

# Passing the SAAAVE Act Into Law

*Endovascular Today* interviews Robert M. Zwolak, MD, Chair of the National Aneurysm Alliance, regarding the legislative process as it pertains to medicine and his involvement with the recent passing of the SAAAVE Act.

**T**he Screening Abdominal Aortic Aneurysm Very Efficiently (SAAAVE) Act became law with President Bush's signing of S.1932, the Deficit Reduction Act of 2005, on February 8. Also known as the Budget Reconciliation Act, the law contains the key SAAAVE provisions that will implement AAA screening as a Medicare benefit. Effective January 1, 2007, SAAAVE will provide for one-time AAA screening as part of the "Welcome to Medicare" physical for males with any history of smoking and those with a family history of AAAs.

## THE LEGISLATIVE PROCESS

**Endovascular Today:** The SAAAVE legislation that was signed into law in February was part of the Deficit Reduction Act of 2005. How did the expansion of Medicare become part of that bill?

**Dr. Zwolak:** The SAAAVE Act started off with its own sponsors and its own energy, but for smaller pieces of legislation such as this, we needed a carrier or omnibus bill. The Deficit Reduction Act was the single major piece of legislation from 2005 that had anything to do with Medicare.

**Endovascular Today:** What was your role in working to get this legislation passed?

**Dr. Zwolak:** I served as Chair of the National Aneurysm Alliance, which is a coalition of medical and surgical specialty societies, foundations, and corporate partners, whose single goal it was to achieve this AAA screening benefit for people at risk. Although I serve as Chair, it was a huge, multiperson, multispecialty, and multientity effort.

**Endovascular Today:** Were there any members of Congress who were particularly helpful in getting this legislation passed?

**Dr. Zwolak:** Oh yes, very much so. In the Senate, there are three people who deserve special note. Senators Jim Bunning (R-Kentucky) and Chris Dodd (D-Connecticut) were the primary authors of the SAAAVE Act itself, and they were with us for the year and a half that it took to get the legislation passed. However, at the last minute, when it looked like the SAAAVE Act was not going to get into the Senate's version of this Deficit Reduction Bill, Senator Rick Santorum (R-Pennsylvania) was good enough to offer the amendment on the floor of the Senate. It was only with the stalwart support of our two primary sponsors and the last-minute willingness of Senator Santorum to introduce this amendment that we managed to get this into the Senate side of the Deficit Reduction Act.

In the House, we had three people who really deserve some credit. Representatives Gene Green (D-Texas), Ron Lewis (R-Kentucky), and John Shimkus (R-Illinois) were the primary sponsors of this legislation in the House and did the yeoman's service in getting a large number of US Representatives to sign on as co-sponsors.

**Endovascular Today:** What lessons did you learn from this legislative experience?

**Dr. Zwolak:** Thousands! The primary lessons—and these are in no particular order—are: first, that despite all the things you hear about Congress not being accessible to the general public and catering to special interests, the SAAAVE Act proved that a straightforward piece of legislation that is good for Americans can get

passed if you work hard enough at it. You can get into the Senate and House offices, talk to the right people, and our Senators and Representatives are very interested in passing reasonable preventive health services such as this.

Second is the fact that you cannot do it alone; one little specialty society will not accomplish anything. You really need to have a coalition of groups and foundations and the knowledge and experience of a lot of different people to get legislation through Congress.

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**Endovascular Today:** What were the most effective lobbying efforts, and which were the least effective?

**Dr. Zwolak:** The most effective is shoe leather; having enough people who understand the legislation who are willing to spend time on the Hill going from office to office. Certainly, one of the main things I learned was that strategically, you have to think of the committees of jurisdiction. With regard to Medicare, in the House, it is the Ways and Means Committee, the Health Subcommittee of Ways and Means, the Energy and Commerce Committee, and the Health Subcommittee of Energy and Commerce. Those are really the key legislators to convince because everyone on the Hill has their own special job to do. I had not realized how focused people are on these various committees. The most effective element is knowing which offices to visit and explaining the bill to their staff in detail, providing them with the medical rationale. You explain that at least 15,000 people die, needlessly, every year from ruptured aortic aneurysms, and they are usually people in their prime of life—people in their 60s, who have just gotten to retirement age, they are just starting to enjoy life, and they keel over from an aneurysm, and you can explain that pretty clearly. You can explain that the mortality of a ruptured aortic aneurysm is 75% to 80%, and the success rate of aneurysm repair is 95% to 98%, and anyone can understand how important it is to try to find people with aneurysms before they die.

