Docket No. FDA-2013-P-0076

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

CITIZEN PETITION BY DUVAL & ASSOCIATES, P.A. AND MINNESOTA MEDICAL DEVICE ALLIANCE REGARDING FDA'S ADMINISTRATIVE PRACTICES AND DEFINITIONAL INTERPRETATIONS IN REVIEWING PREMARKET NOTIFICATIONS SUBMITTED UNDER SECTION 510(k) OF FDCA

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Re: Comments Supporting Citizen Petition No. FDA-2013-P-0076 (Jan. 2, 2013); Petition by Duval & Associates, P.A. and Minnesota Medical Device Alliance Regarding FDA's Administrative Practices and Definitional Interpretations in Reviewing Premarket Notifications Submitted Under § 510(k) of FDCA

Dear Sir/Madam:

The Washington Legal Foundation (WLF) submits these comments in support of Citizen Petition No. FDA-2013-P-0076, filed by Duval & Associates, P.A. and the Minnesota Medical Device Alliance (collectively, MMDA) on January 2, 2013. In particular, WLF concurs with the MMDA that through a combination of guidance documents and regulatory actions FDA has transformed the 510(k) process from one that encouraged the development of new and innovative medical devices into one in which caution has become the overriding consideration.

When Congress in 1976 first authorized federal control over the introduction of new medical devices, it recognized that the many thousands of medical devices already on the market were—with a few notable exceptions—performing their intended functions both safely and effectively. Accordingly, it saw no need to establish a rigorous product-approval process for existing medical devices or for new medical devices that were substantially equivalent to existing devices. Instead, it established a "premarket notification" process (the "§ 510(k) process") whereby manufacturers were permitted to market a new device by demonstrating to

FDA's satisfaction that the device was substantially equivalent to a device already on the market. Over the past four decades, the vast majority of new medical devices have reached the market by means of the § 510(k) process. As the Petition notes, about 3,000 to 4,5000 devices are cleared each year by FDA under the § 510(k) process, vs. the less than 50 highly-complex devices that are approved for marketing each year under the rigorous Premarket Approval (PMA) process. Petition at 14. The success of the § 510(k) process has been a tremendous boon for American consumers; they have reaped the benefits of a domestic medical device industry that has been the world leader in terms of innovation. Moreover, while there can never be complete assurance that all new medical devices will pose no safety risks, the safety record for devices reaching the market under the § 510(k) process has been unsurpassed.

The success of the § 510(k) process is being threatened, however, by recent changes in the manner in which FDA is administering the process. The review procedure is being transformed into one whereby, instead of determining whether a new device is *as* safe as existing devices, FDA is evaluating whether the device meets some absolute level of safety. Importantly, this transformation is taking place without encouragement from Congress. Legislation establishing the § 510(k) process remains in place; indeed, on several occasions Congress has stepped in to make clear that FDA has gone too far in cutting back on the § 510(k) process. The results of FDA's policy change have been devastating; many smaller device companies are facing financial ruin, and product clearance or approval can take so long that American consumers often do not gain access to innovative products until several years later than their

European counterparts.

A significant part of the blame is attributable to inadequate supervision of FDA product reviewers; they are not receiving clear instructions that absolute assurance of safety is rarely attainable and that clearance is warranted under federal law whenever a new device is shown to be as safe as the predicate device. Also to blame are guidance documents issued by FDA that have shifted the § 510(k) process away from the streamlined process intended by Congress. In particular, WLF concurs in the Petition's request that FDA withdraw its December 27, 2011 draft guidance entitled, "Draft Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (hereinafter the "New 510(k) Guidance"). This latest draft guidance substantially alters the evaluation process set forth in previous guidance documents, and does so in a manner that places undue emphasis on undertaking an independent evaluation of the safety of the new device.

Finally, even if FDA's new understanding of the § 510(k) process were a plausible interpretation of the underlying statutes, FDA is seeking to implement that new understanding in a manner that violates the Administrative Procedure Act. When a federal agency seeks to alter its previous interpretation of a federal statute, the APA requires the agency to engage in formal notice-and-comment rulemaking and thereby permit all interested stakeholders to weigh in before the new interpretation is put into place. FDA is violating the APA by adopting its new understanding of federal medical device statutes by means of guidance documents rather than by formal notice-and-comment rulemaking.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law and policy center with members and supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government, and the proper use of our state and federal administrative systems. To that end, WLF has frequently appeared in judicial and administrative proceedings to ensure that administrative agencies adhere to the rule of law. *See, e.g., Shinseki v. Sanders*, 556 U.S. 396 (2009).

