

From the American Venous Forum

## Where evidence, ethics, and professionalism converge



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With the American Venous Forum (AVF) entering its thirtieth year, there is no greater challenge to the integrity of our Society's stated mission of saving and improving lives by reducing venous and lymphatic disease through education, innovative research, and advocacy than the unethical and unprofessional behavior surrounding inappropriate care to patients with venous disease. What began as whispers in the hallways and corners of our meeting many years ago has now burgeoned into an uncontrolled crisis of which we have no idea of the magnitude and with no easy solution in sight. What is clear is that there are too many venous procedures being performed, some or perhaps many of which may be for inappropriate reasons.

### MEDICAL ETHICS

The concept of medical ethics and appropriate treatments, of course, is nothing new. The oath of Hippocrates, which is symbolically rendered during medical school graduation, has origins almost 2500 years ago. After swearing to the Greek gods of healing, Apollo, Asclepius, Hygieia, Panacea, and of course Nicos Labropoulos, among other concepts expressed is the principle of nonmaleficence, "do no harm." Among the many translations, this is stated as "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing"<sup>1</sup> or, in the modern version rewritten in 1964 by Louis Lasagna, Dean of the School of Medicine at Tufts University, and the version used in most medical school graduations today, "I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of over-treatment and therapeutic nihilism. I will remember

that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug."<sup>2</sup> Unfortunately, when these principles are applied to our modern venous world, the Hippocratic Oath has seemingly been reduced to the Hypocritical Oath.

The concept of ethics and appropriateness is not new to presidential addresses. Across all specialties of medicine, there have been numerous presidential discourses on this topic when critical ethical issues have arisen. While the AVF has a multispecialty membership base, for me as a vascular surgeon, there have been some key addresses on this topic within my chosen specialty. In Garland Perdue's 1988 Presidential Address for the North American Chapter of the International Society for Cardiovascular Surgery before their merger with the Society for Vascular Surgery, entitled "The doctors' dilemmas," he addressed concern for the rapid volume expansion of carotid endarterectomies performed in the 1980s by highlighting the play by Bernard Shaw, *The Doctor's Dilemma*, in which a doctor has been recently knighted after developing a new treatment for tuberculosis but faces a difficult decision about who to treat.<sup>3</sup> The theme of Shaw's play and Dr Perdue's address is that poor doctors are easily tempted to perform costly but useless (and in the best case harmless) treatments on their patients for personal gain. In Enrico Ascher's 2004 Presidential Address to the Eastern Vascular Society entitled "Nostrums, quackery, and ethics in vascular surgery: how to remain true to the path of Hippocrates and still feed our families," he outlines the identity and business of vascular surgery in the face of competition from other specialties and the challenge it places on providing appropriate care.<sup>4</sup> That was followed up by Keith Calligaro's 2009 Presidential Address, also to the Eastern Vascular Society, entitled "Do no harm," during which he focused on that principle from the Hippocratic Oath, balancing good outcomes of vascular interventions against risks, and whether we are truly helping our patients against un-necessary harm from "overly aggressive" approaches.<sup>5</sup> And finally, our D. Eugene Strandness lecturer, Peter Lawrence, whose Presidential Address to the Society for Vascular Surgery in 2015 entitled "'Better' (sometimes) in vascular disease management" was a response to the fallout from the *New York Times* article "Medicare payments surge for stents to unblocked blood vessels in limbs" published early that year, a call to action was made for all of us to

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become role models in providing the most “appropriate” treatment.<sup>6,7</sup> Dr Lawrence concluded, “We need to offer our patients the same advice and treatment that we would give to our brother or sister, or mother or father. We need to ‘take that high road’ and always recommend the most appropriate treatment, whether it be medical therapy, open surgery, or endovascular therapy, to become ‘better.’ ” There is no mystery why I invited Dr Lawrence to present our 2018 Strandness lecture on the topic “Managing venous disease: when good results are not enough.” Peter, it was outstanding and was the perfect primer for my Presidential Address today. While that *New York Times* article focused mostly on peripheral arterial procedures, there was passing reference to expansion of venous procedural volume hidden in one of the figures, which has become a spark plug for this issue on the venous side of the circulation as well. Interestingly, in reviewing the past 30 years of outstanding AVF presidential addresses, while there have been suggestions along ethical issues, we have been long overdue for a Presidential Address completely dedicated to this topic, which if anything is a sign of how much this problem as it relates to venous care in today’s environment has permeated all facets of our profession and our AVF Society as a whole.

