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On the cover:
Present at NYSSA’s Past Presidents’ Luncheon, held during PGA 65, were: (standing, left to right) Drs. Robert S. Lagasse, Paul H. Willoughby, Anthony A. Ascioti, Michael H. Mendeszoom, Michael S. Jakubowski, and Alan E. Curle, and (seated, left to right) Drs. Jared C. Barlow, Marilyn M. Kritchman, Gerald S. Weinberger, and Peter B. Kane.
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Thank You for the Opportunity to Serve — Remarks to the NYSSA House of Delegates

OUTGOING PRESIDENT KATHLEEN A. O’LEARY, M.D.
DECEMBER 10, 2011

It is my distinct pleasure to stand before you and comment on the current status of this organization and the pertinent issues we faced during my year as president. One year ago, I felt confident that the NYSSA was on good financial footing, had expert leadership, and was poised to deal with anything that might come its way. I assure you today that none of this has changed.

Financially, we are in great shape. We have sold the co-op office space we owned on Fifth Avenue, purchased new office space on East 40th Street, near Grand Central Station, built that office space out and successfully moved in. The “nuts and bolts” of the build-out were expertly handled by Stuart Hayman, and the rest of the NYSSA staff managed to pull off the move seamlessly, with no interruption in member services. The sale and new purchase resulted in a very favorable impact on operating expenses and our bottom line. Kudos to Stuart and the staff for all their hard work in making this move possible. I must congratulate Drs. David Bronheim, Larry Epstein and Sal Vitale, and Stuart Hayman in selecting the current location. Thanks to all of you for your time and effort.

It appears that PGA 65 will be yet another great PGA, not only from an educational standpoint, but from a financial standpoint. The leadership of the PGA — Drs. Andy Rosenberg, David Wlody and Rich Beers — deserve our gratitude for their dedication to this excellent international meeting and for putting together a wonderful academic experience. Our preregistration numbers have exceeded last year’s numbers! The PGA is a critical and substantial part of what this organization does. Its success or failure impacts our bottom line. There is so much that is beyond our control — local, national and international economies, the strength of the dollar, and travel safety concerns. Yet, in spite of these uncontrollable influences, the PGA continues to draw anesthesiologists from all over — a true testament to its stellar program!

My year has been highly influenced and driven by legislative issues. They are divided into three major areas: Scope of practice, tort reform, and payment-related. Certainly the one that took so much of my time and attention was scope of practice. Attempts by CRNAs over the years to
introduce legislation that would result in independent practice in New York state have never come to fruition. However, this year there were forces at work that made it appear that this might gain traction. Earlier this year, the Medicaid Redesign Team (MRT), put into place by Gov. Cuomo, was given the daunting task of redesigning New York state’s Medicaid program to dramatically cut costs, while ostensibly maintaining quality care. This was on the heels of the Institute of Medicine’s Future of Nursing report, issued in October 2010, in which it was recommended that nurses should practice to the full extent of their education and training. The combination of these two efforts provided an excellent opportunity for the CRNAs in New York to take a different approach to pushing increased scope of practice on their part.

In collaboration with MSSNY and our lobbyists in Albany at Weingarten, Reid and McNally, we were able to monitor, and, indeed, contribute to, the activities of the MRT’s Workforce Flexibility and Change of Scope of Practice Work Group. Dr. Robert Hughes, president-elect of MSSNY and the lone physician on this work group, did an outstanding job representing us. The New York State Association of Nurse Anesthetists introduced a proposal to have independent practice by CRNAs in New York state. This proposal was not advanced by the work group, although it came very close. With our encouragement and guidance, the American Academy of Anesthesiologist Assistants submitted its proposal to introduce AAs in New York state. However, this proposal also was not advanced by the work group.

Where do we now stand with regard to CRNA attempts to advance their scope of practice within New York state? It is anticipated that there will be a task force appointed by the State Education Department to deal with this and other scope of practice issues that came out of the Workforce Flexibility and Change of Scope of Practice Work Group. I predict that there will be changes in the manner in which CRNAs practice in New York state and I believe that we will need to make compromises. However, we should have a voice at the table in these discussions. We are awaiting word from the State Education Department on this topic.

I’d like to recognize three individuals who have served this organization for many years and who will be stepping down from their elected positions. First, Dr. Ken Freese has completed his tenure as ASA Director. Dr. Freese has served in this position for nine years, representing us so well at the ASA. Additionally, in his position as ASA Director, he has served on the Executive Committee of the NYSSA. His analytical mind and “devil’s advocate” approach kept us all on track during difficult times when there were no easy answers. I could always count on him to cut

NYSSA — The New York State Society of Anesthesiologists, Inc.
through the fluff and really get to the heart of the matter. His sage advice was always welcome.

Dr. Marilyn Resurrecion has served this House and the NYSSA for seven years as Speaker, and prior to that for 14 years as Vice-Speaker. For more than two decades she has managed to keep us all on track during difficult debates and challenging votes, both in this House and at Board of Directors meetings. Her guidance and leadership will be missed.

Dr. Sanjeev Chhangani is leaving New York state to practice in Boston and Martha's Vineyard. He has served this society as District 6 Director for several years, serving in that capacity on the Board of Directors and representing anesthesiologists practicing in the Rochester area. He has also served as chair of the Critical Care Committee. I congratulate him on his move and wish him well as he begins a new chapter in his professional career.

I’d like to wrap up my speech today by extending my heartfelt gratitude to several people. First, the NYSSA staff are the unsung heroes of this organization. Stuart Hayman has done an excellent job of steering our organization and has guided the NYSSA staff through the difficult transitions. All of the NYSSA staff work hard all year long, but they work the hardest at a time when many of us are relaxing and socializing during the holiday season, in anticipation of, and during, the PGA. They deserve our sincere thanks for a job well done.

Second, I’d like to thank my colleagues, both here at the NYSSA and at home at Roswell Park Cancer Institute in Buffalo. The Executive Committee of the NYSSA is a tight-knit group of individuals who dedicate a tremendous amount of their time and energy to guiding this organization. No decision is made without considerable debate, numerous e-mails, and frequent conference calls. I have valued everyone’s input. At home at Roswell Park Cancer Institute, my colleagues have covered for me for the unanticipated visits to Albany and the conference calls that have taken up my time. They have also provided me with moral support. For this I am thankful.

Several years ago, as a junior attending, Jerry Barlow approached me about becoming more involved in the politics of anesthesiology. As a former NYSSA president and ASA Director, he had broad insight and helped to direct me down the path that led to my becoming president of the NYSSA. To Jerry I say a special thanks!

Last, and definitely the most important, is my family. My husband, Michael Collins, and my children, John and Nora, are all finally at this
meeting with me. They have all felt the impact of my involvement in the NYSSA. My children have come to hate the term “conference call” as they know this will inevitably disturb dinner or our family time together. The reason I have been able to be so involved is because my husband kept our family on track during the PGA, the ASA, all the conference calls, and the visits to Albany and our offices in Manhattan. His support has made all of this possible. I truly could not have done this without him.

My final words to this group are a follow up to my speech last year: Become more involved in this organization and get your colleagues to do the same. The NYSSA truly has your best interests at heart, but your involvement is needed. As your new president, Dr. Vitale will be counting on you to be responsive and involved. Please don’t let him down.

