

September 28, 2011

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***Re: Docket No. FDA-2011-N-0556: Center for Devices and Radiological Health 510(k) Clearance Process; Recommendations Proposed in Institute of Medicine Report: “Medical Devices and the Public’s Health, the FDA 510(k) Clearance Process at 35 Years;” Request for Comments***

Dear Sir or Madam:

The California Healthcare Institute (“CHI”) welcomes the opportunity to comment on the above referenced docket and Federal Register notice dated August 1, 2011. CHI represents the broad biomedical sector of the California economy and unites more than 270 of California’s leading universities and private research institutes, venture capital firms, and life sciences companies in support of biomedical science and biopharmaceutical and medical technology innovation.

California is home to nearly 1,300 medical technology firms alone, more than any other state in the nation. The more than 112,000 medical technology jobs in California represent roughly one-third of the total U.S. medical technology workforce as well as the largest segment (41 percent) of the total 275,000 California life sciences jobs,<sup>1</sup> including medical technology, biopharmaceuticals, academic research, etc. It is also, most significantly, the source of many of the medical technologies that improve patient and public health around the world such as in diagnosing and treating diabetes, cardiovascular disease, cancer, hearing and vision loss, pain management, and numerous other diseases and conditions. The 510(k) premarket notification process is the clearance mechanism by which the vast majority of CHI member company medical technologies are brought to market.

CHI believes the 510(k) process is a long-standing, proven pathway that both addresses the safety and effectiveness of marketed devices and fosters innovation. Accordingly, for the reasons described below, we disagree with Institute of Medicine’s (“IOM”) conclusion that the 510(k) process should be eliminated and replaced by a new regulatory framework.

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<sup>1</sup> CHI, California Biomedical Industry 2010 Report, *available at* [http://www.chi.org/uploadedFiles/Report\\_2010\\_California\\_Biomedical\\_Industry\\_Report\\_FINAL.PDF](http://www.chi.org/uploadedFiles/Report_2010_California_Biomedical_Industry_Report_FINAL.PDF).

## **I. As the IOM Report Confirms, There is No Public Health Crisis Related to Unsafe or Ineffective Medical Devices**

Since the Medical Device Amendments of 1976 established the 510(k) process, the Food and Drug Administration (“FDA”) has cleared more than 120,000 devices through this regulatory pathway.<sup>2</sup> For the past decade, FDA’s Center for Devices and Radiological Health (“CDRH”) has received approximately 4,000 original 510(k) submissions each year.<sup>3</sup> Devices cleared through the 510(k) process have not created a public health crisis. Rather, a few isolated safety incidents associated with 510(k) cleared devices have resulted in disproportionate media attention and led to unwarranted scrutiny of the regulatory pathway. This has, in turn, led some organizations to make unsubstantiated generalizations about the safety of the 510(k) process. Isolated problems are not indicative of systemic problems and do not invalidate the 510(k) pathway.

The vast majority of 510(k) cleared devices are safe and effective. FDA itself has noted that medical devices in the U.S. have a “strong track record of safety and effectiveness” and that the 510(k) process has “helped support a robust medical device industry . . . and has helped bring lower-risk devices to market for patients who need them.”<sup>4</sup> Several recent, independent studies that examined medical device recall data also concluded that 510(k) regulated medical devices have an excellent safety profile. In one study, a University of Minnesota Law School Professor examined Class I recalls (situations in which there was a “reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death”) of 510(k) cleared medical devices between 2005 and 2009 and found that fewer than one-half of one percent were subject to such a recall.<sup>5</sup> This 99.5% safety rate is consistent with the 99.8% safety rate found by the Battelle Memorial Institute in a study for AdvaMed.<sup>6</sup>

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<sup>2</sup> Heather S. Rosecrans, Director, 510(k) Staff, Office of Device Evaluation, CDRH, *510(k) Workshop: Issues Related to Postmarket Surveillance and New Information about Marketed Devices* 39 (Feb. 18, 2010), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM201345.pdf>.

<sup>3</sup> FDA, CDRH, 510(k) Working Group Preliminary Report and Recommendations 34 in 1 *CDRH Preliminary Internal Evaluations* (Aug. 2010) [hereinafter *510(k) Working Group Report*], available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf>.

<sup>4</sup> Press Release FDA, *FDA To Seek Public Comment on IOM Recommendation*, (July 29, 2011), available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm265908.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm265908.htm).

