PRESIDENT'S MESSAGE

What does success look like for The PSF?

BY MICHAEL NEUMEISTER, MD
PSF PRESIDENT

The vision of The PSF is to improve all aspects of plastic surgery: quality, effectiveness, outcomes and safety. This vision will be advanced through innovation and research. As The PSF goes beyond its charitable responsibilities of support resources and granting funds, it will need to develop a strategy and a meaningful set of "services" to help initiate and foster partnerships with other research institutions such as universities, industry, foundations, the Department of Defense, the National Institutes of Health and the FDA.

We continue to offer funding for investigator-initiated research in the basic science, clinical and clinical trials arenas. We also try to foster new and young researchers in plastic surgery by offering fellowships. However, the Foundation has a capacity to do much more than what it has done in the past.

The specialty's research engine

The PSF has the capacity to be the research engine of our entire specialty – composed of a team that can respond to inquiries from its members, industry and governmental agencies. It has the ability to direct potential researchers to where they need to go, or with whom they need to collaborate. In this light, The PSF should change from a reactive to a proactive research-driven enterprise. Building an infrastructure that will allow us to perform comparative effectiveness studies and systematic reviews will provide the best evidence-based medicine for our patients.

The PSF has an enormous potential to have a significant amount of extramural funds channeled through it, so that growing numbers of research and proactive studies can be performed. This can only be done with improvements in our infrastructure: an infrastructure that can respond quickly to unforeseen concerns, anticipate new issues and house workshops for new projects.

The PSF has had some experience and success with proactive activities in recent years. The Venous Thromboembolism Prevention Study (VTEPS), a prospective cohort study initiated by the PSF Clinical Trials Network within The PSF, enrolled more than 3,600 cases for evaluation to find the most appropriate prophylaxis for venous thromboembolism. Led by Ed Wilkins, MD, and the Clinical Trials Network, this study has resulted in new publications, including those in the journal *PRS*, and in multiple presentations. The study team has now received national and international recognition for its work.

However, the main reason and the final outcome of this study is to improve patient safety and clinical outcomes, and to provide best practices to all of our members within plastic surgery.

Building proactive initiatives

Another proactive program – the multi-institutional, Mastectomy Reconstruction Outcomes Consortium (MROC) – also has been initiated through The PSF. Andrea Pusic, MD, and Dr. Wilkins have now received more than $5 million in NIH funding for this study, which is a patient-reported outcome study designed to define what our patients believe is the most satisfactory type of breast reconstruction.

Another proactive initiative of ASPS/PSF was the TOPS registry. It now contains more than 1 million procedures – including the 450 ASPS members who've submitted cases within the last year. At recent meetings in Washington, D.C., the FDA acknowledged the importance of having a TOPS-like registry for outcomes – and the agency applauded members of the Society and ASPS/PSF for initiating such a registry.

There are many, many more collective initiatives that The PSF can embark upon. There are currently two fat grafting initiatives underway, and a collaboration with ASERF – a breast augmentation reconstruction registry – has been proposed.

The PSF's initiative with the fat grafting registry was triggered by many members, who for some time have had concerns about the safety and efficacy of the various methods of fat grafting. It's hoped that the collaborative efforts between ASERF and The PSF, as well as members who are well versed in fat grafting, will lead to the development of guidelines and safety parameters for fat grafting in aesthetic and reconstructive surgery.

Invest, innovate and create

Every day I go to the O.R. and ask another question about a procedure that's being performed, to continuously make our procedures better; to improve upon safety for our patients; and to obtain more reliable and predictable outcomes. Plastic surgeons are innovative and creative by their nature. The demand for research and innovation in plastic surgery procedures continues to increase, and The PSF should provide the reliable and appropriate support for our specialty.

We need to invest in our infrastructure for this to happen. We need to invest in The PSF. The breast implant crisis taught us that we should be poised to respond to immediate and relevant clinical issues. The PSF was very proactive in dealing with the anaplastic large-cell lymphoma (ALCL) concerns, organizing a research team of clinicians, scientists and epidemiologists. The PSF also continues to work with the FDA in developing a registry for all patients with breast implants and ALCL, so that procurement of data and identification of potential risk factors can be identified in our attempts to evaluate cases of ALCL.

We're building an infrastructure that will allow us to be extremely proactive in our research and innovation in plastic surgery. Through emerging technology and our creative instincts we will foster the growth of our specialty and improve the care we give our patients.