In particular, WLF focuses much of its work on the activities of the Food and Drug Administration. WLF has repeatedly criticized FDA for failing to comply with the Administrative Procedure Act (APA) when adopting new rules intended to have broad application. For example, litigation filed by WLF on behalf of patients and doctors forced FDA in 1994 to retract rules regarding the regulation of allograft heart valves, after FDA conceded that it had not complied with the APA's notice-and-comment procedures before adopting the rules. *Washington Legal Found. v. Shalala*, No. 93-5279 (D.C. Cir. 1994). In a recent case in which WLF played an active role, a federal district court overturned an FDA product classification decision, in substantial part because FDA failed to abide by the APA before changing a long-time regulatory interpretation. *Prevor v. FDA*, 895 F. Supp. 2d 90 (D.D.C. 2012). Since 2006, WLF has operated its "OPDP Watch" project, which critiques warning letters and "untitled" letters issued by FDA's Office of Prescription Drug Promotion (formerly

known as DDMAC). A recurring theme of WLF's critiques is that OPDP regularly announces new legislative rules by means of its warning letters, yet does so without abiding by the APA's notice-and-comment procedures.

WLF has also closely monitored FDA's regulation of the medical device industry. A 2011 WLF Citizen Petition concluded that an Institute for Medicine committee assembled for the purpose of assessing the § 510(k) process (the "IOM Committee") had been put together in violation of the Federal Advisory Committee Act of 1972, and therefore asserted that FDA should not use any advice or recommendations provided in the IOM Committee's July 29, 2011 report. *See* Docket No. FDA-2011-P-0497-0001/CP. WLF has filed formal comments in response to numerous FDA draft guidances regarding medical device regulation. *See, e.g.*, Docket No. FDA-2013-D-0743, "Medical Device Reporting for Manufacturers" (comments filed October 11, 2013); Docket No. FDA-2013-D-0114, "Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements" (comments filed May 23, 2013); Docket No. FDA-2011-D-0429, "Classification of Products as Drugs and Devices" (comments filed Sept. 19, 2011); Docket No. FDA-2011-D-0305, "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions" (comments filed August 30, 2011).

WLF is concerned that the New 510(k) Guidance, by authorizing significantly increased safety reviews of new products submitted under the § 510(k) process, is causing unwarranted delay in product clearance/approval and is thereby depriving American consumers of access to

innovative and lifesaving medical devices. WLF believes that changes wrought by the New 510(k) Guidance, as well as by the adoption of a safety-above-all-else approach by many FDA product reviewers, have not been authorized by Congress and, at the very least, ought not to be adopted until FDA has opened the issue to public debate pursuant to formal notice-and-comment rulemaking procedures.

II. *FDA's Statutory Authority*

The federal government has regulated the sale of medical devices since 1938, when it broadened the Food and Drug Act of 1906 to cover the sale of misbranded or adulterated medical devices. *See* Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 52 Stat. 1049-1051. It was not until 1976, however, that Congress authorized FDA to regulate the introduction of new medical devices into the marketplace. *See* Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (1976) (chiefly codified at 21 U.S.C. § 360 *et seq.*). The MDA classifies medical devices into three categories based on the risk that they pose to the public. Devices that present no unreasonable risk of injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, their manufacturers must comply with FDA performance regulations known as "special controls." § 360c(a)(1)(B). Devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are

designated Class III. § 360c(a)(1)(C).

