

The Food and Drug Administration and Atrial Defibrillation Devices

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Abstract

Context: Atrial fibrillation is a common arrhythmia. It leads to significant morbidity and mortality, primarily from the increased incidence of stroke. The implantable atrial defibrillator, a new therapeutic option for the management of atrial fibrillation, is currently undergoing Food and Drug Administration (FDA) scrutiny for approval to market in the United States.

Data Sources: A review of the basic epidemiology of atrial fibrillation, as well as the current status of accepted treatment options in light of the development of the implantable atrial defibrillator, was conducted. A literature search using the terms atrial fibrillation, implantable defibrillator, Food and Drug Administration, medical devices, and medical device regulatory law was conducted using the MEDLINE and Current Contents databases.

Results: Currently, there is no consensus on the optimal treatment of atrial fibrillation. Despite the lack of definitive studies showing overall benefit associated with maintaining sinus rhythm in patients in atrial fibrillation, the implantable atrial defibrillator may soon reach the general market. We examine

the FDA process for the evaluation of this new medical device and discuss implications for the patient, physician, industry, and health insurers.

Conclusions: Current FDA approval processes for new devices are a compromise between (a) the needs for expediency and encouraging innovation by the medical device industry and (b) the need to ensure that new devices will contribute to improved patient outcomes. We suggest alternative FDA-approval processes that address these issues.

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Atrial fibrillation is an important public health issue. It is a common cardiac arrhythmia, developing in 2% to 4% of individuals over the age of 60 and in up to 10% of individuals over 65.^{1,2} A US hospital utilization survey in 1990 showed that the diagnosis of atrial fibrillation was among the leading causes of hospital admissions, totaling approximately 1 million hospital days.³ Furthermore, atrial fibrillation is associated with strokes and other systemic embolizations.⁴ The cost of treating patients suffering from embolic stroke from atrial fibrillation alone was estimated to be \$18 billion in 1993.⁵

The optimal treatment for atrial fibrillation is not known.⁶ Numerous pharmacologic and nonpharmacologic treatment options are available. Pharmacologic treatments include rate control of the ven-

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tricular response to atrial fibrillation with or without anticoagulation and antiarrhythmic therapy to induce and/or maintain sinus rhythm. Nonpharmacologic treatments include cardioversion with or without antiarrhythmic therapy, ablation of the atrioventricular node with pacemaker placement, surgical obliteration of the left atrial appendage (open or thoracoscopic procedure), catheter or surgical maze and corridor procedures, catheter ablation of ectopic atrial foci, and most recently implantable atrial defibrillators.^{2,7-16}

Advances in technology are a major source of increasing healthcare costs. According to the Health Care Financing Administration (HCFA), "about half the growth in real per-capita health costs is associated with medical technology."^{17, p. C1} For example, between 1997 and 1998, implantable ventricular cardioverter-defibrillator sales increased by 20%, to \$1.2 billion.^{17, p. C17}

The implantable atrial defibrillator is a device that holds significant—but as yet unproven—promise as a treatment for many forms of atrial fibrillation. Unfortunately, the evaluation and testing process with which the manufacturer of the device must comply in order to garner Food and Drug Administration (FDA) approval to market focuses only on safety and a narrowly defined concept of effectiveness. We feel that the current FDA-approval process for new devices is a compromise between (a) the needs for expediency and to encourage innovation by the medical device industry and (b) the need to ensure that new devices will contribute to improved patient outcomes. In this article, we suggest an alternative 2-step FDA-approval process that addresses all of these issues.

We began our review by conducting a literature search using the terms atrial fibrillation, implantable defibrillator, Food and Drug Administration, medical devices, and medical device regulatory law using the MEDLINE and Current Contents databases.

