *See also* 21 C.F.R. § 860.7(d)(1) (2014) (“There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.”); 21 C.F.R. § 860.7(e)(1) (There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.)

22. *See* Chris Schorre, *How long does it take for a 510(k) submission to be cleared by the US FDA?*, EMERGO GROUP, <http://www.emergogroup.com/research/fda-510k-review->

ation.<sup>23</sup> A manufacturer need only show that the new device is substantially equivalent to predicate devices legally marketed in the United States.<sup>24</sup> In stark contrast to the average FDA approval time spent reviewing a PMA application, the FDA spends an average of twenty hours reviewing a 510(k) application.<sup>25</sup>

While Class III devices are statutorily required to be approved through the PMA pathway, most new Class III medical devices reach the market through a loophole in §510(k) clearance.<sup>26</sup> The purpose of §510(k) was to prevent long-standing manufacturers from enjoying a monopoly by allowing competitors of Grandfathered Devices to bypass the PMA application process and market new devices through the §510(k) program.<sup>27</sup> The FDA was tasked with reviewing the different grandfathered Class III devices and deciding whether (1) a PMA application would be required or (2) if the de-

times-research (last visited April 2, 2012); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-494 (1996) (discussing that a determination of substantial equivalence is not considered to be approval and how §510(k) clearance is only considered a green light to market the product); The term “clearance”, instead of “approval”, is used for medical devices that satisfy the §510(k) process because only medical devices that have undergone the “gauntlet of the PMA process” is deemed to be FDA approved. *Id.* While this may seem like a minute difference in semantics, a device that has been approved by the FDA through the PMA process enjoys an almost unfettered preemption of state tort litigation. See generally MICHAEL K. BROWN ET AL., REED SMITH, MEDICAL DEVICE PREEMPTION—IS THERE LIFE FOR PLAINTIFFS’ CLAIMS AFTER RIEGEL V. MEDTRONIC, INC.?, 337(May 2012), available at [www.dri.org/DRI/course-materials/2012-DMD/pdfs/12\\_Brown.pdf](http://www.dri.org/DRI/course-materials/2012-DMD/pdfs/12_Brown.pdf) (discussing key supreme court cases and the high bar plaintiffs must surpass to overcome federal preemption).

23. See Daniel R. Levinson, *FDA’s Clearance of Medical Devices Through the 510(k) Process*, DEPT. OF HEALTH AND HUMAN SERVS. (Sept. 2013), <https://oig.hhs.gov/oei/reports/oei-04-10-00480.pdf>. A device qualifies for §510(k) clearance if a manufacturer can establish that the new device is substantially equivalent to a legally marketed device. *Premarket Notification (510k)*, supra note 4. Unlike a PMA application, a §510(k) is a limited review. 21 U.S.C. § 360c (2014).

24. *Premarket Notification (510k)*, supra note 4. A new device is substantially equivalent to a predicate device if it has the same intended use and (1) the same technological characteristics or (2) different technological characteristics that (a) does not raise new questions of safety and effectiveness and (b) is at least as safe and effective as the legally marketed device. *Id.*

25. *Lohr*, 518 U.S. at 479.

26. See Michael VanBuren, Note, *Closing The Loopholes In The Regulation Of Medical Devices: The Need For Congress To Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 449 (2007).

27. *Lohr*, 518 U.S. at 494; *515 Program Initiative*, FDA (Mar. 22, 2013), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm>

vice could be reclassified to Class I or II.<sup>28</sup>

Unfortunately, reclassification was never finished leaving the door open for fourteen types of Class III devices to enter the market through §510(k) clearance.<sup>29</sup> This is disconcerting as new devices that fall under these 14 devices are all used in supporting or sustaining human life and may be used on patients without ample assurance of safety and effectiveness.<sup>30</sup> Combining different functional components of predicates allows the erection of new devices comprised of different materials and clinical indications for different anatomical parts than their predicates.<sup>31</sup> Using multiple predicates further the uncertainty of the new device's safety and effectiveness.<sup>32</sup> Additionally, the FDA is bound to approve a new device based on a predicate device that has been voluntarily recalled for safety design flaws if the new device is deemed to be substantially equivalent.<sup>33</sup> A device is eligible to be a predicate device so long as the recall was not initiated by the FDA or mandated by court order.<sup>34</sup> This process allows new devices with known safety design characteristics to enter the market.<sup>35</sup>

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28. *515 Program Initiative supra* note 28.