I have been thinking about what topic I would cover in my Presidential Address for several years. But the true codification of my address to you today began after President-Elect Elna Masuda organized an outstanding Villavicencio Symposium at last year’s AVF annual meeting in New Orleans entitled “The UNTHINKABLES in venous care: Is the unethical treatment of venous disease out of control?” During this session, there was a frank and honest discussion of the issues and frustrations we all have been experiencing regarding inappropriate venous treatments from a panel of our key AVF thought leaders, with direct input from our members at the open microphone. The feedback we received as AVF leaders after that session was tremendous. I sat down shortly after the meeting last year with Elna along with the AVF Board of Directors to outline a leadership plan on how AVF can best address this gap in ethics and professionalism, realizing that any meaningful impact would need to cross several leadership cycles of our organization. This leads me to the core content of my Presidential Address. I would like to first share my perspective as someone who cares about what we have been witnessing over the past decade with inappropriate venous care; second, I plan to outline what AVF has been actively engaged in over the past few years within different facets of our organization addressing this crisis; and then close with a call to action to our leadership and members to heighten the level of professionalism and appropriateness expected of the AVF by leveraging our mission

and core values to save and improve lives by reducing venous and lymphatic disease by delivering *quality* and *appropriate* care.

## ETHICAL CONSIDERATIONS IN VENOUS CARE

Full disclosure. I am not a Greek philosopher. I am not an ethicist. I am not a lawyer. I am a vascular surgeon who practices the full scope of vascular surgery with a focused interest in venous disease. And I am someone who cares. My moral fabric I learned from my parents. My dad, who was an obstetrician-gynecologist in private practice, was my role model and taught me to be honest and do the right thing, always. My ethical barometer is my nose—if something doesn’t smell right, it probably is not right. I, like many of you, have become increasingly concerned with the complete disregard to our patients’ dignity and rights that is occurring within venous care in the United States. And the stench is foul.

Medical Ethics 101 teaches us that for a medical practice to be considered “ethical,” it must respect four principles: autonomy (requires patients have autonomy of thought, intention, and action and be free of coercion when making decisions regarding health care procedures); justice (the idea that the burdens and benefits of new treatments must be distributed equally among all groups in society); beneficence (that the procedure be provided with the intent of doing good for the patient); and nonmaleficence (requires that a procedure does not harm the patient or others in society).<sup>8</sup>

I am reminded of the 32-year-old woman who came to see me in our vein clinic a few years ago. She was a pharmacist and her husband was completing his medicine residency. She was 6 months post partum and otherwise healthy. She had noted some spider veins near her ankle after delivering her healthy baby. She had never worn compression stockings. She was seen at another vein clinic in town where she was told that she had three veins in her leg that had flow issues and needed to be treated or that area near her ankle would degenerate into a venous ulcer and she might lose her leg. And oh by the way, she was told she had three bad veins in her other leg that also needed to be treated, and it would require six separate treatments to take care of each vein, plus some injections of those spider veins. Well, that did not smell right to her either and she wanted a second opinion. Other than a few tiny spider veins in her ankle area, her legs were fine. Ultrasound showed that all venous flow was normal. All she really wanted was to make sure she was going to be ok.

Sound familiar? We have all seen these questionable practice patterns in various incarnations for our patients with venous disease: exaggeration of leg complaints in the patient history; documentation of nonoperative measures like compression stockings when none had

been worn; misclassification of exam findings to higher severity categories; incomplete, focused, and quick “look” ultrasound exams specifically performed to identify only venous reflux in the superficial system but no evaluation of the deep system; nonaccredited venous ultrasound testing without use of defined venous duplex criteria; falsification of ultrasound results; financial incentives to ultrasound technologists to find reflux; scare tactics pushing operative corrections; and staged multiple endovenous ablations on the same leg, to name just a few. Now, in an alarming rate, these practice patterns are moving into the deep system with exponentially increasing volumes and inappropriate use of iliac vein stenting for minimal clinical symptoms. We are now on the precipice of these same inappropriateness issues extending into the deep system without learning the lessons of the past decade. Frankly, these fraudulent behaviors can be described as nothing short of predatory—physicians using their position of knowledge, experience, and technical expertise to target unsuspecting patients and their vulnerabilities to benefit the physician at the expense of the patient’s well-being and right to autonomy. Now if that is not a clear violation of Medical Ethics 101, my moral compass needs recalibrating.