Clinical Background

Atrial fibrillation is defined as disorganized atrial activity resulting in ineffective atrial contractions. It is generally easily detected by electrocardiographic techniques. Atrial fibrillation results in a wide range of symptoms and sequelae. Some individuals have no symptoms whatsoever, while others experience congestive heart failure or hypotension. Atrial fibrillation also predisposes the atria to form thrombus that may lead to strokes. The ideal treatment for atrial fibrillation would result in the rapid restoration and maintenance of sinus rhythm without any

side effects from the method utilized. Unfortunately, no treatment methods currently exist that are free from side effects or risks to the patient. Is induction and maintenance of sinus rhythm better than rate control and anticoagulation as treatments for atrial fibrillation? Some small studies have shown hemodynamic improvement with the restoration of sinus rhythm in patients with atrial fibrillation.^{18,19} Other studies showed little change in hemodynamic status in atrial fibrillation versus sinus rhythm in individuals without significant structural heart disease.²⁰ Antiarrhythmic therapy can increase the likelihood of staying in normal sinus rhythm, but with possible side effects from the agents.^{21,22} It is not clear that individuals maintained in sinus rhythm with repeated cardioversions or drug therapy have superior symptom relief compared to individuals undergoing rate control and anticoagulation alone.^{21,23} Small studies have shown that quality of life improves for patients whose atrial fibrillation is controlled by radiofrequency catheter ablation of the atrioventricular node with pacemaker placement.²⁴⁻²⁷ Patients in atrial fibrillation generally report lower quality of life on measures of general health status, such as the Symptom Checklist-Frequency and Severity Scale (SF-36) and other measures.^{24,28-30}

In one published report, Disch et al used a Markov decision-analysis model to examine 4 clinical strategies for management of atrial fibrillation: (1) no treatment; (2) warfarin; (3) electrical cardioversion followed by quinidine to maintain sinus rhythm; and (4) electrical cardioversion followed by low-dose amiodarone to maintain sinus rhythm.³¹ Using available published data from randomized trials using warfarin, randomized trials using quinidine, and longitudinal studies of low-dose amiodarone, the authors concluded that the amiodarone strategy was preferred. However, both sinus-rhythm maintaining strategies were better than the anticoagulation strategy, which was better than no treatment at all.

Regardless of the method of treatment, patients do generally feel that the quality of life with a major stroke may be worse than facing death.^{32,33} Major clinical trials have demonstrated the benefit of anticoagulation in atrial fibrillation to prevent strokes (Table 1).^{3,5} A meta-analysis of 5 of the trials showed a 64% reduction in the risk of stroke in patients treated with warfarin anticoagulation versus placebo.⁴⁴ There are no published studies directly comparing rate control plus anticoagulation with maintenance of normal sinus rhythm using antiarrhythmic agents. The National

Institutes of Health (NIH) have funded a large, randomized multicenter study to compare optimized antiarrhythmic drug therapy administered to attempt to maintain sinus rhythm with optimized therapy that merely controls the heart rate. The principal endpoint is total mortality, with a secondary endpoint being quality of life.^{23,29,45} This study, Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM), is now only in the stage of patient enrollment; it will be many years before follow-up and analyses are completed.^{23,45} Other studies in Europe and by the Veterans Administration are in similar stages of planning or recruitment.

Although there is uncertainty as to the optimal treatment of atrial fibrillation, there has been a con-

certed effort to find a method to induce and maintain sinus rhythm with minimal side effects. An implantable atrial defibrillator device solution for this disorder would have definite advantages.⁴⁶⁻⁴⁸ An implanted device that would sense and then terminate atrial fibrillation as soon as it ensues has been under development by industry sources.⁴⁹ After initial studies in sheep, the technology has rapidly advanced to human devices.⁵⁰⁻⁵² Issues of defibrillation thresholds, risks of inducing ventricular arrhythmias, electrode placement, pain of defibrillation, concomitant antiarrhythmic drugs, and need for anticoagulation are beyond the scope of this article.⁵³ At this time both a combination ventricular and atrial defibrillator and an atrial-only defibrillator are under investigation.⁵⁴ These

Table 1. Comparison of Atrial Fibrillation Anticoagulation Trials³⁴⁻⁴³

	AFASAK	BAATAF	SPINAF	SPAF I	SPAF II	SPAF III	CAFA	EAFI
Year published	1989	1990	1991	1992	1994	1997, 1998	1991	1993
Comparisons made	WA vs ASA vs P	WA vs ASA/P	WA vs P	WA vs ASA vs P	WA vs ASA	ASA cohort and low-dose, fixed-intensity WA plus ASA vs WA	WA vs P	WA vs ASA vs P
Type of trial	Non-blinded	Non-blinded	Blinded	Non-blinded	Non-blinded	Non-blinded	Blinded	Non-blinded
Patients	1007	420	571	1330	1100	892 (ASA) 1044 (WA)	383	1007
Mean age (years)	75	68	67	66	64 and 80	67	67	71 and 77
Stroke endpoint (% per year)								
WA	1.9	0.4	0.9	2.3	Age >75 = 4.6	Combination 7.9, WA 1.9	3.5	4
ASA	3.9			3.6	>75 = 4.3, 0.5*	2.2 [†]		
P	4.6	3	4.3	7.4			5.2	12
Reduction in risks (%)								
WA vs ASA					<75 = 10.5, >75 = 9			
ASA vs P	18			42				16
WA vs P	71	86	79	67			37	69