There are two principal methods by which manufacturers can bring new medical devices to market. The first (and by far the more costly and time-consuming) method is the premarket approval (PMA) process. The PMA process entails the development and submission of substantial scientific evidence for the purpose of providing FDA with "reasonable assurance" that the device is safe and effective for its intended use. 21 U.S.C. § 360e(d)(2). The vast majority of new medical devices reach the market pursuant to the second principal method, the § 510(k) process. Under that process, the manufacturer supplies FDA with at least 90 days advance notification of its intent to market the new device, along with evidence that it is entitled to marketing clearance. *See* FDCA § 510(k), 21 U.S.C. § 360(k). FDA is required to grant marketing clearance if, *inter alia*, it determines that the device is "substantially equivalent" to a pre-existing device. 21 U.S.C. § 360c(f)(1)(A)(ii). Congress adopted the § 510(k) process because it determined: (1) there was reasonable assurance that a medical device was safe if it had been marketed prior to 1976 and safety concerns had not arisen among its users ; and thus (2) there was reasonable assurance that new devices were also safe if they were "substantially equivalent" to those pre-1976 devices. Congress also acted "to ensure that improvements to existing devices [could] be rapidly introduced into the market." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

The Supreme Court has explicitly recognized that the § 510(k) process is not intended to be particularly time-consuming or rigorous. It stated that the process "is by no means

comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Id.* at 478-79. Quoting one commentator, the Court observed, "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification *requires little information,* rarely elicits a negative response from the FDA, and get processed very quickly." *Id.* at 479 (emphasis added). Indeed, it was precisely because the Supreme Court recognized that § 510 devices reach the market with such limited opportunity for FDA safety review that it refused to afford § 510 device manufacturers with the immunity from state-law tort liability that Congress explicitly extended (in 21 U.S.C. § 360k(a)) to manufacturers of devices that have been designed and labeled in accordance with any FDA safety or effectiveness "requirement." *Id.* at 492-94.

In order to be "substantially equivalent" to a predicate device for purposes of the § 510(k) process, a new device must first be determined to have "the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A). FDA then determines whether the device either has "the same technological characteristics as the predicate device" *or* that the manufacturer has submitted information demonstrating that the device "is as safe and effective as a legally marketed device" and "does not raise different questions of safety and effectiveness than the predicate device." § 360c(i)(1)(A)(i) & (ii). If so, the manufacturer is entitled to § 510(k) clearance for its new device. The Petition convincingly demonstrates that FDA personnel have consistently misapplied both prongs of the "substantial equivalence" test.

III. *The "Same Intended Use" Requirement*

In order to establish "substantial equivalence" ("SE"), a manufacturer must first demonstrate that its device has "the same intended use as the predicate device." But as the Petition explains in detail, "same intended use" does not mean that the two devices list precisely the same indications. A 1986 FDA guidance document explained:

> The Center [for Devices and Radiological Health]'s scientific expertise enables it to exercise considerable discretion in construing intended uses in the labeling and promotional materials for predicate and new devices. While a new device must have the same intended use as a predicate device in order to be SE, the Center does not require that a new device be labeled with precise therapeutic or diagnostic statements identical to those that appear on predicate device labeling in order for the new device to have the same intended use. Label statements may vary. Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness that are different from those that were posed by the predicate device's intended use, the new device may be found SE.

FDA, "Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)" (1986). As an example, the guidance document cited use of a pre-1976 dialyzer as a predicate device. Although such devices were labeled for use as part of an artificial kidney system for patients with renal failure, their "principal purpose" was to remove excess water from the vascular system. FDA determined that they were "substantially equivalent" to new devices used as part of a heart-lung machine where the new devices were intended to remove excess water from the vascular system at the end of surgery. FDA concluded, "[T]his is not a different intended use. Differences in the labeling relate only to a nonessential condition that does not bear *materially* on the safe and effective use of the device." *Id.* (emphasis added).

A 1998 guidance document provides helpful criteria for determining whether specific indications claimed by the new device should lead to the conclusion that the device's "intended use" differs from that of the predicate device. *See* FDA "Guidance for Industry: General/Specific Intended Use" (Nov. 4, 1998). Among the listed decision-making criteria is the following:

> **Knowledge Base** – Is there a body of evidence available to the agency regarding a proposed specific use that reflects existing understanding by the medical community that the more specific use is a subset of the general use, rather than a new intended use? That evidence can be derived from such sources as the medical literature and practical guidelines.

Unfortunately, FDA personnel often do not adhere to the 1998 and 1986 standards and are generally unwilling to exercise the same "considerable discretion" in construing intended uses. The MMDA explains in the Petition that its members have repeatedly faced FDA reviewers who quickly (and often without explanation) conclude (based on a "different intended use" determination) that the new device is not SE, yet they have declined even to look at proffered evidence demonstrating that the medical community deems the proposed specific use to be a subset of the general use reflected in the predicate device. A new indication is not, of course, a subset of the general use reflected in the predicate device if it introduces substantial new risks not raised by previous uses; but all too often FDA reviewers reach a "not SE" conclusion based on nothing than the surmise that the new indication "might" create new risks and without ever identifying what those risks might be.

