



Society for Ambulatory Anesthesia

# Ambulatory Anesthesia<sup>SM</sup>

## PRESIDENT'S MESSAGE

### SAMBA's Mission: New Visions, Enhanced Commitment

By Girish P. Joshi, M.D., M.B., B.S.  
SAMBA President

With the expansion of the practice of ambulatory anesthesia, the vision and commitment of SAMBA also has been enhanced. This is now reflected in a new mission statement that was approved recently by the Board of Directors. The new SAMBA mission emphasizes the role of the Society in all ambulatory venues, including office-based practice:

*"The mission of The Society for Ambulatory Anesthesia is to advance the practice of ambulatory anesthesia in all ambulatory venues, to encourage high ethical and professional standards by fostering and encouraging education and research, and to provide professional guidance for the practice of ambulatory anesthesia."*

Another area of potential expansion is international outreach. SAMBA could provide education and professional guidance to our international colleagues who are attempting to commence ambulatory anesthesia programs as well as those who are interested in advancing their current ambulatory anesthesia practice. We can provide advice not only with respect to clinical practice but also in the matters concerning quality of care and research. I believe that such efforts will help to cultivate relationships between SAMBA and international professional societies.

Recently the Committee on Development, under the leadership of John A. Dilger, M.D., suggested that SAMBA establish a "SAMBA Educational Foundation" that would help to

attract more funding to further our mission of education and research. Obviously there are a number of questions regarding the need for such a foundation as well as concerns that it might adversely influence current SAMBA sponsorship. I have appointed a task force to explore the pros and cons of creating such a foundation. Walter G. Maurer, M.D., will chair this task force, which will provide guidance to the SAMBA Board of Directors.

The Committee on Education, under the leadership of Shireen Ahmad, M.D., is developing a mentorship program with the aim of providing guidance in career advance-



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ment, creating opportunities for advancement of members within the organization and providing role models for resident and younger SAMBA members. I am sure these efforts will encourage our resident members to remain involved even after they graduate.

I would also like to report that the SAMBA Clinical Outcomes Registry, or SCOR, is advancing well under the guidance of Lucinda L. Everett, M.D. The project will be available for review at the SAMBA booth (#607) in the American Society of Anesthesiologists Annual Meeting Exhibit Hall in San Francisco. I encourage you to participate in this Web-based database outcomes project, which will

show the outcome trends at your ambulatory care facility, facilitate compliance requirements and compare outcomes with others.

This year's SAMBA Mid Year Meeting will be held on Friday, October 12, 2007, at the San Francisco Hilton. Thomas W. Cutter, M.D., has put together a great program that includes topics of clinical controversies and administrative challenges. Also, the SAMBA Breakfast Panel "Off-Site Ambulatory Anesthesia: Innovation or Pandora's Box?," will be held from 7 a.m. to 8:15 a.m. on Saturday, October 13. Dr. Ahmad, will moderate this

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## Emergence Agitation and Emergence Delirium in Children: Still a Persistent Problem — Some Options for Care

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A recent review suggests that following general anesthesia, emergence delirium (ED) is still a frequent and bothersome problem in children.<sup>1</sup> Emergence agitation (EA) is more common than ED. It is sometimes difficult to distinguish between the two conditions. Recently, Isik and associates<sup>2</sup> used a simple five-point scale to define emergence agitation [Table 1]. They defined delirium as an agitation score  $\geq 4$  for  $\geq 5$  minutes.