To all of you, I say “thank you” for this opportunity to serve as your president. It has truly been an honor and a privilege.
Inaugural Address to the NYSSA House of Delegates

SALVATORE G. VITALE, M.D. — DECEMBER 10, 2011

Earning PRAISE for Our Specialty and Our Society

Practice Professionalism

Our patients should know that we are physicians who are dedicated to the safe and efficient delivery of quality healthcare. All anesthesiologists, including residents, should develop an information card or other form of written communication that can be given to our patients so they know who took care of them and how to contact us if there is a problem with their care. We are doctors, not technicians. It’s time to make this distinction known to our patients.

Practicing professionalism is a concept that is applicable on a wider scale. As anesthesiologists, we should be good citizens in the hospital. This includes serving on committees and volunteering our time to our institutions and our specialty societies. We should be seen as problem solvers and leaders in our profession.

Recognize Our Place in the History of the Specialty

The American Society of Anesthesiologists can trace its roots to a meeting of nine physician-anesthetists who came together at Long Island College Hospital in 1905. From this initial meeting the Long Island Society of Anesthetists was born, eventually becoming the New York Society of Anesthetists and, ultimately, the American Society of Anesthesiologists.

It’s time that the NYSSA received the recognition it deserves as the precursor organization to the ASA. I will be working with the ASA to ensure that this long-overdue recognition takes place, including amending the ASA’s Web site to include the correct history of the organization.

Advocate on Behalf of Our Profession and Our Patients

The year 2012 will be a challenging one for the NYSSA legislatively. Scope of practice will continue to be an issue, as will any proposals that come from the Medicaid Redesign Team, which has been tasked with finding ways to reduce the costs of the Medicaid program. We need to stay informed and to actively advocate on behalf of our profession and our patients. We must convince Gov. Cuomo and his aides that preserving the anesthesia care team is in the best interest of New York patients.
We encourage your continued support of the NYSSA PAC and your increased involvement in all our advocacy efforts.

**Inspire Environmental Leadership**

According to a report by the American Society of Anesthesiologists, operating rooms generate between 20 percent and 30 percent of total hospital waste and hospitals generate millions of tons of medical waste each year.

We can work together to leave a smaller carbon footprint by recognizing the amount of waste we produce and committing ourselves to be more environmentally conscious in the operating room and throughout the hospital. I am forming a new committee to address this issue and I welcome your ideas.

**Support Research and Education**

The NYSSA House of Delegates created the Anesthesiology Foundation of New York, a 501(c)(3) not-for-profit corporation, to develop starter grants for young New York state anesthesiologists, and to provide
funding for international anesthesiologists from poor countries to participate in educational opportunities in the U.S. The research that we fund through the foundation will benefit all New Yorkers, and the anesthesiologists we educate will bring the benefit of that education back to their home institutions and the patients they serve.

For the Anesthesiology Foundation of New York to fulfill its mission, we need the support of all our members.

**Expand NYSSA Educational Opportunities**

While the NYSSA hosts the second largest anesthesiology conference in the U.S., we can and should be doing more to educate our members. My goal is to expand upon the NYSSA’s current meeting services by working with other not-for-profit anesthesiology organizations throughout the state to find ways to collaborate on educational meetings. To that end, the NYSSA will co-sponsor a meeting with NYU in the spring.

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**66th PGA Scientific Exhibits**

**Poster Presentations**

**Medically Challenging Case Reports**

If you are interested in submitting applications to exhibit your projects at the upcoming 66th *PostGraduate Assembly in Anesthesiology* — December 14-18, 2012, please visit the NYSSA Web site for instructions to submit online:

Go to [www.nyssa-pga.org](http://www.nyssa-pga.org) and click on *PGA 66*.

*Deadline for filing is August 15, 2012.*

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A Glimpse of Things to Come

JASON LOK, M.D.

The recent Communications Committee meeting, held during the 2011 PGA, featured a discussion about some exciting changes planned for upcoming issues of *Sphere*. The committee also discussed the various ways that we are enhancing the NYSSA’s online presence, as well as our public relations activities.

The regular feature articles highlighting New York hospital anesthesiology departments will be phased out by the end of the year. If you would like your department to be showcased, please contact me soon. *Sphere* will transition to feature articles about NYSSA members who donate their time and skills performing charitable work, such as missions. These articles will be intended to counterbalance our regular articles on scope of practice and reimbursement issues. We will be calling for submissions from those who can share their memorable experiences and tough challenges they have faced, along with detailed photos of the location served. Look for more information in upcoming issues of *Sphere*, in e-mails from the NYSSA, and in our postings on Facebook.

Also in development, the editors of *Sphere* are considering interviewing members with unique or interesting hobbies. We currently have pilots and caterers among us. Who knows what other special talents your fellow members possess. Other ideas discussed at our meeting included articles examining the pros and cons of anesthesia-related issues and perhaps a feature article on the intraoperative use of acupuncture. What controversial anesthesia-related issues would you like discussed?

Along with *Sphere*, there is also work being done to enhance our online community. Having completed the recent headquarters move and the PGA, attention can now be focused on our archive of past *Sphere* issues, along with audio and video content. Our Facebook site contains recently posted videos on such topics as injection safety, a discussion of seven important metrics for measuring OR efficiency by NYSSA President-elect Dr. Michael Simon, and a link to a nice blog about our recent PGA by the president of the California Society of Anesthesiologists, Dr. Kenneth Pauker. You can also find many pictures from our recent PGA for you to reminisce or view vicariously. So, please participate by browsing the link: www.facebook.com/nyssapga?sk=wall.
Regarding public relations, Dr. Donna-Ann Thomas will again promote our societal presence at the New York State Fair, to be held August 23 to September 3, 2012. If you are interested in volunteering your time in Syracuse, please note the dates now, as there will be more information coming.

If you have any additional ideas or suggestions regarding content you would like to see in *Sphere*, please feel free to e-mail me at jlokmd@yahoo.com or Stuart Hayman at stuart@nyssa-pga.org. Thanks in advance for your interest and consideration.
From the Executive Director

The NYSSA: Stable and Strong

STUART A. HAYMAN, M.S.

The U.S. economy continues to flounder, our fragile recovery threatened by the economic uncertainties escalating in Europe. Beyond the continued economic question marks, the U.S. is seeing an amplification of negative rhetoric associated with the presidential election. This ugly political discourse resembles the worst of reality TV. As if all of this wasn’t enough, it appears that the “Occupy” movement is going to be with us for some time. I can’t help but be reminded of the turmoil of late ‘60s and early ‘70s.

Fortunately, when one looks to the NYSSA and the PGA, we see the consistency, stability, and diligence of a leadership that continues to put the organization first. The NYSSA is very fortunate to have such a strong group of leaders who have worked passionately to ensure the financial strength of the organization and the educational integrity of the PostGraduate Assembly. On the business side, the NYSSA’s Executive Committee is led by your new president, Dr. Salvatore Vitale. He is assisted by the immediate past president, Dr. Kathleen O’Leary; the president-elect, Dr. Michael Simon; the vice president, Dr. Lawrence Epstein; the treasurer, Dr. David Bronheim; the new secretary, Dr. Vilma Joseph; and the new ASA director, Dr. Scott Groudine.