We should be proud of our Plastic Surgery Foundation, and we should be honored to give back to the Foundation – to give solely back to our specialty. PSN

EDITOR'S MESSAGE

Professionalism will be the key to weathering health care storms

BY C. SCOTT HULTMAN, MD, MBA
PSN EDITOR

The end of all our exploring
Will be to arrive where we started
And know the place for the first time.
– T.S. Elliott

Sometimes the story needs to start at the end. Professionalism matters more than most of us may realize. It is the component of medicine that helps define our identity as physicians – and a beacon that can illuminate our path forward as healers of patients and caretakers of society.

Since becoming a physician more than 20 years ago, I have witnessed change in medicine so rapid that our colleagues from the middle of the 20th century might not recognize the landscape of today. During this brief wrinkle of time, the delivery of health care has become exponentially complex, due in part to changing social needs, a continuously expanding body of knowledge, and burgeoning institutional constraints. Just as Yahoo, My Space and Napster have given rise to Google, Facebook and Spotify over the past decade, HMOs and capitated care are being replaced by ACOs and concierge medicine.

Modern media have solved some problems but created others: We now live in a post-industrial age where information wants to become free while, paradoxically, that same information becomes more valuable. In the past, whoever controlled the supply of resources, such as water and oil, held dominion over the masses. Today, whoever controls the flow of information has power. The digital frontier is no longer an area where few have travelled; we currently reside in a digital domain where ideas are born, are converted to bits and bytes, and propagate across the globe, almost instantaneously. Because our ability to communicate is quickly evolving, the relationships we have with each other are also changing. The line between patients and providers and payers has blurred. We are all stakeholders.

Medicine's strange evolution

Health care now includes so many elements that would be foreign to our ancestors: marketing and entrepreneurship and innovation, growth of the health-insurance-industrial complex, the decline of private practice, and rise of consolidated health care systems. In plastic surgery, we have shifting boundaries in scope of practice, development of subspecialties such as microsurgery and craniofacial surgery, and the emergence of new fields like tissue engineering and anti-aging medicine. In fact, health care has morphed in some sectors into entertainment, produced by opportunists who participate in reality TV shows and consumed by an audience that exists outside the sanctity of the doctor-patient relationship.

Ironically, as access to knowledge has increased, access to health care has not.

Despite these vast changes in technology, business and society, the mission of organized plastic surgery – ASPS, The PSF, American Board of Plastic Surgery, American Association of Plastic Surgeons and all of our sister societies – has largely remained the same: to promote the safe, ethical and efficacious practice of medicine by maintaining the highest standards possible in clinical care, research, advocacy, education and certification. While we need to reaffirm the strength of our traditions and work within our current structure, we must also rise to the challenges that we face individually and collectively in the 21st century. The central guiding principle that will help us navigate our turbulent health care systems will be the protection of our identity as professionals. Professionalism, it turns out, may be the most important of the six core competencies that define us as physicians.

Tenets of professionalism

George Sheldon, in his 1998 Presidential Address to the American College of Surgeons, identified five critical and necessary tenets that characterize us as professionals:

- Altruistic engagement in social service
- The requirement of special education, knowledge and training
- The ability and willingness to apply knowledge and skill to a greater societal good
- Conformance to and development of a body of ethics
- Autonomy and the right to regulate

With this set of criteria, physicians, lawyers and clergy are clearly professionals. Investment bankers, serial entrepreneurs and politicians – despite contributing to society – do not meet all of these criteria.

Professionalism must be understood in the context of a covenant between the physician, the patient and society. The social contract that physicians create with society exists in sacred space: we are granted the privilege of self-regulation in exchange for our commitment to take care of those who are less fortunate, those who are at risk, those who cannot advocate for themselves. Not only is this commitment made to the individual, but our pledge also extends to society, to protect the health of populations. When physicians wander from their sense of altruism, act out of self-interest or violate their ethical principles, the social contract is broken and we lose our professional identity. The physician may remain a healer, capable of compassion and caring, but the protected status as professional disappears. The most important function of organized plastic surgery, in my opinion, is to carefully guard this social contract by defining, maintaining and enforcing the highest standards of professionalism.

Medical students values

I currently teach a course on medical professionalism to all medical students who plan to enter surgery, anesthesia, obstetrics/gynecology and the surgical subspecialties. At the beginning of the course, the students complete an online questionnaire asking them to rank the core competencies in order of importance. "Professionalism" scores fourth out of six – after "Medical Knowledge," "Clinical Skills" and "Communication." Reassuringly, though, the students strongly believe that Professionalism can be taught, learned and evaluated. The best way to teach professionalism is through mentoring and modeling, two methods that we distinctly control, through our behavior and our attitudes.