<sup>5</sup> The 99.5% safety rate was derived by dividing the total number of 510(k) submissions between 2000 and 2009 (39,747) by 10 to get an annual average, then multiplying that number (3974.7) by 5 to get an approximation of the 510(k)s submitted in the 5 year period examined for recalls (19,873). The total Class I recalls between 2005 and 2009 (89) was then divided by the 5 year average of 510(k) submissions. Ralph F. Hall, University of Minnesota Law School, (Using Recall Data to Assess the 510(k) Process), (July 28, 2010), available at <http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUL-28/06%20Hall.pdf>.

<sup>6</sup> The Battelle study found that between January 2005 and May 2010, 77 devices that had been cleared through the 510(k) process were removed from the market due to Class I recalls. Battelle Memorial Institute, *510(k) Premarket*

IOM's report, therefore, is a solution in search of a problem. To justify such a drastic position—the complete elimination of the 510(k) process as soon as reasonably possible—there should be a clear and compelling need for such a step. But when IOM's own report clearly acknowledges that there is no such a public-health crisis related to unsafe or ineffective medical devices, it is difficult to mount any reasonable defense of IOM's position.<sup>7</sup>

## II. FDA's Current 510(k) Process Adequately Addresses Safety and Effectiveness

As FDA has repeatedly acknowledged, one of the aims of the 510(k) pathway is to assure, through a quality review process, that marked devices, subject to general and applicable special controls, provide a reasonable assurance of safety and effectiveness.<sup>8</sup> IOM's conclusion that the 510(k) process does not address safety and efficacy is unsubstantiated. Safety and effectiveness are addressed through the 510(k) process as well as complementary regulatory mechanisms.

### A. Substantial Equivalence Addresses Safety and Effectiveness

The IOM erroneously concluded that the concept of substantial equivalence—a cornerstone of the 510(k) process—is divorced from evaluations of safety and effectiveness when, in fact, substantial equivalence determinations consider safety and effectiveness. The Federal Food Drug and Cosmetic Act (“FDCA”) provides that a determination of substantial equivalence to a predicate device may be made when the device has the same intended use as the predicate device and either has the same technological characteristics as the predicate, *or* has different technological characteristics, but the information (including data, if applicable) submitted demonstrates the device is substantially equivalent to the predicate device and is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.<sup>9</sup> In fact, FDA's implementing regulations describe the appropriate supporting data, additional information, and performance data as factors to be considered when assessing substantial equivalence.<sup>10</sup> Specifically, FDA may require that a manufacturer submit data related to bench, animal, and clinical performance testing, biocompatibility, electromagnetic compatibility and electrical safety, sterilization, shelf life, and

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*Notification Evaluation*, (Sept. 2010), available at <http://www.advamed.org/NR/rdonlyres/255F9405-677D-45B1-BAC8-0D4FD5017054/0/510kPremarketNotificationEvaluation.pdf>.

<sup>7</sup> Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years 5* [hereinafter *IOM Report*], available at, [http://www.nap.edu/catalog.php?record\\_id=13150](http://www.nap.edu/catalog.php?record_id=13150).

<sup>8</sup> *510(k) Working Group Report*.

<sup>9</sup> FDCA § 513(i)(1)(A).

<sup>10</sup> 21 C.F.R. § 807.87, § 807.92.

software if it is needed to evaluate whether a new device is at least as safe and effective as the relevant predicate device(s).<sup>11</sup>

Once a manufacturer obtains clearance for a device, it is required to obtain another 510(k) clearance before marketing the device with a modification that could significantly affect its safety or effectiveness or that constitutes a major change in intended use.<sup>12</sup> Further, a device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.<sup>13</sup> Thus, the 510(k) process and determinations of substantial equivalence directly address safety and effectiveness. FDA may also utilize performance standards, special controls, and a variety of general controls to ensure the safety and effectiveness of a device.

#### B. Performance Standards and Special Controls Address Safety and Effectiveness

FDA may establish specific performance standards for class II devices if the Secretary determines the standards are necessary to provide reasonable assurance of the safety and effectiveness of the device.<sup>14</sup> Such performance standards shall include, when necessary: (i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems; (ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device; (iii) provisions for the measurement of the performance characteristics; (iv) provisions requiring that the results of each or of certain types of tests of the device show conformity with the portions of the standard for which the test(s) were required; and (v) a provision requiring the sale and distribution of the device be restricted (but only to the extent allowed under FDCA § 520(e)).<sup>15</sup> Further, performance standards shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.<sup>16</sup> These performance standards can be used as an additional mechanism to ensure the safety and effectiveness of a 510(k) cleared device.

In addition to performance standards, FDA has the statutory authority to impose special controls. These controls are utilized to manage device risk and performance as appropriate for the particular device. Special controls include postmarket surveillance, patient registries, and development and dissemination of guidelines (including guidelines specific to the

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<sup>11</sup> FDCA § 513(i)(1)(A)(i)(I); see FDA, *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (Aug. 12, 2005), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084396.pdf>.