The unfortunate part about this trend is that development of minimally invasive techniques of thermal and nonthermal ablation, catheter-directed clot removal, and venous stenting have been disruptive technologic advances that have changed the way we provide venous care and really have benefited many. President-Elect Masuda organized an outstanding David S. Sumner Venous Summit a few days ago on “AVF 30 years: Past, Present, and Looking to the Future!” In considering our venous practice over the past 30 years of AVF, what used to be high ligation, saphenous stripping, and stab phlebectomy requiring a few days as an inpatient and extended recovery period is now endovenous closure with thermal energy, mechanochemical, glue, or foam sclerosant and microphlebectomy as an outpatient with a short recovery and excellent outcomes and quality of life measures; what used to be a highly morbid operation of open venous thrombectomy with compartment fasciotomies and potential limb loss is now catheter-directed or pharmacomechanical thrombolysis with several different catheter options and techniques available; what used to be open release of iliac vein compression is now a venogram, intravascular ultrasound, and venous stent placement with rapid recovery. In my short career, I have witnessed these and other generational advances in venous care that have been truly good for our patients.

In general, as new medical technology and treatment options are introduced, there is a natural tendency for procedural volume increase. I first observed this trend with laparoscopic cholecystectomy in the 1990s. After observing the first lap chole performed in the state of

Vermont as a medical student, an 8-hour case by the way, with about 20 people packed into the operating room suite, by the time I finished general surgery training in Oregon 6 years later, lap chole had become commonplace, shifting from an attending-level case to a junior resident-level case. The debate that began in response to the increased volume trend in lap cholecystectomy was whether the indication for the procedure had truly changed or was there just overutilization. Similarly, with the introduction and adaptation of these new venous technologies, we would expect there to be an increase in procedural volume over time. However, when procedural volume increases exponentially beyond what is considered reasonable, that is when warning flags are raised. In the venous world, the expansion of venous procedure volume has been further amplified by practice pattern shifts, which have included moving these procedures from the inpatient to outpatient setting; growth of self-standing vein clinics and outpatient imaging centers; a reimbursement system that favors outpatient delivery of care; and the overall capitalization of venous care with “how to do it” vein courses, marketing platforms, industry promotion of devices, and the market forces that drive these trends. The net effect is extension of these technologies into areas that they were not originally intended or indicated and the erosion of ethical boundaries to fraudulently allow further expansion of these lucrative procedures to financially support those that deliver inappropriate venous care. The tail is truly wagging the dog.

The domino effect of this trend is that eventually market forces shift in the other direction. There is a constant barrage from insurance carriers now regarding new policies and reimbursement for venous procedures. At the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Panel on Lower Extremity Chronic Venous Disease July 20, 2016,<sup>9</sup> which was covered during our Sumner Summit at last year’s annual meeting, despite a multisocietal representation that included many of our AVF thought leaders, the net result of that review process was a recommendation to the Centers for Medicare & Medicaid Services (CMS) for low confidence of evidence supporting current venous practice. Furthermore, in an effort to financially disincentivize venous procedures, there has been a consistent effort at CMS to redefine the valuation assigned to venous *Current Procedural Terminology* procedural codes with recent Relative Value Scale Update Committee reviews on endovenous ablation in 2015, venous ultrasound in 2017, and phlebectomy coming up in 2018. In response, local coverage determination plans for Medicare and private payers like Blue Cross Blue Shield, Aetna, United-Healthcare, and others are actively restricting coverage plans directed at limiting care to our patients with venous disease. What this means is that insurance companies, not the provider, are determining what is best for

