

Johnson & Johnson

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933-

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March 23, 1998

Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Drive Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0477

To Whom It May Concern:

Johnson & Johnson respectfully submits these comments, in duplicate, in response to the Advanced Notice of Proposed Rulemaking (ANPR) entitled "Refurbishers, Rebuilders, Reconditioners, Servicers, and "As-Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Requests for Comments and Information." 62 Fed. Reg. 67011 (Dec. 23, 1997).

We shall address each of the issues on which the Food and Drug Administration (FDA) has solicited comments. However, Johnson & Johnson believes that all of the issues raised by FDA collectively warrant a general discussion. This discussion is necessary because FDA has failed to explain how the elements of the ANPR protect the public health and has failed to provide a legal justification for:

1. Exempting broad classes of manufacturers from some or all of the general controls provisions without regard to Section 513 of the Federal Food, Drug and Cosmetic Act.
2. Using legally irrelevant criteria such as device ownership to form regulatory policy.
3. Imposing dissimilar regulatory requirements on manufacturers that distribute similar products.

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I. GENERAL COMMENTS

A. Purpose of the 1976 Amendments

Implicit in FDA's ANPR is the assumption that the FDA has the discretion to dispense with pre-market controls for broad classes of manufacturers as long as disclosure of the fact that the product is refurbished or is being sold "As-Is" occurs. The inclusion of post-marketing controls over devices in The Federal Food, Drug, and Cosmetic Act of 1938 (the "Act") was considered by Congress to be an appropriate response to the proliferation of false therapeutic claims during an era which saw the sale of rather technologically naive devices. In contrast, the three-tiered device classification process and premarket requirements of the Medical Device Amendments of 1976 (MDA) were precipitated by Congress's concerns about the technological complexities intrinsic to "modern" devices. A brief account of concerns held by Congress is illustrative:

[In contrast to the concerns that led to the inclusion of post-market controls in the Act] FDA began focusing more attention on hazards from legitimate medical devices around 1960. The post-war revolution in bio-medical technology had resulted in the introduction of a wide variety of sophisticated devices. New developments in the electronic, plastic, metallurgy, and ceramics industries, coupled with progress in design engineering, led to invention of the heart pacemaker, the kidney dialysis machine, defibrillators, cardiac and renal catheters, surgical implants, artificial vessels and heart valves, intensive care monitoring units, and a wide spectrum of other diagnostic and therapeutic devices. Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use. (Emphasis added).

H.R. Rep. No. 94-853, 94th Cong., 2nd Sess., at 7-8 (1976). Indeed, Congress's concerns are even more valid today, as the explosion of technology has continued to accelerate for the past 20 years. The MDA's device-specific classification requirements continue to address the concerns Congress expressed above -- concerns not dependent upon disclosures in labeling or advertising.

Congress's conclusion that postmarket controls are inadequate as a general remedy for all devices is dispositive with regards to FDA's consideration of exempting remarketers en masse from some or all of the general controls provisions of the MDA. While FDA certainly has the authority to exempt manufacturers -- of all types -- from many of the general controls found in the

classification requirements.

Section 513 of the Act (as amended) provides specific processes and findings necessary to relieve a manufacturer from compliance with any general controls for a specific device. Notably, Section 513, which may be used by FDA to exempt a device from one or more general control requirements, speaks to findings peculiar to individual devices. Should FDA choose to pursue a course intended to relieve remarketers of the burden of compliance with one or more of the general controls provisions, it must do so consistent with Section 513 and 21 CFR Part 860 of the FDA regulations governing classification and reclassification. The remarketing of today's sophisticated medical devices, such as cardiac and renal catheters, heart valves, defibrillators and heart pacemarkers, cannot collectively be found to not change the collective group's safety, efficacy, or intended use; instead, such findings must be affirmatively demonstrated to FDA for each individual device type on a manufacturer-by-manufacturer basis. This is not just common sense; it is the law, and FDA has not considered these legal constraints in its ANPR.

B. Other Relevant Legal Provisions

1. "Ownership"

The MDA and its amendments have never considered device ownership relevant to the controls to be placed on the manufacturer of a device. No mention of ownership appears in the law, including Section 301, FDC Act ("Prohibited Acts") nor in FDA's implementing regulations in Parts 807, 820, or anywhere else. Rather, it is the activity one is engaged in that may subject one to general controls and violations.

For instance, Section 509(b) of the Act (as amended) provides that "...every person who owns or operates any establishment...engaged in the manufacture, preparation, propagation, compounding, or processing of...a device...shall register..." The term "manufacture, preparation, propagation, compounding, or processing" includes "repackaging or otherwise changing the container, wrapper, or labeling of any ...device package in furtherance of the distribution of the...device from the original place of manufacture to the person who makes final delivery for sale to the ultimate consumer or user..." Section 510(a)(1), Act. Section 510(k) provides that each person who is required to register and who proposes to introduce a device into interstate commerce for commercial distribution shall file a premarket notification with FDA. In FDA's regulations, so-called "toll-manufacturers" are subject to registration, listing, good manufacturing practices, and premarket notification, the latter requirement being waived only if the device's specifications are dictated by the person who actually will distribute the product (usually meaning the one who owns the device).