We also present these medical students with different scenarios designed to challenge their perceptions about professional-

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PSF, ASPS partner with FDA to create comprehensive ALCL registry

BY KATIE CROTTY

Recent reports of a possible link between women with breast implants and anaplastic large cell lymphoma (ALCL) have garnered a great deal of attention in the plastic surgery community. In an effort to learn more about the potential association between breast implants and this rare condition, The PSF, ASPS and the FDA have entered a partnership to conduct research and develop a comprehensive breast implant-ALCL registry called the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE).

PROFILE seeks to increase the scientific data on the condition by identifying – both retrospectively and prospectively – confirmed cases of ALCL in women with breast implants.

"PROFILE is another important initiative that The PSF has undertaken to address immediate concerns of our members and the patients we serve," says PSF President Michael Neumeister, MD. "The PSF was proactive in responding to this unforeseen medical issue, and PROFILE is a very well thought-out collaborative effort between The PSF, ASPS and the FDA."

"For ASPS, The PSF and our members, patient safety always comes first," says ASPS President Malcolm Roth, MD. "Although this entity appears to be exceedingly rare, and in most cases relatively benign, we are eager to begin the PROFILE study and look forward to collaborating with the FDA. We have identified an exceptional group to look at the data and help us answer all of the questions regarding the association between ALCL and patients with breast implants."

The PROFILE study will be led by Andrea Pusic, MD, associate attending physician at Memorial Sloan Kettering, on behalf of ASPS/PSF, and epidemiologist Cara Krulewitch, PhD, on behalf of the FDA.

"This new registry will provide key data to help us better understand the epidemiology and etiology of breast implant-associated ALCL," says Dr. Pusic. "This is an important patient safety initiative and it is important that we all take the time to report new cases."

Dr. Krulewitch says the registry will foster a better understanding of the role of the implant itself in the etiology of primary ALCL in women with breast implants.

"The data from the registry will be available for analytical epidemiological studies and will provide health care practitioners and patients with important information," she says. "The data will also contribute to our understanding of the potential risk factors and criteria for detection and management of primary ALCL in women with breast implants."

As the PROFILE registry is being developed, plastic surgeons or other physicians that have a patient with confirmed or suspected ALCL are asked to report the case to MedWatch at *www.accessdata.fda.gov/scripts/medwatch* – and to also contact The PSF at *ALCL@plasticsurgery.org*.

For more information, including resources for reporting an ALCL case in MedWatch and relevant literature about ALCL in women with breast implants, please contact *ALCL@plasticsurgery.org*. PSN

ASPS, French society monitor developments on PIP silicone gel breast implants controversy

ASPS has been monitoring the developing situation in France regarding suspected, defective silicone breast implants manufactured by Poly Implant Prothèse (PIP), which was required to halt production of the implants in 2010 after the company was found to be using non-approved silicone gel that is believed to pose an increased risk of rupture.

Thanks to colleagues at the Société Française de Chirurgie Plastique Reconstructrice et Esthétique (French Society of Plastic Reconstructive and Aesthetic Surgery) with whom ASPS signed a Memorandum of Understanding in 2010, the Society has been receiving real-time information from plastic surgery leaders in France.

Last month, the French Ministry of Health advised the estimated 30,000 French women with PIP silicone implants to have their implants removed. At *PSN* press time, other European health ministries appear to be awaiting the French decision before deciding on their own courses of action. As many as 400,000 women in 65 countries in Europe and Latin America are estimated to have PIP implants. PIP silicone gel-filled implants were never approved for use in the United States, so an American woman would had to have been implanted outside the United States in order to have received the implants that are now the subject of concern.

A lawyer for PIP founder Jean-Claude Mas told Agence France Presse on Dec. 27 that PIP knew it was not in compliance but claims the silicone used in the implants was non-toxic. He added that it had not been proven that the implants were more likely to leak.

For our international members, we believe that while the current focus of attention is in France, approximately 80 percent of PIP implants were exported to other countries including the United Kingdom, Spain, Brazil, Argentina, Chile, Colombia and Venezuela. There are also reports that implants under the brand name "M," distributed by a Dutch company in Germany – and possibly elsewhere in Europe – may also be PIP implants that were rebranded as "M" implants.

