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Docket No. FDA-2016-D-2021

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COMMENTS

of

**WASHINGTON LEGAL FOUNDATION**

to the

**FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH & HUMAN SERVICES**

Concerning

**DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF:  
“DECIDING WHEN TO SUBMIT A 510(k)  
FOR A CHANGE TO AN EXISTING DEVICE”**

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED  
AT 81 *FED. REG.* 52443 (AUGUST 8, 2016)

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November 11, 2016

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**202-588-0302**

November 11, 2016

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

**Re: Draft Guidance for Industry and FDA Staff:  
Deciding When to Submit a 510(k) for a Change to an Existing Device  
81 Fed. Reg. 52,443 (August 8, 2016)  
Docket No. FDA-2016-D-2021**

Dear Sir/Madam:

Washington Legal Foundation (WLF) appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Draft Guidance (cited above) regarding when a change in an existing medical device triggers a requirement that a manufacturer submit a new premarket notification (510(k)) to FDA.

WLF applauds the detailed nature of the Draft Guidance, which provides device manufacturers with a roadmap in making decisions regarding the need to file a new 510(k). While the current guidance document (issued in 1997) has served manufacturers well for many years, it undoubtedly is in need of updating. Moreover, the Draft Guidance is a marked improvement over FDA's ill-fated 2011 draft document, which the agency was eventually forced to withdraw in the face of congressional opposition.

While there is much to commend in the Draft Guidance, these comments set out several suggested changes. In particular, WLF is concerned by the Draft Guidance's offhanded reference to manufacturers' alleged right to make unilateral changes to product labels. That

issue has serious implications for products-liability litigation; WLF urges FDA to delete all references to unilateral label changes and instead address that issue in a separate, more comprehensive regulatory proceeding.

**I. *Interests of WLF***

Washington Legal Foundation is a public-interest law firm and policy center with members and supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote free enterprise, civil liberties, limited and accountable government, and the rule of law. To that end, WLF has frequently appeared in judicial and administrative proceedings to ensure that administrative agencies adhere to proper procedures. *See, e.g., Peres v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015); *Shinseki v. Sanders*, 556 U.S. 396 (2009); *Tennessee v. FCC*, 832 F.3d 597 (6th Cir. 2016).

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 twice 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*, 67 F. Supp. 3d 125 (D.D.C.

2014); *Prevor v. FDA*, 895 F. Supp. 2d 90 (D.D.C. 2012). WLF's "OPDP Watch" project critiques warning letters and "untitled" letters issued by FDA's Office of Prescription Drug Promotion; 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 mandatory notice-and-comment procedures.

WLF is concerned that portions of the Draft Guidance propose adoption of substantive rules for which FDA is required to employ formal notice-and-comment rulemaking procedures prescribed by the APA. WLF raised similar concerns with respect to a February 2013 FDA draft guidance and again with respect to a July 2013 draft guidance. *See* "Distinguishing Medical Device Recalls from Product Enhancements; Reporting Requirements," 78 Fed. Reg. 12,329 (Feb. 22, 2013) (WLF comments filed on May 23, 2013); "Medical Device Reporting for Manufacturers," 78 Fed. Reg. 41,869 (July 9, 2013) (WLF comments filed on October 11, 2013).

## **II. *Statutory and Regulatory Background***

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq.*, to regulate the sale and distribution of drugs and medical devices to the public. The principal method by which device manufacturers obtain FDA authorization to market their products is the 510(k) "substantial equivalence" premarket notification procedure. *See* 21 C.F.R. §§ 807.81 *et seq.*

FDA regulations require the manufacturer of a currently marketed 510(k) medical device to submit a new 510(k) premarket notification to FDA if the device "is about to be significantly changed or modified in design, components, method of manufacture, or intended use." 21

C.F.R. § 807.81(3). FDA regulations define “significant changes or modifications” as follows:

- (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, *e.g.*, a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
- (ii) A major change or modification in the intended use of the device.

21 C.F.R. § 807.81(3)(i) & (ii). FDA regulations elsewhere require all marketed 510(k) devices to bear FDA-approved labels.