A significant portion of the NYSSA’s annual resources is utilized producing the association’s international conference, the PGA. Fortunately, it has been a successful undertaking, even during this period of international financial instability and recession. Dr. Andrew Rosenberg, the PGA general chair, works diligently year-round to ensure that the PGA upholds its standing as one of the premiere international educational meetings for anesthesiologists. Dr. Rosenberg is enthusiastically assisted by Dr. David Wlody, Scientific Programs chair, and Dr. Richard Beers, Scientific Programs vice chair. These gentlemen work with PGA committee members and staff to optimize the NYSSA’s use of organizational resources in order to put on the best educational conference possible.

As many of you know, this was another year filled with challenges and change for the NYSSA. Clearly, building out and moving into the new
headquarters last September was an important change for the organization for many reasons. I would be remiss if I didn’t point out what a wonderful job your staff did to make this a seamless move for the members. We continued to process registrations and conduct business as usual throughout the entire process. I am proud of the entire staff and hope you will join me in thanking them for their dedicated service.

On a personal note, the month of January marked the beginning of my 14th year working on behalf of New York’s physicians. More importantly to you, I am celebrating the successful completion of my fourth PGA. I am happy to report that it was yet another successful, well-attended educational meeting. This year, we offered 321 hours of educational opportunities and we were honored to have more than 300 renowned speakers and instructors. While the final financial numbers are not in yet, we fully anticipate that this was another financially successful PGA.

As 2012 begins to unfold, many Americans are bracing themselves for a continued sluggish economy and a divisive election season. Members of the NYSSA should rest assured that your organization remains stable and strong, and we are on track for another productive and successful year.

Your NYSSA staff: (Left to right) Debbie DiRago, Lisa O’Neill, Denise O’Neill, Stuart Hayman, MaryAnn Peck, Kathy Felicies-Rojas, and Will Burdett.
In Memoriam

Joseph F. Artusio Jr., M.D.
1917-2011

New York has benefited from the presence of giants in the medical field of anesthesiology: Rovenstine, Apgar, Papper, Orkin, Blancato, among others. These are the great men and women who did the research that made it so safe to undergo surgery, who created clinical practices and brought the benefits of their knowledge and experience to so many medical students and residents. They are gone, and now another giant of the specialty has passed away. Joseph Francis Artusio Jr. died on December 21, 2011, at the age of 94.

Joe was born in New Jersey in 1917 and graduated from St. Peter’s College in Jersey City. He then attended the Cornell University Medical College, receiving his M.D. degree in 1943. He interned at Bellevue Hospital in New York City and then was called to serve in the U.S. Army. After a quick course in anesthesiology, Joe entered the war in Italy and soon became chief of anesthesia at the 170th Evacuation Hospital. After the war, Joe returned to Cornell for more formal training in anesthesiology. One year after completing his residency, Joe became the attending anesthesiologist in charge at The New York Hospital and rose in academic rank at Cornell from assistant professor of surgery (anesthesiology) to professor of anesthesiology in surgery. In 1967, Joe became the founding chair of the independent Department of Anesthesiology at Cornell. Joe took pride in the fact that he had the longest tenure for an academic chief of a major academic department of anesthesiology when he retired in 1989 — 41 years.

And what years they were! He did major research in the non-flammable anesthetics. He was a driving force in both the ASA and the NYSSA and served both these organizations as a lecturer, committee chairman, and mentor to those who have attempted to follow in his footsteps. He
served the NYSSA well, acting as chairman of the Scientific Programs Committee of the PostGraduate Assembly and then as general chairman of the PGA.

These were times of transition in medicine and in our specialty and he guided the PGA into the greatness that it now maintains. Innovative ideas, stimulating panels and the finest speakers were his contributions to the PGA. The stature of this meeting and the pride in which it is held by all members of the NYSSA are directly attributable to the efforts of Joe Artusio. In 1991, Joseph Artusio was the PGA Rovenstine lecturer, and in 1998 he received the NYSSA Distinguished Service Award.

Joe served his alma mater with distinction, having been president of the Cornell Alumni Association and the recipient of the Cornell Alumni Award of Distinction and New York Hospital’s Distinguished Service Award. Somehow he found time to serve on the Pelham, New York, Board of Education, including one year as its president. In 1967, he was Pelham Man of the Year.

As important as these accomplishments are, Joe is best remembered by his former residents as an excellent teacher, an outstanding clinician, and a fine, caring and true gentleman. It was great pleasure to have him take you by the hand (literally) in the operating room and teach airway management. “In anesthesia, just secure the airway, and the rest is easy.” Residents did their best to incorporate his clinical skills into their clinical management and, hopefully, some of us did.

Joseph Artusio, M.D., lived a full, giving life. He will be missed.

Alexander W. Gotta, M.D.
Jack Egnatinsky, M.D., Receives the 2011 NYSSA Distinguished Service Award

Jack Egnatinsky, M.D., received NYSSA’s Distinguished Service Award at the 65th PGA. Dr. Egnatinsky was honored for his many years of contributions to the NYSSA.

Dr. Egnatinsky served as the District 5 delegate to the NYSSA House of Delegates from 1975-1981 and as the district director from 1991-1996. He was chair of the NYSSA Committee on Public Education and Information from 1982-1988, during which time he established NYSSA’s presence at the New York State Fair. In 1986, he received the NYSSA Recognition Award for his work as the Public Education and Information chair.

Dr. Egnatinsky served as chair of the NYSSA Committee on Government, Legal, and Economic Affairs from 1988-1996. He earned the NYSSA Certificate of Appreciation for his pioneering work as chair of this committee.

Dr. Egnatinsky has served as a clinical assistant professor and a clinical professor with the Department of Anesthesiology at SUNY Upstate Medical University and as chief of anesthesia and medical director of Harrison Center Outpatient Surgery Center. He made frequent contributions to the PGA as a panel host for a variety of topics and has given numerous lectures to residents.

Dr. Egnatinsky was nominated for this award by Dr. Richard Beers, who recognized him as “a leader who has had a significant role in making the NYSSA what it is today.”
A Look at the 65th PostGraduate Assembly in Anesthesiology Opening Session

Broadway performers provide entertainment prior to the start of the 27th Robertazzi Memorial Panel opening ceremony.

David Reich, M.D., chair of the Mount Sinai Department of Anesthesiology, speaks at the 27th Robertazzi Memorial Panel opening ceremony.

Steven Shafer, M.D., adjunct professor of anesthesiology at Columbia University, speaks at the 27th Robertazzi Memorial Panel opening ceremony.
Andrew Rosenberg, M.D., PGA general chair, welcomes everyone to the 65th annual PGA.

ASA President Jerry Cohen, M.D., addresses attendees at the 27th Robertazzi Memorial Panel opening ceremony.

Stephen Thomas, M.D., moderator of the 27th Robertazzi Memorial Panel opening ceremony.

Jack Egnatinsky, M.D., speaks after receiving the 2011 Distinguished Service Award.

Mark Warner, M.D., speaks at the 27th Robertazzi Memorial Panel opening ceremony.

Richard Dutton, M.D., M.B.A., speaks at the 27th Robertazzi Memorial Panel opening ceremony.
The 65th Annual PGA Scientific Awards and Posters

Winners were recognized by Stephen Vitkun, M.D., and Rhoda Levine, M.D., of the Scientific Exhibits and Poster Presentations Committee.
The 65th Annual PGA International Scholars Reception

Jane Fitch, M.D., ASA first vice president, speaks to the international scholars.

