

Membership votes 'Yes' to three-year renewal of PSEC

BY MIKE STOKES

Witnessing a wave of recent media reports that have shown journalists sharpening their focus on the importance of verifying ABPS certification for cosmetic and reconstructive procedures, the membership of ASPS overwhelmingly (87 percent) approved extending the annual \$400 special assessment through 2014 to fund the Plastic Surgery Education Campaign.

The vote took place during the ASPS/PSF Annual Business Meeting on Sept. 26 in Denver, where ASPS Public Education Committee Chair David Reath, MD, detailed how the Society's decision this year to bring the bulk of the PSEC's creative activities in-house has resulted in significant cost savings – while expanding the reach of the campaign to unprecedented levels.

Dr. Reath explained that the \$2 million investment by ASPS membership over the past year has generated \$10 million in advertising value – a 500 percent return – through television, radio, print and online coverage.

"Our messages are being picked up and spread across many different media," Dr. Reath told the audience. "The PSEC is our most successful and strategic tool to combat 'white coat deception.' Our competitive environment is only going to get more difficult, but we're seeing a shift in the perception of plastic surgeons protecting our turf to protecting the public and our patients."



ASPS members voted to extend the PSEC through 2014 during the 2011 Annual Business Meeting in Denver.

Honoring heroes

The ASPS Annual Business Meeting opened with a video tribute to plastic surgical pioneer Ralph Millard, MD, who passed away in June, and a moment of silence for the other ASPS members who have died during the past year.

2011 ASPS President Phil Haeck, MD, also expressed the Society's gratitude to plastic surgeons serving in the military – including Raj Ambay, MD, a Candidate for Membership and major in the U.S. Army Reserve, who was recruited to serve in the field for several months with the 24th Special Forces.

"When they first found out that I was a plastic surgeon, they asked, 'What's a plastic surgeon going to do for us in Special Forces?'"

Dr. Ambay told the audience. "What they found out was that a plastic surgeon became the ultimate general surgeon because I could treat the face, hand, abdomen, chest, soft tissue – and I had the opportunity to do just that, including a laparotomy at 85 m.p.h. and a thoracotomy in a cave. It was an incredible experience that I will never forget. Moreover, I will never forget the training that I received, and I won't forget that behind that training is all of you who take care of these soldiers when they come back to the United States."

Dr. Ambay concluded by presenting to ASPS an American flag flown over the Al Asad Airbase in Iraq on May 14 and signed by the commander of the base.

State of the union

Recapping a presidential term that was bookended by the FDA white paper and safety signal on ALCL and breast implants in January, and an FDA panel hearing on post-approval studies for silicone breast implants in September, Dr. Haeck reported that ASPS remains on solid financial footing and membership remains strong – 98 percent of all board-certified plastic surgeons in the United States are members of the Society. He added

that international membership continues to be an area for growth, but noted that all membership categories will continue to see an influx of valuable new products and services, such as AMP – the new plastic surgery group purchasing organization (see article on page 10) – to generate non-dues revenue.

2011 PSF President John Persing, MD, discussed an active year for The PSF, which included a name change, new logo and dedicated website at ThePSF.org. He further detailed the need for continued support of the Foundation, noting that the new "Drive for 75" campaign (see article on next page) had spurred more than \$60,000 from more than 40 percent of the annual meeting attendees.

Other business

Nominations for the ASPS/PSF Nominating Committee were also accepted with Anu Bajaj, MD; Bob Basu, MD; Geoffrey Keyes, MD; Linda Phillips, MD; and Paul Weiss, MD, being selected. Paul LoVerne, MD, was selected as an alternate.

Al Aly, MD, editor-in-chief of the Plastic Surgery Education Network (PSEN), demonstrated the educational portal and encouraged ASPS members to visit psenetwork.org for access to key journal articles, surgical videos, self-assessment tools and more.

To close the meeting, Dr. Haeck handed the gavel to incoming ASPS President Malcolm Roth, MD, to close the meeting, and Dr. Persing did the same for new PSF President Michael Neumeister, MD. psf.org

ASPS/PSF Board of Directors

Unified specialty, science prevail at FDA hearings

BY MIKE STOKES

Data collection was a recurring topic of discussion during the ASPS/PSF Board of Directors meeting on Sept. 22 in Denver. Announcing that ASPS and the FDA had agreed to jointly create a national breast implant registry to gather data on cases of ALCL in women with breast implants (see article on page 22), 2011 ASPS President Phil Haeck, MD, also reported on the recent FDA panel hearings on post-approval studies for silicone breast implants.

Dr. Haeck hailed as a victory for science the collaborative effort of the 11 ASPS and ASAPS representatives who provided testimony to the FDA's General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee at hearings held Aug. 30-31 in Gaithersburg, Md. He said the panel showed great interest in the plastic surgeons' ideas for improving the post-market studies.

Following a day of presentations by implant manufacturers as well as activists who have long claimed silicone implants are related to various systemic diseases, Dr. Haeck says ASPS and ASAPS worked together to focus their message and emphasize the dozens of epidemiological reports that have proven that no link exists between connective tissue disorders and silicone.

He said this emphasis on scientific evidence over conjecture moved the discussion toward ways to enhance data collection methods, including the use of existing studies and registries to supplement manufacturer data (see article on page 26). When solicited for input on how to improve patient retention for the follow-up studies, the plastic surgeons provided a number of suggestions, such as combining manufacturer data, conducting focus groups that



2011 PSF President John Persing, MD, (left) and 2011 ASPS President Phil Haeck, MD



also include women with saline implants, reducing the size of the 27-page patient questionnaire and eliminating the requirement for a MRI every two years, which are cost-prohibitive and tend to result in a number of false positives.

"It went from a circus to science overnight," Dr. Haeck said, recognizing the contributions of those who testified. "It made me proud to be a plastic surgeon."

"It was one of my best days in organized plastic surgery," added ASAPS President Jeffrey Kenkel, MD. "The great thing is that we responded as a group."

Enhanced nominating process

The Board approved a recommendation by the Governance Task Force to revise language in the ASPS/PSF Nominating Committee Policy (and Bylaws) to clarify the length of time a member would be eligible to serve on the committee and to identify the immediate past-presidents as co-chairs of the Nominating Committee, which has long been tradition but never codified.

The task force also drafted advisories for the co-chairs to ensure the nominating process is free of positive or negative bias by requiring committee members to recuse themselves from discussions involving a candidate that might test their ability to

remain impartial, such as sharing a practice with a candidate for office.

"Obviously this is an imprecise statement in determining when a conflict exists, and that has to be left to the individual committee member," said Governance Task Force co-Chair Michael McGuire, MD. "But by including this notice in the policy, it informs the committee that it is something to be considered."

Cost-cutting recommendations

Balancing increasing travel and hotel costs against the intrinsic value of meeting face-to-face to conduct the business of the Society and Foundation, the Trustees were asked in July to review the expenses associated with hosting board and committee meetings and present their findings and any recommendations for reducing costs. In the report, the Trustees advised against eliminating any Board meetings but recommending testing the viability of electronic conferencing capabilities as a substitute for one board meeting in 2013 (after existing contracts with hotels have been honored).

The Trustees also proposed hosting more board and committee meetings at the ASPS Executive Office and/or hotels near O'Hare Airport in Chicago as a means of reducing expenses. The Trustees also proposed further restrictions to the reimbursement

policy for subspecialty organizations that have representatives on the Board.

Supporting research

National Endowment for Plastic Surgery (NEPS) Council of Advisors Chair Norman Cole, MD, announced the official launch of "The PSF Drive for 75" (see article on next page) and nominated Gary Culbertson, MD, Sumter, S.C., and Richard Greco, MD, Savannah, Ga., to fill two open positions on the NEPS Council of Advisors. Dr. Haeck also congratulated Dr. Cole for taking the lead in revitalizing the Foundation's development activities.