our patients. While this certainly is directed to those abusers of the system, there is no differentiation in these global coverage decisions, and the unfortunate fallout is that practitioners who are trying to do the right thing are restricted from providing appropriate care, and patients who would truly benefit from these procedures are now being denied care. These health policy trends have created a tremendous resource strain not just on the AVF but on other venous societies as well, which are needing to dedicate increased time and effort to respond to these challenges, always one step behind, then playing catch up to try to correct these policy mis-steps. It's a draining and vicious cycle that is all too often being repeated with more and more frequency. In fact, the efforts of our Health Policy Committee under the leadership of Chair and Past President Fedor Lurie and Chair-Elect Kathleen Ozvath this past year have been nothing short of tremendous, dealing with advocacy issues on short notice and implementing rapid responses to several crises, all through the dedication and volunteerism of our committee members. As the onslaught of these advocacy issues continues to rise, it is clear we will need to dedicate more resources to these efforts as well as expand our current collaborations with the Society for Vascular Surgery, American College of Phlebology, Society for Interventional Radiology, Society for Vascular Medicine, and other like-minded organizations to this end.

As part of this current pendulum swing, outliers on Medicare claims are also being identified, and the number of Medicare fraud claims against venous practitioners is on the rise. Having had the recent opportunity to review charts for a legal firm defending a recent Medicare fraud claim, I will share several observations. Reviewers contracted by Medicare essentially perform a chart audit to determine an estimate on what percentage of procedures were inappropriately billed to Medicare, and from that a percent of dollars from these claims is what the practitioner owes back to Medicare plus a penalty for each violation determined as part of the settlement. Organizations hired by Medicare to perform these reviews are often incentivized to find inconsistencies (which one could argue carries ethical issues in and of itself), and the actual percent determination then becomes the legal point of defense. What struck me the most was the concept that this practitioner was considered guilty and the point of the review was to just determine how guilty so they could settle on a lesser dollar amount. In reviewing these charts for the legal firm that was defending the practitioner, I was actually impressed with the Medicare reviewer's detail and insight into the inconsistencies found in the medical record, which was made easy by the flagrant disregard for accurate documentation, which was mostly done algorithmically to attempt to satisfy medical justification for the procedure, not necessarily to document what was

actually important for the patient's care—a full display of the inappropriate behavior patterns behind the decision-making process. While we might consider these increased efforts at identifying those practitioners who are providing fraudulent care a positive with justice served and others on notice, I would argue that the negative impact on the perception of our profession that is created (ie, if there is one bad apple, the whole bunch must be infected) may be more damaging to the many of us who are trying to do the right thing, not to mention all the added resources and expense that are dedicated to these efforts.

### **ETHICAL FOUNDATION OF THE AVF**

So on the cusp of our thirtieth anniversary, I would like to reflect where the AVF has been actively engaging these questions of ethics, professionalism, and appropriateness.

The AVF was founded in 1989 as an academic colloquium to facilitate the exchange of basic and clinical research in venous and lymphatic disease under a mandate from the joint council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery. From its scientific foundation within vascular surgery, the AVF has accordingly evolved currently into a multi-specialty organization, which encompasses a much wider scope commitment to venous and lymphatic health through innovation, research, education, awareness, advocacy, and collaborations than has ever existed in our 30-year history. At the core of our values is professionalism and integrity, quality evidence-based venous care, pursuit of scientific knowledge, and advocacy for our patients with venous and lymphatic diseases. The footprint of our organization is much greater than it has ever been but will need to get even bigger to be able to effectively address these issues of ethics, professionalism, and appropriateness.

### **EVIDENCE-BASED DECISION-MAKING**

In Mark Meissner's AVF 2008 Presidential Address, "I enjoyed your talk, but ...: evidence-based medicine and the scientific foundation of the American Venous Forum,"<sup>10</sup> the essence of our obligation toward sound quality evidence-based medicine was summed up in his concluding statement:

As physicians, we also have obligations to our individual patients and to society. All of us should commit to evidence-based practice, understanding that this does not require submitting to "a tyranny of the evidence," but integrating our own clinical expertise, the patient's values and preferences, and the best evidence available from the literature. We further have an obligation to know the data regarding the treatments we prescribe, particularly when there is a trade-off

between associated risks and benefits. We should also demand some proof of clinically relevant efficacy before subjecting our patients to costly new therapies of unproven benefit. Finally, we need to individually participate in scientifically questioning the existing evidence and generating new evidence.

