

*VIEWS EXPRESSED DO NOT REPRESENT FDA*

written by Dr. Michael Fleming

Dr. Fleming was recently honored to be appointed to a four year term as a Consultant to the Center for Devices and Radiologic Health of the Food and Drug Administration. His tasks include advising FDA on matters related to the safety and effectiveness of medical devices to include dental products. Dr. Fleming is the former Consumer Representative on the Dental Products Panel of the Food and Drug Administration (FDA). He has also served as the Acting Consumer Representative on the Circulatory System Devices Panel that advises FDA on matters related to products and devices utilized within the heart and blood vessels.\*

Dr. Fleming's new role as a Consultant requires him to periodically interface with the FDA and other designated stakeholders with respect to medical device review and regulation. His specific role as a Consultant or panel member is to impartially and objectively evaluate scientific data, clinical trial designs, risk assessments and other matters brought before an advisory panel to enhance FDA's regulatory decision making process.

Dr. Fleming receives many inquiries regarding his opinion on such matters as water fluoridation, dental filling materials, root canals and other important matters affecting the health and well being of Americans. Dr. Fleming's statements about these issues are his personal opinions only but reflect many years of scientific study and involvement in a number of different public venues. They do not necessarily reflect views held by the FDA or any other regulatory agency.

Dr. Fleming is a dental professional and, as such, cannot dispense medical advice with respect to any device, medical condition or procedure reviewed before any FDA advisory panel that is the purview of physicians.

Dr. Fleming's ongoing challenge to consumers of dental and medical services is to become a conscious consumer. That is, patients need to be proactive in their own health care choices and be vigilant and knowledgeable about the services and products offered in today's competitive and rapidly changing environment.

\* CDRH advisory panels do not regulate but only advise the FDA on matters related to the reasonable assurance of safety and effectiveness of medical devices. Further information about Advisory Panels, Consultants and their functions can be found at [www.fda.gov](http://www.fda.gov).