ASPS will continue to monitor the situation and keep members informed of further developments. PSN

Editor

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ism, ranging from boundary issues to substance abuse to misuse of social media. Scenarios that most bother the students regarding breaches in professionalism included: "Arriving to work impaired by alcohol," "Making a sexual advance on a patient," "Saying a racist 'joke,'" "Lying about patient information" and "Committing Medicare fraud."

Scenarios that the students did not feel were egregious included "Advertising on a billboard," "Exceeding work-hour restrictions as a resident," "Using equipment provided by a drug company" and "Treating one's own family member." Such beliefs are most likely based upon cultural perspectives, determined in part by generational differences.

Surgeons face so many challenges in this brave new digital world: new paradigms of education, new perceptions of life/work balance, new types of media and new social structures. Professionalism may represent the single-most powerful force that we can harness to define ourselves as physicians. It is our anchor that will keep us steady in the rough seas of health care reform and change. But professionalism is also our lighthouse, showing us the way home to near and distant shores where physicians can practice the art and science of medicine, while honoring the social contract and protecting those who we serve.

As the new chief medical editor for *PSN*, I plan to explore several areas of health care that affect us as plastic surgeons: scope of practice and competition, the changing structure of the doctor-patient relationship and how to harness innovation as a core competency of our discipline. My job will be relatively easy, due to the outstanding staff with whom I will collaborate, from the writers to the editors to the administrative support team. The difficult challenge will be to deliver work that matches the quality of those who have preceded me. However, I have always tried to exceed expectations. Happy New Year! PSN

Online ASPS In-Service Exam registration deadline set for Feb. 17

The ASPS In-Service Examination offers plastic surgeons a highly effective tool to rigorously evaluate their skill levels and provides an opportunity to earn up to 30 *AMA PRA Category 1 Credits*™. The exam will be accessible online from March 5-April 2.

The early-registration deadline is Jan. 31, with the final registration deadline set for Feb. 17. All results will be available online as of May 4.

The In-Service Exam undergoes systematic updates over the course of each year to provide current information on plastic surgery's core areas, with relevant questions posed in the categories of Craniomaxillofacial; Cosmetic/Breast; Comprehensive; and Hand/Extremity.

"The In-Service Exam delivers a self-directed, interactive learning experience that will keep surgeons' skills sharp – and their knowledge base fresh and comprehensive," says ASPS In-Service Committee Chair Stephen Chidyllo, MD. "In large part, that's what makes this exam such an invaluable self-assessment tool for plastic surgeons."

For information on registration, fees, computer system requirements and other specifics relating to the exam, go to *plasticsurgery.org/ISE*.

For further information, contact Andrea Hoffman, ASPS Education Programs administrator, at *ahoffman@plasticsurgery.org*. PSN

Plastic surgeon named ASSH president – first since '98

W.P. Andrew Lee, MD, Baltimore, director of the Department of Plastic and Reconstructive Surgery at Johns Hopkins University School of Medicine, has been elected president of the American Society for Surgery of the Hand (ASSH). He is the first plastic surgeon in 13 years to be elected ASSH president.

Dr. Lee has led five hand transplant surgeries – including the nation's first double-hand transplant and first above-arm transplant – from March 2009 to September 2010 as chief of plastic surgery at the University of Pittsburgh Medical Center (UPMC).

"Being chosen to lead a premier medical organization – particularly one with such a rich history – is a great honor and great responsibility," Dr. Lee says. "I look forward to continuing my work with a group that counts among its membership some of the country's most highly regarded surgeons."

Johns Hopkins CEO and medical faculty dean Edward Miller, MD, lauded Dr. Lee's skills and dedication. "We're very fortunate to have Dr. Lee on faculty," he says. "This well-deserved appointment reinforces Dr. Lee's reputation as one of the field's shining stars. We're proud and delighted that our colleague will be leading the society forward."

Among Dr. Lee's many accomplishments is the groundbreaking "Pittsburgh Protocol," an anti-rejection therapy that reduces the number and amount of drugs introduced into patients for immunosuppression after transplantation.

Dr. Lee was installed as ASSH president during the organization's 66th annual meeting held in Las Vegas in September. PSN

Three of five hand transplant recipients from surgeries led by W.P. Andrew Lee, MD, while at the University of Pittsburgh Medical Center (from left): Jessica Arrigo, Chris Pollock and Sheila Advento.