

The ASCRS TASS Task Force and the FDA's TASS Initiative

The dissolution of a partnership.

BY NICK MAMALIS, MD

Toxic anterior segment syndrome (TASS) is an acute, sterile, postoperative inflammatory reaction following anterior segment surgery. Among the multiple potential causes are issues with the cleaning and sterilization of instruments as well as problems with the fluids or medications used during surgery or during the immediate postoperative period. In early 2006, a large outbreak of TASS led to the establishment of a TASS task force by the American Society of Cataract and Refractive Surgery (ASCRS). The ASCRS TASS Task Force included ophthalmologists, nurses, members of industry, the FDA, and the Centers for Disease Control. This group held regular meetings and conference calls, and it published a review of the potential causes of TASS as well as recommendations for the cleaning and sterilization of ophthalmic instruments.^{1,2}

At the ASCRS meeting in San Diego on April 27, 2007, the task force discussed a proactive initiative to improve the analysis of the potential causes of TASS. A letter to Kesia Alexander, PhD, at the FDA dated June 1, 2007, outlined that the ASCRS and I were interested in proceeding with a collaborative effort by the task force and the FDA. The task force met again at the ASCRS meeting in Chicago on April 4, 2008, to discuss the formation of a formal TASS Registry. The FDA provided funding to the Intermountain Ocular Research Center (IORC) at the University of Utah in Salt Lake City through a contract to collect data from pre-

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vious analyses of TASS outbreaks as well as the data from the ASCRS, which were analyzed at the IORC. An institutional review board protocol at the University of Utah was developed for this purpose. In addition, funding was provided to help develop questionnaires to initiate a more proactive TASS program. The work on these new questionnaires was built on questionnaires previously developed by the ASCRS task force and the IORC. The contracts between the FDA and the University of Utah were done directly, because the test data from the ASCRS were analyzed and housed at the University of Utah. The ASCRS and the IORC then shared these data and original questionnaires with the FDA pursuant to a confidentiality agreement and was actively involved in the development of the next generation of questionnaires.

THE FDA'S PERSPECTIVE: THE PROACTIVE TOXIC ANTERIOR SEGMENT SYNDROME PROGRAM

**By Malvina Eydelman, MD;
Michelle Tarver, MD, PhD; Kesia Alexander, PhD;
and Michelle McMurry-Heath, MD, PhD**

Today's public health issues require considerable input and effort from a variety of sources, including governmental agencies, consumer groups, patients' representatives, and health industry organizations. All of these groups must be able to collaborate quickly and often to prevent the spread of disease, truncate outbreaks, and promote the adoption of safer health care practices.

We recognize the importance of strong partnerships. Although the FDA's Center for Devices and Radiological Health (CDRH) is a part of a regulatory agency, we value partnerships for scientific input, medical and health care expertise, and the dissemination of information.

Past outbreaks of toxic anterior segment syndrome (TASS) serve as critical examples of the need for collaboration. During these outbreaks, we partnered with the US Centers for Disease Control and Prevention to identify and remove from the market several medical products that acted as contributors.

Even the best collaborations may not produce the desired results, and our efforts with the Centers for Disease Control and Prevention failed to identify the culprit behind the 2006 TASS outbreak. We therefore went back to the drawing board, outlined the factors that inhibited the investigations, and at the 2006 annual meeting of the American Academy of Ophthalmology (AAO) announced the Proactive TASS Program,^{1,2} designed to prevent and mitigate these outbreaks.

Again, we sought input from and collaboration with professional organizations and other expert bodies. Our work with the AAO and the American Society of Cataract and Refractive Surgeons (ASCRS) helped to improve communication and the adverse event reporting of incidents of TASS.

Because ours is a governmental agency, our participation in formal partnerships or agreements is subject to rules and regulations that protect transparency and the public trust. Although we have been able to establish agreements in some areas with some entities, others may not come to fruition.

In the past, we have been privileged to investigate certain aspects of TASS via a contract with Nick Mamalis, MD, a professor at the University of Utah's

Department of Ophthalmology and Visual Sciences in Salt Lake City. His work under this contract helped us to assess the utility of certain data related to TASS and to develop new data collection tools for a new TASS registry.

At the end of the contract with Dr. Mamalis, the CDRH and ASCRS unsuccessfully attempted to establish a formal collaborative agreement to further this particular work. The lack of a formal agreement does not reflect a lack of commitment or effort on the parts of Dr. Mamalis, the ASCRS, and the FDA in combating TASS.

It is our hope that everyone continues to recognize the advances made in combating TASS that have been achieved through the collaborative efforts of the ophthalmic community, especially by Dr. Mamalis, the ASCRS, the AAO, and the FDA. We also hope that everyone will be encouraged to find ways to work together in the future.

It is of paramount importance that ophthalmologists continue to participate in all TASS efforts, including providing data for registries to augment the understanding of the causes of TASS and to better protect the public from outbreaks.

In order to successfully tackle TASS outbreaks and other public health challenges, the CDRH looks forward to working transparently with all available partners. We cannot succeed alone.

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1. Eydelman M. Investigating TASS—the FDA's role, spotlight on endophthalmitis and TASS. Paper presented at: The 2006 Annual Meeting of the AAO; November 12, 2006; Las Vegas, NV.

2. Eydelman MB, Tarver ME, Calogero D, et al. The Food and Drug Administration's Proactive Toxic Anterior Segment Syndrome Program. *Ophthalmology*. 2012;119:1297-1302.

The proactive TASS Reporting and Surveillance program as well as the new questionnaires were developed and finalized during almost 3 years of collaboration between the ASCRS task force and the FDA group headed by Michelle Tarver, MD, PhD. A meeting of members of the ASCRS and FDA was held in Bethesda, Maryland, in January 2011 to discuss the project's timeline with the selected software vendor that would configure an electronic registry and to put the final agreements in place. In March 2011, while discussing the cooperative research and development agreement for the proactive TASS reporting program, much to the surprise of everyone from the ASCRS involved, the FDA claimed full ownership of the new questionnaires to the exclusion of the ASCRS and the IORC. Multiple attempts were made to work out an agreement between the ASCRS' lawyers and lawyers from the government. During these legal negotiations, the FDA not only claimed unlimited rights to the new, jointly developed registry questionnaires but also to all of the data that had been collected by the ASCRS and the IORC. The breakdown of the negotiations on the TASS registry led to the dissolution of the partnership between the IROC, the ASCRS, and the FDA and was deeply disconcerting to members of the task force who were involved in this pro-

cess. After hundreds of hours of hard work on this project, the matter could not be resolved due to the intransigence of the FDA.

I was profoundly disappointed by the FDA's announcement of the proactive TASS program³ with absolutely no acknowledgement of the extensive involvement of the ASCRS task force and the IORC. The ASCRS TASS Task Force and the IORC continue to study the causes of TASS and to provide analyses and recommendations to surgeons and surgical centers that are having problems with TASS. This initiative continues to be carried out completely independently of the FDA's initiative through the financial support of the ASCRS. ■

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2. ASCRS Adhoc Task Force on cleaning and sterilization of intraocular instruments: recommended practices for cleaning and sterilizing intraocular surgical instruments. *J Cataract Refract Surg.* 2007;33:1095-1100.
3. Eydelman MB, Tarver ME, Calogero D, et al. The Food and Drug Administration's proactive toxic anterior segment syndrome program. *Ophthalmology.* 2012;119:1297-1302.