Elizabeth Frost, M.D., chair of the International Scholars committee, addresses the international scholars at the opening reception.
The 65th Annual PGA Workshops
The 65th Annual PGA House of Delegates Meeting

(Left to right)
Jason Lok, M.D., Christopher Campese, M.D., Vilma Joseph, M.D., M.P.H., and Andrew Rosenberg, M.D.

Congressman Andy Harris, M.D.

Jung Kim, M.D., and Marilyn Resurreccion, M.D.

Outgoing House of Delegates Speaker Marilyn Resurreccion, M.D., receives a plaque from incoming Speaker Charles Gibbs, M.D.

Sanjeev Chhangani, M.D., M.B.A., outgoing chair of the Critical Care Medicine Committee, is recognized by Kathleen O’Leary, M.D.
Outgoing ASA Director Kenneth Freese, M.D., and Kathleen O’Leary, M.D.

From left, Jared Barlow, M.D., Michael Jakubowski, M.D., and Mark Lema, M.D., Ph.D., past presidents of the NYSSA.

Dr. Kathleen O’Leary’s family members, Nora Collins, Michael Collins and John Collins, attend the meeting.

ASA President-elect John M. Zerwas, M.D., outgoing House of Delegates Speaker Marilyn Resurreccion, M.D., and Kathleen O’Leary, M.D.

ASA President Jerry Cohen, M.D., addresses the House of Delegates.
Scenes From the Scientific Panels

Sven Staender, M.D., (left) and Cor Kalkman, M.D., speak at the International Forum.

(Left to right)
Scientific Programs Chair David Wlody, M.D., PGA General Chair Andrew Rosenberg, M.D., and Daniel Sessler, M.D., 41st E.A. Rovenstine Memorial lecturer.

Kathleen O’Leary, M.D., Salvatore Vitale, M.D., Michael Simon, M.D., Lawrence Epstein, M.D., and Scott Groudine, M.D.
PGA General Chair
Andrew Rosenberg, M.D.,
talks with attendees at the Speaker’s Reception.

From left, James Osorio, M.D., Vinod Malhotra, M.D., and Vidya Malhotra, M.D.

Salvatore Vitale, M.D., ASA President-elect John M. Zerwas, M.D., and Scott Groudine, M.D.

Michael Schoppmann, Esq., (left) and Michael Simon, M.D.

Maris Rosenberg, M.D., Stuart Hayman, M.S., and ASA Director of Meetings Christopher Wehking, CMP.
The 65th Annual PGA Technical Exhibits
The 65th Annual PGA President’s Reception

Immediate Past President Kathleen O’Leary, M.D., enjoys the reception in her honor.

From left, Michael Jakubowski, M.D., Susan Jakubowski, and Peter B. Kane, M.D.

Lobbyist Perry Vallone (left) and NYSSA President Salvatore Vitale, M.D.

NYSSA Vice President Lawrence Epstein, M.D., and Mrs. Erica Epstein.

Mrs. Rene Gibbs and Charles Gibbs, M.D.
Kathleen O’Leary, M.D., Michael Simon, M.D., Jerry Cohen, M.D., Scott Groudine, M.D., and Robert Lagasse, M.D.

Rose Berkun, M.D., lobbyist Perry Vallone, and Ms. Patti Spawlding.

Michael Mendezsoon, M.D., M.B.A., (left) and Michael Jakubowski, M.D.

Salvatore Vitale, M.D., (left) and Michael Simon, M.D.

Mark Lema, M.D., Ph.D., and Kenneth Pauker, M.D., president of the California Society of Anesthesiologists.
Maris Rosenberg, M.D., Andrew Rosenberg, M.D., and Jerrold Lerman, M.D.

(Left to right) Anjali Dogra, M.D., Vilma Joseph, M.D., M.P.H., Mrs. Janie Lok and Jason Lok, M.D.

From left, Francine Yudkowitz, M.D., Kathleen O’Leary, M.D., Ms. Sun Whang, and Jung Kim, M.D.

Robert Reid and Shauneen McNally
Plans are already under way for the 66th annual PostGraduate Assembly in Anesthesiology.


Register at: www.nyssa-pga.org
Getting the Word Out

GABRIEL BONILLA, M.D.
RESIDENTS AND FELLOWS SECTION PRESIDENT

The year 2011 is gone and 2012 has arrived! Ringing in the new year is a festive event. And hopefully 2012 doomsday predictions are inaccurate so that we may be able to continue enjoying this tradition. But the transition into a new year is not only about festivities. It is also an ideal time for reflection and planning.

On December 10, 2011, the Residents and Fellows Section (RFS) held its PostGraduate Assembly (PGA) meeting. It would not have been possible without the assistance of Dr. Richard Beers, who was instrumental in contacting the meeting’s speakers, including Mr. Charles Assini and Drs. Salvatore Vitale, Jerry Cohen, Kenneth Newman, Cynthia Lien, Keith Ruskin, and Ethan Fried. Thank you to all who participated and congratulations to Dr. Vitale on becoming the new NYSSA president!

The meeting’s theme, “Getting the Word Out,” was inspired by a discussion I had with Dr Vitale. The idea behind this theme was to encourage anesthesiologists to cease playing the role of an anonymous physician who has little communication with the patient. As anesthesiologists, we perform important tasks in order to keep our patients safe and these tasks are all too often overlooked. As one of my attendings once told me, “There is nothing more subtle than a smooth anesthetic.” We have not been our own profession’s advocates in proving there is more to anesthesiology than rendering patients unconscious in what appears to be an effortless manner. It takes many years of basic science and clinical training to acquire the skill set to safely administer anesthetics. Dr. Conrad Murray can certainly attest to that. One of the consequences of our failure to educate the public is non-anesthesiologists trespassing onto our scope of practice, and thus compromising patient care and our profession’s existence.

This year, the RFS encourages you to vanquish the general public’s lack of awareness. You can help accomplish this by acting on two different levels. Speak to your patients about what it is we do to protect their health while under anesthesia and become involved in professional
anesthesiology societies such as the NYSSA. Speaking directly to our patients is the grass-roots solution while involvement in the NYSSA and anesthesia-related political action committees (i.e., ASAPAC and NYAPAC) gives us a voice in legislative circles. For residents and fellows, these steps are great habits to incorporate in our practices. And for even the most seasoned of attendings, it’s never too late.

Please take action. It is vital that we safeguard high-quality patient care and the advancement of anesthesiology, or else the future of patient care and our profession will be as grim as 2012 doomsday predictions. ■
PGA 65 marked the 19th anniversary of the PGA International Scholars Program, a unique program that has afforded the NYSSA admiration as a society and provided the organization much publicity overseas. For PGA 65, 16 international scholars were selected. Only one was unable to attend.

Scholars, all of whom are recommended by senior anesthesiologists in the United States or overseas, receive different financial awards, determined by their individual applications (a rigorous process), ranging from free registration to shared hotel accommodations, and, if funding allows, some contribution toward transportation costs, all of which are reimbursed after arrival. In addition, technical exhibitors and publishing firms have been extremely generous in donating equipment and books. Scholars are invited to and often do present posters, a process that often ensures some financial support from their home institutions. The program has been used as an award at the European Anesthesia Meeting (free registration). Fourteen countries were represented this year, including Nepal, Peru, Slovakia, Thailand, Spain, Columbia, Egypt, the United Kingdom, Estonia, Germany, Honduras, Greece, Jamaica and Mexico.

