



## **John V. Kelsey, DDS, MBA**

(awarded in Atlanta, 2007)

Dr. Kelsey is a graduate of the Georgetown University School of Dentistry and has a Master of Business Administration degree from the University of New Mexico. He is a career officer in the U.S. Public Health Service (USPHS). He spent the first nine years of his career in USPHS practicing clinical dentistry in the Indian Health Service in Arizona and New Mexico.

In 1987, Dr. Kelsey transferred to the Food and Drug Administration (FDA). Initially he was in the Office of Orphan Products Development (OPD), serving as Deputy Director for six years. OPD is the office in the FDA responsible for promoting the development of drugs and other products to prevent and treat rare diseases.

Following his years at OPD, Dr. Kelsey transferred to the Division of Dermatology and Dental Products (DDDP) in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), as Dental Team Leader, a post which he still holds. As a clinician in a new drug review division, Dr. Kelsey is responsible for the review and approval of new drugs for dental indications.

Almost a decade ago, Dr. Kelsey volunteered to represent OND on the MedDRA Points-to-Consider Working Group (PtC WG), at a time when use of MedDRA for reporting adverse events in clinical trials for drug approval was growing dramatically. At FDA he provided training for drug reviewers who review AE data coded in MedDRA, arranged guest speakers on the topic and coordinated the distribution of the MedDRA Browser to OND reviewers. In 2008, FDA's Office of International Programs asked Dr. Kelsey to represent the Food and Drug Administration (FDA) on the MedDRA Management Board (MMB). In addition to service on the PtC WG and the MMB, Dr. Kelsey is a member of the Expert Working Group, which advises the MedDRA Maintenance and Support Services Organization (MSSO) on a variety of topics.