Ten years later, those words still resonate when we consider the current ethics crisis we face as an organization. AVF has partnered with the Society for Vascular Surgery in creating clinical practice guidelines on the care of patients with varicose veins and associated chronic venous diseases in 2011 under the leadership of Peter Gloviczki, which we have just initiated discussion with the Society for Vascular Surgery on updating, and management of venous leg ulcers in 2014 under the leadership of Tom O'Donnell and myself.<sup>11,12</sup> After AVF's last strategic planning meeting in 2014, then-President Fedor Lurie, subsequent President John Blebea, and current Vice President Brajesh Lal established the AVF's Guidelines Committee with independent governance to allow creation of guidelines without external conflicts of interest while still functioning under the AVF Board of Directors. The outcomes of that effort under our current Committee Chair, Anil Hingorani, are guidelines for compression, management of endothermal heat-induced thrombosis, and venous ultrasound, which are nearing completion with expected publication in the upcoming year, and new proposed guidelines on the role of intravascular ultrasound and management of iliofemoral venous outflow obstruction planned in the near future. The *Handbook of Venous Disorders*, fourth edition, published in 2017 under the editorship of Peter Gloviczki, is the only comprehensive text on venous disease highlighting guidelines of the AVF in each chapter and was honored by the British Medical Association in 2017 for surgical specialty textbooks.<sup>13</sup>

However, while AVF has excelled in promoting the science behind evidence-based guidelines, the challenge is that while these guidelines provide an infrastructure for clinical decision-making, they are a dynamic entity, and strengths of recommendations and weighting of evidence will change as new information becomes available. Furthermore, the perception of bias related to these guidelines can lessen their impact. For example, when presenting at MEDCAC on lower extremity chronic venous disease in 2016, we were all surprised at the lesser importance placed on these and other published guidelines, which we as practitioners hold in such high esteem, by the MEDCAC panel composed of mostly public health experts with little to no venous disease expertise. This is the same MEDCAC panel who placed higher level of trust on what we all considered to be an extraordinarily flawed systematic review commissioned by CMS and performed by the Agency for Health Research and

Quality on treatment strategies for patients with lower extremity chronic venous disease, which of course became the most influential document driving the low confidence ratings on the key questions that were rated by the MEDCAC panel.<sup>14</sup> Finally and most pertinent to the ethical questions at hand, because clinical practice guidelines just weigh out a treatment decision based on GRADE of evidence but defer the clinical decision to the provider who may weigh in other patient-related factors before determining the best option, there is no connection to appropriateness or inappropriateness. The overall assumption is that the evidence-based guideline will be used in an ethical manner, yet this is not always the case, as these guidelines can be misinterpreted or misrepresented. This is where evidence and ethics have seemingly diverged in venous care. Our challenge is to merge evidence and ethics back together, and at this convergence we will find appropriateness.

### ETHICS STANDARDS TASK FORCE

In response to this growing ethical divergence, right after the annual meeting last year, I partnered with our President-Elect Masuda and we created an Ethics Standards Task Force to examine the areas within our organization that needed improvement within our previously established ethical and professional standards. With Elna as Chair and me behind the scenes pulling the presidential strings, we empowered and expanded our pre-existing Ethics Committee to critically examine AVF from this ethical perspective. Three working groups were created to address ethical and professional standards of our members, conflict of interest for our leadership, and appropriateness of venous care as a whole. The efforts of this task force are still a work in progress, but I would like to share with you where we are in the process.