The least effective means would have to be trying to communicate via e-mail; the people who work in these

offices are just inundated by e-mails, which are seemingly impossible to keep up with.

## PATIENT ELIGIBILITY

**Endovascular Today:** Presently, this legislation limits screening to males over 65 years with either a history of smoking or a family history of aneurysms. Why are these specific limitations in place?

**Dr. Zwolak:** The United States Preventive Service Task Force looked at aortic aneurysm screening in 2004 and 2005. In January 2005, they published their recommendations in the *Annals of Internal Medicine*, and the Task Force, after having reviewed the world's literature, suggested that males 65 to 75 years old who had ever smoked 100 cigarettes or more were at highest risk for developing an abdominal aortic aneurysm and merited screening.

The family history story is a little bit different. There are not many people in the US with a positive family history for aortic aneurysms, and the studies that suggest that people with a family history of aortic aneurysms are at risk are small in size; however, they are high-quality. We believed that the data were so compelling that the bill would not have been whole without including men and women with a family history of aortic aneurysms, and because that is a very small population compared to the male smokers, the House and Senate members who were our primary sponsors were willing to add that to the legislation.

The legislation is also limited to new inductees into the Medicare system and is linked to the “Welcome-to-Medicare Physical.” This is a significant limitation of the legislation that was absolutely necessary in 2005 if it were going to be included in the Deficit Reduction Act. We would have preferred to have this benefit potentially accessible to all beneficiaries who are at risk, but because of the fiscal limitations this year, it simply was not possible. We hope to eventually capture everyone, but progress will have to be made 1 year at a time. For this past year's window of opportunity, we thought that this benefit was better than no benefit.

## A WORK IN PROGRESS

**Endovascular Today:** Now that the legislation has passed, what are the revised goals of the National Aneurysm Alliance?

**Dr. Zwolak:** We're now focusing more on efforts at the CMS level, which concern three major points. First, education of physicians is paramount. Aortic aneurysm, even though it is ranked as the 10th lead-

ing cause of death in men older than 65, is not a disorder that is particularly well known. Second, educating patients that this new benefit exists will be terribly important. We have been working with the agency to try to explore all the print and Web-based notification options for AAA screening publicity.

The third point is that the agency has to implement an appropriate code—a “G” code—so that if a provider wants to perform one of these ultrasounds, he or she would actually get paid for it. In the regular Medicare fee schedule, if you do not have signs or symptoms, you do not qualify for any of the standard tests. So, although there is a regular CPT code for a retroperitoneal ultrasound test, which is what this service would be, you could not use the existing CPT code because the patient has no signs or symptoms. Therefore, CMS needs to make a “G” code, which will be specific for the ultrasound screening for AAAs.

**Endovascular Today:** Is it correct that the final bill did not include a national education program, nor did it include an information campaign or a standards section?

**Dr. Zwolak:** That is correct. The bill, as it was originally written, included funding and an unspecified amount of money for public and physician education. Those provisions disappeared for budgetary reasons as a compromise toward getting the bill passed as part of the Deficit Reduction Act. The proposed national education and information campaigns would have targeted both physicians and patients, and the standards section would have identified and created a standard of quality control on the ultrasound testing itself.

I think that the congressmen and their staffs were a little hesitant or lacked confidence on the issue of quality standards. The professional societies have been trying for years to push CMS to adopt quality standards for vascular ultrasound testing but, the agency has never been convinced that they should implement quality standards for Medicare beneficiaries who would be undergoing ultrasound tests—either general radiological ultrasound or vascular ultrasound. Because such standards have not previously been made official, Congress may have been hesitant to impose them.

### THE IMPACT OF SAAAVE

**Endovascular Today:** What effect does the passing of SAAAVE have on private health insurers?

**Dr. Zwolak:** I think that SAAAVE will serve as a model to the private health insurers in that they should consider AAA screening. Aetna actually has incorporated a

benefit for some of their private plans for AAA screening, announcing in 2004 that they believed it was appropriate to provide that benefit for their policy holders. I have not heard of any other private insurers who are now offering that policy or offering that sort of preventive service, but the fact that it is part of the Medicare program now would hopefully serve as a model for the rest of the carriers.