AFASAK = Copenhagen Atrial Fibrillation Aspirin and Anticoagulation study; BAATAF = Boston Area Anticoagulation Trial for Atrial Fibrillation; SPINAF = Veterans Affairs Stroke Prevention in Atrial Fibrillation trial; SPAF-I = First Stroke Prevention in Atrial Fibrillation trial; SPAF II = second Stroke Prevention in Atrial Fibrillation trial; SPAF-III = third Stroke Prevention in Atrial Fibrillation study; CAFA = Canadian Atrial Fibrillation Anticoagulation study; EAFI = European Atrial Fibrillation Trial; WA = warfarin; ASA = aspirin; P = placebo.

*In patients without congestive heart failure, hypertension, or prior thromboembolism.

[†]In patients without recent congestive heart failure or left ventricular fractional shortening of 25% or less, previous thromboembolism, systolic blood pressure greater than 160 mm Hg, or female sex at age older than 75 years.

devices may not be appropriate for every individual with atrial fibrillation. However, in certain individuals, the devices may eliminate or decrease the need for other expensive and/or side-effect-prone therapies (such as external cardioversion, antiarrhythmic agents, hospitalizations, and anticoagulation). The target market could be large, given the relatively high prevalence of atrial fibrillation.

In June 1997, an atrial defibrillator device was made commercially available in the European Union, after review of implantations in 50 patients.⁵⁵ The same device is currently undergoing Food and Drug Administration (FDA)-sanctioned investigational testing in the United States, with 140 devices implanted worldwide and 25 US hospitals participating in a clinical trial as of March 1998.⁵⁶ Published human study data are currently limited to predominantly abstract formats and a few articles. Two abstracts were published in association with presentations at the 70th Scientific Session of the American Heart Association (1997, Orlando, FL). The abstracts came from the same group, with a total of 4 patients. The first abstract examined detection and synchronization of atrial defibrillation,⁵⁷ and the other abstract evaluated success of defibrillation (20 of 26 shocks were successful in 4 patients over a mean of 6.4 ± 4.4 months).⁵⁸ Lau et al published probably the first article on human experience with implanted atrial defibrillators, reporting on the 3 implantations.⁵² Wellens et al and Josephson recently published an article on the clinical use of the implanted atrial defibrillator.^{59,60} They reported on 51 patients with recurrent atrial fibrillation who underwent implantation of an atrial defibrillator. The authors found that during a follow-up period of 259 days in 41 individuals, 96% of 227 spontaneous episodes of atrial fibrillation were successfully cardioverted by the implanted atrial defibrillator.

The available data are thus far encouraging in terms of feasibility of implantation, safety, and efficacy of termination of atrial fibrillation. As is the case for all medical devices, however, the evaluation of the implantable atrial defibrillator by the FDA will be limited to a determination of whether the data submitted by the manufacturer provide a "reasonable assurance of safety and efficacy." Rigorous testing such as that resulting from a randomized trial will not be required. Of course, a randomized trial of atrial defibrillator implantation versus sham surgery could not be performed. Neither will there be outcomes or cost-effectiveness studies

available. Before addressing possible improvements in the evaluation process, we will look at the current FDA-evaluation process.

The Implantable Atrial Defibrillator and the FDA

The implantable atrial defibrillator is currently undergoing evaluation by the FDA for approval in the United States. The device is classified as a Class III device, based on the likelihood of serious adverse effects associated with use of the device. (The lowest-risk devices fall into Class I, intermediate-risk devices into Class II, and the highest-risk devices into Class III.) The atrial defibrillator is undergoing clinical trials under an Investigational Device Exemption (IDE) in preparation for submission of a Premarket Approval (PMA) application. Under an IDE, a device may be used in clinical trials, but these devices are generally not covered by Medicare carriers or private payers. A PMA is required for all Class III devices without a pre-1976 device equivalent, to prove that the device is safe and effective before the device may be marketed to the public.