**Membership pledge.** In an effort to define principles of professionalism and ethics that we expect of AVF members, a subcommittee was formed with Past President Tom Wakefield as team leader and including Past Presidents Joann Lohr, Frank Padberg, and Peter Henke and Secretary Hal Welch, and we thank you for your efforts. AVF had an older version of a Code of Conduct within our policy manual. In examining precedence from other societies including the American Medical Association, American College of Surgery, and Society for Vascular Surgery, among others, we determined that as an organization, AVF needed a stronger ethical statement and process. A new Membership Pledge has been created to reflect our core values and elevate the meaning of being an AVF member to the forefront. What I am sharing with you today is a draft version of that pledge that will be open for membership comment shortly after the annual meeting and prior to Board approval. The goal will be for our members to sign this upon joining AVF and then to renew annually (Table). There are other details within the body of the

**Table.** Proposed membership pledge of the American Venous Forum (AVF)

Membership pledge of the American Venous Forum
As a condition of membership in the American Venous Forum, I pledge:
• To practice evidence-based venous and lymphatic medicine and/or surgery with integrity, courtesy, and compassion.
• To provide appropriate care in the best interest of my patients.
• To treat all without bias.
• To maintain confidentiality in my patient and professional interactions.
• To collaborate, cooperate, and respect my professional colleagues.
• To participate in scientific knowledge and continuing medical education in the art and science of venous and lymphatic practice.
• To provide accurate information without purposeful misrepresentation concerning venous and lymphatic disease to my patients and the public.
• I make this pledge freely and upon my honor.
Thereby, I pledge to abide by the American Venous Forum code of ethics.
Signature _____

Pledge that define accountability, professional excellence and integrity, personal gain and self-dealing, equal opportunity-diversity-inclusivity, respect of confidential information, and fostering collaboration and cooperation. As our membership approaches 1000 members, we would expect our members to take this pledge not only as it applies to the AVF but also in how it translates to their clinical practice and care of patients. Those that cannot make this pledge should not be members. While we may risk losing a few, we hope that being a member of the AVF means something to every one of our members more than the paper certificate we receive upon joining and that our AVF brand continues to maintain the extraordinary level of integrity, quality, and professionalism that our society has earned over its 30-year history. By setting an example of what we expect of those that treat venous and lymphatic disease in our own membership, we hope this translates to others as a standard of what all of us who provide venous care should achieve.

**Conflict of interest—Leadership and organization.**

While we hold our membership to a high level of ethics and professionalism, we need to hold our leadership to a higher standard to avoid potential conflicts of interest. The Institute of Medicine has defined a conflict of interest as “a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest.”<sup>15</sup> The primary interest is usually the patient but for the AVF can also include policy implementation, research integrity, guideline creation, or unbiased medical education. Secondary interests can include financial gain, professional prestige, influence of industry, or advancement of other goals. Although it is not possible to avoid all potential conflicts of interest, trust between physicians and patients is based on the premise that physicians will put the needs of the patients first. At our

societal level, trust between our AVF leadership, our members, and the venous community is equally paramount.

AVF currently has a conflict of interest policy to hold our leadership accountable that “the affairs and decisions of the AVF shall be conducted and made in a fair and impartial manner, without influence from Board members and key employees whose interests conflict with those of the AVF.” It requires that Board members must divulge financial, professional, or personal relationships that could give rise to conflicts of interest annually and updated at every Executive Council and Board meeting. For any action for which there may be a conflict of interest, that Board member will recuse himself or herself from decision-making deliberations that could be affected by such a relationship and abstain from any vote required.

With the open payment system as required by the Affordable Care Act that houses information about payments from drug and device companies to physicians and teaching hospitals, there is increased scrutiny and need for better transparency.<sup>16</sup> Today, anyone can go to [www.cms.gov/openpayments/](http://www.cms.gov/openpayments/) and access reported financial information about AVF leadership. Whether perceptions meet reality is different, but unless we as AVF leaders have a better system of transparency in place that allows us to manage perceived or real conflicts of interest, we are at risk for undermining the trust our membership has in our AVF leaders. A second subcommittee was formed with Past President Rob McLafferty as team leader and including Past Presidents Tom O’Donnell and John Blebea to address the question of whether the AVF leadership needs better transparency. After 10 months of development at the subcommittee and task force levels, a proposed draft of a new conflict of interest policy was just presented to the AVF Board of Directors this past week and will also be followed by an open comment

period. The AVF Board of Directors will need to consider the following concepts: whether the conflict of interest policy should be extended to include, in addition to the Board of Directors, all councils, committees, working groups, or any other volunteer service for the Forum or its Foundation; whether all potential direct financial relationships with industry during the leadership terms of service should be restricted; whether we need to establish a system of improved disclosure and transparency to our members and other constituents; and developing a fair review process by empowering our Ethics Committee to review questions of conflict of interest and make recommendations to the Board of Directors.