Other news

The International Scholarship Visiting Professor Committee announced six Visiting Professors for 2012. They are:

- Amy Alderman, MD, Atlanta
- Chares Butler, MD, Houston
- Paul Cederna, MD, Ann Arbor, Mich.
- Bahman Guyuron, MD, Cleveland
- Elizabeth Hall-Findlay, MD, Banff, Alberta, Canada
- Foad Nahai, MD, Atlanta

Plans were announced to make Pathways to Leadership a budget-neutral program through individual fund-raising efforts. Applications for the program will be accepted beginning in 2012.

Dr. Haeck also reported on the growing role of evidence-based medicine (EBM) in plastic surgery and reviewed recent steps by ASPS to introduce the concept to membership, including rating levels of evidence in appropriate PRS articles, developing EBM guidelines and a tutorial available online through the Plastic Surgery Education Network at psenetwork.org. psf.org

PSF 'Drive For 75' campaign aims to help the specialty help itself

BY JIM LEONARDO

The most important PSF fund-raising effort of the last two decades is now underway. The "Drive for 75," which officially launched during *Plastic Surgery THE Meeting* in Denver, is designed to significantly increase the number of ASPS members who contribute to The PSF.

"Less than 25 percent of us currently contribute to The PSF," said ASPS past President Norm Cole, MD, during the annual meeting's Opening Ceremonies. "We can do better than that. This campaign aims to raise that to 75 percent... Our specialty is small; we're not perceived by the public to be a group in need. We're going to have to take care of ourselves."

The Drive for 75 was conceived by Sepehr Egrari, MD, Belleville, Wash., to bring attention to the low number of contributors – and to urge plastic surgeons who haven't contributed to open their pocketbooks for the good of the specialty in general – and their own practices.

"There's a cycle that I compare to a 'typhoon' of scientific endeavors that occurs with research, and individuals like myself use the results to improve the delivery, betterment and establishment of care – and then patient care, which is the bottom line," says Dr. Egrari. "All of this can occur because of that single contribution made a year or two years ago."

The last major fund-raising project the Society championed occurred 20 years ago in reaction to the silicone breast implant crisis, and it yielded the National Endowment for Plastic Surgery.

Unlike the Endowment, which generates interest that is used to support immediate issues facing the specialty, Dr. Cole says the Drive For 75 donations are available to fund research on emergent issues. "All funds contributed will go directly into The PSF treasury to be used for additional research and other projects," he says.

"These contributions will not only improve the specialty as a whole, but that cycle and progression will improve our status as practicing plastic surgeons throughout the country – the whole world, actually," says Dr. Egrari.

More than simply fund raising

In separate interviews with *PSN*, Drs. Cole and Egrari noted that plastic surgeons who've shied away from donating to The PSF may be missing a crucial point – that contributing will benefit their own patients and practices – as well as the specialty. "A common response I get is that they've got the money to contribute, but they don't know what the Foundation is or what they're giving money for," Dr. Cole says.

"These won't be 'luxury' donations for wish-list items," Dr. Egrari maintains. "These will be for hard research – the core and lifeblood of plastic surgery, which is what The PSF does. These will address technology, innovation, research and humanitarian effort – the four pillars of The PSF and the absolute core of our specialty."

Dr. Egrari says challenges for the specialty to innovate, as well as challenges coming from beyond its walls, make shoring-up plastic surgery through research increasingly important as time marches on.

"In this era of evidence-based medicine and the encroachment by other specialties, we need to establish ourselves as the dominant force in aesthetic and reconstructive surgery," he says. "This is particularly true on the reconstructive side; there are oncologic surgeons performing breast reconstruction and

bariatric surgeons doing massive weight-loss body contouring. So we have to re-establish this specialty and take care of each other to remain the dominant force."

ASPS members can only do that through research and an evidence-based mentality – which Dr. Egrari calls "the new paradigm in our field. If we let that go and expect our leadership to do our work for us, then we'll miss the boat. A number of individual efforts will be required to make the whole – and forgive the analogy, but we have to stick together like a band of freedom fighters."

Changing times

For years, the Foundation had housed the full educational component of the Society as well as its fund-raising arm. The name change from PSEF to The PSF in 2010 reflected education's relocation under the ASPS umbrella.

"I believe that what happened with that move was that members, particularly the younger ones, lost sight of the absolutely critical link between their donations and innovative research that can affect their patients – and their livelihood," Dr. Cole says.

He provided a scenario to clarify how these donations affect physicians.

"Let's say I've got a solo private practice and I read the academic journals, but I want answers on how I can provide services that are more cutting-edge and provide a product in a very competitive environment," Dr. Cole says. "If I received a correspondence from The PSF that began, 'New breakthrough for capsular contraction' – man, I'd open that right up. Then give me links to carry me further, and more to get further beyond that. I want to see: 'We've studied this condition to determine a possible causative effect on that condition, and there was none,' or 'We did find a link – and here's what you do to help your patients.' To make our efforts meaningful to the men and women in their clinics and O.R.s, we have to provide research that itself has meaning."

But Dr. Cole acknowledges that to provide that research, The PSF leaders need to know what meets the needs of plastic surgeons, "and to that end, we're conducting research to see what our members want. But I'm learning a lot about our members; a lot of people want to earmark different things."

By the numbers

Last year, The PSF invested nearly \$750,000 to support 34 investigator-initiated research projects – such as VTE risk outcomes in reconstructive surgery patients, fat/stem cell grafting research and composite tissue transfer – that are answering clinically relevant questions and enhancing treatment opportunities and safety for patients.

The PSF Research Grant and Fellowship Program (see article on page 32) includes, but isn't limited to, such projects as:

- Pilot Research Grant and Combined Pilot Research Grant
- Research Fellowship Grant
- National Endowment for Plastic Surgery Grant
- PSF/AAAPS Academic Scholar



Phillip Wey, MD (left); Linda Phillips, MD; Geoffrey Gurtner, MD, and Gary Culbertson, MD at the Drive for 75 display in the Plastic Surgery Plaza.



First, best chance

To the audience at the Opening Ceremonies, Dr. Cole pointed out pledge cards that had been placed upon each seat inside the Colorado Convention Center ballroom. In a final effort to impress upon ASPS members the priority with which The PSF is approaching this effort, he informed them that Drive For 75 member proxies would be stationed at the rear of the room to take possession of completed cards.

"There's not a single person in this room who cannot afford \$100; no one should leave here without having made a pledge," Dr. Cole concludes. "I will see you in the back of the room." *PSN*

To contribute to The PSF Drive For 75, go to ThePSF.org/support/drive-for-75.

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which is a compilation of all of the leaders of our sister societies, and we rely on them to bring back information from their organizations about what The PSF should be looking at right now in terms of research. We develop a priority list based on the input from all of the societies – not just a committee isolated within The Foundation – and that's how we allocate our research funds. We stay right by embracing and engaging our sister societies in all aspects of research.

Dr. Greco: *Each generation of plastic surgeons has different attitudes toward work, family time and ways to engage. What changes can be made to address the educational and professional needs of our members?*

Dr. Roth: It would be presumptuous for either one of us to tell you what we personally would like to see. It's something that the Executive Committee has been actively analyzing during the past couple of years – how many meetings we have, the types of meetings we have, and how can we make those meetings more meaningful. We have certainly heard from the younger plastic surgeons and our residents, and we know the way they learn is very different from the way we learned. Books are, for some of them, passé. They learn on the fly and not within the same constraints of the day; the hour is not as relevant – they would like the ability to start something at 9 o'clock and stop at 9:10. Get back to it 11 at night and maybe again at three in the morning. Therefore, we have to be able to provide access to education in different formats. The Plastic Surgery Education Network (PSEN) is a great opportunity for us, and it will continue to grow. Reaching out to our members and hearing what they'd like from us will drive us.