The incidence of this problem has been reported to occur between 20 percent to 80 percent; it is likely that the higher incidence is attributable to

EA and the lower frequency to ED. This undesirable emergence issue in children has become more of a problem since practitioners started using sevoflurane and desflurane, two insoluble anesthetics with otherwise favorable pharmacokinetic properties. The incidence also differs significantly from study to study because of differences in the perioperative care plan implemented. Variations in the use of supplemental regional anesthetic techniques and adjunct medications — namely anticholinergics, droperidol, barbiturates, opioids, NSAIDs, benzodiazepines, metoclopramide — all influence the emergence profile of children during recovery from general anesthesia. The definition and grading of ED also is not easy with some authors using “crying” and/or “thrashing requiring restraint” to distinguish agitation from ED. It usually manifests in the first 30 minutes following emergence and is usually short-lived (typically five to 15 minutes). The exact etiology is not known,



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but rapid emergence (with the insoluble anesthetics), postoperative pain, age, and child temperament and preoperative anxiety appear to play a role. It is most common in children aged two to five years, suggesting that brain maturation exercises a significant influence. There is some evidence that familial factors contribute to its

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# What Is a 'Biologic,' and Why Should I Be Concerned About Safety Issues?

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Corresponding with this year's SAMBA Annual Meeting — and taking place just a few blocks away — the 3rd Annual San Diego Health Policy Conference on May 4, 2007 (sponsored by the California Western School of Law [CWSL] and the Institute of Health Law Studies), proved to be another excellent forum on several timely safety and security issues pertaining to the practice of anesthesiology and medicine. Organized by Bryan A. Liang, M.D., Ph.D., J.D., Professor of Law at CWSL and Associate Professor of Anesthesiology at the University of California-San Diego, the primary area of focus was on the class of medicinal products known as biologics. Biologics (or biological medicines) are products that are primarily manufactured by living tissue. Examples of biological products include blood and blood components, vaccines, recombinant proteins and gene therapy. Two well-known biological medicines are Epogen® (recombinant erythropoietin-alpha, used to fight anemia in renal dialysis patients) and alpha interferon (used to treat hairy-cell leukemia, hepatitis C and chronic hepatitis B).

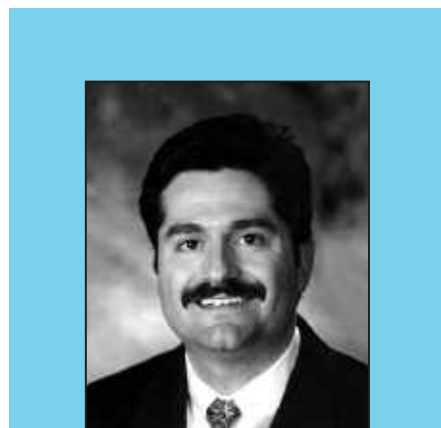
Safety and security issues have become paramount in biologics because, like "generics" for conventional drugs, there is an increased interest in cost savings and allowing secondary manufacturers to produce copies (known as "follow-on" medicines in the United States and "biosimilars" in the European community). Part of the problem with biologics is that they represent very complex, large molecular weight compounds that are uniformly susceptible to impurities and microbial contamination. Biologics also can be altered extensively by

minor fluctuations in temperature (both during the manufacturing process and while sitting on the shelf). Like their generic drug counterparts, there is the potential for error and abuse in the biologic drug manufacturing process (the U.S. Congress is just now trying to decide how to regulate this new market of pharmaceuticals). In addition the potential for counterfeiting and/or adulteration of legitimate products remains high. Remember the recent Tour de France controversies? There exists, already, an extensive black market for biologics such as Epogen, or "Epo," (e.g., professional cyclists who "dope up" to increase red cell counts and hence oxygen carrying capacity) and "HGH" (e.g., bodybuilders looking to increase muscle mass).

There is a rampant and increasing risk of counterfeit drugs nationwide,<sup>1</sup> and the threat to patient safety may be even greater with biological medicines. Part of the problem with biologics is that patients (and even physicians) tend to have a poor understanding of what this category of medical product really is; furthermore, the International Medical Products Anti-Counterfeiting Taskforce

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(composed of international organizations and World Health Organization members) is having a difficult time arriving at suitable strategies for containing "fake" biologics. This same task force is arguably having even less success in effectively raising awareness of the scope of the problem. The U.S.-based Partnership for Safe Medi-



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cines has made strides toward addressing this issue.<sup>2</sup> The Partnership for Safe Medicines is a coalition of patients, physicians, academics, industry groups and pharmacists who all share the goal of protecting the safety of prescription medications.