29. *See 515 Project Status*, FDA (Feb. 21, 2014), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm>. The FDA launched the 515 program initiative in an effort to reclassify the remaining Class III devices in need of review. *Id.*

30. *See 510(k) Ancestry, supra* note 10 at 97.

31. *Id.*

32. *See, e.g., REVIEW OF THE REGEN MENAFLEX, supra* note 7, at 3.at 3.

33. Alex Nussbaum, *Medical Device Loophole Needs Closing by Congress, FDA Device Chief Says*, BLOOMBERG NEWS (Feb. 28, 2012), <http://www.bloomberg.com/news/2012-02-28/fda-device-chief-says-approval-loophole-needs-closing.html> ("By law, the FDA has to approve devices that cite an eligible predicate unless the older device has been ordered off the market by the agency or a court order. [. . .] Because most companies opt for voluntary recalls before they reach that point, the devices can continue to serve as a basis for future products, Shuren [director of the FDA's CDRH] said).

34. *Id.*

35. *Id.*

## III. POTENTIAL RISKS OF § 510(K) CLEARANCE

The DePuy ASR XL hip replacement system illustrates the potential danger of using multiple predicates in the §510(k) premarket notification.<sup>36</sup> A class action suit was filed on behalf of over 8,000 ASR XL patients and is projected to cost the company \$4 billion dollars in patient settlement costs.<sup>37</sup> The device's alleged safety design defects coupled with the unsound approval through the §510(k) process resulted in patients suffering from a lack of mobility, high levels of toxic metal in the blood stream, and the necessity for revision surgery to replace the ASR XL.<sup>38</sup>

While a conventional artificial hip is made of metal and plastic, the DePuy ASR XL used the designs of multiple predicates to create a metal-on-metal ball and socket design, resulting in metallic debris to be released into the body.<sup>39</sup> DePuy produced two models of the ASR Systems: the ASR XL Acetabular Hip System (ASR XL) and the ASR Hip Resurfacing system (ASR Resurfacing).<sup>40</sup> Both models had similar metal-on-metal components but required different surgical methods of replacement.<sup>41</sup> The ASR

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36. See *The 510(k) Ancestry*, *supra* note 10, at 98..

37. Lisa Parker, *Plaintiffs Face Agonizing Decision In Hip Implant Settlement*, NBC CHICAGO (Mar. 11, 2014), <http://www.nbcchicago.com/investigations/Plaintiffs-Face-Agonizing-Decision-In-Hip-Implant-Settlement-249671721.html#ixzz2xhVCqGZT>.

38. See generally Deborah Cohen, *Out of joint: The story of the ASR*, BRIT. MED. J. (May 14, 2011), <http://www.bmj.com/content/342/bmj.d2905> [hereinafter *Out of Joint*]; Complaint at ¶17, *Kransky v. DePuy Orthopaedics, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011).

39. See Barry Meier, *Johnson & Johnson in Deal to Settle Hip Implant Lawsuits*, N.Y. TIMES (Nov. 19, 2013), <http://www.nytimes.com/2013/11/20/business/johnson-johnson-to-offer-2-5-billion-hip-device-settlement.html>.

40. Jef Feeley & David Voreacos, *J&J Said to Reach \$4 Billion Deal to Settle Hip Lawsuits*, BLOOMBERG (Nov. 13, 2013), <http://www.bloomberg.com/news/print/2013-11-12/j-j-said-to-reach-4-billion-deal-to-settle-hip-lawsuits.html>; *Important Information About the ASR Hip System Recall*, DEPUY SYNTHES (2013), <http://asrecall.depuy.com/depuy-asr-recall-usen>.