Dr. Neumeister: We shoot ourselves in the foot by bemoaning the fact that younger surgeons don't do things the same way we used to do them. The next generation isn't just taking out a textbook and reading – they take out their iPads and pick up the same information faster with access to different types and sources of information. Our websites need to be interactive so that it's very easy to find information, and PSEN is key. It's going to be one of the strongest education portals in the surgical fields – if not in all – of medicine, for all the information that's available not only for residents or trainees, but for practicing plastic surgeons. That is going to be the biggest and strongest education tool that we can invest in and make available to everyone.

Dr. Papay: *What are the top three current problems facing the field of plastic surgery – and are there any solutions in the near future?*

Dr. Neumeister: If you look at what's current, a lot of people might say we need to look at ALCL right now and determine if it's a true entity related to implants – and I agree with that. From a bit more of a global plastic surgery research picture, however, I don't think we have really embarked on the subject of aging skin. We look at all different aspects. We use fillers, Botox®, the anti-inflammatory effect to treat symptoms rather than the condition itself. The NIH is interested in this, and there are funding mechanisms for it. We need to embrace it to a greater extent – identify ways to protect the skin, prevent the damage and perhaps reverse some of the changes.

Soft-tissue loss is still a big problem, and that encompasses a huge amount of what we do, from wounds to composite tissue allotransplantation. Those are all soft-tissue losses and still a problem that we need to look at. We don't have wounds down yet; there are many different dressings out there because there's not one by itself that does the job. In the future, it might be that we take biopsies of these wounds, do a genetic analysis and create an individual portfolio for a dressing for

each patient. CTA still is not where it's going to be in the future – we still have to use immunosuppressives that have secondary effects, but at some point it would be nice just to replace a damaged ear, because it's safe to do and the secondary effects of the immunosuppression are not there.

Finally, obesity – taking fat away and then putting it back in. We need more clinical trials and basic science for fat grafting.

Dr. Roth: I'll start with one of Dr. Alderman's key issues that I think is really critical: We know that one in eight women is going to get breast cancer, and they often aren't aware of their options for reconstruction. And even if they are aware, there has



Clockwise from top right: Steven Bonawitz, MD; Francis Papay, MD; Amy Alderman, MD; Richard Greco, MD; PSN Editor Michele Shermak, MD

been on occasion – more occasions than we care to think about – a perceived problem of getting access to a plastic surgeon to perform the reconstruction. The challenge is to work with breast surgeons and oncology groups to set up practice patterns to make sure that women have access to preoperative discussion with a plastic surgeon and access to a plastic surgeon to see them through their reconstruction. A similar challenge lies ahead for hand and microsurgery.

The economy has probably been beneficial for preservation of some reconstructive aspects of what we do. A couple of years ago, the Young Plastic Surgeons Forum did a survey that showed academic plastic surgeons compared with private practice plastic surgeons worked a comparable number of hours, had comparable vacation days – and have comparable incomes. You can make a very good living doing reconstructive surgery. In our teaching programs, we have to encourage our residents to be as skilled as possible in reconstruction. It's an edge for them against economic downturns, but it's also something that, in many cases, is much more gratifying than getting a nice cosmetic surgery result. We need to work very carefully at making sure we don't lose sight of our core – and that's reconstructing lives.

Dr. Alderman: *At the end of this demanding year, what are you going to do for your wives?*

Dr. Roth: [Laughs] I'm very fortunate that because my wife is a consultant who can basically work from anywhere, I'm going to have her by my side for virtually all of my travel. I stepped into the presidency knowing I'll have her there to keep me sane. Throughout this coming year, I'll let her direct me in how I can reward her for all the support that she's going to be giving me, as she has already.



Dr. Neumeister: Tuscany. My wife has always wanted to see Tuscany, so she's going to go to a spa in Tuscany. In the meantime, she's renovating our house, and she just loves to do that, so she has free reign – even though one of the big windows she has busted out a wall to make room for cost more than her Prius.

Dr. Bonawitz: *Fast forward a year as you're finishing up your term. Looking back, how will you define success?*

Dr. Roth: I'll be sitting in this seat for a year, but I'm not driving the organization – ASPS continues to move forward. I'd like to see us stronger. I'd like to see us increase the educational opportunities – not just in terms of the number of meetings, but rather in ways of providing access to education. PSEN will be a huge part of that. My personal advocacy engagement has led me to setting a goal of seeing at least five more states pass truth-in-medical-education and advertising laws – that would be significant. Even more significantly, I would like to see the public finally understand what board certification means as it relates to plastic surgery. I would like to see the power of the PSEC, the power of our

message and plain common sense encourage journalists to work with us to get the word out to patients.

Dr. Neumeister: I want two things. I want our members to look at The PSF and say, "That's a damn good research engine we have." And I want the public to say, "That's a research engine that changes lives."

I want the infrastructure of The PSF to be such that people believe they can get their ideas into collaborative research and really change things – ideas that say *We see a problem here – you guys may not have identified it, but I have and I bet there are others who have, too.* Then we get groups together that can actually work on it as consensus groups. But without the infrastructure, that won't happen as an isolated research pocket. If we get together, we can have a greater power of research for our members and for the public. I hope people will recognize that.

Dr. Papay: *Years ago, there were discussions about The PSF being a resource center where someone with an idea could find help designing a study, writing a grant and getting the research done. Is that what you're looking at doing?*

Dr. Neumeister: I would like The PSF to become the "University of PSE" where it becomes the place to go for all your research endeavors and be a collaborative effort for our whole Society. Over the last four years or so, we've laid the foundation and now it's time to start building that infrastructure. There should be a go-to place, and The PSF is probably the place where we can build upon that idea – to find someone who does basic science in that field and who can help you develop it and help with writing grants and getting funding.

It would be great to have research coordinators who can do collective or systematic reviews on comparative data. We don't have that right now, but if we could build that infrastructure – and that means we're going to have to invest in it – then you can get an idea backed by The PSF, and it suddenly becomes a funded project. There are clinical trials that The PSF has initiated that have led to changes in practice and to multi-million dollar awards from the NIH; the MROC, which is a breast reconstruction clinical trial, started with a \$50,000 National Endowment for Plastic Surgery grant – and it was just awarded \$5.5 million from the NCI. The MROC started with just a few people saying, "Hey, we should do this."

Dr. Papay: *With ObamaCare potentially on the horizon and economic changes leading to different types of practice patterns and the way plastic surgeons are associated with hospitals, ACOs, etc., how do you feel health care reform will affect the Society and the ability of the members to be a part of ASPS?*

Dr. Roth: My first task force is going to address all the different issues related to health care reform and the realities of the marketplace. Funding health care reform will be a slow process, and whether the Supreme Court makes a determination that it has to change, be repealed or just go away doesn't change the reality that we're seeing hospital systems gobbling up practices. One of the charges of the task force will be looking at how to break down the usual walls and boundaries that have led to the solo practitioner operating on his or her own, staying away from the hospital and competing directly with other plastic surgeons. Ideally, we might see collaborations such as in Spokane, Wash., where ASPS members began marketing and absorbing costs as a unit as others had

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Annual meeting

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symposia delved into topics ranging from 3-D imaging to complex craniofacial problems, aesthetic injectable trends – and sculpture.

Among the most popular courses were those that took a head-on approach to controversy and contention, including “Complications with Lower Lid and Lid-Cheek Junction Surgery,” “After the Flip Dies... Now What? Is it Still Microsurgery?,” a lecture on plastic surgery and robotics, and the ALCL and oncoplastic surgery panels.

