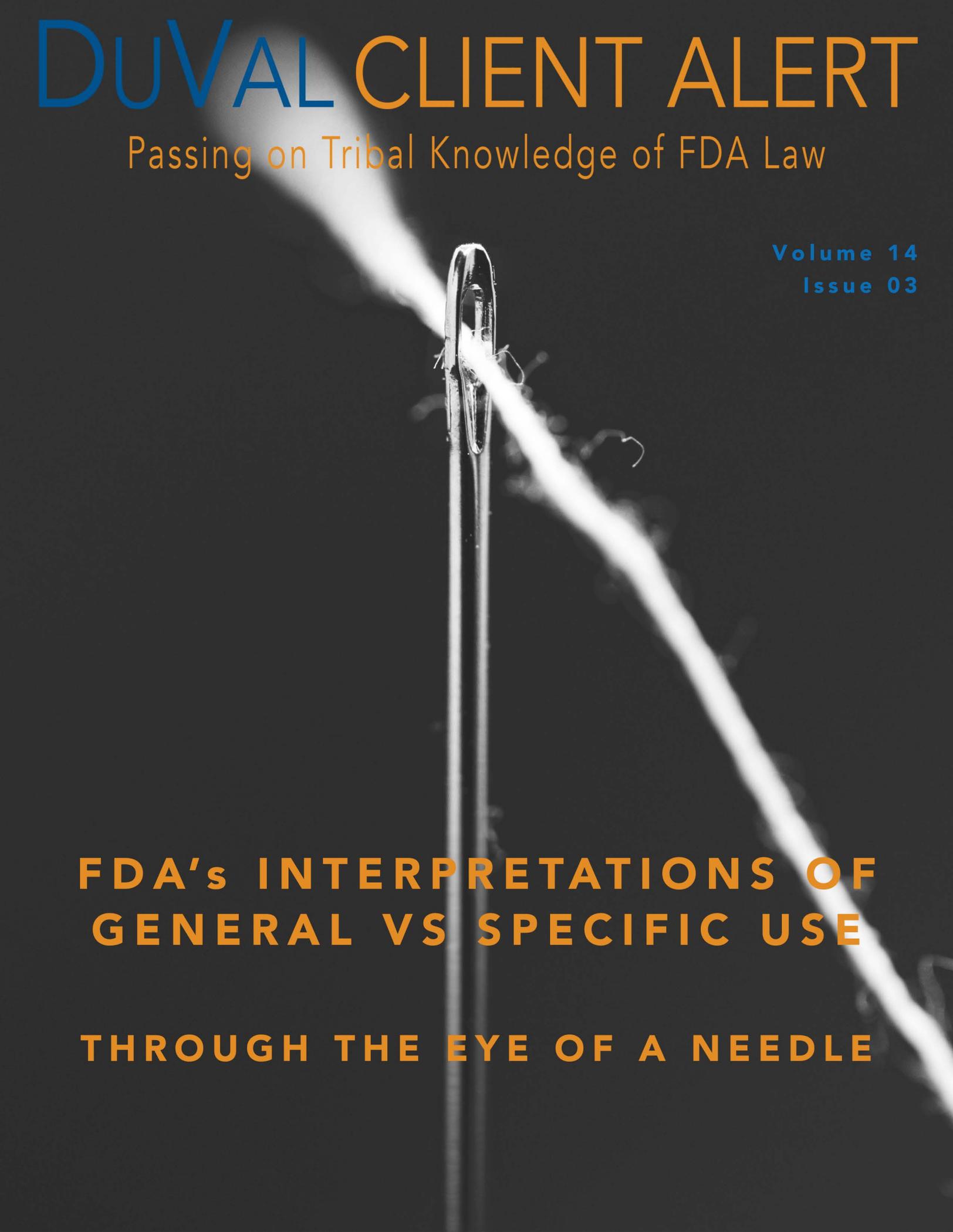


DUVAL CLIENT ALERT



Passing on Tribal Knowledge of FDA Law

Volume 14

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**FDA'S INTERPRETATIONS OF
GENERAL VS SPECIFIC USE**

THROUGH THE EYE OF A NEEDLE

FDA's Interpretations of: General vs. Specific Use

Through the Eye of a Needle

EXECUTIVE SUMMARY

FDA is reinterpreting FDA's view of "general versus specific intended use" so narrowly that FDA now considers almost every new indication for a 510(k) device to be a new intended use in contravention of the specific intent of the Congress. This Client Alert discusses FDA's (re)interpretation of its existing older guidance documents (K86-3 and the General/Specific Use Guidance). It also discusses where FDA seems to be headed with its newly proposed 510(k) guidance document "*Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*," (hereinafter "the New 510(k) Guidance") (challenged by our firm in a Citizen Petition filed in January 2013).