41. *Hip Replacement vs. Hip Resurfacing*, N.Y. TIMES (Feb. 26, 2010, 10:37 AM), <http://consults.blogs.nytimes.com/2010/02/26/hip-replacement-vs-hip-resurfacing>. *How safe are metal-on-metal hip implants?* *supra* note 9, at 4; The ASR XL was used for traditional hip replacements where the neck of the femur, the ball, is surgically removed, and the implant is inserted deep inside the bone. *Id.* In contrast, the ASR Resurfacing only required replacing the joint surfaces with the ASR resurfacing implant. *Id.* While the PMA requirements may have prevented the ASR resurfacing device to be used, later studies would prove

Systems were designed so that the metal surfaces would trap a layer of naturally occurring fluid and prevent the metal surfaces from touching.<sup>42</sup> In theory, the naturally occurring fluid would have become thicker and result in less wear and tear of the implants.<sup>43</sup> However, test would should that the all metal implant would become more likely to strike each other and release metallic debris inside the patient.<sup>44</sup>

Because of the ASR Resurfacing device's cutting edge surgical technique, the FDA required a full clinical trial to prove safety and effectiveness.<sup>45</sup> While the ASR Resurfacing device was never approved because of safety and effectiveness concerns,<sup>46</sup> the FDA cleared the ASR XL due to the use of multiple predicates.<sup>47</sup> Upon approval, the ASR XL was marketed to young, active patients as a superior alternative to the traditional hip devices with lower revision rates.<sup>48</sup>

DePuy cited six predicate devices to establish substantial equivalence and gain §510(k) clearance for the ASR XL.<sup>49</sup> In determining substantial equivalence, the FDA seemed to incorrectly determine that the device was either (1) the same intended use as the predicate and the same technological characteristics or (2) that the different technological characteristics did not

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that the ASR resurfacing device had twice the revision rate when compared to conventional hip implants. *Id.*

42. See *How safe are metal-on-metal hip implants?* *supra* note 9 at 2.

43. See *Out of Joint*, *supra* note 39, at 2.

44. See Barry Meier, *Implant Risk Was Assessed Inadequately, Court Is Told*, N.Y. TIMES (Jan. 31, 2013), [http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?\\_r=0](http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?_r=0).

45. See *Out of Joint*, *supra* note 39, at 2.

46. To receive approval, the ASR resurfacing device was required to undergo clinical testing to prove safety and effectiveness for the intended use. See Deborah Cohen, *Out of joint: The story of the ASR*, BRIT. MED. J. (May 14, 2011) [hereinafter *Out of Joint*], <http://www.bmj.com/content/342/bmj.d2905>. Because of the clinical test requirement, the FDA was apprised of the high rate of femoral knee fractures. *Id.*

47. See *510(k) Ancestry*, *supra* note 10, at 98; Cohen, *supra* note 48, at 2.

48. See *How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

49. *510(k) Ancestry*, *supra* note 10, at 98. FDA approval focused on three characteristics of the ASR XL: the porous bone ingrowth surface, metal-on-metal articulation, and large femoral head sizes. *Id.* Substantial equivalence was determined by comparing each characteristic to six different predicate devices. *Id.*

raise new questions of safety and effectiveness and that the device is as safe and effective as the marketed device.<sup>50</sup> The use of multiple predicates to determine substantial equivalence is flawed because it only compares the device's subparts to a respective predicate instead of comparing the entire device to a predicate. Substantial equivalence was not determined by comparing the ASR XL device to the six predicates, but instead compared each individual characteristic to the respective predicate device.<sup>51</sup>

If the FDA used the first prong of substantial equivalence, it was based on a piecemeal analysis of each functional characteristic to a different corresponding predicate device.<sup>52</sup> None of the predicates cited by the ASR XL contained all three functional characteristics.<sup>53</sup> The FDA defends the §510(k) review process by arguing that the new device is merely combining the functionality of two predicates, but this logic fails where the combination of predicates gives rise to a significantly different, new device with uncertain consequences.<sup>54</sup> The ASR XL metal-on-metal implant, as well as the 14 unclassified Class III medical devices, should not be able to bypass a meaningful clinical trial and unethically shift the potential risks to patients.<sup>55</sup>

In the alternative, it was still improper for the FDA to clear the ASR XL based on a finding that the device did not raise new concerns for safety because of the device's higher than average failure rates for metal-on-metal hip systems should have raised safety and effectiveness concerns.<sup>56</sup> Addi-

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50. *Premarket Notification (510k)*, *supra* note 4.

51. *510(k) Ancestry*, *supra* note 10, at 98.

52. *See* MDR RATE IN 510(K) DEVICES, *supra* note 5, at 3.