The educational offerings also came with strong doses of entertainment and fun, with plastic surgeons squaring-off in intellectual battles royale. Plastic surgeons matched wits (and traded barbs) in contests such as the Reconstructive Bowl (mentees beat the mentors), Residents Bowl (Stanford beat Michigan), Plastic Surgery Jeopardy (Steve Haase, MD, is this year's champion) and Iron Surgeon (J. Peter Rubin, MD, claimed the honor) – all part of a concerted effort by

organizers to provide educational content in creative ways.

“The imagination demonstrated in these lively plastic surgery educational courses and events is really a testament to our instructional course and scientific panel leaders,” says Neil Fine, MD, Annual Meeting Program Chair. “The depth, quality, variety and reach of this year's annual meeting from an educational standpoint proves that the Society's priority is its members, and by extension, the patients of plastic surgery. We left Denver as better educated, better prepared plastic surgeons – and the direct beneficiaries of these educational efforts will be our patients.”

Speakers elevate the meeting

Plastic Surgery 11 was taken to a higher level by those who spoke inside the packed ballrooms and conference rooms spread throughout the Colorado Convention Center. Perhaps nowhere was interest more focused, however, than during two lectures delivered separately by two renowned plastic surgeons.

Henry Kawamoto, MD, delivered the

Kazanjan Lecture on Sept. 25, taking the audience on a trip through his plastic surgery career, beginning with his hard-working father as role model through his mentors inside and outside the UCLA Center for Health Sciences, where he's a clinical professor of plastic surgery.

Laurent Lantieri, MD, professor of plastic surgery at Assistance Publique Hopitaux de Paris, head of plastic surgery at Henri Mondor Hospital and annual meeting Maliniac Lecturer, on Sept. 26 regaled his audience with facts surrounding facial transplantation and how problems related to that procedure were overcome. If one follows the teachings of Apollo 13 flight director Gene Krantz – widely known for the saying “Failure is not an option” – then all plastic surgeons should be able to perform facial transplantation, Dr. Lantieri told the audience.

A surprise performance

While several social and networking events brought enjoyment to *Plastic Surgery 11* attendees, two of the more noteworthy offer-

ings were the PSF International Reception and the Presidential Gala. The International Reception was held Sept. 25 within Peaks Lounge at the Hyatt Regency Convention Center. Inside, guests from many of the 46 countries represented at the annual meeting forged new friendships and renewed old ones in a relaxing atmosphere, while the westward-facing picture windows afforded a spectacular view of a late-September Denver sunset.

The Presidential Gala titled “PINNACLE,” held Sept. 26 in the Hyatt's Capitol Ballroom, allowed ASPS members, spouses and guests to dance to the sounds of Fifty Amp Fuse. The packed ballroom was treated to a non-advertised entertainment special when Dr. Haeck (drums), PSF immediate-past President William Kuzon, MD (guitar), PSF past President Peter Neligan, MD (guitar) and ASPS Executive Vice President Michael Costelloe (guitar) – picked up instruments and sat-in on a few rock 'n' roll songs, to the delight of a surprised audience.

The Gala was supported by Medicis Aesthetics, which also unveiled the compa-

ASMS president's address

Thank you, mentors, for giving me the gifts of humility and joy

The following is an edited version of the Opening Ceremonies address of 2011 ASMS President Steven Buchman, MD:

It has been a wonderful and productive year for the American Society of Maxillofacial Surgeons.

We've reorganized and transitioned to a different management company, and the future looks bright. I want to thank the members of our Board of Trustees, who've helped us to reinvigorate and expand the value and contributions of the ASMS – resulting in new programs and improved ways in which the society works with each other and with our membership.

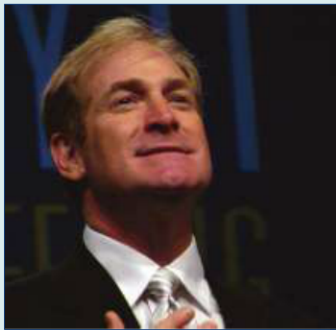
Our Website Committee has performed stellar work, making our site at maxface.org more relevant and more user friendly. Our Education Committee has also continued to push the boundaries of innovation and instruction. In addition to our basic course, which remains the cornerstone of our brand, we have advanced the ASMS mantle by taking on two new and exciting projects. The first is a cutting-edge course aimed at the practicing plastic surgeon: Advances in Facial Restoration and Rejuvenation. This lab cadaver course will give participants a unique opportunity to have talented faculty give personal instruction on the latest techniques, while participants can actually attempt these procedures and use the products for themselves.

In addition, we've entered an agreement in principle to join with the American Society of Craniofacial Surgery to co-sponsor and extend its summer course for craniofacial Fellows, with ideas and innovations that are sure to bring the course to the next level.

Indeed, it's an exciting time for our organization. I encourage you to join us. The ASMS is accessible enough to allow meaningful efforts to make a real difference and impactful enough to make your contributions count.

It truly has been both an honor and a privilege to serve as the 65th president of the American Society of Maxillofacial Surgeons over this past year. I'm humbled by the long list of eminent surgeons who've held this office before me, such as Varaztad Kazanjian, MD, our third president, and Reed Dingman, MD, our sixth president – who, like myself, hailed from the University of Michigan. In fact, he started the plastic surgery training program there.

I've been lucky enough to have crossed



Steven Buchman, MD

paths with many of our society's leaders over the course of my career – surgeons like Henry Kawamoto, MD, our 44th president, and Paul Manson, MD, our 50th president, who both helped shepherd my career.

In an ironic twist, Samuel Shatkin, MD, our 31st president, has a grandson, Adam, who's now training with me in our plastic surgery program at the University of Michigan with the desire to become a craniofacial surgeon.

These relationships between teacher and student, between mentor and mentee, and between colleagues link us to each other – as well as to the next generation of our specialty. These relationships help us to sew the fabric and build the tradition of fellowship and excellence that bind us together as a community of plastic surgeons. Winston Churchill once said: “We make a living by what we get, we make a life by what we give.” I'm sure that if you closely examine your life, inevitably there will be a figure that helped or guided you into being the person you are today.

Whether you're in academics or private practice, I think opportunities to teach, advise and support those early in their training and careers are all around us – if we make a point to seek them out.

The word “mentor” originates from the Greek poet Homer, who in the epic *The Odyssey* describes an old friend who guides young Telemachus – the son – in making his way through manhood and ultimately in search of his lost father, Odysseus.

Mentorship guides us to understand the inheritance within us and the possibility of achieving our full potential in our chosen profession. A true mentor assists with important transitions and helps decipher

the priorities for our lives.

The role of mentors is ubiquitous throughout history. Socrates was a mentor to Plato, who, in turn, was both a teacher and a mentor to Aristotle. And Aristotle was the chief mentor to Alexander the Great.

One of my favorite quotes on the subject of mentoring is from Sir Isaac Newton, who said: “If I could see further than others, it was because I stood on the shoulders of giants.”

Idly contemplate your life, and you'll find an entire cast of players who've neither starring roles nor simple cameo bits. Woven through our days on this planet is a variety of individuals who are not only vital to our development as people, but who also play roles that are recursive in nature.

I contend that each of us lives the hero's journey – not once, but many times, and that each time we choose wisely we complete a level. There are some special people with whom we come into contact, share a portion of the ride, who help us on our journey and without whom we would not fulfill our destiny. Many of those special people are our mentors.

Early on, our parents are our main mentors – not only guiding us, but teaching us right from wrong. Grandparents also serve as particularly wonderful mentors. Slightly removed from the everyday aggravation of child-rearing, they can provide a loving and detached perspective, and often they can see both sides of most issues.

Once a career path is chosen, it's the kindness of strangers and the interest and benevolence of others that can make all the difference. Certainly in my case that was true.

I was able to meet individuals who understood, as Mark Van Doren once said, that “the art of teaching is the art of assisting discovery.” I've met people in our specialty who took joy in contributing to the success of another individual.