FDA has issued the Draft Guidance to assist manufacturers in determining when a change or modification in design, components, method of manufacture, or intended use qualifies as “significant.” FDA is to be commended for the comprehensiveness of the Draft Guidance; the examples it provides of factual situations for which FDA deems changes to be either significant or not significant should be particularly helpful in assisting manufacturers in determining whether they should submit a new 510(k).

### **III. *Unilateral Label Changes***

WLF’s concerns regarding the Draft Guidance focus on Section A, entitled “Labeling Changes.”<sup>1</sup> In particular, WLF is concerned by the following paragraph in Subsection A2, which offhandedly states that FDA will permit manufacturers, in some instances, to make unilateral changes in their product labels in seeming violation of FDA labeling regulations:

Changes in the labeled contraindications for device use generally could significantly affect safety or effectiveness of a device and should typically be reviewed by the

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<sup>1</sup> WLF has not identified any concerns regarding Section B (changes in the technology, engineering, or performance of a device) or Section C (changes in the material from which a device is manufactured).

Agency, however, FDA recognizes that, in general, the addition of a contraindication based on new information is important to public health. Because of this, manufacturers are encouraged to add new contraindications to their labeling and to notify existing users of their device as expeditiously as possible whenever a pressing public health need arises. The new labeling should be submitted to FDA as part of a new 510(k) that is prominently labeled “change being effected” (CBE, in Figure 2 - Flowchart A). FDA does not intend to take enforcement action against a device marketed with the modified labeling that is submitted as part of a new CBE 510(k) while the 510(k) is pending. Manufacturers should ensure they are thoroughly familiar with the definition of a contraindication in such situations.

Draft Guidance, Lines 519-531.

As FDA is undoubtedly aware, whether a manufacturer has a right to change its product labels without advance authorization from FDA has enormous ramifications for product-liability litigation. Many lawsuits filed against drug and device manufacturers are based on a claim that the manufacturer failed to place adequate safety warnings on its product labels. The Supreme Court has held that if a manufacturer may not modify its FDA-approved product labels without obtaining advance approval of the change from FDA, then state-law tort actions asserting that the label contained inadequate warnings are impliedly preempted by federal law. Under those circumstances, federal law prohibits a manufacturer from making the unilateral label change that a tort claimant asserts it should have made, and thus the state-law claim is barred under “impossibility preemption” doctrine. *PLIVA v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

As the Draft Guidance recognizes, FDA regulations normally prohibit 510(k) device manufacturers from making significant labeling changes without prior FDA authorization. Accordingly, device manufacturers are able to assert a substantial implied-preemption defense to

failure-to-warn claims; that defense is in addition to whatever express-preemption defense might also be available. *Cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). By announcing a “we won’t take enforcement action against violators” policy, FDA appears to be cutting the legs out from underneath an otherwise-valid litigation defense.<sup>2</sup>

Any decision by FDA to significantly alter its 510(k) device labeling rules is a “substantive” rule change that requires compliance with the APA’s formal notice-and-comment requirements. 5 U.S.C. § 553(b) & (c). Indeed, FDA’s “changes being effected” policy with respect to devices subject to pre-market approval (PMA) requirements was adopted through notice-and-comment rulemaking. *See* 21 C.F.R. § 814.39. If FDA wishes to adopt a CBE policy with respect to 510(k) devices, it must do so in compliance with the APA, not in an offhanded aside in a draft guidance.

There may be instances in which new safety-related information obtained by a device manufacturer is so urgent that the manufacturer should not wait the 30 days normally required by § 807.81(3) before adding a contraindication to its product label. But if so, the implications of such a policy are sufficiently important that FDA should initiate regulatory proceedings that would spell out in detail when such unilateral action is required, not simply announce a non-enforcement policy in a single sentence contained in the Draft Guidance. WLF notes that the regulation governing unilateral label changes by PMA device manufacturers requires

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<sup>2</sup> Similar FDA CBE-related efforts have met stiff resistance from industry groups and Congress, largely because they would have led to substantially increased litigation exposure. *See, e.g.*, “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products – Proposed Rule,” 78 Fed. Reg. 67,985 (November 13, 2013).

manufacturers to wait 30 days after providing FDA with notification of a proposed change before making a unilateral change. 21 C.F.R. § 814.39(f). The Draft Guidance does not explain why FDA believes a similar 30-day waiting period is not warranted for the addition of contraindications to the labels of 510(k) devices.