It is easy to understand the incentives that can cause FDA reviewers to reach a "different

intended use" conclusion too hastily. Reviewers are naturally disposed toward excessive caution born of a desire to avoid responsibility for clearing what turns out to be a dangerous device; no reviewer wants to be known as the official who cleared the next Dalkon Shield. Moreover, some reviewers may disagree with Congress's permissive approach to medical device marketing and may have decided unilaterally to adopt the more conservative approach recommended by the 2011 report of the IOM Committee. Moreover, the so-called "*De Novo* Process" – the approval process authorized by 21 U.S.C. § 360c(f)(2) for low-to-moderate risk devices that have been determined not to be SE – provides reviewers with an easy way out. By rejecting the "same intended use" claim, reviewers can nudge a manufacturer in the direction of using the *De Novo* Process and thereby justify requests for significantly more safety and effectiveness information.

Many device manufacturers have appealed rejection of their "same intended use" claims, and the success of many such appeals is strong evidence that FDA reviewers are acting too hastily in rejecting those claims. But if reviewers were given proper training regarding the "same intended use" requirement, manufacturers would not be forced to pursue costly and time-consuming appeals, and senior FDA personnel would not face as many "whistleblowers" – disgruntled FDA employees who bring their safety concerns to the attention of sympathetic Members of Congress.

FDA exacerbated the problem with its 2011 release of the New 510(k) Guidance. Despite the Supreme Court's admonition that "510(k) notification requires little information," *Lohr*, 518 U.S. at 479, and despite the New 510(k) Guidance's recognition that "the 510(k)

review standard is comparative" (as opposed to the PMA standard, which requires "an independent demonstration of safety and effectiveness") the New 510(k) Guidance asserts emphatically that a proposed device creates a new intended use if it raises "a safety or effectiveness issue" that was "not considered in reviewing the 510(k) for the predicate device." That assertion finds no support in the text of the FDCA or its legislation history, and differs sharply from FDA's prior position. The FDCA does not require that the safety or effectiveness issue raised by the new indication have actually been considered (and deemed manageable) in connection with review of the predicate device. The new device is deemed SE so long as any safety and effectiveness issues raised by the new indication were also present in connection with the predicate device, regardless whether those issues were actually considered. Indeed, in many instances, they will *not* have been considered. That will be true by definition in every case in which the predicate device is a pre-1976 device; such devices were grandfathered by the MDA and thus never went through any safety and effectiveness review. Congress has nonetheless determined that the new device meets the "same intended use" standard so long as its new indications do not raise *new* safety and effectiveness issues.

The New 510(k) Guidance is likely to increase the tendency of FDA reviewers to err on the side of caution, and to move in the direction of the *De Novo* Process by issuing a not SE determination. It is not difficult for FDA personnel to dream up potential safety and effectiveness concerns when reviewing a § 510(k) notification. The New 510(k) Guidance may well suggest to them that those concerns are sufficient to justify a determination that the new

device has a different "intended use," without regard to whether those concerns are also relevant to the predicate device. Accordingly, FDA should withdraw the New 510(k) Guidance and instruct reviewers to instead rely on the aforementioned 1986 and 1998 guidance documents.

IV. *The Technological Characteristics Requirement*

The second prong of the "substantial equivalence" test requires FDA to determine whether the new device has "the same technological characteristics as the predicate device." 21 U.S.C. § 360c(i)(1)(A)(i). If so, then the new device is "substantially equivalent" to the predicate device. Even if it does not have the same technological characteristics, the manufacturer is still entitled to an SE determination if it supplies information demonstrating that the device "is as safe and effective as a legally marketed device" and "does not raise different questions of safety and effectiveness than the predicate device." § 360c(i)(1)(A)(ii).

The Petition demonstrates at length that FDA reviewers have been exhibiting the same anti-approval bias when considering the technological characteristics requirement that they exhibit when considering the "same intended use" requirement. Petition at 33-38. In particular, many reviewers start with a presumption that if the new device is technologically different from the predicate device, then it must raise new questions of safety and effectiveness. *Id.* at 34. That presumption is scientifically unfounded and has no statutory basis. In the absence of hard evidence to the contrary, reviewers may not reject the manufacturer's information demonstrating that the new device "does not raise different questions of safety and effectiveness than the predicate device."