**Endovascular Today:** How many additional lives are estimated to be saved by SAAAVE?

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**Dr. Zwolak:** That is linearly proportional to how many beneficiaries we can convince to take up this screening benefit. It is a fact that in the US, although there are a fair number of preventive service benefits, the uptake rate has been disappointingly low. We hope to improve on this rate with education. Also, the fact that AAAs are such a lethal disorder and the ultrasound screening is so incredibly innocuous may help encourage patients to be screened. At least 15,000 Americans die each year of ruptured aneurysms. Most of those people are Medicare beneficiaries. I would be pleased if we could find most of those, but I fear that the number will be less based on the uptake.

**Endovascular Today:** What are the estimated costs to screen?

**Dr. Zwolak:** Medicare will decide what they are going to pay for this ultrasound screening test, but the two models that currently exist are the hospital outpatient prospective system and the Medicare fee schedule for physicians’ offices. The closest service is the code that I mentioned before (CPT-76775), which is a limited retroperitoneal ultrasound; the payment for that from the Medicare fee schedule this year (2006) is \$87.16—with some adjustments based on your geographic modifiers. The hospital-based outpatient prospective payment system is going to be more. The technical payment for the hospital is \$94.52, and the physician interpretation fee is \$30.00.

However, those are the corresponding existing

codes if a patient should have signs or symptoms that would lead for this test to be done. CMS will have to decide how close they think the new “G” code will be to one or the other of these payments and, in my opinion, it is essentially the same but, obviously, that will be their decision.

**Endovascular Today:** Do you anticipate that the screening costs will be offset by other gains in treatment or with regard to technique or technology in the future?

**Dr. Zwolak:** The screening costs will be offset, to some extent, by converting a patient who comes into the hospital with a ruptured aortic aneurysm who absorbs many thousands of dollars in hospital resources in an attempt to save that person’s life. That patient will be shifted from an emergency to an elective treatment, wherein the payments for elective aneurysm repair and the resources used are substantially less. For every aneurysm patient who is converted from the treatment of a ruptured aneurysm to elective treatment of an aneurysm, there will be savings.

The catch is that perhaps the majority of patients die at home or outside the hospital—so they don’t cost Medicare anything. Those patients who would have died at home from a ruptured aneurysm will be converting to elective repair, and therefore, they are actually going to cost the system more in health care resources.

**Endovascular Today:** What about those aneurysms that are found by the ultrasound but are not large enough to require treatment?

**Dr. Zwolak:** With those patients, who will likely be in the majority, we can try to convince them to quit smoking, and we can evaluate and treat their high blood pressure. It has been shown in the American Vascular Association’s screenings that a very substantial proportion of patients found to have AAAs also have untreated hypertension. There is an opportunity here to use medical therapy to treat those AAA patients who have an aneurysm that is too small to require immediate treatment, and we can try to convince them not to smoke, treat their hypertension, evaluate their cholesterol, and get them on all the medications that we think are good for people with vascular disease.

## MAXIMIZING POTENTIAL BENEFITS

**Endovascular Today:** Now that screening is being reimbursed, how do you go about spreading the word to the affected community and what should endovascular

specialists be doing to further ensure that patients are properly screened?

**Dr. Zwolak:** We need to ensure that the primary care physicians, general practitioners, and now the new element—the nurse practitioners, the physician assistants—are part of our educational programs. It is also especially important to talk to family members if a patient arrives in your office and has an aortic aneurysm; take the time to ask: Do you have brothers or sisters? Have they been screened? Do you have any children? Are the children 50 years old or older? Everyone can take part in the educational program. The societies are putting that high on their list for trying to spread the word by Web site and by educational articles. We have contacted the AARP and are trying to convince them to have a small article in their monthly journal.

**Endovascular Today:** Is there anything that industry can do to further assist in these efforts?

**Dr. Zwolak:** Industry has been absolutely tremendous in helping with the National Aneurysm Alliance Partnership and has been fantastic in terms of providing support. There are some companies that have funded special screenings provided by the American Vascular Association. Some other industry partners have their own screening programs up and running across the country as part of wellness programs. All the major device manufacturers and many of the major ultrasound companies have been extremely helpful with both our efforts in Washington, as well as trying to provide education.