In addition to an International Welcome Reception, attended by the officers of the PGA and the NYSSA, there is a farewell breakfast meeting for the NYSSA and ASA officers spend time with the international scholars at PGA 65.
international scholars. This event has become quite spectacular in that pharmaceutical companies have donated large amounts of equipment (mostly airway devices) and publishers have provided boxes of textbooks. One company made up gift packages for all the scholars with supraglottic devices and other items. Some of the texts were so avidly sought that we had to hold a raffle.

Funding for the program comes from several sources. Seed money is provided by the NYSSA and supplemented by donations from individuals and Mount Sinai Medical Center. Thanks to the formation of the Anesthesiology Foundation of New York last year, contributions to the program are now tax deductible.

After their return home, several scholars sent letters of appreciation for the opportunities and funding provided. The following are some of the comments we received:

“The scientific program was ingeniously constructed.”

“... the chance to meet authors of many important studies …”

“It was my longtime dream to know an American Society.”

“I will bring the knowledge … to improve my practice and teach my residents.”

“This experience will improve my practice and care for patients.”

“I plan to integrate more patient safety issues.”

“I am certain that the experience will benefit my country greatly.”

“... the chance to experience this unique assembly …”

“... the PGA in New York was the biggest and most impressive …”

“... the extraordinary scientific level …”

“My wish ... the International Scholars Program will continue ... really means a lifelong experience which is not otherwise possible or affordable.”

Since its inception in 1993, 262 scholars from 51 countries have been awarded some degree of funding to attend the PGA. If you have identified a scholar from another part of the world who might benefit from attending the 66th PGA, please consider nominating him or her (before the end of June). The application form is available on the NYSSA Web site or by contacting Debbie DiRago at Debbie@nyssa-pga.org. Even better, please consider donating to this worthy cause.

Elizabeth A. M. Frost, M.D.
International Scholars Committee
District 1 Members Hold Annual Business Meeting

On November 17, 2011, NYSSA’s District 1 held its annual business meeting in the Marco Polo Restaurant in Cobble Hill, Brooklyn. Elections for delegates and alternate delegates to the NYSSA House of Delegates were held. District Director and Government and Legal Affairs Committee Chair David Wlody gave an update on the political landscape in Albany and summarized the new political challenges to the safe practice of anesthesiology.

Distinguished guests included NYSSA Executive Director Stuart Hayman and NYSSA President-elect (now President) Salvatore Vitale, who outlined his plans for his presidential year.

Many thanks to Ms. Adrienne Dansiger of SUNY-Downstate, who made arrangements for the meeting.
NYAPAC Fundraiser a Success

In October 2011, an NYAPAC fundraiser was held at the home of Dr. Rose Berkun. The guest speaker was Michael Schoppmann, Esq., who gave a presentation on ACOs, a topic that is confusing to many physicians. His presentation made it clear how ACOs operate and what the benefits may be of joining them. The fundraiser was well attended. Thanks to general contributions by local anesthesiologists, a substantial amount was raised for NYAPAC.

Kathleen O’Leary, M.D., (far right) provides an update on the NYSSA’s legislative initiatives.

Michael Schoppmann, Esq., NYSSA’s legal counsel, gives a presentation on ACOs.

NYSSA members show their support for NYAPAC by attending the fall fundraiser.
When the FBI, OIG, IRS, OSHA (etc., etc.) Knocks on Your Door

MICHAEL J. SCHOPPMANN, ESQ.
KERN AUGUSTINE CONROY & SCHOPPMANN, P.C.

The list of entities empowered to take adverse action against physicians continues to grow at an alarming rate. The key to managing a physician's risk is understanding what these entities are, what they are not, and how to handle any intrusion/investigation appropriately.

Anti-Physician Acronyms

- BOM – Board of Medicine
- DEA – Drug Enforcement Agency
- AG/FCA – Attorney General/False Claims Act
- CMS – Centers for Medicare & Medicaid Services
- OIG/FBI – Office of the Inspector General/Federal Bureau of Investigation
- HMO – Health Maintenance Organization
- FTC – Federal Trade Commission
- HIPAA – Health Insurance Portability and Accountability Act
- CLIA – Clinical Laboratory Improvement Act
- EMTALA – Emergency Medical Treatment and Active Labor Act
- OSHA – Occupational Safety and Health Administration
- MEC – Medical Executive Committee
- IRS – Internal Revenue Service

What ties these entities together in such an unprecedented manner is the mandatory cross-referral, cross-reporting and intra-communications they are required to engage in whenever a complaint, an investigation, and/or an action involves a physician or medical practice. To facilitate this legal interweaving, each of these entities also has direct access to a central physician-based depository of data on each and every practicing physician in the United States:

The National Practitioner Data Bank

- Medical malpractice
- Hospital actions
- Licensing actions
- Health plans/Managed care company actions
- Government actions
For physicians facing even the most seemingly benign or innocuous inquiry by any of these entities, certain questions and considerations must be preeminent in their minds, regardless of guilt or innocence.

**Written Correspondence**

Virtually nothing sent to a physician or a medical practice today is “educational” and/or “informational.” The true legal role of such correspondence is that it serves as a notice of investigation, nothing less.

**Records Requests**

Escalating the level of investigation, entities that request records are thereby devoting more assets to the investigation. Careful consideration must be given as to how to produce records, what records to send, and what records not to send.

**Subpoenas**

Entering into the formal legal process, certain adverse entities also possess the power to subpoena records and/or documents. Such a measure is a serious escalation and significant legal event in the life of an investigation and/or action. Attempts to avoid service are counterproductive and legal counsel should always be consulted before issuing even a single document. Moreover, a subpoena does not compel a physician or a medical practice office staff member to speak with the investigators or offer a statement of any form.

**Investigators**

Many physicians harm themselves in a permanent, uncorrectable manner by falling prey to common yet effective tactics utilized by investigators. Either through charm, false promises of leniency, and/or intimidation, physicians all too commonly speak freely and recklessly with investigators prior to understanding the true nature of the investigation, their legal rights, and/or the threat of the underlying action. No physician, or medical practice employee, should ever speak with any investigator without first securing the benefit of experienced healthcare counsel, proper preparation, and/or first determining if such a discussion should ever take place.

**“After the Knock”**

Even the most informal initial contact by an investigator should prompt an immediate and well-coordinated reaction by the physician/medical practice. Instructions should be provided to employees regarding potential direct contact with them (even at home) and the confidentiality of any issues at the practice. Employees should be informed that the practice has
legal counsel in place to represent the practice and each employee should be provided with counsel’s contact information.

**How to Avoid a “Knock at the Door”**

Understanding that good intentions and ignorance of the ever-changing, increasingly complex laws and regulations governing physicians are not defenses to an investigation and/or action is the first step every physician must accomplish in order to reduce the risk of being investigated. Once having come to that understanding, every physician should then undertake a risk assessment, under the protection of attorney-client privilege, of his/her practice and practice methods. Risk areas include, but are not limited to: patients; medical malpractice actions; hospital actions; and interacting with state or federal agencies, insurance companies, and/or managed care companies.