ANALYSIS

An overarching concern with FDA power

The more concerning goal of FDA narrowly defining intended use is that FDA can exercise more control over medical devices. By deciding that an

individual indication statement constitutes a new intended use, FDA maintains a higher degree of control over industry and inappropriately inserts itself into the practice of medicine. Instead of allowing devices to find their natural niche in medical use following a general clearance, FDA imposes its will on the process. This stems from a philosophical belief, that government knows better, and a fundamental paternalistic distrust that the patients must be protected **from** physicians exercising poor medical judgment. This means, for example, that an individual 510(k) device cleared five or ten years ago may have been safely used by physicians in different contexts not originally specified in the general intended use statement cleared by FDA – regardless of whether that context is anatomic location, patient population, tissue type, or whatever.

But that is not the case today. FDA can revisit these individual uses, decide they are off-label, and send a warning letter to the manufacturer alleging promotional violations. FDA's newly published draft guidance seems supportive, but in the trenches of CDRH that is not how things are interpreted. Indeed, that same device cleared today for a general use would have a difficult time marketing a specific use beyond its sometimes overly broad general clearance. **Today, FDA might require multiple clearances – one for each indication statement – where one or two would suffice in the past.**

The past practice that a company could stage its 510(k) indications by gaining clearance with a general, boilerplate intended use statement and then come back to FDA on successive occasions to obtain additional clearances for new indications, sometimes accompanied by a modicum of data and sometimes not, is beginning to become a thing of the past. That approach served both FDA and industry well when it allowed both parties to see how the first clearance performed in the marketplace and often allowed for the practice of medicine to indirectly and informally drive measured expanded use. **But again, we believe it is hard for FDA to cede control of the practice of medicine to the medical community when it**

comes to medical devices, even though FDA is not supposed to interfere with the practice of medicine.

The historical moorings of existing FDA guidance

One of the primary ways FDA is re-inventing the 510(k) program is to re-interpret when newly proposed language rises to the level of a ***new intended use***. FDA pays lip service to the general rule, articulated in longstanding guidance documents, that the labeling of the subject device need not be identical to the predicate device and that “label statements may vary.” In the longstanding, and still applicable, K86-3 Blue Book Memorandum, FDA states as follows:

The Center'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 different from those that were posed by the predicate device's intended use,*** the new device may be found SE.

CDRH Premarket Notification Review Program 6/30/86 (K86-3) (510(k) Memorandum #K86-3) (emphasis added in bold, italics and underlining).

Ironically, companies will still see FDA faithfully quote K86-3, typically in Not Substantially Equivalent (NSE) or Additional Information (AI)

letters, when it believes a new indication “alters the intended therapeutic/diagnostic/etc. effect.” This phrase will usually be cited with little to no accompanying analysis to justify FDA’s position, even though K86-3 and its companion guidance, the “General/Specific Intended Use” guidance, offer a helpful and thoughtful framework to assist industry and FDA in determining when a specific use is rightfully part of a general intended use. It’s as if FDA need not explain itself simply because it is FDA and, therefore, can making the conclusory pronouncement that the newly proposed use “alters the intended therapeutic/diagnostic effect.” **FDA’s pronouncements frequently proceed out of positional power, as opposed to the strength or persuasiveness of its analysis.**

It is interesting to note that Congress specifically requested that FDA provide guidance to industry on how it will effectuate Congress’ intent for the intended/indication for use issue in the Senate Report to FDAMA in 1997. It states:

The committee believes that FDA should state its policy regarding reliance on general use predicates in the context of a regulation. The regulation should state when reliance on a general use predicate is appropriate. **FDA should permit premarket notification submitters to provide information showing that specific uses for a device are reasonably included within a predicate's general use. For example, if the medical literature shows that a newer device is used for several specific uses within a predicate's general use, then FDA should permit the general use predicate to be the basis for a substantial equivalence finding for the newer device.** The FDA's regulation should seek to describe rules that the agency and industry can follow.