This evaluation process is the result of many pieces of legislation over the years, beginning with the Pure Food and Drug Acts of 1906; and followed by the Federal Food, Drug, and Cosmetic Act of 1938; the Medical Device Amendments of 1976⁶¹⁻⁶³; and finally the FDA Modernization Act of 1997.⁶⁴ Detailed analyses of these acts and amendments are beyond the scope of this article. Suffice it to say that the evaluation process for pharmaceuticals and medical devices has been under scrutiny by the federal government—hence the repeated amendments over the years. Differences between the evaluation process for pharmaceuticals and that for medical devices are a source of debate.^{63,65-70}

The clinical trial being conducted to evaluate the implantable atrial defibrillator is simple, prospective, and unblinded. The manufacturer must show that the device is safe and effective as labeled, that is, the device can convert atrial fibrillation to normal sinus rhythm, but does not have to show that patient outcomes are improved. In fact, with the Modernization Act of 1997, Congress explicitly limited the FDA's scrutiny of medical devices—in terms of evaluation of effectiveness—only to those claims made by the manufacturer.⁷¹ Mortality reduction, morbidity reduction, reduction in medication use—none of these factors need to be shown to obtain a PMA. The manufacturer will not be required to show that the device is better than or even comparable to other currently available treatments. With the

advent of the Modernization Act of 1997, the FDA is required to allow the manufacturers to use the least burdensome means available to demonstrate safety and efficacy.⁷¹ In addition, postmarket surveillance will now be at the discretion of the FDA and not officially mandated as it has been in the past, and may be of shorter duration.

The manufacturer has deemed that there is a market for such a device, having invested substantial capital in its research and development. A difficult and expensive FDA-approval process would have discouraged and perhaps even stymied the development of an implantable atrial defibrillator. The FDA Modernization Act of 1997 codifies changes in the device approval process made by the FDA over the past 4 to 5 years. These changes were designed to simplify and speed the process of device evaluation and approval. The new law also allows the manufacturer to disseminate information regarding off-label use.⁷²

This new law may help diffuse the critics of the FDA. Manufacturers had complained for many years that the FDA was too slow to approve medical devices. The companies have contended that it is far easier to bring a device to market in other parts of the world, particularly in Europe. Critics have purported that many life-saving or life-prolonging devices might never be developed and brought to market because of the high costs of initial research and development, added to the cost of clinical trials to prove safety and efficacy. The cost of bringing a Class III device (such as the implantable atrial defibrillator) to market is far greater than that for a Class II device—often 20 times greater.⁷³

The implantable atrial defibrillator is an example of the new cooperation between the FDA and manufacturers (Table 2). The manufacturer of the device currently undergoing clinical trials approached the FDA early in the process, obtaining approval to test the device under an IDE.⁷⁴⁻⁷⁶ The company also recently received authorization from the FDA to increase the number of medical centers in the United States participating in the clinical trial.⁷⁷ Despite this greater cooperation, the device was placed on the open market in the European Union countries in June 1997—far earlier than it will be made available in the United States.⁵⁵

However, availability in the European Union does not equate with widespread acceptance of a device. The European and Japanese models for device approval differ from the US model.⁸⁷⁻⁹⁰ Most of the countries in the European Union have price- or profit-control policies that apply to devices (and similarly to pharmaceuticals), policies that restrict

which products may qualify for reimbursement.⁸⁸ Pricing and reimbursement decisions are made separately from the device approval process (which is predominantly concerned with the safety of the device). Exclusion from a reimbursement list will effectively exclude a device from a national market because the majority of healthcare in European Union countries is paid for by governments.⁸⁷ This is equally true in Japan, which has a similar 2-tiered approval system, and where National Health Insurance covers almost 100% of the Japanese population.⁹¹

Discussion

As an immensely common and problematic arrhythmia in this country, atrial fibrillation consumes a tremendous amount of resources and attention. Our treatment options are not only unproven as yet, but some are also undesirable. Single or repeated external electrical cardioversions are associated with patient discomfort as well as with the risks of repeated sedation. Rate control plus anticoagulant therapy exposes the patient to risks of continued atrial fibrillation and of bleeding. Antiarrhythmic agents have side effects that may even be life threatening.