None of these provisions distinguish between owners and non-owners of the devices. In fact, the courts have consistently held not that passage of title has relevance to whether one is commercially distributing a device, but, rather, that it is the activity that one is engaged in that is determinative. See United States v. Articles of Drug...HCL, 568 F.Supp. 29, 31 (D.N.J. 1983) (“An article is ‘held for sale’ if it is used for any purpose other than personal consumption.”) Moreover, refurbishers cannot escape regulation under the theory that they are merely acting as agents of the true “owners” of the devices they are refurbishing. If manufacturing is occurring, and the owners and agents are not complying with the general controls, FDA may take enforcement action against the violative product at any stage in the collaborative manufacturing process. See also United States v. Device Labeled “Cameron Spittle, Amblyo-Syntonizer,” 261 F.Supp. 243, 246 (D.Neb. 1966) (“The government may condemn a device even though not inherently dangerous and not presently in interstate commerce...Once an article is misbranded, it has violated the law and is subject to seizure at any time thereafter...”).

FDA’s Compliance Policy Guide (CPG) No. 7124.28 represents a policy that does turn on ownership. At the time it was issued, it operated to distinguish between reconditioners/rebuilders and servicers. “Servicers,” as the term was commonly understood, did not take ownership, but performed a task generally regarded as mere maintenance. Today, however, distinctions based on ownership have no meaningful boundary in the marketplace. Almost any device today can be sold, consigned, lent, leased, smart leased, etc., in order to defeat the Congressional scheme protecting public health and/or to create competitive advantages. Such malleable distinctions should not be included in any guidance FDA pursues in this area.

Because ownership is not relevant in the law or FDA’s regulations, FDA should revert back to the principles that are relevant, namely, the activity one is engaged in, such as manufacturing. By focusing on the legally defined and recognizable activity of manufacturing, rather than on ill-defined new concepts such as “As Is” remarketing, FDA will have a greater opportunity to fulfill its public health mandate and to ensure a level playing field among direct competitors.

2. Health Care Costs

Historically, it has been FDA’s position that health care costs are not relevant to its missions. This position is, of course, the only one FDA could take, as premarket approval/clearance and other legal criteria make no mention of cost savings or even lives likely to be saved.

Curiously, FDA stated in the ANPR:

FDA has preliminarily noted that rising health care costs and health care expenses have apparently contributed to the expanded sales of a growing variety of remarketed devices. (ANPR at 67012.)

While such a comment would not normally require response, the fact that FDA appears to be considering allowing “As Is” devices to be sold, and has refused to subject remarketed devices of all sorts to the same controls as those applied to original equipment manufacturers (OEMs), the agency has fostered an inference that FDA is incorporating a health care cost criterion into its considerations in this area. FDA should make clear in the record that it is not now taking into account health care costs when constructing any policies in this area.

3. The Legally-Required Level Playing Field

FDA has not proposed the precise consequences of being a refurbisher, a servicer, or an “As-Is” manufacturer. However, FDA is not at liberty to subject one person who makes a widget to one set of controls (based on FDA’s assignment to that person the title of “manufacturer”) and another person to a different set of controls (by assigning to that person the title of “As Is” or “refurbisher”). In reality, OEMs, and what FDA calls remarketers of all types are direct competitors. For FDA to assign unequal regulatory burdens to these competitors is arbitrary and capricious agency conduct that violates the Administrative Procedure Act (APA). See United States v. Diapulse Corporation of America, 748 F.2d 56, 62 (2nd Cir. 1984) (“The FDA must [regulate] even handedly” and may not “grant to one person the right to do that which it denies to another similarly situated.” The court also said, “Deference to administrative discretion or expertise is not a license to a regulatory agency to treat like cases differently.”)

II. SPECIFIC COMMENTS

A. Definitions

On page 67012 of the ANPR, FDA solicits comments on three classes of manufacturer. We have one general comment: these new classes of manufacturer are unnecessary, confusing and as mentioned, legally suspect, depending on their as yet unrevealed regulatory consequence. The law defines the term “manufacture, preparation, propagation, compounding, or processing of.... a device” and prescribes consequences for those activities. Johnson & Johnson believes it is the only term necessary. Having said that, we offer the following:

1. Refurbishers

FDA's ANPR does not explain the consequence of being a refurbisher. Therefore, to comment on the suitability of the term "refurbisher" is premature and potentially hazardous to the development of a sound policy.

With that caveat, the ANPR speaks only to a subset of refurbishers (and "As Is" remarketers), which by definition are likely to have the least impact on patient safety. That is, FDA's definition of "refurbishers" is limited to those persons who do not significantly change a finished device's performance or safety specifications, or intended use. It is unclear how FDA will regulate the activities of refurbishers, etc... that could significantly change the performance or safety specifications of a finished device. It could be assumed that FDA intends to maintain the view that all such entities remain subject to all provisions of the law and applicable regulations consistent with the language of CPG 7124.28. However, FDA makes no such statement in the ANPR and, in fact, indicates that it intends to revise this CPG based on its experience in this area and the comments to this ANPR, while providing no insight into what changes FDA is contemplating. This notice would have been an appropriate forum for FDA to share the views it has established to date, based upon its experience in this area. Without such a disclosure, the proposal is incomplete and confusing.