However, these principles also need to extend to the AVF organizationally as relationships between professional medical societies and the pharmaceutical and medical device industries have come under increasing scrutiny. Reading an excerpt from the proposed draft that outlines the rationale and need for better transparency:

Through its many activities, the AVF makes distinctive contributions to the advancement of venous and lymphatic care. The AVF's educational venues (Annual Meeting, textbooks and CME courses) inform members of new and established diagnostic and treatment procedures. AVF Practice Guidelines and Reporting Standards establish evidence-based, optimal patient care. The AVF also engages in public outreach through its web site and other venues to promote venous health and education. A public agenda is also manifest in health policy initiatives that advocate for the particular interests of AVF members, patients and for what we believe is best for Forum as a whole. The development of these and other AVF activities reflect a depth of expertise and maturation of authority that have significant influence inside and outside our organization. Therefore, any compromise of scientific integrity or unqualified commitment to patient care must be anticipated and avoided.

Currently, the AVF receives a significant amount of its annual revenue from industry support. This comes from unrestricted grants for the Annual Meeting, income derived from the Annual Meeting exhibits, symposia and fellow/physician courses, and unrestricted grants to support AVF research projects.

In fact, our organization has an inverted economy that could not survive without the additional support we receive, just on our current annual dues and meeting registration fees alone.

Thus, there exists a significant financial relationship between the AVF and industry that is subject to external scrutiny. The chief concern, of course, is

that industry through its financial support of AVF may influence educational and other Forum activities in a manner that would compromise clinical decision-making. On the other hand, a healthy relationship between AVF and industry can promote optimal and excellent health care. Collaboration can lead to research, innovation, new treatments, and expanded educational activities.

So in order to clarify and promote a healthy and ethical relationship with industry, the call to action for the AVF as an organization is to improve our policy regarding our relationship with industry to include transparency, full disclosure of all individual and AVF financial relationships with industry, and the maintenance of appropriate barriers between industry relationships and programmatic decisions.

**Appropriateness.** So we now come full circle to the issue of appropriateness. The purpose of galvanizing the professional and ethical standards of our members and becoming more transparent in our leadership and organizational relationships with industry first and foremost is that it will elevate the credibility of AVF, already well respected, to a much higher level to allow us to better address the issue of appropriateness and lead this effort across the spectrum of venous stakeholders. In an effort to address the issue of appropriateness, a third subgroup of the AVF Ethical Standards Task Force was organized earlier this year under President-Elect Elna Masuda as team leader and includes Society for Vascular Surgery Past President Peter Lawrence, Past President and Founding Member Bob Kistner, Dan Monahan, Jose Almeida, Steve Elias, Past President Fedor Lurie, and William O'Brown. Conference calls were initiated 6 months ago, and efforts are proceeding to develop appropriateness statements. While these statements are currently in early draft form and are not yet ready for prime-time display, I will share the following with you—this is very complex and challenging.

Much like an evidence-based guideline, the concept of appropriateness in general refers to the relative weight of the benefits and harms of a medical or surgical intervention. However, the concept of appropriateness extends beyond clinical practice guidelines: an appropriate procedure is one in which the expected health benefit exceeds the expected risks by a sufficiently wide margin that the procedure is worth doing, exclusive of cost. While an appropriateness statement may be linked to evidence or a guideline statement, it then applies a judgment about what a provider should or in some cases should not do, of what is appropriate or not. It is not graded like an evidence-based statement for strength of the recommendation; it may have absolutes—clearly appropriate or inappropriate—but can have an uncertain gray zone in between in that it may be appropriate or inappropriate in certain situations.