**Endovascular Today:** Would thoracic aortic aneurysms be detected under the same screening process?

**Dr. Zwolak:** Sometimes, but only when the thoracic aortic aneurysm extends into the abdomen. It could be detected with ultrasound, but the ultrasound is not effective in the chest because the lungs have so much air that it just blinds the ultrasound.

**Endovascular Today:** Are there any other vascular diseases that might be detected in this screening?

**Dr. Zwolak:** The screening is very specific for AAAs. The only way to “nibble around the edges” is if the primary care providers, in thinking about aneurysms, think about vascular disease and about the risk factors for vas-

cular disease. In that sense, it may raise awareness of all sorts of vascular disease, but the legislation itself is very specific.

**Endovascular Today:** If screening is positive for an AAA, does the legislation have any impact on what the quality of care is from that point forward?

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**Dr. Zwolak:** There are a couple of important points that need to be made. First, the aneurysm screening legislation is written as a “one-time-only” screening. Aortic aneurysms grow so slowly that if you do not have an aortic aneurysm when you are 65 years old at your entry into Medicare, the likelihood of your developing one that will then go on to be the reason why you die is extremely low. There are pretty good scientific data to suggest that there is very little value in any repeat screening, even out as long as 10 years.

Second, what if the screening finds an aortic aneurysm, what is going to happen? There are no guidelines in this legislation about what to do with those patients afterward. However, once a patient is known to have an aortic aneurysm, the subsequent imaging tests—follow-up ultrasounds or CT scans, for instance, would be paid for by the Medicare system. Once a diagnosis is established, Medicare will cover subsequent diagnostic procedures. When the aneurysm becomes large enough for treatment, the procedure would be covered by Medicare.

The third item raises the question of guidelines. The legislation does not specify a threshold for treating AAAs relating to their size upon discovery. There are some such guidelines in the literature, but there is not universal agreement on how to monitor AAAs and at what size to treat them.

**Endovascular Today:** As a vascular surgeon who has been heavily involved in the screening effort, are there particular aspects to the different screening programs that you have found to be better able to identify the patients at risk?

**Dr. Zwolak:** I think that the Preventive Service Task Force really got the biggest possible piece of the pie by recommending AAA screening to male-ever smokers, and I think we picked up a small but a very important

piece with family history. One thing that the Preventive Service Task Force did that I totally disagree with was to give a “D” recommendation toward screening any women, and I think that that was a mistake. Although women develop AAAs less frequently than men, perhaps on the basis of one woman to every four men, women certainly do die from them too, and the Preventive Service Task Force’s “D” recommendation suggests that screening women for AAAs carries more potential harm for the women than any potential benefits.

We pressed the Task Force on the potential ways in which screening women could cause more harm than any benefit. First, is there risk to the ultrasound test itself? The obvious answer that everyone agrees to is “No.” We use ultrasound to examine millions of women, including pregnant women to examine their fetuses. Across the board, ultrasound is believed not to carry danger. Second, is there psychological harm? There are actually half a dozen studies in the published literature that have tried to analyze the anxiety level associated with screening for AAAs, and although there is a measurable blip in anxiety just before and during the ultrasound screening, it disappears shortly thereafter. As would be predicted from an intuitive perspective, people might feel a bit anxious about the screening beforehand, but when they find out that they do not have an aneurysm, their anxiety goes away. Those people who find out that they do have an aneurysm can become a little bit anxious about it, but in general, people would rather know if there is a problem.

**Endovascular Today:** Will screening companies be required to become certified to perform screening?

**Dr. Zwolak:** Right now, if you had a screening company and you decided you wanted to become certified or accredited or credentialed, you would not be able to find an accrediting body that gives out such a credential. It is my understanding that the Intersocietal Commission for the Accreditation of Vascular Laboratories is working toward developing a separate entity that would not be under their umbrella, but it would be a separate entity that would evaluate and accredit screening facilities.

**Endovascular Today:** Will this screening undergo budgetary evaluation every year by Congress?

**Dr. Zwolak:** No. It is incorporated in the Social Security Act in the provision for Medicare, and it stays there unless or until someone removes it or changes it. ■