The Senate Report provides an example that if the medical literature shows a device is used for specific uses within a device's general use, FDA should permit the general use predicate to be the basis for a substantial equivalence determination for the newer device. FDA rarely allows this to happen. Our firm would be hard-pressed to find many examples in the last several years where FDA has allowed that to happen. This would not be the first or last time FDA seemingly ignores legislative direction and molds the 510(k) program in its own image/vision for the program.

The K86-3 guidance goes on to provide helpful analytical points FDA (should) consider in determining the safety and effectiveness questions raised by the indication for use. The CDRH once said it considers such points as:

- 1) physiological purpose (e.g., removes water from blood, transports blood, cuts tissue);
- 2) condition or disease to be treated or diagnosed;
- 3) professional or lay use;
- 4) parts of the body or types of tissue involved; and
- 5) frequency of use, etc.

Conventional Dialyzer: This type of pre-Amendments device is in class II. The pre-Amendments devices are labeled for use as part of artificial kidney system for patients with renal failure. The principal purpose of the device is to remove excess water from the vascular system. Some new devices that have been found SE are labeled for use as part of a heart-lung machine to remove excess water from the vascular system at the end of surgery. ***Again, the Center concluded that this 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, and moreover, there are no other significant changes (in technology, design, etc.); therefore, the devices are substantially equivalent.***

The labeling differences relating to the subclavian catheter [discussed above], the conventional dialyzer for use with the heart-lung machine, and the blood tubing set for plasmapheresis, ***are not significant enough to require a finding that the devices are for different intended uses.*** Moreover, the specific uses associated with the labeling modifications do not present issues of safety and effectiveness different from those posed by the use of their predicate devices, and therefore, the devices can be found SE in terms of intended use.

See *Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3) (510(k) Memorandum #K86-3)* (emphasis added in bold and italics).

Again, this example from FDA's guidance is actually encouraging, not discouraging. Unfortunately, FDA is drifting away from this type of interpretation unless the sponsor fights hard to keep it.

The difference between "intended use" and "indications"—the umbrella analogy. This has been a confusing point for industry. When we teach industry on what are "indications" in relationship to a general "intended use" statement cleared by the FDA, we use the analogy of an umbrella. A general intended use statement is, in reality, a bundle of specific indications for uses, albeit not stated specifically in the cleared general intended use statement. ***Without specifically stated indications, the device could often be used for everything and yet nothing.*** Ironically, FDA finds it perfectly acceptable if a company promotes a device in some impractical, overly broad, general way in which that device can be used without getting specific.

What are physicians to do with advertising and promotion that is broad and unspecific when health care providers need to know the types of patients in whom the device will have utility? And if FDA wants data on every possible type of patient in which a moderate risk, Class II device might have utility, a

company will not be able to spend all the money needed to conduct all the clinical trials necessary to bring the device to market in the U.S. (even though it will invariably have a CE Mark in Europe). In the end patients are deprived of valuable therapies due to a flawed approach now in vogue at FDA. The K86-3 guidance then goes on to provide examples which illustrate these concepts. One such example involves a conventional dialyzer being used first as part of an artificial kidney system and later found SE for use as part of a heart-lung machine. While the specific uses seemed wildly different, the intended use remained the same. FDA's commentary in the quote above is apropos to this discussion and is quoted after the example, i.e., "the labeling differences... are not significant enough to require a finding that the devices are for different intended uses."

One way to look at this is to consider an ablation device cleared for the ablation of soft tissue. Can it be used to ablate cardiac soft tissue? This probably is an acceptable indication under the general intended use statement. If the device can be used to ablate cardiac tissue, can it be used to specifically treat atrial fibrillation (the Cox-Maze procedure)? This, admittedly, is an unacceptable indication extension under the general intended use statement. Certain indications for use are contemplated by the general clearance and fall comfortably under the protective reach of the intended use umbrella—protected from the elements, i.e., protected from the criticism of FDA that the uses are off-label. When the uses are pushed too far, e.g., when the "tool," for ablating soft tissue—even cardiac tissue—becomes a "treatment," i.e., for atrial fibrillation, the use is deemed outside the protective reach of the umbrella and is deemed off-label. One is a proper indication for use falling under the general intended use statement. The other falls outside the protective reach of the umbrella and is deemed off-label, i.e., not a proper extension of the intended use statement.