<sup>12</sup> 21 C.F.R. § 807.81(a)(3).

<sup>13</sup> FDCA § 513(i)(2).

<sup>14</sup> FDCA § 514.

<sup>15</sup> FDCA § 514(a)(2)(B).

<sup>16</sup> FDCA § 514(2)(C).

submission of clinical data in a 510(k)), recommendations, and other appropriate actions.<sup>17</sup> Special controls can be very specific in nature and FDA has the authority to include them as required conditions in 510(k) clearance orders.

### C. General Controls and Enforcement Address Safety and Effectiveness

In addition to the special controls noted above, all devices are subject to general controls, unless specifically exempted. These general controls, in conjunction with the 510(k) process, directly address issues of safety and effectiveness. For example, a device manufacturer must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications.<sup>18</sup> FDA can require that manufacturers track medical devices, and all must submit medical device reports (“MDRs”) whenever they receive information from any source that “reasonably suggests” that one of their devices “[m]ay have caused or contributed to a death or serious injury” or “has malfunctioned and that this device or a similar device [marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”<sup>19</sup> Moreover, FDA has the power to “restrict” certain devices with respect to their sale, distribution, or use if it determines they have the potentiality for harmful effect and there cannot otherwise be reasonable assurances of safety and effectiveness.<sup>20</sup> Finally, FDA may ban a device that “presents substantial deception or an unreasonable and substantial risk of illness or injury,”<sup>21</sup> issue a mandatory device recall,<sup>22</sup> reclassify a device,<sup>23</sup> or obtain court orders in order to seize unsafe devices.<sup>24</sup> FDA, therefore, has numerous authorities that provide it with comprehensive authority over 510(k) devices.

## III. The 510(k) Process Fosters Innovation

The 510(k) process fosters innovation and advances the public health by bringing important medical devices to the market. CHI disagrees with IOM’s conclusion that it is impossible to determine whether the 510(k) process facilitates or inhibits innovation. IOM itself failed to maintain a consistent position with respect to innovation as it acknowledged the regulatory process can facilitate innovation by making new devices available to consumers in a timely manner.<sup>25</sup> Devices generally have shorter life cycles than drugs and incremental changes

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<sup>17</sup> FDCA § 513(a)(1)(B).

<sup>18</sup> 21 C.F.R. Part 820.

<sup>19</sup> FDCA § 519(e); 21 C.F.R. §§ 803.40(a), (b); 803.50(a).

<sup>20</sup> FDCA § 520(e).

<sup>21</sup> FDCA § 516. Banned medical devices can no longer be legally marketed and therefore may not be cited as a predicate device.

<sup>22</sup> FDCA § 518.

<sup>23</sup> FDCA § 513(e).

<sup>24</sup> FDCA § 304(g).

<sup>25</sup> *IOM Report* 158.

are common. These modifications frequently occur over a relatively short time period and constitute the very essence of innovation. The 510(k) regulatory pathway allows device manufacturers to maintain flexibility, while simultaneously ensuring cleared devices are safe and effective. Further, the definition of substantial equivalence explicitly takes technological changes into consideration.

The 510(k) process and the concept of substantial equivalence squarely contemplate the fact that devices may undergo a continuous process of design and innovation. The three types of 510(k) submissions—Traditional, Special, and Abbreviated—foster innovation by requiring manufacturers to provide to FDA the information that is needed to determine whether a device demonstrates substantial equivalence. The type of 510(k) that is submitted depends on whether and to what extent the modifications could significantly affect safety and effectiveness. Special and Abbreviated 510(k)s may expedite the submission and review process. These processes foster innovation by allowing companies to continuously make incremental changes. These changes would not be practical if a new PMA were required with each modification.

The 510(k) process is extremely flexible in that it takes into account the scope of the innovation as well as current standards. This flexibility may expedite the submission and review process, so new devices can reach the market in a timely manner. In comparison to a PMA, a device cleared under 510(k) is often able to reach the market faster and at a lower cost. A class I or II device cleared through the 510(k) process has a mean approval time of 3-6 months, whereas a Class III device PMA approval has a mean approval time of 12-24 months.<sup>26</sup> The relative speed in which a product may be brought to market through the 510(k) regulatory pathway encourages manufacturers to make improvements to devices that they otherwise may not make. It also fosters competition among manufacturers and creates market pressures to have the most efficient and cost effective product available.