**Risk Assessment**

A proper physician-based risk assessment should include, but not be limited to, a review of all contracts, codes of conduct, bylaws, procedures and protocols, documentation requirements (from any source), and other structural mandates.

**Defensive Documentation**

One of the most commonly exploited weaknesses inherent in a physician’s methods is the failure to secure timely documentation of events, including, but not limited to, corroborating statements from witnesses (both internal and external to the medical practice).

**The “Golden Rule”**

In light of these new, harsh realities and as a key part of any risk management effort, no physician, no medical practice employee should ever speak to, or allow anyone else to speak to, investigators, the media, and/or attorneys (other than their own healthcare counsel).

What is not said, what is not sent, and what is not done may well become more important to the defense of, and potential dismissal of, an investigation than any theory of law, court ruling, and/or appellate review.

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*Kern Augustine Conroy & Schoppmann, P.C., is general counsel to the NYSSA. The firm has offices in New York, New Jersey, Pennsylvania and Illinois. The firm’s practice is solely devoted to the representation of healthcare professionals. The Web site is [www.drlaw.com](http://www.drlaw.com). Mr. Schoppmann may be contacted at 800-445-0954 or via e-mail at schoppmann@drlaw.com.*
Obsession With Feet

DIVINA J. SANTOS, M.D.

There is a professional reason to be obsessed
With epidural anesthesia, on a patient’s feet.

Both feet and ankles flushed,
Warm to touch, blood vessels dilatory,
Voila, anesthesia is A-OK!

If one foot is cold and the other warm
Anesthesia is only half of one.

If both are warm, expect the patient not to complain
Unless density of block is unsatisfactory for degree of pain.

In teaching learners the art and science of neuroaxial block
They must know the objective signs of epidural anesthesia

Not wait for the patient’s groans, squirms, and screams.
A good working epidural analgesia extends to anesthesia
Surgeons appreciate enough to say, “Anesthesia, you rock!”

Without direct visualization, but with a touch that is educated,
The anesthetic in the epidural space is injected.

There is frequently a high rate of success.
Still, its efficacy early on, one needs to assess.
Is it complete? Not in the space? Inadequate?
Recognize, admit, accept, and correct.
Ego must never be put on the line.
Focus on the absence or presence of a positive sign.

Divina J. Santos, M.D., is an obstetrical anesthesiologist.
The Department of Anesthesiology of the Mount Sinai School of Medicine, New York, NY presents the 31st Annual Symposium: Clinical Update in Anesthesiology, Surgery and Perioperative Medicine

With International Faculty and Industrial Exhibits
With Free Regional Anesthesia Workshops
Course Directors: G. Silvay, M.D., Ph.D. and M. Stone, M.D.

Marriott Curacao Beach Resort & Emerald Casino Curacao, Netherlands Antilles January 20-25, 2013

For information and abstract forms contact: marc.stone@mountsinai.org
For information about industrial exhibits contact: bob.williams@mountsinai.org
I had the privilege of making a presentation at the PostGraduate Assembly (PGA) Current Issues Panel on the state of affairs regarding the nurse anesthetist scope of practice issue. Below please find my outline on Gov. Cuomo’s Medicaid Redesign Team (MRT), which was part of my presentation:

My PowerPoint Presentation “Current Issues Panel – Scope of Practice: Update – Gov. Cuomo’s Medicaid Redesign Team (MRT)” can be accessed on the New York State Society of Anesthesiologists Web site (members only document) on the “Legislative/Regulatory Issues” page under “Medicaid Redesign Team (MRT)” section at:

http://members.nyssa-pga.org/scripts/4disapi.dll/4d cgi/members/legislat ive.html

Please also note that we will be posting and linking updated MRT reports, information, and related documents on the NYSSA Web site. I strongly encourage you to access this information.

Current Issues Panel: Gov. Cuomo’s Medicaid Redesign Team (MRT)

• Created in 2011 by Gov. Cuomo to reduce Medicaid spending. Recommendation included in Gov. Cuomo’s 2011-12 budget.

• “Phase II” – Creation of Work Force Flexibility/Scope of Practice Work Group. For more information about the MRT and about the work group:
  • Redesigning the Medicaid program:
    www.health.ny.gov/health care/medicaid/redesign/
  • MRT: Workforce Flexibility and Change of Scope of Practice Work Group:
    www.health.ny.gov/health care/medicaid/redesign/workforce_flexibility.htm
  • Work Force Flexibility/Scope of Practice Work Group:
    • Charged with the duty to develop a multi-year strategy to redefine and develop the workforce to ensure the comprehensive needs of New York’s population are met in the future and to consider changes
in scope of practice for mid-level providers to “promote efficiency and lower Medicaid costs.”


• The work group voted to send the following 13 proposals to the full MRT to be acted upon by the full MRT on December 13, 2011.

  Update-The MRT accepted the following proposals on December 13, 2011:

  1. Permit advanced aides, with supervision and training by a registered nurse, to assist self-directing and non-self-directing consumers with routine pre-poured medications.

  2. Creating an advanced home care aide certification and expanding the ability of registered nurses to assign tasks to such aides.


  4. Remove the requirement that certified nurse practitioners enter into a collaborative agreement with a licensed physician.¹

  5. Collaborative practice of dental hygienists and redefining the definition of dental hygiene.


  7. Enable physician home visits.

  8. New York State Primary Care Service Corps (PCSC) — A service-obligated scholarship program to be administered by the Department of Health that would provide loan repayment for non-physician clinicians in exchange for a service obligation in a medically underserved area.

  9. Extend to July 1, 2016, the exemption that programs or services operated, regulated, funded or approved by the Department of Mental Hygiene, the Office of Children and Family Services, the Department of Correctional Services, the State Office for the Aging, the Department of Health or local government unit or social services district have from the laws providing for the licensure of social workers, psychologists and mental health practitioners.

  10. Removal of physician supervisory ratio of physician assistants.²
11. Promote underutilized programs such as the Consumer Directed Personal Assistance Program that are cost-effective and build on consumer strengths.

12. Children’s Dental Health Certificate — Amend education law, Section 903, 2.a. to include registered dental hygienists as an additional oral health provider able to perform school readiness oral health examination and by means of follow-up, case manage to enroll children within a dental home.

13. More importantly, a proposal to establish an advisory committee to the State Education Department’s Office of Professions was adopted as part of the work group’s final recommendations. As far as some of the specifics of the recommendation:

a. Purpose of the advisory committee is to support a “collaborative, comprehensive and systematic assessment of all proposals designed to improve health workforce flexibility in the state, including, but not limited to, proposals to develop, expand, or modify scopes of practice for healthcare professionals and/or scopes of services for assistive health personnel.”

b. Standing members of the advisory committee would include: “State agencies, such as DOH, OMH, OASAS, DOL, SUNY, CUNY, state legislative staff, professional associations representing nurses, physicians, nurse practitioners, physician assistants, etc.; provider associations, representing hospitals, nursing homes, home care agencies, health centers, etc.; health worker unions such as 1199; the Center for Health Workforce Studies, and other relevant organizations such as the Paraprofessional Healthcare Institute, the New York State Area Health Education Center and consumer groups.”

c. The process: “At SED’s request for review of proposal to improve workforce flexibility, a small work group will be convened, drawn from the standing membership of the Advisory Committee as well as relevant SED staff.” Such a work group would consist of no more than 10 members and include a member of the health profession seeking the change, one member of the health profession affected by the proposed change, one member representing an affected provider group, and others potentially impacted, including state agencies, labor unions and consumers.

d. The Center for Health Workforce Studies (part of the University of Albany, School of Public Health) will serve as staff to the
committee tasked with convening work groups, preparing reports that summarize all relevant data and information.

e. Each proposal submitted to SED’s Office of Professions would have to include the following: description of the proposed change; statement of the problem; alternatives considered and rationale for selecting proposed action; impacts on the public that identifies potential benefits and harms, related to safety, quality of care and access to care; implications for education and training; economic implications to the state and general public; a list of states where the proposed change is currently allowed; known support and opposition to the proposal; reference all research that has been conducted to measure impacts of proposed change on cost, quality and access to care. Any recommendations are subject to statutory action.