#### ***IV. Need for a Safe Harbor Provision***

WLF commends FDA for recognizing the role that the Quality System Regulation (QSR) can play in a manufacturer's evaluation and documentation of device modifications/changes. Adherence to the QSR should provide manufacturers with significant guidance in determining whether a new 510(k) must be submitted. Documentation of the evaluation process will also permit manufacturers to demonstrate to FDA inspectors that they have carefully considered whether a new 510(k) is required.

WLF urges FDA to revise the Draft Guidance to make explicit that adherence to the QSR will generally absolve the manufacturer from liability for failing to submit a new 510(k) when the manufacturer has made a good-faith determination that no new 510(k) is required. Particularly in light of recent federal government decisions to initiate criminal proceedings against individuals who allegedly violated federal requirements to seek a new 510(k) for an existing device,<sup>3</sup> creating a safe harbor is warranted both as a matter of procedural fairness and as a means of inducing increased compliance with QSR documentation requirements.

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<sup>3</sup> See Jeffrey S. Buckholtz, *et al.*, "The *US v. Vascular Solutions* Acquittal: Three Lessons for Targets of 'Off-Label Promotion' Enforcement," WLF LEGAL BACKGROUNDER (April 29, 2016).

**V. *An Inappropriately Broad Definition of “Labeling”***

The Draft Guidance appropriately distinguishes between a device’s “label” and its “labeling.” It defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article.” Lines 2667-68 (citing Section 201(k) of the FDCA, 21 U.S.C. § 321(k)). “Labeling” is defined more broadly to include “all labels and other written, printed, or graphic matter (1) upon any article or its containers or wrappers, or (2) accompanying such article.” Lines 2670-73 (citing Section 201(m) of the FDCA, 21 U.S.C. § 321(m)). That portion of the definition of “labeling” is unobjectionable. But the Draft Guidance then expands upon the definition, stating, without any statutory or case-law citation, that “labeling” can also include, “in some instances, promotional literature.” Lines 2672-73.

That broadened definition is unwarranted because it is contrary to Supreme Court case law. The error is of crucial significance, because it has the effect of permitting FDA to charge 510(k) device manufacturers engaged in allegedly improper promotion with having violated the file-a-new-510(k) requirement. If promotional activity could qualify as a “labeling” change (which it cannot), then such charges would be permissible because, as FDA explains:

[T]his guidance identifies several types of labeling changes or modifications that have a major impact on intended use and thus would require submission of a new 510(k). FDA interprets major changes in intended use to be a type of change that could significantly affect safety or effectiveness.

Draft Guidance, Lines 378-81.

The FDCA defines “labeling” as “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21

U.S.C. § 321(m). While *Kordel v. United States*, 335 U.S. 345 (1948), held that the word “accompanying” as used in § 321(m) is to be defined broadly, *Kordel* still required that there be a spatial relationship between a product and the written material alleged to constitute “labeling” for that product. In other words, “promotional material” that lacks any spatial relationship with the device (*e.g.*, materials provided to doctors who are not also being provided the device) *is not labeling*. Accordingly, even if FDA officials conclude that the distribution of promotional materials that discuss an off-label use violates some other provision of federal law, such distribution is not a “labeling change” within the meaning of federal law.

WLF is not claiming that device manufacturers have a completely unfettered right to promote their 510(k) devices for off-label uses. Under appropriate circumstances, such promotion might constitute evidence that the device is “misbranded.”<sup>4</sup> But FDA errs in asserting that promotional material constitutes “labeling” and thus can be consulted in determining whether a “labeling change” requires the submission of a new 510(k). WLF urges FDA to amend the Draft Guidance by deleting the reference to “promotional material” from its definition of “labeling.”

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<sup>4</sup> Of course, any such “misbranding” charges are subject to substantial First Amendment defenses. See *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

**CONCLUSION**

WLF commends FDA for its comprehensive effort to update the 1997 guidance document. It urges FDA to amend the Draft Guidance in the manner outlined above.

Sincerely,

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