Peter Randall, MD, taught me about the magic of pediatric plastic surgery and the ability to change a child's life. Linton Whitaker, MD, who trained me as a plastic surgery resident at the University of Pennsylvania, genuinely taught me the value and the true gift of constructive criticism – and I am better for the fact that he cared enough to share that gift with me.

At UCLA, I had the privilege to meet and train with one of my most fascinating mentors – the inimitable Dr. Kawamoto. He loved his job, he loved to be a surgeon and he loved craniofacial surgery. His enthusiasm was contagious and he infused in me a

desire to be like him in so many ways.

He worked hard and played hard, and he was extraordinarily devoted to his fellows. There was little time for sleep, he would say, so catch it when you can! He continues to be a pillar of support.

Finally, there have probably been no greater guides on our road to knowledge as surgeons than our patients themselves. I truly feel privileged to have had the opportunity to work with them throughout the years.

They've taught me humility and joy, and they've brought tears to my eyes. And they have given me the confidence and courage to push the limits of reconstruction. What wonderful blissful and innocent faith and trust they put in us, as we toil to make the world see on the outside what we all know is the beautiful inside of each of their loving souls.

Classically, a mentor is an older and wiser trusted advisor. I cannot help but think, however, that these children have guided me. Surely, providence has imbued their spirit to help us to become better surgeons. Surely, the essence of these children embodies a hero's journey. There could be no more special people to share that journey with than the patients I've had the privilege to treat.

Being a plastic surgeon allows so many of us to truly live a charmed life. Each of us has the opportunity to pay our good fortune forward by finding the time and opportunity to mentor another. Finding that opportunity is empowering, as it allows us to make a consequential difference in our own life and in another's at the same time.

Or, in perhaps a much grander way, as said by Gandhi: “Be the change you want to see in the world.”

Finally, indulge me an opportunity to thank those closest to me.

All of the work I do takes time – precious time – and it is, of course, a zero sum game. The time I spend as ASMS president has been given to me as a present by the most precious people in my life: my family. I could not have been luckier in life than to be blessed with the most understanding and loving wife and children, who are in my thoughts even when I cannot be there to tuck them in.

I'm truly honored to have had the opportunity to address all of you, my valued colleagues, here tonight. To be able to celebrate and share this honor with my parents, Nathan and Lillian Buchman; my wife, Cindy; and my four children, Lauren, Brevin, Ally and Bradyn, is a gift I'll cherish for the rest of my life.

Thank you so much.

Gathering data is key to answering ALCL questions

BY JIM LEONARDO

The Society's dedication to gathering information, providing direction and helping plastic surgeons to answer tough questions associated with anaplastic large cell lymphoma (ALCL) and breast implants was made clear during "ALCL and Breast Implants – Plastic Surgery's Proactive Response, State of the Science and Collaboration with the FDA," the 2011 President's Panel held Sept. 24 in Denver.

Designed to provide ASPS members with current information and address gaps in the ALCL knowledge base, the panel was developed in response to questions arising from the FDA announcement in late January that the agency was investigating a possible connection between ALCL and breast implants. The FDA has publicly stated that ALCL is



Allergan Medical's Michael Oefelein, MD, discusses ALCL at the 2011 Presidents Panel

extremely rare, and literature reviews have revealed that of the estimated 10 million implants provided worldwide since 1989, only 34 cases of ALCL have been identified.

In addition to noting that no link has been established between breast implants and

ALCL – and that the condition has manifested in patients with and without breast implants – the annual meeting panel reinforced the need to support a national breast implant registry currently in development as a joint venture between ASPS/PSF and the FDA to "identify the primary risk factors and criteria for detection and management of ALCL," ASPS President Phil Haeck, MD, told the audience.

"The issue around causality and implants has yet to be resolved," said panelist Andrea Pusic, MD, who discussed the development of the registry. "These are the things the registry can help to explore."

Dr. Pusic added that the registry's creation should demonstrate that the Society and Foundation are doing all it can to ensure patient safety. "We're also making sure the correct response to this issue is based in sci-

ence, not hysteria," she said. "That's what this registry's all about."

Summarizing information gathered since the condition was discovered, Dr. Haeck noted that ALCL has occurred within the breast implant capsule, but "remember that ALCL can occur *in* the breast – and that's a completely different animal. . . . We're talking about ALCL appearing in the breast implant capsule. [In that event,] localized treatment may be all that is needed; absence of the disease spread beyond that capsule means these patients most likely don't need radiation and chemotherapy.

"The problem with the data we have now, as we've gone back to do retrospective reviews on cases 10-15 years old, is that it's almost impossible to know what the implant was [that was given to any particular ALCL sufferer]," he added. "There may be an operative report and some findings in a chart, but the implant itself would be long gone. Currently, it's clear that we're going to find some were saline implants, some were silicone and some were textured. That's all we're going to know about it. The registry will give us a lot more information."

"The registry also ensures that patient education, clinical algorithms and policy decisions surrounding implants will not be based on anecdotal information, but rather on a full, high-level understanding of the epidemiology and etiology of ALCL," Dr. Pusic said.

Observations on ALCL

Panelist Michael Oefelein, MD, a trained urologic surgeon who oversees late-phase clinical trials in urology, dermatology, health/bariatrics, and breast and facial aesthetics at Allergan Medical, told the audience that ALCL needs to be classified differently than it has been in the mainstream press.

"It's a syndrome rather than a disease," he said. "A syndrome is a pattern of signs and symptoms that can inform a physician as to a common potential outcome, yet the mechanism of action and path of physiology isn't completely understood. [Thinking of ALCL as a syndrome] might help inform us on how to go forward. . . and think through this problem."

He added that ALCL generally presents as swollen, tender breasts with peri-prosthetic fluid collection, with rare incidences of adenopathy, fever and D-cell symptoms.

Dr. Oefelein noted that his information was gleaned from sources that included a RAND Commission review of ALCL-related data and the FDA's review of the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) database.

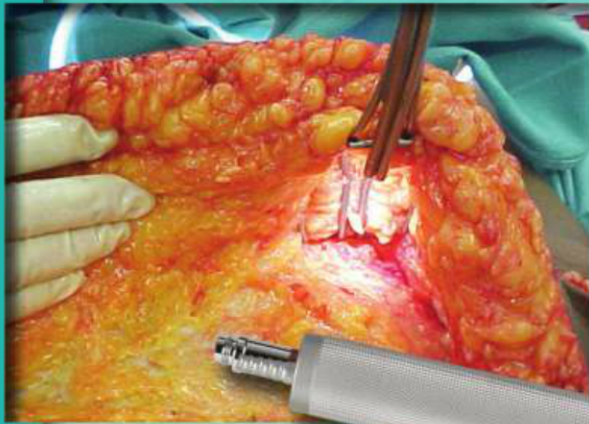
The RAND review concluded that "this is a rare entity that seems to be associated with breast implants, but there seems to be no evidence of causation," he said. "RAND thought that given the generally indolent but potentially heterogeneous and aggressive course of the disease, different treatment may be considered. Especially in the early stage, the potential for performing just capsulectomy and avoiding chemotherapy is an important takeaway."

The SEER study's focus on breast implants and ALCL showed "a risk of about 1 per 30 million; that's extremely rare," he said. "It's important to note that this database doesn't code for the presence or absence of breast implants – so this 1 per 30 million should be viewed as a combination of women with and without breast implants."