The RAND/UCLA Appropriateness Method was developed in the mid-1980s as part of the RAND Corporation/University of California Los Angeles (UCLA) Health Services Utilization Study, primarily as an instrument to enable the measurement of the overuse and underuse of medical and surgical procedures.<sup>17</sup> The rationale behind the method is that randomized clinical trials—the "gold standard" for evidence-based medicine—often are either not available or cannot provide evidence at a level of detail sufficient to apply to the wide range of patients seen in everyday clinical practice. While robust scientific evidence about the benefits of a treatment may be lacking, physicians must nonetheless make decisions every day about how to treat. Consequently, the RAND/UCLA Appropriateness Method combines the best available scientific evidence with the collective judgment of experts to yield a statement regarding the appropriateness of performing a procedure at the level of patient-specific clinically pertinent detail. In the RAND/UCLA Appropriateness Method, the literature review is performed around a clinical question, and an expert panel rates the benefit-to-harm ratio of the procedure on a scale of 1 to 9, where 1 means that the expected harms greatly outweigh the expected benefits and 9 means that the expected benefits greatly outweigh the expected harms. After additional panel structured discourse, the procedure is rated as appropriate, uncertain, or inappropriate in accordance with the panelists' median score and the level of disagreement. While the appropriateness rating is retrospectively determined, it can then be prospectively applied as a clinical decision aid tool. While the RAND/UCLA Appropriateness Method has been applied to many procedures in the United States, it has not yet been used for venous procedures. As our Ethical Standards Task Force begins to create statements of appropriateness, adapting a methodology such as the RAND/UCLA Appropriateness Method may allow a validated approach to addressing these issues. Some preliminary discussions have already occurred about this process.

## COLLABORATION

As AVF begins to delve deeper into the questions of appropriateness, there needs to be a wider net of inclusion. In our collaborative relationship with the Society for Vascular Surgery Patient Safety Organization, Jose Almeida has already initiated discussion on how to leverage data from the Vascular Quality Initiative Varicose Vein Registry into these appropriateness questions. While AVF may be leading this effort currently, including other venous stakeholders such as American College of Phlebology, Society for Vascular Medicine, Society of Interventional Radiology, Society for Vascular Surgery, and others will be essential in our ability to move forward with consensus. Extending appropriateness care to clinical practice through our participation in organizations such as the Intersocietal Accreditation Commission Vein Center, under which all of these stakeholders including AVF have Board

representation, would be a vehicle to allow wider adaptation. The American College of Surgeons and Society for Vascular Surgery have begun discussions on a vascular certification program based on appropriateness. With our new Society for Vascular Surgery-AVF collaborative agreement, I am a member of the Standards Writing Group; having AVF expertise at the table to assist with venous questions of appropriateness as part of these standards will allow even wider dissemination.

Finally, educating our patients about what is appropriate or inappropriate will be critical. Launched in 2012 by the American Board of Internal Medicine and *Consumer Reports*, the Choosing Wisely campaign<sup>18</sup> promotes conversations between clinicians and patients to help patients choose care that is supported by evidence, not duplicative of other tests or procedures already received, free from harm and truly necessary. To help patients engage their health care providers and empower them to ask questions about what tests or procedures are right for them, patient-friendly materials have been created on the basis of specialty societies' list of recommendations of tests and treatments that may be unnecessary. There are only two current recommendations on venous disease—avoiding ultrasound in patients with asymptomatic spider veins and inferior vena cava filters for prophylaxis. Currently, of the 75 specialty society partners, AVF is not a partner. AVF needs to engage with a model such as Choosing Wisely to help public outreach on what is appropriate over a wider spectrum of venous problems.

## CALL TO ACTION

In conclusion, however we get there, these efforts are still a work in progress, but I assure you the AVF is well positioned to continue building on this momentum moving forward. As AVF enters its thirtieth anniversary, I assure you that our organization is strong and expanding. Our members and leaders are passionate and thoughtful. We do not settle for anything but the utmost in values of professionalism and integrity, quality evidence-based venous care, improved venous disease awareness, pursuit of scientific knowledge, and advocacy for our patients with venous and lymphatic diseases. In that regard, we now need to leverage these strengths to address appropriateness of care across the entire venous and lymphatic disease spectrum.

In closing, I want to challenge you, our members. My call to action for you is to reflect on the core values of what the AVF stands for and how these relate to your own values. Are you providing the utmost quality, evidence-driven, and appropriate care to your patients? We have that obligation to our patients to settle for nothing less.

I have been proud as your President this past year of all that we have accomplished and have set forth to achieve in the very near future. Rest assured that as we crest our thirtieth year, we are healthy and well poised for our next 30 years.

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