Thus, a simple, safe method of treating atrial fibrillation—perhaps such as the implantable defibrillator—would be very desirable. The implantable atrial defibrillator may have a large impact on the future of atrial fibrillation management in appropriate patients. All involved parties will be affected: patients, physicians, the manufacturer, and the insurance industry. In fact, the scenario truly exemplifies the struggle we are having today in the United States with medical products and their regulation. We wish to advance medical care and provide the best possible treatments (be they drug or device) for the public as soon as they become available. Conversely, the safety of patients is of utmost importance (new treatments must be better than the status quo and “first—do no harm”).

In addition to issues of efficacy in comparison with present standards of care, the impact of the implantable atrial defibrillator on the cost of treatment in this patient group must be considered. Based on the rapid dissemination of previous cardiac devices such as pacemakers, balloon angioplasty catheters, and coronary stents, the implantable atrial defibrillator may experience a rapid growth in use once it is approved. Because the device itself, physician fees, and follow-up are likely to be costly, consideration of how this device will affect total

costs in this patient population should be given. On the one hand, the device may prevent hospitalizations and improve outcomes in patients with atrial fibrillation, making use of the device a “dominant strategy” in terms of cost effectiveness. On the other

hand, the device may be less effective and more costly than standard therapy. None of these issues is likely to be resolved prior to FDA approval and widespread use of the device. (There may be randomized trials performed after approval of the device. Such

Table 2. Timeline for Development and Approval of Implantable Atrial Defibrillator ^{7,45,55,56,74-86}

Date	USA	Europe	AFFIRM (approximate)
1962	Atrial fibrillation first terminated by electricity by Zoll and Linerthal		
1990	InControl, Inc. formed (Redmond, WA)		
October 1995		First implanted atrial defibrillator, London, England	Phase I—planning (6 months)
February 6, 1996		Application to European countries for clinical trials	Phase IIA—start-up (6 months)
February 20, 1996	Application to the FDA (IDE application)		
March 25, 1996	FDA grants permission for 5 US centers (hospital defibrillation only) as Category A Medicare device		
April 8, 1996	First US implant of device (METRIX™) in Milwaukee, WI		
July 28, 1996	First US hospital defibrillation of implanted atrial defibrillator		Phase IIB—main recruitment phase and follow-up (36 months)
September 3, 1996		First implant of METRIX™3020 in Ghent, Belgium	
December 31, 1996	Four US sites	20 European sites	
June 5, 1997	FDA clearance to expand to 25 US sites (170 patients, Category B Medicare device), allow patient-activated defibrillation		
July 4, 1997		First out-of-hospital defibrillation (patient activated), Eskilstuna, Sweden	
October 15, 1997	27th US implant (Baltimore, MD)		
December 9, 1997	100th US implant (Atlanta, GA)		
March 5, 1998	25 US hospitals participating in clinical trial		
September 1998	InControl, Inc. purchased by Guidant, Inc.		
July 2000			Phase III—follow-up (24 months)
July 2002			Phase IV—analysis (12 months)

AFFIRM = Atrial Fibrillation Follow-up Investigation of Rhythm Management study; FDA = Food and Drug Administration; IDE = Investigational Device Exemption.

trials may address issues of comparisons of the device to current standards of care—similar to recent implantable cardioverter-defibrillator trials.) For many payers, the issue of cost effectiveness must be addressed before any agreement is made to pay for newly approved devices. Whether or not the manufacturer can and should provide data to support these decisions is not clear. This is currently not required by the FDA.

If the atrial defibrillator becomes available on the open market in the United States, physicians will have to decide whether the device is appropriate for their patients. These decisions will be made without any true effectiveness data and without any knowledge about whether maintenance of sinus rhythm by any means is superior to rate control plus anticoagulation in atrial fibrillation. There will be substantial pressure from patients who will want to benefit from this novel, technologically advanced treatment device (demand for “the latest and greatest medical treatment”). It is likely that there will be a financial incentive for physicians to implant this device.

Public and private health insurers will be placed under extreme pressures with the dissemination of these devices. The health insurance industry is constantly under public and physician pressure to provide coverage for medical devices. Unfortunately, scientific evidence of effectiveness is often not available. Currently, technology assessment by health plans is quite limited.⁹² They cannot afford to allocate sufficient resources to evaluate all new technological devices prior to inclusion in their health plans. In addition, the cost and outcome data needed to complete the technology assessment are often not available. Payment decisions are often made based on the total cost of the new device balanced against patient and physician demand. Thus, the health insurance industry relies on the manufacturer, the FDA, and investigators to provide adequate assessment of effectiveness.