Dr. Oefelein added that race may also play a factor: There have been no cases reported among the Asian-Oriental or African-Caribbean categories. "Is this a

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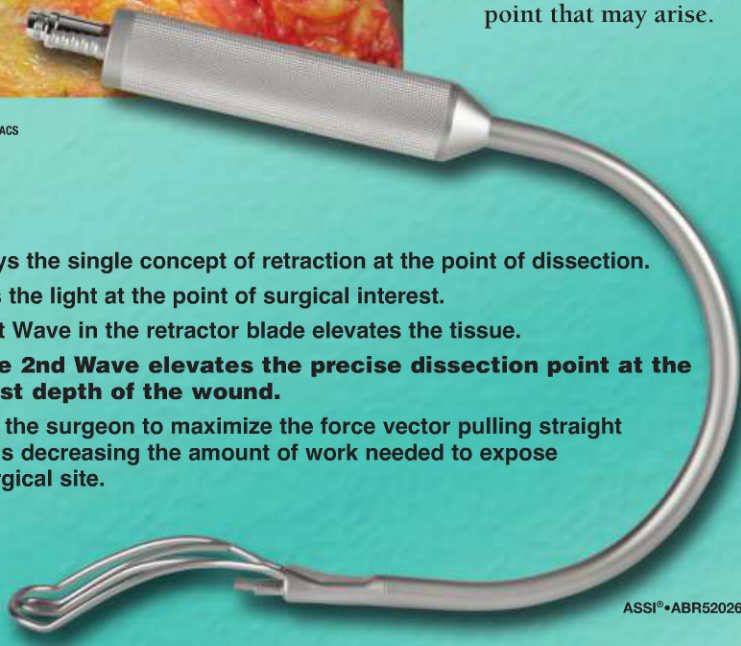
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FDA panel reaffirms safety of silicone implants

BY LORI SHOAF

The Food and Drug Administration's (FDA) General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee conducted a hearing on Aug. 30-31 in Gaithersburg, Md., to evaluate the progress of long-term post-approval studies (PAS) mandated when silicone gel-filled breast implants were approved by the Agency to return to market in 2006.

The hearing included a review of data targeting performance and long-term safety of breast implants and suggestions for improving future studies.

The panel heard a range of perspectives on the device from patients, women's health and consumer groups and medical professionals—

including ASPS and ASAPS representatives.

While implant opponents continued to raise concerns about the availability of silicone breast implants, FDA personnel who spoke at the hearing pointed to the Agency's May 2011 white paper "Update on the Safety of Silicone Gel-Filled Breast Implants," to affirm the safety and effectiveness of the device. The white paper noted that data and scientific literature reveal no correlation between silicone breast implants and connective tissue disease.

"ASPS has always taken a stand for patient safety," ASPS President Phil Haeck, MD, told the panel. "We want the best for our patients, and we've been a leader in pursuing outcomes data that support therapeutic decision-making by our members."

Additional testimony by representatives of breast implant manufacturers Allergan Inc. and Mentor/Johanson & Johnson focused on current data, adverse events, follow-up rates for the current PAS, methods to improve patient follow-up and potential changes to current and future studies—including new methods of data collection.

ASPS testimony

In addition to Dr. Haeck, ASPS members Steven Bonawitz, MD; Andrea Pusic, MD (who helped create the BREAST-Q[®]); and ASPS/PSF Board Vice President of Health Policy and Advocacy Robert X. Murphy Jr., MD, testified before the panel. The ASPS leaders provided several recommendations in their testimony that would improve the

post-approval studies and potentially change labeling for the device, including:

- The literature does not support the use of MRI as a screening tool for asymptomatic patients, particularly given the cost/benefit equation and the potential detrimental effects of false positives. In addition, the MRI requirement appears to be a detriment to maintaining enrollment of patients in the study.
- ASPS continues to support investigation of alternatives for implant rupture screening.
- A key limitation in current studies is the reliance on prospective data collected from U.S. patients; therefore, ASPS recommends that data should be gathered from existing sources inside and outside the United States to fill gaps. Specifically, the FDA should consider data sources such as the Australian, British, Canadian and Danish registries, among others, as supplemental data to achieve end points, as these registries are older and have more data than the PAS. When combined with data already collected, these alternative data sources could enhance post-approval data without the costly need to pursue women lost to follow-up.
- ASPS supports changes to the studies that make it less burdensome for enrolled patients and physicians to comply. For example, Allergan now allows patients to fill out the questionnaire online and by telephone. Additionally, Mentor has modified its study website for easier access and use. The Society supports any further changes that make it less burdensome for patients to complete appropriate follow-up.
- ASPS believes the FDA should carefully consider and prioritize the clinical questions they want answered in future PAS with an eye toward reducing burden and improving compliance for patients and surgeons.
- Post-market surveillance through case reports, registries and other databases, such as the ASPS Tracking Operations and Outcomes in Plastic Surgery (TOPS)—a HIPAA compliant, confidential national database of more than 1 million plastic surgery procedures—and the narrowly focused ALCL registry currently under development, are also critical adjuncts to the post-approval studies.

"The TOPS registry can serve as a valuable resource and tool for broadly collecting procedural-specific and longitudinal outcomes data related to breast implant procedures," Dr. Murphy told the panel. "TOPS data fields could easily be expanded to facilitate and formalize data collection for the purpose of developing a national breast implant registry. These efforts can inform and supplement global data collection to enhance the post-approval studies and breast safety."

Dr. Pusic told the panel that accumulating data beyond the current PAS will increase the knowledge base. "We believe additional data from outside the existing construct may be needed to supplement these studies," she said.

"New initiatives can be employed such as data mining from existing international resources to answer questions," she added. "Clearly, there's a need to improve the studies to achieve the endpoints."

ASPS representatives also discussed the need to foster further innovation relative to breast implants, as well as the high levels of satisfaction among plastic surgery patients with silicone breast implants—a position reaffirmed by the FDA white paper.

FDA reactions, recommendations

The FDA hearings also yielded a number of highlights and recommendations. During the public portion of the silicone-gel breast implant proceedings, the panel:



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- Discussed the 35 percent of women in the PAS who are lost in follow-up, and noted that it seemed to be an appropriate assumption due to the many follow-up and enrollment challenges the companies and clinicians face. However, when discussing both current and future post-approval study designs, the panel had many ideas to increase follow-up compliance.
- Recommended that the questionnaires be web-based and revised to be more understandable for enrollees, as the current paper questionnaire is too lengthy and tedious. The panel noted that confidentiality is important to patients, and it recommended emphasizing to enrollees that they're assisting research that targets women's health.
- Noted that consideration should be given to providing incentives for physicians and patients to improve follow-up rates.
- Discussed study methodology and the potential for obtaining better data with fewer patients or conducting multiple studies to address different data endpoints, rather than a single large study.
- Reached a consensus that it was necessary to assess failure rates in terms of long-term effectiveness, and agreed that 15 years was a reasonable expectation for the life of breast implant devices.
- Discussed the use of registries that may collect a larger amount of data and can capture rare occurrences. The panel also noted that pooling registry data from various databases could help identify rare endpoints, and that smaller cohort studies could capture more common endpoints.
- Indicated that a breast implant registry of all patients could provide answers to many long-term questions – particularly those related to possible association with rare adverse events.
- Debated current scientific data on the approved product labeling recommendations for MRI screening for silent rupture, and questioned the efficacy of this recommendation given the cost to patients and potential for false positives.
- Heard concerns by some of its members that high-resolution ultrasound may be a reasonable technology option in the future, particularly for detecting ruptures on the front surface of the implant, while MRI can detect ruptures of the entire breast implant – including the back wall.
- Noted that future studies for newer breast implants that utilize the same technology as those already approved should be combined with implants already marketed to answer any additional data endpoints. This type of data pooling would allow for comparisons to be made.
- Felt that a post-approval registry should be created to capture all breast implant data.

The panel also emphasized the importance of participation by third-party stakeholders – for example, professional societies like ASPS – to improve current and future post-approval studies.

What happens next

The FDA is reviewing the data and presentations as well as the panel recommendations. The Agency plans to engage the stakeholder community on changes to post-approval studies and the improvement of data collection. ASPS will continue its longstanding dialogue with the FDA regarding these studies and the safety of silicone implants.