FDA's statement is also too broad to reflect the variety of activities performed by refurbishers etc. Most activities performed by refurbishers on devices that are labeled for reuse may not "significantly change a finished device's performance or safety specifications, or intended use" providing the refurbishers have complied with the Quality Systems Regulation. There is, however a growing practice, the reuse of devices labeled for single-use only, that deserves FDA's full attention. FDA's statement regarding refurbishers cannot be applied to this growing subset of device reuse.

FDA has correctly maintained that changing a single-use disposable device to reusable is a change in intended use that requires a 510(k) clearance, Blue Book Memorandum #K97-1. Original equipment manufacturers are required to show FDA data in the 510(k) demonstrating: the materials used can withstand the rigors of reuse, the design is such to allow easy cleaning, a validated cleaning and resterilization method, and how many times the device can safely be reused. If FDA requires this type of information from the OEM who understands the device design, materials, performance and specifications, then surely FDA should exercise the same level of control over refurbishers who may or may not have full knowledge of these same things. FDA's reply to this argument in recent public meetings has been that FDA has not been made aware of any major public health problem created by the practice of reusing single-use devices and, therefore, is using its regulatory discretion in not enforcing a premarket clearance requirement on refurbishers. This statement

turns the current regulatory construct regarding premarket clearance on its head, and violates the level playing field principles articulated in Diapulse.

If FDA were to use the same logic with respect to OEMs, very few 510(k) notifications would ever be required. While FDA appears willing to act only after a health risk has been positively identified for reuse, the Act's general controls are predicated upon an assumption that a product is unsafe until proven otherwise. The fact that FDA seems willing to set aside this most basic regulatory concept for single-use devices that are being reused is arbitrary.

2. "As Is"

The concept of an "As Is" remarketer is in direct conflict with the Act. The entire fabric of device regulation is woven around the concept that the public must be protected and that it has a right to assume that a device is safe and effective for the use for which it is labeled and promoted. For FDA to say that a given entity can sell a device, the operational condition of which is unknown and must be determined by the user prior to patient exposure, represents a return to a caveat emptor concept that Congress determined to be wholly inappropriate for medical devices. The concept is so contrary to the entire history and purpose of device regulation that it should be dropped from consideration.

3. Servicers

We have no comment on this definition here. However, refer to our comments under II.B.

B. Revisions Under Consideration

On page 67012, under heading V., FDA states:

FDA intends to evaluate the current regulatory approach with respect to marketers who are refurbishers, "As Is" remarketers and servicers, as defined in this document, and is soliciting comments on whether FDA should retain the current regulatory approach, or whether the agency should use alternative approaches to regulate these types of remarketers.

It is not apparent to us what the current regulatory approach is for "As Is" manufacturers. There is no place for this activity under U.S. law, and it is inconsistent with the public trust accorded FDA.

With regards to refurbishers, FDA's CPG 7124.28 should be revised to drop the ownership requirement. The ownership criterion is antiquated and

legally irrelevant. Servicers, to the extent they are manufacturers, should be treated the same as refurbishers, and the same as OEMs. To the extent that the manufacturer-servicer is the OEM or is working as an authorized representative of the OEM, no additional regulation may be necessary. However, manufacturer-servicers that are not affiliated with the OEM should have to demonstrate to FDA through conformity with the general controls that they know how to service individual device types. We emphasize the distinction here between servicers who merely maintain devices, and those that are engaged in actual manufacturing. We note that 510(k)'s are presently not required for most low-risk devices. For the higher risk categories, servicing -- to the extent it equals manufacturing -- could present risks. It is the responsibility of the manufacturer-servicers to demonstrate the lack of safety or efficacy issues, not the other way around.

C. Numbered Questions

1. Has FDA appropriately defined the terms, "refurbisher," "As Is" remarketers, and "servicers"? If not, what changes to the definitions should be made?

Again, the only definition that is legally relevant is "manufacture." FDA's hyper-technical alternative definitions to manufacturer are unnecessary and ill conceived legally. Even if one were to desire additional definitions, one first must know the consequence of the definitions in order to adduce the appropriateness of the definition to the consequence. Because FDA has not put forth regulatory controls different than that of fully regulated manufacturers, it is not apparent why alternative definitions are necessary. If FDA intends to have lesser requirements for these new categories of manufacturers, we oppose any discrimination against OEMs for both public health and competitive reasons. Please refer to our General Comment section.

2. What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing?

Very little reliable evidence is available for a very good reason; when such problems are reported, they are often attributed to the OEM, not the remarketer. Identification of equipment as being remarketed is often impossible. In any case, the burden is not on the public to demonstrate a lack of safety and efficacy (as it was until 1976); the burden is on each individual remarketer to affirmatively demonstrate the safety and efficacy of each device.

Robert H. O'Holla
Robert H. O'Holla
Vice President, Regulatory Affairs

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