## Biologics in More Detail<sup>3</sup>

Biological medicines are sophisticated physiological molecules that are manufactured with the assistance of living tissue (yeast, bacteria and mammalian cell lines). In the United

States, expenditure for the top biological drug erythropoietin exceeds \$2 billion per year. In aggregate, biologics cost almost \$60 billion worldwide in 2005. The cost is expected to far surpass \$100 billion by the year 2010. Across the globe, biologics are used to treat cancer, AIDS, hepatitis and many other disease states in well over a

quarter of a billion people at any given time.

The production of biologic drugs is exponentially more complex than the manufacturing process involved in the making of conventional medicines. Most medicines have molecular weights in the range of several hundred (e.g., simple aspirin = 180 mw). Erythropoietin, however, weighs in at a molecular weight of 30,000. The proper manufacturing of biologics demands several hundred internal quality tests, and the conditions for making these compounds can be quite hard to properly create (or reproduce). It has been estimated that the "start-up" for the corporate production of a single biological medicine can easily exceed \$1 billion. Due to variability in the growth and genetic activity of living tissue, attempts to copy biologics can never result in exact replicas.

When Johnson and Johnson began marketing Eprex® in Europe at the turn of this century (using the same recipe for erythropoietin as the company Amgen used to make Epogen for use in the United States), hundreds of serious cases of red cell aplasia resulted because of an allergic im-

munogenicity reaction. The current explanation for this widespread complication is blamed on an errant reaction between a stabilizing agent and the rubber stopper used in packaging.

### The Politics of Biologics

Considering the complexity of the manufacturing process for biological medicines, as well as the potential for widespread abuse and patient injury through improper "follow-on generics" or counterfeiting, California Congressman Henry Waxman (D-CA) has been pushing an extension of the the Hatch-Waxman bill (1984) — H.R. 1038, introduced on February 14, 2007 to define the process by which biologic generics may be created and marketed to the public. Some have criticized the Waxman proposal as being overly naïve and misguided because it allows too many loopholes for error with potentially deadly consequences.

In order to speed drugs to the market, the Waxman approach leaves open several crucial safety concerns:


- It defines comparable drugs as allowing impurities, errors and changes in genetic "post-translational" events, infidelity of ge-

netic transcription, differences in amino acids and other evidence of protein degradation.

- It allows differences in molecular structure, mechanisms of action, route of administration, dosage, purity and potency.
- It has no mandates for pre-approval immunogenicity studies.
- It does not define the need for risk management plans.

In conclusion, the issues surrounding the field of biological medicines extend to the practice of anesthesiology — "biologics" offer great promise, but many potential safety pitfalls, for the American health care consumer.

### References:

1. Dorin AF. Terrorism and Viagra — Medicinal drugs sold over the Internet. August 2006, *San Diego Physician*.
2. [www.SafeMedicines.org](http://www.SafeMedicines.org).
3. 3rd Annual San Diego Health Policy Conference on Safety Issues and Biologic Drugs. May 4, 2007, Hilton Harbor Island Hotel. 

## SAMBA's Mission: New Visions, Enhanced Commitment

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panel. I encourage you all to take advantage of these excellent educational opportunities.

Finally, as the year comes to an end, it will be time to renew your SAMBA membership. Please

renew it online at [www.sambahq.org](http://www.sambahq.org). Online renewal is easy and will significantly reduce the time spent by SAMBA staff in processing membership applications.

I would like to emphasize that we are looking at ways to serve

SAMBA members better and would like your suggestions or comments. Please e-mail me at [girish.joshi@utsouthwestern.edu](mailto:girish.joshi@utsouthwestern.edu) with your suggestions and comments — they are always welcome. 