Additionally, ASPS has signed a Collaborative Research and Development Agreement with the FDA to establish a registry to study the possible association between anaphylactic large cell lymphoma (ALCL) and breast implants. Discussions are underway to establish a work plan and timeline, and solicit subject matter experts. The Society anticipates that it will take six to 12 months to set up the registry and finalize a work plan. [ENR](#)

AAPS Academic Scholar is a humble innovator

BY JAMES CHANG, MD



It is a great honor and pleasure to highlight 1991 AAPS Academic Scholar Michael Longaker, MD, past president of the Society of University Surgeons and a past chair of the Plastic Surgery Research Council. He's also among only a handful of surgeons who've been elected to the American Society for Clinical Investigation and the prestigious Institute of Medicine.

I first met Dr. Longaker in 1991, when he was a surgical resident in the University of California-San Francisco (UCSF) research laboratory; I was a visiting medical student from Yale University, looking for my own research laboratory. After meeting in the cafeteria at 8 a.m., he took me on a blistering pace that lasted throughout the day and

included conferences with various senior scientists. His characteristic enthusiasm immediately sold me on the laboratory; therefore, I'm considered Dr. Longaker's first research Fellow among the more than 100 Fellows that he's had since.

Anyone who has spent time with Dr. Longaker knows of his incredible drive for excellence and his brilliant mind for scientific inquiry. Therefore, and not surprisingly, the AAPS Selection Committee in 1991 placed a very safe bet on him when it identified him as a young plastic surgeon with great potential to become a successful academician based on his or her potential for research and innovation – and named him its Academic Scholar.

Raised just outside of Detroit, Dr. Longaker earned his undergraduate degree from Michigan State University, where he



Michael Longaker, MD, and his family

was a 6-foot-1-inch guard on the 1979 NCAA Basketball Championship team with Magic Johnson. I can attest to this personally, and I've attended basketball games with Dr. Longaker where he still refers to Magic Johnson as "Earvin" – his given first name.

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concentrations of aprepitant, concomitant administration should also be approached with caution.

Aprepitant is a substrate for CYP3A4; therefore, coadministration of EMEND with drugs that strongly induce CYP3A4 activity (eg, rifampin, carbamazepine, phenytoin) may result in reduced plasma concentrations of aprepitant that may result in decreased efficacy of EMEND.

Ketoconazole: When a single 125-mg dose of EMEND was administered on Day 5 of a 10-day regimen of 400 mg/day of ketoconazole, a strong CYP3A4 inhibitor, the AUC of aprepitant increased approximately 5-fold and the mean terminal half-life of aprepitant increased approximately 3-fold. Concomitant administration of EMEND with strong CYP3A4 inhibitors should be approached cautiously.

Rifampin: When a single 375-mg dose of EMEND was administered on Day 9 of a 14-day regimen of 600 mg/day of rifampin, a strong CYP3A4 inducer, the AUC of aprepitant decreased approximately 11-fold and the mean terminal half-life decreased approximately 3-fold.

Coadministration of EMEND with drugs that induce CYP3A4 activity may result in reduced plasma concentrations and decreased efficacy of EMEND.

Additional Interactions: EMEND is unlikely to interact with drugs that are substrates for the P-glycoprotein transporter, as demonstrated by the lack of interaction of EMEND with digoxin in a clinical drug interaction study.

Diltiazem: In patients with mild to moderate hypertension, administration of aprepitant once daily, as a tablet formulation comparable to 230 mg of the capsule formulation, with diltiazem 120 mg 3 times daily for 5 days, resulted in a 2-fold increase of aprepitant AUC and a simultaneous 1.7-fold increase of diltiazem AUC. These pharmacokinetic effects did not result in clinically meaningful changes in ECG, heart rate, or blood pressure beyond those changes induced by diltiazem alone.

Paroxetine: Coadministration of once-daily doses of aprepitant, as a tablet formulation comparable to 85 mg or 170 mg of the capsule formulation, with paroxetine 20 mg once daily, resulted in a decrease in AUC by approximately 25% and C_{max} by approximately 20% of both aprepitant and paroxetine.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Teratogenic effects:* Pregnancy Category B: Reproduction studies have been performed in rats at oral doses up to 1000 mg/kg twice daily (plasma AUC_{0-24h} of 31.3 mcg•hr/mL, about 1.6 times the human exposure at the recommended dose) and in rabbits at oral doses up to 25 mg/kg/day (plasma AUC_{0-24h} of 26.9 mcg•hr/mL, about 1.4 times the human exposure at the recommended dose) and have revealed no evidence of impaired fertility or harm to the fetus due to aprepitant. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Aprepitant is excreted in the milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for possible serious adverse reactions in nursing infants from aprepitant and because of the potential for tumorigenicity shown for aprepitant in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of EMEND in pediatric patients have not been established.

Geriatric Use: In 2 well-controlled chemotherapy-induced nausea and vomiting clinical studies, of the total number of patients (N=544) treated with EMEND, 31% were 65 and over, while 5% were 75 and over. In well-controlled postoperative nausea and vomiting clinical studies, of the total number of patients (N=1120) treated with EMEND, 7% were 65 and over, while 2% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Greater sensitivity of some older individuals cannot be ruled out. Dosage adjustment in the elderly is not necessary.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies were conducted in Sprague-Dawley rats and in CD-1 mice for 2 years. In the rat carcinogenicity studies, animals were treated with oral doses ranging from 0.05 to 1000 mg/kg twice daily. The highest dose produced a systemic exposure to aprepitant (plasma AUC_{0-24h}) of 0.7 to 1.6 times the human exposure (AUC_{0-24h}=19.6 mcg•hr/mL) at the recommended dose of 125 mg/day. Treatment with aprepitant at doses of 5 to 1000 mg/kg twice daily caused an increase in the incidences of thyroid follicular cell adenomas and carcinomas in male rats. In female rats, it produced hepatocellular adenomas at 5 to 1000 mg/kg twice daily and hepatocellular carcinomas and thyroid follicular cell adenomas at 125 to 1000 mg/kg twice daily. In the mouse carcinogenicity studies, the animals were treated with oral doses ranging from 2.5 to 2000 mg/kg/day. The highest dose produced a systemic exposure of about 2.8 to 3.6 times the human exposure at the recommended dose. Treatment with aprepitant produced skin fibrosarcomas at 125 and 500 mg/kg/day doses in male mice.

Aprepitant was not genotoxic in the Ames test, the human lymphoblastoid cell (TK6) mutagenesis test, the rat hepatocyte DNA strand break test, the Chinese hamster ovary (CHO) cell chromosome aberration test, and the mouse micronucleus test.

Aprepitant did not affect the fertility or general reproductive performance of male or female rats at doses up to the maximum feasible dose of 1000 mg/kg twice daily (providing exposure in male rats lower than the exposure at the recommended human dose and exposure in female rats at about 1.6 times the human exposure).

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Allergic reactions, which may be serious, and may include hives, rash, and itching, and cause difficulty in breathing or swallowing, have been reported in general use with EMEND. Physicians should instruct their patients to stop taking EMEND and call their doctor right away if they experience an allergic reaction.

EMEND may interact with some drugs including chemotherapy; therefore, patients should be advised to report to their doctor the use of any other prescription or nonprescription medication or herbal products.

Patients on chronic warfarin therapy should be instructed to have their clotting status closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of the 3-day regimen of EMEND 125 mg/80 mg with each chemotherapy cycle, or following administration of a single 40-mg dose of EMEND for prevention of postoperative nausea and vomiting.

Administration of EMEND may reduce the efficacy of hormonal contraceptives. Patients should be advised to use alternative or backup methods of contraception during treatment with EMEND and for 1 month following the last dose of EMEND.