While the 1986 and 1998 guidance document included a warning against such a presumption—as well as a requirement that the two devices should be deemed to have the same "technological characteristics" unless the differences were "consequential"—the New 510(k) Guidance includes no such warning. Indeed, the New 510(k) Guidance is written in a complex, "granular" manner that divides the process into three steps and seems to encourage reviewers to find that the "technological characteristics" requirement has not been met. *See* Petition at 14.

Step One requires "identification of technological characteristics of the new and predicate device." The New 510(k) Guidance directs a manufacturer to include in its § 510(k) submission not only detailed information regarding all technological features of the device (far more information of this sort than previously required) but also to identify the "clear purpose" of each aspect of the device "within the context of the overall design and intended use." The Guidance adds, "In cases where this [clear purpose] is not apparent, it is important for the 510k) submission to provide a discussion of how a particular device design or component contributes to the overall use and function of the new device." The Guidance never explains, however, why FDA views this information is "important"; the importance of the information is far from self-evident, given that the purpose of each component bears no obvious relation to whether the new device has "the same technical characteristics" as the predicate device. One is strongly tempted to conclude that FDA seeks this information because it desires to use the information to assist in efforts to incorporate other requirements into the § 510(k) process—a desire that, as the Petition demonstrates, FDA has regularly attempted to put into practice in recent years. *See, e.g.*,

Petition at 31-32. The FDCA cannot plausibly be interpreted as authorizing the request of such "purpose" information.

The Guidance requires, as Step Two in the evaluation process, that reviewers undertake a side-by-side comparison of the technological characteristics of the new and predicate devices to determine whether those characteristics are identical. While previous guidance documents concerned themselves only with "consequential" differences, that word has been deleted from the New 510(k) Guidance. It makes clear that § 360c(i)(1)(A)(i)'s criterion is not satisfied unless the technological characteristics of the two devices are "the same." Moreover, because of the greatly increased volume of technical information that manufacturers are required to supply in connection with Step One, the New 510(k) Guidance virtually assures that reviewers will conclude, at the conclusion of Step Two, that the technological characteristics of the two devices are not "the same."

Step Three requires reviewers to evaluate the differences in technological characteristics of the two devices "to determine whether they raise different questions of safety and effectiveness for the new device as compared to the predicate device." The New 510(k) Guidance provides only one additional explanatory sentence for Step Three: "A 'different question of safety or effectiveness' is a question raised by the technological characteristics of the new device that was not applicable in the 510(k) for the predicate device, and poses an important

safety or effectiveness concern for the new device."[1] The Guidance then proceeds to provide multiple examples of new devices that flunk the "technological characteristics" requirement but no examples of new devices that meet the requirement. The substance and tone of the Guidance contrast sharply with that of the 1986 guidance, which focused primarily on whether the technological changes in the new device were "consequential" and explained that the "consequential" determination should be based on: (1) whether "the new device poses the same type of question about safety and effectiveness as a predicate device"; (2) whether "there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of the new technological characteristics"; and (3) whether "there are data to demonstrate that new technological characteristics have not diminished safety or effectiveness." It is reasonable to conclude that one or more of the three examples listed in the New 510(k) Guidance would have resulted in an SE determination if evaluated under the 1986 guidance. The primary basis for FDA's determination that the new devices in its three examples were not SE was its assertion that the use of different materials (*e.g.*, "native polymer versus recombinantly-produced synthetic tissue") required a conclusion that "there are different questions of safety and effectiveness." But under the 1986 standard, reviewers would have been required to ask whether, despite the differences in material, the new device "does not raise

[1] A possible interpretation of this sentence is that FDA considers a new device not to be SE if the technological characteristics of the new device raise safety and effectiveness questions that were not actually considered during the § 510(k) process for the predicate device. If that is the meaning intended by FDA, then this provision is inconsistent with the statutory language, for reasons identical to those discussed in connection with the "same intended use" requirement.

different questions of safety and effectiveness than the predicate device" because the two devices pose "the same *type* of question about safety and effectiveness." WLF respectfully submits that the 1986 guidance more faithfully adheres to the language and intent of 21 U.S.C. § 360c(i)(1)(A) than does the New 510(k) Guidance.