The European Union and Japanese 2-tiered systems separate to some degree the safety/quality assurance/effectiveness process from the reimbursement-approval system.^{87,93} This system has been challenged by industry as a barrier to free trade in the European market. However, these challenges have not met with favorable reception in the judicial arena.^{87,89} The European Union system as it stands may not be applicable in the United States. We do not have the degree of national insurance that countries in Europe and Japan currently have; we have a multitude of third-party pay-

ers. Nevertheless, perhaps some portion of the system could be integrated into our current process to improve the evaluation of devices such as the implantable atrial defibrillator.

Future Directions

The FDA, and more specifically the Center for Devices and Radiological Health, provides a system for evaluation of new medical devices that places the safety of patients first and foremost, but recognizes the concerns and needs of companies that develop and manufacture the devices. Given the shortcomings we have presented and recognizing the limitations faced in device evaluation, we would like to make some general suggestions for how the process might be improved.

First, we must apply as much as possible the rigors and demands of evidence-based medicine to the clinical evaluation of the implantable atrial defibrillator (and all other medical devices). This will ensure that the testing process is as scholarly and complete as possible. The research must be conducted by individuals without a vested or financial interest in the device. The device must be compared to the “status quo” treatments. Second, physicians must not be too quick to adopt the device. Careful scrutiny of the available data and careful patient selection are important. Third, data should be collected on an ongoing basis and subjected to the best scientific scrutiny utilizing the latest epidemiology and health services research methods. A complete registry of all implantations should be maintained and analyzed periodically. Finally, the data collected and results obtained must be made readily available to physicians and to health plans to enable them to make informed decisions about the use of the atrial defibrillator.

Practically speaking, these principles may prove quite difficult to adopt. One alternative would be to devise a 2-step FDA-approval process. After the device is shown to be safe and efficacious, the FDA could give preliminary approval to market the device. The device would then be monitored for percent market share or dollar return—reaching a threshold would result in additional requirements for clinical efficacy and cost-effectiveness data. The FDA would then require adequately powered Phase IV clinical trials comparing the new therapy with current therapy. Funding for these trials could be derived from both the medical device and the health insurance industries, and from government agencies such as HCFA or the NIH.

A less comprehensive, but also less politically charged stop-gap solution would be a voluntary

registry. Patient enrollment could be facilitated by the device industry, by linking the enrollment process to existing mandatory implantation registration requirements. This voluntary registry would allow prospective collection of clinical outcome and cost data from atrial defibrillator patients. This data could then be compared with a matched group of patients with atrial fibrillation not treated with the implantable atrial defibrillator and preliminary conclusions drawn about the relative utility of the defibrillator device. A voluntary registry could be paid for through a combination of funds from the device industry, insurance industry, and government. The registry would continue to collect data even after the device is FDA-approved.

We suggest utilization of valid international data whenever appropriate—for either the 2-tier system or within the framework of the voluntary registry. If scientifically valid data that address the issues of effectiveness and clinical utility are available from (for example) European clinical trials of the device, then these data could also be included, perhaps reducing the necessary size or cost of the new studies. Ethical and standards of care issues are not within the scope of this article.

Conclusions

Physicians may soon be faced with the dilemma of having access to a safe device that may in fact be very successful at terminating atrial fibrillation, but have unknown utility in patient outcomes of morbidity and mortality. Patients may demand to have the device. Third-party payers will have to decide if they will include implantable atrial defibrillators in their plans and for what specific indications. This scenario will arise without the scientific basis of a completed trial (the in-progress AFFIRM trial) showing definitively whether or not sinus rhythm is better than atrial fibrillation—given the costs and side effects of treatments. We feel the current FDA-approval process for new devices is a compromise of expediency and encouraging innovation versus safety and patient outcomes. We have suggested 2 alternatives: a 2-step FDA-approval process or a voluntary registry. Either of these processes may provide patients, physicians, and insurers with the data necessary to make appropriate treatment and coverage decisions. Regardless of what measures are implemented by the FDA, continued careful scientific scrutiny of the implantable atrial defibrillator (and all new medical devices) is required.

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