53. *See 510(k) Ancestry*, *supra* note 10, at 98; Heather Thompson, *Researchers Say DePuy Hip Ancestry Shows 510(k) Flaws*, (Feb. 19, 2013) <http://www.mddionline.com/article/researchers-say-depuy-hip-ancestry-shows-510k-flaws>; *Ancestry list available* at <http://www.nejm.org/doi/full/10.1056/NEJMp1211581>. In fact, none of the ninety-five devices in the ASR XL ancestry device list had the same combination of characteristics. *Id.*

54. MDR RATE IN 510(K) DEVICES, *supra* note 5, at 3.

55. *See How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

56. *See Premarket Notification*, *supra* note 24; Deborah Cohen, *Revision rates for metal on metal hip joints are double that of other materials*, BRIT. MED. J. (2011).

tionally, the ancestry for the predicate devices used for the ASR XL dated back more than five decades, including three devices that are no longer in use due to the device's high revision rates.<sup>57</sup>

The current statutory landscape does not distinctly provide for the FDA to reject the use of predicates that were voluntarily recalled by the manufacturer for safety design defects.<sup>58</sup> No obligation is placed on the manufacturer to establish that the defect was considered or fixed in the new device.<sup>59</sup> In fact, a medical device is five times as likely to undergo a recall if its predicate was recalled for safety design issues.<sup>60</sup> The law must be changed to reduce the risk that new devices have the same flawed characteristic as defective devices.<sup>61</sup>

#### IV. RECOMMENDATIONS TO STRENGTHEN THE §510(K) PROCESS

While the DePuy product liability litigation sheds some light on the §510(k) premarket notification, the scrutiny of this pathway is not new.<sup>62</sup> In 2009, the FDA turned to the Institute of Medicine (IOM) to review the §510(k) process.<sup>63</sup> The study concluded that the §510(k) pathway was not

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57. *510(k) Ancestry*, *supra* note 10, at 98.

58. Gergana Koleva, *Loophole in FDA's Approval Process for Medical Devices Prompts Letter from Congress*, FORBES (Aug. 17, 2002, 3:13 PM), <http://www.forbes.com/sites/gerganakoleva/2012/08/17/loophole-in-fdas-approval-process-for-medical-devices-prompts-letter-from-congress>.

59. *Medical Device Loophole Leaves Patients At Risk – Consumers Union Responds to Medical Device Industry on Recalled Predicates*, CONSUMERS UNION (May 20, 2012, 6:14PM), <http://safepatientproject.org/document/medical-device-loophole-leaves-patients-at-risk>.

60. Nussbaum, *supra* note 33.

61. *See Medical Device Loophole Leaves Patients At Risk – Consumers Union Responds to Medical Device Industry on Recalled Predicates*, CONSUMERS UNION (May 20, 2012, 6:14PM), <http://safepatientproject.org/document/medical-device-loophole-leaves-patients-at-risk>.

62. *See generally*, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS & INST. OF MED., *MEDICAL DEVICES AND THE PUBLIC'S HEALTH* 4-8 (The Nat'l Academies Press, 2011) [*hereinafter* *MEDICAL DEVICES AND THE PUBLIC'S HEALTH*], available at [http://www.nap.edu/catalog.php?record\\_id=13150](http://www.nap.edu/catalog.php?record_id=13150) (criticizing the flaws of the §510(k) process).

63. *Id.* at 4. Specifically, the Institute was asked to determine 2 questions: (1) Was the current §510(k) clearance process protect patients optimally and promote innovation in support of public health? (2) If not, what legislative, regulatory, or administrative changes are

designed to evaluate safety and effectiveness of new devices and that the FDA's liberal interpretation of substantial equivalence is being used to avoid requiring PMAs for new and novel Class III devices.<sup>64</sup> It recommended that the FDA abandon the §510(k) process for an integrated premarket and post-market regulatory framework.<sup>65</sup> Even though the IOM's comprehensive regulatory framework is a commendable goal, it does not address present concerns regarding the §510(k) process.<sup>66</sup> To prohibit the §510(k) from being used as a regulatory loophole, it is important to restrict the use of multiple predicates and empower the FDA to reject new devices based on defective predicates.<sup>67</sup>