FDA's New 510(k) Guidance Actually Provides Helpful Definitions

Although our firm has challenged the implementation of FDA's New 510(k) Guidance document, it does have some features that are good. For example, FDA for the first time provides definitions for the difference between an "intended use" and an "indications" for use, as follows:

"'Intended Use' means: 'the general purpose of the device—or what the device does—and encompasses the indications for use....'

'Indications for Use' means: 'the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.'"

See Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], at Section IV. D. 1.

These definitions are useful and consistent with our general historical position on them.

FDA's philosophical (we guess) shift in approach. It is highly unlikely today's FDA would make the interpretation provided above and in many, if not most, of the other examples cited in the older guidance documents. We attribute this to a philosophical shift and risk averseness in decision making. In the past FDA has taken a broader view of when a specific indication for use was part of the general intended use and, therefore does not create a new intended use. FDA used to believe that the general intended use was a bundle, if you will, of specific uses. Many specific indications were a logical subset of the general use. For example, often a device used as a "tool" could state the various and specific anatomic locations or patient populations in which it could be used, as long as the manufacturer did not

make specific therapeutic or treatment claims. ***The idea was that a generally cleared device had to be used somewhere and specific indication statements could tell physicians where.***

That was then, this is now.

Today, FDA has mostly abandoned its own guidance documents which assist FDA and industry in determining when a proposed labeling change creates a new intended use. Industry has far too long ceded ground to FDA on this principle and an institutional inertia has developed within FDA. The most important of the documents addressing these issues are FDA's "Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)" and "Guidance for Industry: General/Specific Intended Use, issued on November 4, 1998." These thoughtful documents actually reflect an understanding that the 510(k) program a) was designed to allow some labeling changes, even new indications for use, as long as they did not rise to the level of a new intended use; b) contemplated that new language, even new indications, could be accommodated under the 510(k) program, and c) did not so restrictively interpret the 510(k) program so that reasonable medical and scientific extrapolations could be made to modestly extend the labeling, and therefore use. By doing so, FDA cooperated with the natural flow of medical practice. As physicians, using good medical judgment, found uses for a tool, FDA did not attempt to interfere with its use and allowed manufacturers to promote that use.

Companies should argue their position using the General/Specific Intended Use guidance

When companies make submissions, they should not concede their position to FDA. Often review staff and a Branch Chief may not agree with the company, but management above them (Division Directors and Office Directors) will. The key to getting review staff and a Branch Chief to agree with your original position on general versus specific intended use is to

construct the argument carefully so it a) is logical and compelling, b) demonstrates to lower level staff the company actually knows what it is talking about, and c) which impliedly suggests the company may appeal an adverse decision which makes no sense. The General/Specific Intended Use guidance document is especially helpful in deciding when a proposed labeling change falls under the current general intended use statement for its device. This guidance lists “Levels of Specificity” and “Decision Making Criteria” to determine if the claim sought fits within the general intended use statement. We quote the “Levels of Specificity” and “Decision Making Criteria” below.

- Levels of Specificity for therapeutic (including preventive) medical devices:

Identification of function (e.g., cut)

Identification of tissue type (e.g., soft tissues)

Identification of an organ system (e.g., GI tract)

Identification of a specific organ (e.g. liver)

Identification of a particular disease entity (e.g., resection of hepatic metastases) or target population

Identification of an effect on clinical outcome (e.g., use of medical device improves the rate of durable complete remissions with chemotherapy)

- Decision-Making Criteria

The criteria that follow are provided as guidance on the Agency’s decision-making process for determining substantial equivalence or non-equivalence for general/specific uses. The list of criteria should not be considered to be all-inclusive. Nor should the list be viewed as a scale which can be used to calculate a particular outcome. Rather, these criteria should be seen as important contributing factors, which, when used appropriately, can help the agency consistently arrive at

reasonable regulatory decisions that relate to the safety and effectiveness of medical devices. These criteria should be evaluated in connection with the Levels of Specificity described earlier in this document.

Risk – Does a specific use introduce new risks not normally associated with the general use of the device?

Public Health Impact – Does a specific use impact public health to a significantly greater degree than the general use of the device? Differences in public health impact can result from changes in target population. These changes may have quantitative dimensions, but routinely will also affect safety and effectiveness because of major qualitative differences in how the device is to be used (e.g. diagnosis vs. screening, cutting soft tissue vs. treating breast cancer).

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 practice guidelines.

Endpoints – To what degree can the performance or clinical endpoints (e.g., ability to ablate tissue; prevention of STDs) used to evaluate the general use be applied to the specific use?

