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**Steven I. Gutman, M.D.**, is a board certified pathologist with degrees from Ohio State University (BS), Cornell University Medical College (MD) and the State University of New York at Buffalo (MBA). He completed residency training in pathology at The New York Hospital (anatomical pathology) and the Mayo Clinic (Clinical Pathology). After 10 years of experience as clinical pathologist and chief of the laboratory service at the Buffalo, VA Medical Center, he joined the Division of Clinical Laboratory Devices as a medical officer in 1992; he was promoted to division director in 1993. In November he became the director of the Office of In Vitro Diagnostic Device (IVD) Safety and Evaluation, a new office in the Center for Devices and Radiological Health.