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August 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

***Re: Docket No. 98N-0331: Draft Guidance for Staff, Industry, and Third Parties
Implementation of Third Party Programs Under the FDA Modernization Act of 1997***

Dear Madam/Sir:

The Advanced Medical Technology Association (AdvaMed) is a Washington, D.C.-based trade association and the largest medical technology association in the world. AdvaMed represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's members manufacture nearly 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the \$159 billion purchased annually around the world.

AdvaMed is pleased with the opportunity to provide comments on the draft guidance for implementation of the third party review program and on the proposed expanded list of eligible devices.

General Comments

AdvaMed commends the agency for proposing to expand the list of Class II devices eligible for third party review by allowing third party review of all class II devices regulated by the Center for Devices and Radiological Health (CDRH) that are not prohibited from third party review under Section 210 of the FDA Modernization Act of 1997 (FDAMA). AdvaMed believes that all Class II devices that are not prohibited from third party review by statute should be eligible. AdvaMed supports the fact that the prohibitions for third party review eligibility defined in the statute did not include the lack of a device-specific guidance document for the device. The additional criterion, imposed by the agency for the current list of eligible devices, that a device specific guidance document be available before that device could be made eligible for third party

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review, is not consistent with the intent of FDAMA. Therefore, AdvaMed believes that any Class II device, whether or not a device-specific guidance is available, that meets the statutorily defined criteria for inclusion into the third party review program should be included in the program. AdvaMed is pleased that FDA has abandoned the requirement for a device specific guidance document in the proposed list of eligible device.

Section 210 of FDAMA specifies that an Accredited Person may not review a Class II device which is intended to be permanently implantable or life-sustaining or life-supporting. AdvaMed is concerned about the definition for "permanently implantable" that FDA uses as it created the expanded list of eligible devices. It appears that the agency may be using the definition for implant that is a device which is "intended to remain implanted continuously for a period of thirty days or more." AdvaMed believes that FDA should be consistent in its application of the definition for a "permanently implantable" device and use its new definition for a permanently implantable device recently defined in the tracking regulation (April, 2000). This definition more appropriately defines a permanently implantable device, which is not temporary or intended for explantation, as a device "intended to be implanted in the human body for more than 1 year." Using the definition of implantation for more than a year rather than the short-term implantation period of thirty days would allow some devices, such as trauma devices that are implanted only until healing is complete, to be eligible for the pilot program. AdvaMed recommends that the agency use this definition as it reviews its expanded list of eligible devices to ensure that all devices which meet the criteria established in FDAMA are indeed listed.

Specific Comments:

Eligibility of Accredited Persons

FDA has established additional criteria for Accredited Persons to be permitted to review submissions for devices for which there is no device-specific review guidance. One of the criteria requires that the Accredited Person have previously completed three successful reviews under the third party program and that at least one of the reviews be in the same or similar medical specialty area as the device the Accredited Person now plans to review. AdvaMed believes that these additional criteria are unrealistic and will result in a limited number of devices without device-specific guidance documents actually reviewed under the new third party pilot program. Currently there are 12 accredited persons and several of those have not yet had experience in reviewing any submissions under the third party program because of its infrequent use. Therefore, the number of Accredited Persons meeting these new criteria will be scarce. AdvaMed is concerned that the result will be a lack of eligible third party reviewers to review the increased number of eligible submissions. AdvaMed believes that the criteria FDA originally established for an accredited person to become qualified for review of specific product types is sufficient. AdvaMed is not opposed, however, to the requirement that the Accredited Person

contact the appropriate Office of Device Evaluation Branch Chief before initiating a review for a Class II device that does not have a device-specific guidance. However, AdvaMed recognizes the agency's concern for third party review of devices lacking specific guidance documents and is willing to work with the agency to develop programs designed to assist accredited persons. For example, a retrospective review of recently cleared 510(k) submissions could be one mechanism by which a third party reviewer could gain experience with device submissions for which there is no specific guidance document and qualify as an accredited person for this category of devices.

Proposed Expansion Pilot List of Devices for Third Party Review

AdvaMed recommends that the agency add the following devices to the expansion pilot list of devices because we believe that these devices meet the eligibility criteria established by FDAMA.

Cardiovascular Panel

870.1220	DRF	Electrode recording catheter or probe
870.1220	MTD	High density array intracardiac mapping catheter
870.2700	DQA	Oximeter
870.2700	MUD	Tissue saturation oximeter
870.2710	DPZ	Ear oximeter
870.2800	MWJ	Ambulatory electrocardiograph (without analysis)
870.4220	DTQ	Cardiopulmonary bypass heart-lung machine console
870.4240	DTR	Cardiopulmonary bypass heat exchanger
870.4250	DWC	Cardiopulmonary bypass temperature controller
870.4300	DTX	Cardiopulmonary bypass gas control unit
870.4370	DWB	Roller-type cardiopulmonary bypass blood pump
870.4380	DWA	Cardiopulmonary bypass pump speed control
	LIT	Catheter, angioplasty, peripheral, transluminal

Gastroenterology Panel

876.5540	MPB	Catheter, hemodialysis, non-implanted
876.5820	FJI	Hollow capillary fiber dialyzer
876.5820	MSE	Hemodialyzer, Re-use, Low Flux
876.5860	KDI	High Permeability dialyzer
876.5860	MSF	Hemodialyzer, Re-use, High Flux

Immunology Panel

866.5660	NBT	Antibodies, Saccharomyces Cerevisiae
866.5660	MVM	Autoantibodies, Endomysial (tissue transglutaminase)
866.5660	NBS	Autoantibodies, LKM-1 (liver/kidney microsome, type 1)
866.5660	NBO	Autoantibodies, Skin (desmoglein 1 and desmoglein 3)
866.5660	MVJ	Devices, Measure, Antibodies to Glomerular basement membrane(GBM)
866.5660	DBL	Multiple Autoantibodies, Indirect Immunofluorescent, antigen, control
866.5660	MID	System, Test, Anticardiolipin Immunological
866.5660	MSV	System, Test, Antibodies, B2-Glycoprotein 1 (B2-GP1)
866.5660	MOB	Test System, Antineutrophil Cytoplasmic antibodies (ANCA)

As the agency finalizes the proposed expansion pilot list of devices for third party review, AdvaMed recommends that FDA consider the addition of Class I and II exempt devices that require a 510(k) submission when the limitations for exemption have been exceeded.

AdvaMed is encouraged by the agency's steps to increase the usage of the third party review program by initiating the 12-month expansion pilot program and would like to work with the agency in developing educational programs intended to educate the device industry, the agency and accredited persons on the successful use of the program.

AdvaMed appreciates the opportunity to provide comments on this draft guidance and proposed expansion list of eligible devices.

Sincerely,



Janet Trunzo
Associate Vice-President
Technology and Regulatory Affairs