Tool or treatment? – To what degree is the device used by the physician intended to perform a task (e.g., a scalpel) as opposed to "being" the treatment (e.g., extra corporeal shock wave lithotripter)?

Adjunctive therapy – To what degree does another product not routinely needed for the general use need to be used in conjunction with the device to achieve the specific use safely and effectively?

Design changes – To what extent does a modification to a medical device to facilitate the specific use render it less applicable to the other aspects of the general use?

Guidance for Industry: General/Specific Intended Use, issued on November 4, 1998.

Today FDA's administrative default position is to take almost any labeling change and denominate it as a new intended use which means a 510(k) SE determination is not possible. This is typically done with little or no analysis provided to the manufacturer. This Administration has taken the "Decision Making" tools found in the General/Specific Intended Use guidance document and interpreted them so narrowly that there are few labeling changes today that would ever qualify for as an indication under a cleared general intended use statement. ***But, again, a well-constructed argument in the original 510(k) gives the sponsor its best chance of winning at the review level and certainly sets the company up well for an appeal, if necessary.***

Concerns with the new 510(k) draft guidance document

As set forth above, the new draft guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," dated December 27, 2011, begins by explaining the difference between "intended use" and "indications for use." These are two definitions that have not been explicitly defined and have been confused for years. We

applaud FDA for finally providing those definitions. FDA's new guidance also states the following, which is encouraging, because it continues to recognize (as in past FDA guidance) that there can be differences in populations, diseases, etc. and the device still can have the same intended use:

As discussed in the Intended Use Section of this guidance, ***differences in indications for use, such as the population for which a device is intended or the disease a device is intended to treat do not necessarily result in a new intended use.*** Such differences result in a new intended use when they affect (or may affect) the safety and/or effectiveness of the new device as compared to the predicate device and the differences cannot be adequately evaluated under the comparative standard of substantial equivalence.

Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," dated December 27, 2011, at page 4 (emphasis added).

The concern is that this definition changes the existing statutory and regulatory standard for the 510(k). FDA cannot legislate change, only Congress can. The standard for a 510(k) is does it have a) the same intended use, b) the same technological characteristics, and c) if there are different technological characteristics, do they raise different questions of safety and effectiveness? In the proposed New 510(k) Guidance the FDA states that ***"Such differences result in a new intended use when they affect (or may affect) the safety and/or effectiveness of the new device as compared to the predicate device*** and the differences cannot be adequately evaluated under the comparative standard of substantial equivalence." Although this seems to make sense, superficially, it greatly and inappropriately expands FDA's ability (and authority) to decide an intended use does not fall under a general intended use.

FDA is supposed to determine if the specific indication for use falls under the general intended use. If it does, it goes without saying that the sponsor must provide data to establish its safety and effectiveness in the new use. The requirement for substantiation does not change. ***But the definition of intended use does not allow FDA to consider if the use affects or may affect the safety or effectiveness of the new device, because typically it will.*** That is why FDA rightfully asks for an (appropriate) Least Burdensome amount of performance data. The statute and regulations do not allow FDA to look at when the device affects or may affect safety and effectiveness to determine if an indication for use falls under an intended use.

Even when there is a different technological characteristic the inquiry is limited to whether the new technological characteristic ***raises different questions*** of safety and effectiveness. It is not the much lower threshold FDA proposes, i.e., whether it ***affects or may*** affect safety or effectiveness. The entire substantial equivalence definition presumes that the proposed indication or new technological characteristic of the proposed device affects or may affect the safety or effectiveness of the device. Again, that is why companies must provide substantiating data. As a result, FDA is attempting to throw devices off the 510(k) pathway, and on to the de novo or PMA pathway, by using its own inappropriate interpretation of the law.

The older guidance documents rightfully focus on the quality and character of the affect, not that mere fact there will be an affect. K86-3 Blue Book Memo and the General/Specific Use guidance documents focus on criteria that help characterize the nature and extent of the affect, not that there is one (see, e.g., “Levels of Specificity” and “Decision Making” criteria). FDA’s newly proposed guidance attempts to overly-simplify and short-change the analysis. It may reinforce (and undergird) FDA’s natural propensity to find a new indication does not fall under a general intended use.