The medical device industry is particularly sensitive to the increased costs and burdens of additional regulatory requirements. A majority of the medical device innovation that eventually comes to market is spearheaded by small medical technology companies. Indeed, approximately 80% of medical device companies have fewer than 50 employees and 98% have fewer than 500 employees.<sup>27</sup> Additional regulatory requirements are associated with increased costs. These costs would likely have a detrimental effect on the operation and sustainability of these small companies. Many innovative and life-saving devices currently on the market may not have been developed if not for the 510(k) process.

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<sup>26</sup> CHI, *Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry*, Appendix B, at 23 (Feb. 2011), available at [http://www.chi.org/uploadedFiles/Industry\\_at\\_a\\_glance/Competitiveness\\_and\\_Regulation\\_The\\_Future\\_of\\_America's\\_Biomedical\\_Industry.pdf](http://www.chi.org/uploadedFiles/Industry_at_a_glance/Competitiveness_and_Regulation_The_Future_of_America's_Biomedical_Industry.pdf).

<sup>27</sup> Exvere Inc., *Medical Device Manufacturing Market Update* at 2 (Feb. 2011) available at [http://exvere.com/pdf/medical\\_device\\_manufacturing\\_market\\_update.pdf](http://exvere.com/pdf/medical_device_manufacturing_market_update.pdf).

IOM's recommendation to eliminate the 510(k) process will stifle innovation. If all devices have to be approved through the PMA process, the increased time and costs may prevent companies from pursuing technological changes. Even if review time does not increase, significant changes to the 510(k) process will, at a minimum, create regulatory uncertainty. This uncertainty will also directly affect industry's ability to efficiently bring new devices to market.

#### **IV. CHI Remains Concerned about FDA's 510(k) Working Group Recommendations**

CHI joins FDA<sup>28</sup> in its opposition to IOM's recommendation to eliminate the 510(k) process. We support the use of the 510(k) pathway to assure that marked devices provide a reasonable assurance of safety and effectiveness and foster innovation. In order to achieve this goal, we believe FDA's processes must be predictable, transparent, and timely. Accordingly, we support reasonable improvements to the 510(k) process. However, CHI remains concerned about some of the preliminary recommendations FDA's 510(k) working group made in its August 2010 interim evaluation.

CHI does not support the following proposals discussed by the working group: (1) Combining the terms "intended use" and "indication for use;" (2) Creating a new Class IIb of devices; (3) Reducing the scope of 510(k) eligibility by eliminating or restricting the use of split and multiple predicates; (4) Expanding the scope of de novo review and equating de novo review with a PMA-like process; (5) Requiring the filing of mandatory modification updates, labeling updates, and manufacturing process information; (6) Adding a GMP compliance requirement to the clearance process; (7) Requiring additional postmarket information; (8) Requiring FDA to consider possible off-label uses; and (9) Expanding FDA's rescission authority.

We previously summarized our concerns about these proposals in comments submitted in response to the CDRH Working Group's Preliminary Report and Recommendations (Docket No. FDA-2010-N-0348), attached hereto as Exhibit A. CHI remains opposed to these nine proposals for the reasons articulated therein.

#### **V. FDA Should Mend, Not End the 510(k) Process**

We are not aware of any concrete data which support the contention that the 510(k) process is fundamentally flawed. Indeed, such assertions often appear to be based on conjecture and speculation. For the reasons detailed above, the 510(k) regulatory pathway, combined with existing FDA processes and authorities, assures that cleared medical devices are safe and effective. Critically, IOM itself acknowledged that the 510(k) pathway has not resulted in a public health crisis.

CHI believes that if the 510(k) pathway is implemented as intended and in a consistent and transparent manner, it will satisfy the public health goal of ensuring cleared

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<sup>28</sup> "FDA believes that the 510(k) process should not be eliminated" but is open to additional proposals and approaches for continued improvement of its device review programs. News Release, FDA, *FDA To Seek Public Comment on IOM Recommendations*, (quoting Jeffrey Shuren, M.D., Director, CDRH) (July 29, 2011).

devices are safe and effective and foster innovation. CHI supports improvements in the training and management of oversight within FDA. Such improvements may help FDA implement the current 510(k) process in a fair and consistent manner. We also support FDA's efforts to publish additional clear guidance, subject to notice and comment, focused on the 510(k) process.

We appreciate this opportunity to share our comments and look forward to future opportunities to engage with FDA on improving the 510(k) process.

Sincerely,

A handwritten signature in black ink that reads "Todd E. Gillenwater". The signature is written in a cursive style with a large, prominent 'T' and 'G'.

Todd E. Gillenwater  
Senior Vice President, Public Policy