Points listing NYSSA’s Care Team proposal and NYSANA’s CRNA scope of practice proposal (independent practice).

<table>
<thead>
<tr>
<th>NYSSA-Anesthesia Care Team</th>
<th>NYSANA-CRNA Scope of Practice</th>
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<tbody>
<tr>
<td>■ Adopt the Anesthesia Care Team model by mandating the existing safe anesthesia standard embodied in current Health Department regulations because this standard has resulted in unprecedented safe anesthesia care.</td>
<td>■ Create Nurse Practitioner in Anesthesia (“NP in Anesthesia”) category-collaboration model will enhance the ability of nurse anesthetists to provide anesthesia services in underserved areas, reduce costs to hospitals.</td>
</tr>
<tr>
<td>■ Define the role of the anesthesiologists while working in the Care Team by incorporating language to define terms such as “immediately available,” “physically present,” and “supervision” to clarify and improve the standard of care.</td>
<td>■ Anesthesia delivered by CRNAs alone is the most cost-effective anesthesia delivery model and is the only model that generates net revenue for hospitals.</td>
</tr>
<tr>
<td>■ Ensure that anesthesia care provided to Medicaid patients is not weakened or diminished but instead enhanced because it guarantees an anesthesiologist or</td>
<td>■ Allows hospitals the flexibility to transform patient care in a manner that is consistent with current state and federal reform initiatives to address healthcare workforce shortages.</td>
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Continued on next page
I would be happy to respond to any questions, comments, or suggestions that you may have about this important topic. Please feel free to e-mail me at CJAssini@HRBCLaw.com.

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and cc: GKCarter@HRBCLaw.com

1. Subject to legislative approval.
2. Subject to legislative approval.
From the NYSSA Residents Section

Publish Your Case Report in *Sphere*

- If you have an interesting case
- If you are ready to share your experience
- If you are interested in building your CV

You can submit your case report for publication in *Sphere*. All cases will be reviewed and the most interesting published.

Submit your case report via e-mail to maryann@nyssa-pga.org. Subject: Article for Sphere

If you have questions, call MaryAnn Peck at NYSSA headquarters: 212-867-7140.

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CMEcorner

Check out the newest feature on the NYSSA Web site: a scrolling banner that links you to the latest information and guidelines to help you help your patients.

At [www.nyssa-pga.org](http://www.nyssa-pga.org) you can explore such headlines as:
- During Cardiac Arrest: Remember C-A-B
- Obesity is a major risk factor for cesarean delivery
- Ultrasound guidance for IJ cannulation decreases risk of inadvertent arterial cannulation

Click on a banner to read the most up-to-date information on the subject of your choice.

Go to [www.nyssa-pga.org](http://www.nyssa-pga.org) and look for the scrolling banners at the top of your screen.
Different situations require different sedative solutions

The first and only alpha₂ agonist indicated for sedation.¹,²
- Nonintubated patients prior to and during surgical and other procedures.²
- Initially intubated and mechanically ventilated patients during treatment in an intensive care setting.²
- Administer Precedex® by continuous infusion not to exceed 24 hours.²

Important Precedex Safety Information
- Clinically significant episodes of bradycardia, sinus arrest and hypotension have been associated with Precedex infusion and may necessitate medical intervention.
- Moderate blood pressure and heart rate reductions should be anticipated when initiating sedation with Precedex.
- Prolonged exposure to dexmedetomidine beyond 24 hours may be associated with tolerance and tachyphylaxis and a dose-related increase in adverse events.

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(dexmedetomidine hydrochloride) injection

1 INDICATIONS AND USAGE
1.1 Intensive Care Unit Sedation
Precendex is indicated for the sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Precendex should be administered by continuous infusion not to exceed 24 hours.

Precendex has been continuously infused in mechanically ventilated patients prior to extubation, during extubation, and post-extubation. It is not necessary to discontinue Precendex prior to extubation.

1.2 Procedural Sedation
Precendex is indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.

2 WARNINGS AND PRECAUTIONS
2.1 Drug Administration
Precendex should be administered only by persons skilled in the management of patients in the intensive care or operating room setting. Due to the known pharmacological effects of Precendex, patients should be continuously monitored while receiving Precendex.

2.2 Hypotension, Bradycardia, and Sinus Arrest
Results from significant episodes of bradycardia and sinus arrest have been reported with Precendex administration in young, healthy volunteers with high vagal tone or with different routes of administration including rapid intravenous or bolus administration.

2.3 Transient Hypertension
Precendex has the potential to increase bradycardia and sinus arrest. Clinicians should be prepared to intervene. The intravenous administration of anticholinergic agents (eg, glycopyrrolate, atropine) should be considered to modify vagal tone. In clinical trials, glycopyrrolate or atropine were effective in the treatment of most episodes of Precendex-induced bradycardia. However, in some patients with significant cardiovascular dysfunction, more advanced resuscitative measures were required.

2.4 Arrhythmia
In some patients receiving Precendex have been observed to be arrhythmic and/or have experienced atrial fibrillation and/or supraventricular tachycardia. Hence, transient hypertension has generally not been necessary, although reduction of the loading infusion rate may be desirable.

2.5 Atropine
Atropine should be administered concomitantly with Precendex.

2.3 Transient Hypertension
Precendex has been observed primarily during the loading dose in association with the initial peripheral vasodilator effects of Precendex. Treatment of the transient hypertension has generally not been necessary, although reduction of the loading infusion rate may be desirable.

2.4 Arrhythmia
Some patients receiving Precendex have been observed to be arrhythmic and/or have experienced atrial fibrillation and/or supraventricular tachycardia. Hence, transient hypertension has generally not been necessary, although reduction of the loading infusion rate may be desirable.

2.5 Atropine
Atropine should be administered concomitantly with Precendex.

2.6 Tachycardia
Precendex subjects experienced at least one event related to withdrawal within the first 24 hours after discontinuing study drug and 7 (3%) Precendex subjects experienced at least one event within 24 hours after withdrawal of study drug. The most common events were nausea, vomiting, and agitation.

2.7 Tachycardia and Hypertension
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2.10 Tolerance and Tachyphylaxis
Use of dexmedetomidine beyond 24 hours has been associated with tolerance and tachyphylaxis and a dose-related increase in adverse reactions (see Adverse Reactions 11.1).

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2.18 Tolerance and Tachyphylaxis
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2.33 Tolerance and Tachyphylaxis
Use of dexmedetomi...
The number (%) of subjects who had a dose-related increase in treatment-emergent adverse events by maintenance adjusted dose rate range in the Precedex group is provided in Table 5.