Some of the discussion in the guidance simply outlines issues to be considered but do not go as far as the General/Specific Intended Use or the K86 Blue Book Memo guidance documents to provide a framework for analysis of how to determine when a newly proposed indication falls under the umbrella of the general intended use statement. While the new guidance does provide a useful explanation about how the FDA goes about making its decision, it provides only one example of how it would work. The example it does provide of a general surgery device is not particularly helpful. The newly proposed guidance also does not capture the concept found in the flow chart to the K86 Blue Book Memo of whether the labeling “differences alter the intended therapeutic/diagnostic/etc. effect” in deciding whether the use is the same intended use.

Another problem with the newly proposed guidance is that the emphasis is essentially narrowed to a focus on whether the indication is somehow different, and not whether it is a logical extension of the intended use. The analysis must start with the intended use, not the subsidiary indication for use. Considered this way, it is like saying “this tree looks different than this one,” as opposed to the proper analysis of stating “this tree seems to belong in this forest.”

We believe that FDA, in practice, has created artificial distinctions for when it concludes a use is on or off-label. This derives from three goals, one of which is meritorious, i.e., the FDA wants to ensure manufacturers are not over-stating the claims for the device for which there is no substantiation. The other two, to garner more control and authority over industry and to gain new users fees, are not.

The CoAxia NeuroFlo example. As an example of how FDA can use its interpretive decision making to support its power and control over device use and to support its frequent request for more and more data. Consider the actual case of a dual balloon catheter, already 510(k)-cleared for use in the descending aorta to divert blood flow from the lower extremities to the upper extremities, such as in the cerebral, cardiac and pulmonary

vasculature. In addition to two 510(k) clearances, the device has a Humanitarian Device Exemption (HDE) for use in cerebral ischemia patients. Accordingly, this device would thus be used in patients who need more blood in the head, such as those with cerebral ischemia or, arguably, ischemic stroke. The manufacturer conducted a 500+ patient randomized trial showing safety in using this device in ischemic stroke patients. The study also showed, on a post-hoc basis, a safety benefit, i.e. a reduction in mortality. Based upon this very solid data, the manufacturer sought a modest extension of the current labeling for use in ischemic stroke patients. FDA's review staff, almost inexplicably, fought this requested labeling for several years.

The question the FDA considered was whether the manufacturer should be able to clarify the labeling to state the device is a "tool" that could be used safely in ischemic stroke patients as long as the manufacturer did not claim the device as a "treatment" for ischemic stroke. The manufacturer argued that since patients with ischemic stroke are a clear subset of patients with cerebral ischemia, the tool claim is a specific indication logically and rightfully falling under the general intended use. In this therapeutic segment there is a lack of treatments available for patients with ischemic stroke (less than 10% of the 650,000 stroke patients each year benefit from acute treatment). Consider the cost to society if FDA does not allow such a device to be used to treat stroke patients who have few to no options. The manufacturer argued that FDA should: a) examine FDA's "Decision Making" criteria to determine if the claim could fall under the intended use, and b) assess the sponsor's data to see if the new use raises any new questions of safety and effectiveness that are not answered by the data. If the use could plausibly fit under the general use and the data support the use, the 510(k) path should be available to the manufacturer.

This example is taken from CoAxia's NeuroFlo catheter and FDA's review division (DONED) which ruled that the device was NSE because the proposed use constituted a new intended use. FDA found, according to

FDA's General/Specific Use guidance, that the proposed indication for use in ischemic stroke "involve the diagnosis, therapy or prevention of a particular disease or entity or entities, especially where such entity carries clinical implications not normally associated with other general uses of the device." FDA's decision with the CoAxia device shows how subjective this determination/interpretation is because this device can be used (off-label) in ischemic stroke patients today and the anatomic placement and physiologic purpose is identical for both the general use (redirection of blood flow to the cerebral vasculature) and specific use (redirection of blood flow for ischemic stroke). Moreover, FDA made its NSE decision without ever formally reviewing the clinical trial data.

If FDA wanted to embrace the 510(k) program and Least Burdensome requirements, it could just as easily justified a decision to find that the proposed use fell comfortably within the general use and granted substantial equivalence. The amount of clinical information was more than satisfactory to support the proposition that the device is safe for use in ischemic stroke. Instead, FDA used its NSE decision to treat the device – twice cleared and once HDE-approved – to force the device onto the PMA path (with a de novo stop in between) and support a request for yet another large clinical trial, thus effectively killing the company (by putting it out of business) and denying physicians and patients the beneficial use of this technology.