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ALCL panel

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syndrome of Caucasians, genetics or behavior – or something we haven't considered?" he said. "This is very important."

Also, clusters or multiple cases have been reported in particular practices – for example, in Michigan, Kansas and Australia. "This raises fundamental questions: Why such a rare event occurs more than once in a particular practice?"

"Spontaneous remission has been reported without chemotherapy," he added. "This also is important."

Dr. Oefelein noted that a plastic surgeon in Knoxville, Tenn., encountered a case that further adds to the mysterious nature of ALCL. "He performed an explant and sent fluid for culture and, to a great deal of surprise, learned of a diagnosis of CD-30-positive infiltrating anaplastic cells consistent with ALCL," he said. The physician brought the patient back into the O.R. six days later for a complete capsulectomy – and found no residual infiltrating malignant cells in the capsule.

"We'd all agree that cancer just doesn't go away in six days," Dr. Oefelein told the audience. "This is an important observation as to what actually might be going on. Removing the breast implants might be mitigating the stimulation of whatever process was going on; the case spontaneously resolved. This case is important. It reaches further as to a genetic fingerprint."

Information is crucial

Dr. Pusic said the need to gather relevant information in a timely manner became clear to her on the day the FDA mentioned ALCL in conjunction with breast implants. "That day, every time I walked into my office, the phone was ringing off the hook," she said. "Every time I walked into an examining room, I was met with the same worried

look and same question: 'What's this thing about breast implants causing cancer?'"

"From the beginning, ASPS and The PSF have had insight on this," she added. "By taking a proactive stance and working with the FDA and breast implant manufacturers, we've been able to get out front to establish a path that will ensure patient safety."

"With this registry, we'll be gathering in-depth information on individual cases as well as looking at ALCL in a broader epidemiological context," Dr. Pusic said. "It will help us answer important clinical questions such as: Which women are most at risk? How is ALCL best diagnosed? What's its clinical course, and how is it best treated?"

She addressed ASPS members' responsibility with the registry: "It will be voluntary, but to make this work, we all need to take the time to report cases if we see them," Dr. Pusic told the audience. "The Foundation's committed to making this process as simple and easy as possible."

Plastic surgeons who suspect ALCL in a patient should send an e-mail to alcl@plasticsurgery.org. "We have a new ALCL registry coordinator and she'll walk you through the process," Dr. Pusic said. "For now, if you have a confirmed case, she'll also direct you to MedWatch. But once our registry's fully operational, you won't need to go to MedWatch; our registry and MedWatch will be wired to speak directly to each other. That means, too, that if a non-plastic surgeon – for instance, a medical oncologist – goes to MedWatch, we'll still capture that case." All correspondences will be met with a return packet that will include key papers on diagnosis and treatment, she said.

The reality is that many more suspected than confirmed cases will be detected, she added. "Most of us never will have a case of ALCL, but most of us will field questions from anxious patients with breast implants."

Continued on page 37

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gical background shouldn't be allowed to do certain procedures that require a specific skill set. We also need to be available. In terms of breast reconstruction, if we're not available for the general surgeon after he does the mastectomy, we're going to lose those.

Dr. Alderman: *What initiatives will you take for plastic surgeons to regain control over breast reconstruction and not lose patients to the "surgical oncologist," as we're seeing in Europe?*

Dr. Roth: For the Sydney International Breast Cancer Congress next year in Australia, ASPS and each of our MOC international partner countries have agreed to draft a joint recommendation for all breast cancer patients to have access to a preoperative consultation with a plastic surgeon and for a plastic surgeon to be involved in all aspects of the reconstruction. There are some challenges because, in some countries, plastic surgeons may not be doing every aspect of the plastic surgery, but everybody agrees that the plastic surgeon should be involved through the entire process. If we can get the message out that it's an international standard for plastic surgeons to work with the oncologists, cancer specialists and radiologists as a team – we'll be a long way to getting that taken care of.

Dr. Neumeister: We need to be positive

ALCL panel

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Dr. Pusic said. "What's the right thing to say? That it's a rare disease with a likely incidence of one in 1 million among women with breast implants. Also, if the patient develops swelling and/or pain around her implant, she should see you – and you'll investigate. Finally, if ALCL is detected, it's generally a highly treatable condition managed without surgery.

"We've always thought that 'cancer' has to come up in a discussion on breast implants and all its risks," she added. "Breast cancer in general has to. Beyond that, if you want to discuss ALCL, you must have your own position before going into that exam room, of how extensively you want to discuss cancer with that patient."

She said potential breast implant patients can be told that while no surgical procedure is 100 percent safe, they can be given the full risk/benefit equation "presented in the context of, and relative to, their own risk/benefit comfort level and their own values. They also should know they're establishing a long-term relationship with their ABPS-certified plastic surgeon – and if they have future questions or concerns, we will be available."

Dr. Oefelein agreed that breast cancer should be mentioned. "You have to approach each case as, 'It could be [a possibility]. You want to [discuss] what things could harm your patient – and it's a good question – but you need to do that in the context of odds.'"

Should the registry perform as its developers hope and expect, questions and issues raised during the President's Panel should soon have more detailed answers, the researchers agreed.

"All of us as clinicians still have questions," Dr. Pusic said. "The registry will allow us to look at the different patients and the different approaches to management, and ultimately come out with what should be a very clear algorithm for management and treatment that will describe plus/minus radiation, plus/minus chemotherapy."

"There's such a homogeneous presentation" involved with ALCL, Dr. Oefelein said. "You don't want to under-treat, but you don't want to over-treat. (Best treatment comes) only through rigorous study and understanding of predictors of outcomes." **PM**

For more information, go to www.fda.gov/Safety/MedWatch/default.htm or e-mail alcl@plasticsurgery.org.

about what we do and be present for the oncologists. If we're not available, or if they find it easier to do something without us, we are doing ourselves a disservice and they will take it away from us.

Dr. Papay: *What is your vision of a plastic surgeon's practice 20 years from now?*

Dr. Roth: I think we will see more super-specialization. I was speaking to one of our international guests from Shanghai the other day, and I asked him what his area of practice was. His answer was ear reconstruction – that's all he does. The more you do something, the better you tend to get, and when you can focus your energies into a specific area, you can learn everything there is to learn and be the best.

Dr. Neumeister: I think we'll also see huge multimedia rooms as part of the office space, with touch screens where you can easily write notes and draw diagrams as part of a consultation – and then save it for each specific

patient to review on a website at home. Right now, a patient who has just been told that she has breast cancer will come to see me about breast reconstruction and then go home thinking we haven't talked about anything at all – which is understandable because she's just been told she has cancer. With these multimedia additions, everything you discuss will be there for the patient to review through some online source. Education will also be extremely different in terms of simulators and skills labs, and the iPad issue might be quite different – maybe we'll have little holograms instead of actually carrying a tablet.

Dr. Shermak: *I was surprised to learn that many residents and those taking their boards are not taking the next step toward ASPS membership. How are you going to engage those younger people to become active in the organization?*

Dr. Neumeister: They're asking themselves what's the value, what's in it for me?

Program directors have to tell their residents that The PSF does the kind of research that has changed the way we practice.

Dr. Roth: It's also about making clear the value of membership. PSEN is one example, and we just launched AMP – a free group purchasing program that will enable ASPS members to save money on things for their practices while, at the same time, helping the Society decrease the cost to be a member. We are actively reviewing additional opportunities and will have some exciting announcements over the next year of additional new membership benefits that will help our members' bottom lines as well as the organization's. And these could be very far-reaching and not even limited to the practice of plastic surgery. Perhaps we can offer travel discounts, dining discounts – we're looking at many different opportunities.

Dr. Neumeister: I wonder if there will be any discounts to Tuscany. [Laughs] **PM**

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