Nor can the New 510(k) Guidance be squared with the FDCA's "Least Burdensome" requirement. Section 513(i)(1)(D)(i) of the FDCA, 21 U.S.C. § 360c(i)(1)(D)(i), provides:

> Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

The extraordinary detail of the technological information that the New 510(k) Guidance directs manufacturers to supply to FDA cannot possibly constitute the "least burdensome means" of demonstrating substantial equivalence, particular with respect to a statute characterized by the Supreme Court as one that "requires little information." *Lohr*, 518 U.S. at 479. Nor is the Guidance's apparent bias against "substantial equivalence" determinations consistent with the terms of a federal statute that, according to the Court, was intended "to ensure that improvements to existing devices can be rapidly introduced into the market." *Id.* at 478.

In sum, FDA should withdraw the New 510(k) Guidance because it does not accurately implement the 510(k) process mandated by Congress.

V. Failure to Comply with the APA

Even if FDA's new understanding of the § 510(k) process were a plausible interpretation

of the underlying statutes, FDA is seeking to implement that new understanding in a manner that violates the Administrative Procedure Act.

Congress adopted the § 510(k) process in 1976 at the same time that it began regulating the introduction of new medical devices into the market. Throughout most of the ensuing years, FDA liberally construed the § 510(k) process's "substantially equivalent" requirement such that "510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Lohr*, 518 U.S. at 479.

Although the statutory provisions governing the § 510(k) process have not changed, FDA now espouses a far more limited interpretation of the term "substantial equivalence," a change that will make it much harder for manufacturers to obtain clearance under the § 510(k) process. FDA undoubted takes the position that its new interpretation of the FDCA is a plausible interpretation of the statutory language. WLF respectfully disagrees, for the reasons set forth in Parts III and IV above. But even if FDA were correct in its interpretation of the FDCA, the APA does not permit an administration agency to (as here) change its new interpretation of the statute it administers, without first complying with the APA's formal notice-and-comment requirements, which are set forth at 5 U.S.C. § 553(b) & (c). It is undisputed that FDA's issuance of a draft guidance document did not satisfy those formal requirements.

The APA imposes formal notice-and-comment requirements on all "legislative" rules. A rule is legislative (and thus subject to notice-and-comment procedures) if the rule "effectively amends a prior legislative rule." *Am. Mining Cong. v. Mine Safety & Health Admin*, 995 F.2d

1106, 1112 (D.C. Cir. 1993). As the D.C. Circuit has explained, unless an agency action that modifies its prior interpretation of a formal regulation is subject to notice-and comment rulemaking requirements, "the agency could evade its notice and comment obligation by 'modifying' a substantive rule that was promulgated by notice and comment rulemaking." *Syncor*, 127 F.3d at 94-95 (quoting *Paralyzed Veterans of America v. D.C. Arena, L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997)).

FDA adopted its regulations implementing the § 510(k) process with the understanding that "substantial compliance" was to be liberally construed and that § 510(k) submissions from manufacturers were to be evaluated in the manner set forth in previous guidance documents. As evidenced by the New 510(k) Guidance, FDA has substantially altered its interpretation of the statute. Under those circumstances, the New 510(k) Guidance is a "legislative" rule and cannot be adopted unless FDA first complies with the APA's formal notice-and comment procedures. Accordingly, FDA should withdraw the New 510(k) Guidance. If FDA wishes to adopt the rules set forth therein, it should do so initiating a new, formal rulemaking proceeding.

VI. *Conclusion*

The Washington Legal Foundation respectfully requests that FDA grant the MMDA's Citizen Petition. FDA should withdraw the New 510(k) Guidance and announce that it will once again adhere to § 510(k) evaluation policies set forth in guidance documents issued in 1986 and 1998. FDA should also initiate a new training program for all FDA reviewers to ensure that they fully understand the requirements of the MDA and that they are reminded that § 510(k) clearance should be granted as a matter of course whenever a manufacturer demonstrates "substantial equivalence" to a predicate device, as that term was understood by Congress.

Sincerely,

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel

/s/ Cory L. Andrews
Cory L. Andrews
Senior Litigation Counsel

cc: Margaret Hamburg, FDA Commissioner
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