Some tips for your 510(k) submission and promotion

Tip One: *Ensure the device claim is substantiated and remains a "tool" claim and not a "treatment" claim.*

If this applies to your device, understand that FDA understandably clears devices with a general umbrella claim that it can be used for a general intended use such as a device for soft tissue ablation. FDA often reviews

devices that are “tools” for general use, versus “treatments” per se. When, for example, a manufacturer decides to claim a device cleared for soft tissue ablation can be used in cardiac ablation that is simply a specific anatomic location in which the “tool” may be used and still be within the general intended use. Cardiac tissue is soft tissue and if a physician were to be so inclined to ablate cardiac tissue with this device, nothing should prevent that from happening because FDA deems it an off-label use. When a claim is made that the same device can be used to treat atrial fibrillation, FDA is concerned that the claim for safe and efficacious use is unsubstantiated. FDA under its guidance calls these “therapeutic” or “treatment” claims. So an ablation device can be used to ablate cardiac tissue but cannot be claimed for use in treating atrial fibrillation.

The same is true of a device cleared for surgical aspiration device being used for liposuction. The general intended use statement for aspiration does not contemplate use for liposuction. In this case, the “tool” becomes the “treatment.” Similarly, think of a device used to safely remove salt and water from fluid-overloaded patients, similar to a dialysis machine. How does a manufacturer sell that device if they cannot describe the type of patients who might benefit from this use? If the manufacturer claims this device treats congestive heart failure, FDA might justifiably argue the tool has become the treatment. But if the manufacturer simply claims the device removes fluid from fluid-overloaded patients who present themselves with such etiologies such as severe burns, renal failure, congestive heart failure, among other maladies, the tool remains a tool. But the labeling now describes the types of patients who may benefit from this tool.

So make a tool claim and state a number of types of patients, conditions and/or anatomical locations for which the device may be used. Focusing on one type of patient, condition or anatomical location actually creates more issues for the company than to make a broader, more all-encompassing, less specific claim.

Tip Two: *Be strategic about your intended use statement—use the 510(k) as an advocacy document.*

Address these issues in advance in your 510(k) submission, don't leave them to chance. Position your device to meet the published guidance language and craft the submission to fit within them. Even quote portions of these guidance documents to demonstrate your familiarity with them and attempt to fit within them. It demonstrates respect for FDA's guidance and your attempt to follow them closely in making your submission. More importantly, it shows sophistication and an implied willingness to push/advocate your position. For example, use the "Levels of Specificity" and "Decision Making Criteria" in the General/Specific Use guidance to make your case. There must be a balance between having too much argumentation upfront in a 510(k) submission because it will look like you are defending your position well before you need to. Conversely, without any positioning upfront, you may be subject to a reviewer who a) is not knowledgeable about the guidance criteria, b) will take a position that fits their personal belief system (i.e. risk averseness and FDA's view is always right), and c) doesn't know your level of sophistication upfront.

Also, you can use an amalgam of 510(k) statements to construct your intended use statement. Be careful not to be too creative in constructing your intended use statement or you will create problems for yourself with the Agency.

Tip Three: *Make sure you understand the contours of the law, regulations, and guidance.*

That is the key to drafting your 510(k) and interfacing with the Agency. You need to be able to properly articulate and advance/defend your position and make rebuttals to the Agency staff. Without knowledge of the law, regulations and guidance, you are at the mercy of FDA's unfettered discretion and unarticulated positions. And if you need to appeal the

decision of a reviewer or Branch Chief, know that at the level of the Division Director, Office Director or Deputy Director for Science and Policy, they do know their stuff—so you had better know it too.

Tip Four: *When you market your general intended use strategize about how that can be done with management and marketing.*

When a company obtains a general clearance for its device and knows there will be specific, uses to which it may be put—uses that may be potentially controversial with FDA—it must dialogue and strategize internally how the device will be marketed or it will unfairly expose the sales and marketing organizations to FDA enforcement should they be too aggressive in their promotional efforts. This could draw FDA’s attention in the form of a warning letter or worse. It behooves management, with marketing and sales, to strategize about how this device can be marketed. This is the subject of our Client Alert that addresses the three “buckets” of promotion, dissemination and communication *“DuVal Client Alert: Lawful Pre-Approval & Pre-Clearance Communication”* which can be found on our website under the “Resources” section at www.duvalfdalaw.com.

DuVAL & ASSOCIATES

Drug, Device and Food Law

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