First, the §510(k) pathway application should be restricted only to Class I and II devices.<sup>68</sup> The fact that a majority of Class III devices are cleared through the §510(k) pathway defies Congressional intent.<sup>69</sup> The FDA should make it a priority to reclassify the remaining fourteen remaining Class III pre-amendment devices and ensure that Class III devices undergo PMA review to provide reasonable assurance of safety and effectiveness.<sup>70</sup>

Second, new devices using more than five different predicate devices should be required to clinically establish that combining the different functional components do not create uncertainty in safety and effectiveness.<sup>71</sup> §510(k) devices that cite six to ten predicates are associated with an in-

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recommended to achieve the goals of the §510(k) clearance process optimally. *Id.*

64. *Id.* at 5. 87

65. *Id.* at 7-8.

66. *Id.* at 8.

67. Nussbaum, *supra* note 33.

68. Research conducted by the IOM found an association between devices that cited 6-10 predicates and an increased §510(k) recall rate. See Theresa Wisemann, *Public Health Effectiveness of the FDA 510(k) Clearance Process*, INST. OF MED., 87 (2011), <http://www.iom.edu/Reports/2010/Public-Health-Effectiveness-of-the-FDA-510k-Clearance-Process-Measuring-Postmarket-Performance-and-Other-Select-Topics.aspx>; See also Nussbaum, *supra* note 33. The research also found that Class III devices were 3 times as likely to be recalled under §510(k). *Id.*

69. See MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 62, at 92.

70. See *Medical Device Loophole Leaves Patients At Risk* *supra* note 61.

71. IOM research also found that Class III devices were 3 times as likely to be recalled under §510(k). See Wisemann, *supra* note 68 at 91.

creased recall rate when compared to §510(k) devices that cited one to five predicates.<sup>72</sup> The ASR XL is an example of the hazards in comparing singular characteristics of the new devices to multiple predicates.<sup>73</sup> By requiring scientific evidence of safety and effectiveness, the manufacturer bears the burden to prove that the device is free from unreasonable risk of injury before it can be marketed.<sup>74</sup>

The FDA should have the flexibility to reject new devices based on defective predicates unless the new device was designed to improve upon the recalled device's defect.<sup>75</sup> In 2012, Massachusetts Representative Edward Markey introduced H.R. 3847 for the purpose of ensuring that medical devices were not marketed based on a finding of substantial equivalence to a recalled or removed predicate device.<sup>76</sup> The bill called for clear statutory authority to deny predicates resulting from a recalled device to be denied.<sup>77</sup> Although H.R. 3847 was never enacted, the sound principles of the bill should be reconsidered and adopted by Congress.<sup>78</sup>

## V. CONCLUSION

The need for innovative, lifesaving devices to reach the market and patients must be balanced with an assurance that the device will be safe and effective.<sup>79</sup> The use of multiple predicates to find a §510(k) substantial equivalence does not adequately review the actual risks for Class III devices.<sup>80</sup> Regardless of whether the FDA or a manufacturer initiates a design re-

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72. *Id.*

73. *See generally* *How safe are metal-on-metal hip implants?* *supra* note 9.

74. *See* *How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

75. Nussbaum, *supra* note 33.

76. H.R. 3847, 112th Cong. § 2 (2012).

77. *Id.* (amending the Federal Food, Drug and Cosmetic Act to allow the rejection of new devices based on defective predicate devices).

78. H.R. 3847..

79. Doug Schoen, *Medical Innovation and Safety: A delicate balance*, *Forbes* (Mar. 5, 2012), <http://www.forbes.com/sites/dougschoen/2012/03/05/medical-innovation-and-safety-a-delicate-balance/>

80. *See* Nussbaum, *supra* note 33 (noting that Class III devices were 3 times as likely to

call, future devices relying on recalled device(s) should have to prove that they addressed the design defect and the new device is free from unreasonable risk. The unknown risks that Class III devices pose when they are cleared with inadequate predicates is an unethical burden that patients should not have to bear.<sup>81</sup>

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be recalled under §510(k).

81. See Barry Meier, *Implant Risk Was Assessed Inadequately, Court Is Told*, N.Y. TIMES (Jan. 31, 2013), [http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?\\_r=0](http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?_r=0).