Table 5: Treatment Emergent Adverse Events Occurring in Dexmedetomidine- or Midazolam-Treated Patients in the Randomized Active Comparator Continuation Long-Term Intensive Care Unit Sedation Study

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Dexmedetomidine (n=254)</th>
<th>Midazolam (n=237)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>56%</td>
<td>56%</td>
</tr>
<tr>
<td>Hypertension requiring intervention</td>
<td>28%</td>
<td>27%</td>
</tr>
<tr>
<td>Bradycardia²</td>
<td>42%</td>
<td>19%</td>
</tr>
<tr>
<td>Bradycardia requiring intervention</td>
<td>5%</td>
<td>1%</td>
</tr>
<tr>
<td>Systemic hypertension²</td>
<td>12%</td>
<td>42%</td>
</tr>
<tr>
<td>Tachycardia²</td>
<td>23%</td>
<td>44%</td>
</tr>
<tr>
<td>Tachycardia requiring intervention</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Diastolic Hypertension²</td>
<td>12%</td>
<td>15%</td>
</tr>
<tr>
<td>Hypertension²</td>
<td>11%</td>
<td>15%</td>
</tr>
<tr>
<td>Hypertension requiring intervention²</td>
<td>19%</td>
<td>30%</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>9%</td>
<td>13%</td>
</tr>
<tr>
<td>Paresis</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Agitation</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Constipation</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Renal Failure Acute</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Acute Respiratory Distress Syndrome</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Generalized edema</td>
<td>2%</td>
<td>6%</td>
</tr>
<tr>
<td>Hypoglycemia/nephrome</td>
<td>1%</td>
<td>7%</td>
</tr>
</tbody>
</table>

1 Includes any type of hypertension.

2 Hypertension was defined in absolute terms as Systolic blood pressure of >90 mm Hg or Diastolic blood pressure of >50 mm Hg in absolute terms as >25% lower than pre-study drug infusion value.

3 Bradycardia was defined in absolute terms as <40 bpm or in relative terms as >30% lower than pre-study drug infusion value.

4 Hypertension was defined in absolute terms as Systolic blood pressure of >180 mm Hg or Diastolic blood pressure of >100 mm Hg or in relative terms as >25% higher than pre-study drug infusion value.

5 Tachycardia was defined in absolute terms as >100 bpm or in relative terms as >25% greater than pre-study drug infusion value.

The following adverse events occurred between 2 and 5% for Precedex and Midazolam, respectively: renal failure acute (2.5%), ESRD, acute respiratory distress syndrome (2.5%, 2%), and respiratory failure (4.3%, 3.3%).

Table 6: Number (%) of subjects who had a dose-related increase in Treatment Emergent Adverse Events by maintenance adjusted dose rate range in the Precedex group

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Precedex mg/kg/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 0.7 mg/kg/hr</td>
</tr>
<tr>
<td>N=35</td>
<td>N=95</td>
</tr>
<tr>
<td>Confusion</td>
<td>8%</td>
</tr>
<tr>
<td>Agitation</td>
<td>5%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>5%</td>
</tr>
<tr>
<td>Oedema peripheral</td>
<td>3%</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>2%</td>
</tr>
<tr>
<td>Acute Respiratory Distress Syndrome</td>
<td>1%</td>
</tr>
</tbody>
</table>

* Average maintenance dose for the entire study drug administration.

Procedural Sedation

Adverse reaction information is derived from the two trials for procedural sedation in which 218 patients received Precedex. The mean total dose was 1.6 mg/cc/kg/hr (range: 0.5 to 6.7), mean dose per hour was 1.2 mg/kg/hr (range: 0.3 to 6.1) and the mean duration of infusion of 1.5 hours (range: 0.1 to 15.2). The population was between 16 to 93 years of age, 28% <65 years of age, 50% male and 61% Caucasian.

Treatment-emergent adverse reactions occurring at an incidence of >2% are provided in Table 6. The most frequent adverse reactions were hypotension, bradycardia, and dry mouth (see Warnings and Precautions (5.2). Pre-specified criteria for the vital signs to be reported as adverse reactions are footnoted below the table. The decrease in respiratory rate and hypoxia was similar between Precedex and comparator groups in both studies.

Table 7: Adverse Reactions Experienced During Post-approval Use of Precedex

<table>
<thead>
<tr>
<th>Body System</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disorders, General</td>
<td>Blood pressure fluctuation, heart disorder, hypertension, hypotension, myocardial infarction</td>
</tr>
<tr>
<td>Central and Peripheral System Disorders</td>
<td>Distress, headache, neurolgia, neuritis, speech disorder, convulsion</td>
</tr>
<tr>
<td>Gastrointestinal System Disorders</td>
<td>Abdominal pain, diarrhea, vomiting, nausea</td>
</tr>
<tr>
<td>Heart Rate and Rhythm Disorders</td>
<td>Arrhythmia, ventricular arrhythmia, bradycardia, hypoxia, atrioventricular block, cardiac arrest, extrasystoles, atrial fibrillation, heart block, t wave inversion, tachycardia, supraventricular tachycardia, ventricular tachycardia</td>
</tr>
<tr>
<td>Urinary and Biliary System Disorders</td>
<td>Increased gamma-glutamyl transpeptidase, hepatic function abnormal, hyperbilirubinemia, aspartate aminotransferase</td>
</tr>
<tr>
<td>Metabolic and Nutritional Disorders</td>
<td>Acosis, respiratory acidosis, hyperkalemia, increased alkaline phosphatase, thirst, hyperglycemia</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td>Agitation, confusion, delirium, hallucination, illusion</td>
</tr>
<tr>
<td>Red Blood Cell Disorders</td>
<td>Anemia</td>
</tr>
<tr>
<td>Renal Disorders</td>
<td>Blood urea nitrogen increased, oliguria</td>
</tr>
<tr>
<td>Respiratory System Disorders</td>
<td>Apnea, bronchospasm, dyspnea, hyperventilation, hypoxia, pulmonary congestion</td>
</tr>
<tr>
<td>Skin and Appendages Disorders</td>
<td>Increased sweating</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td>Hemorrhage</td>
</tr>
<tr>
<td>Vision Disorders</td>
<td>Photopsia, abnormal vision</td>
</tr>
</tbody>
</table>

10 OVERDOSAGE

The tolerability of Precedex was studied in one study in which healthy subjects were administered doses at and above the recommended dose of 0.2 to 0.7 mg/kg/hr. The maximum blood concentration achieved in this study was approximately 13 times the upper boundary of the therapeutic range. The most notable effects observed in two subjects who achieved the highest doses were first degree atrioventricular block and second degree heart block. No hemodynamic compromise was noted with the atrioventricular block and the heart block resolved spontaneously within one minute.

Five patients received an overdosage of Precedex in the intensive care unit sedation studies. Two of these patients had no symptoms reported; one patient received a 2 mcg/kg loading dose over 10 minutes (this is the recommended loading dose) and one patient received a maintenance infusion of 0.6 mcg/kg/hr. Two other patients who received a 2 mcg/kg loading dose over 10 minutes, experienced bradycardia and hypotension. One patient who received a loading bolus dose of unlabeled Precedex (18.4 mcg/kg/hr) had cardiac arrest from which he was successfully resuscitated.

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