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Overall these FDA initiatives are very laudable and will certainly help restoring the trust of the public in advanced medical imaging, trust that was most certainly damaged by recent unfortunate, yet isolated incidences, where patients were actually harmed by medical radiation. There is indeed a need for enhanced transparency, better patient education, more dialogue between patients and their healthcare providers, and increased involvement of the patient in the decision process leading up to an imaging study.

It is important to note that virtually all initiatives proposed by the FDA are long held core principles and recommendations of the premier professional organization of our field, the American College of Radiology (ACR). The College has always been championing the ALARA (as low as reasonably achievable) principle, which stipulates that the least amount of radiation is used that still allows a definitive diagnosis. The College strives to ensure adherence to this principle and to provide the highest quality service by a variety of credentialing and benchmarking mechanisms. To date, however, the participation in the ACR quality initiatives is largely voluntary. More importantly, many medical imaging studies involving radiation are performed by physicians of medical specialties other than Radiology (and thus outside the ACR sphere of influence), who by virtue of their education in a different medical field are less sensitized and less well trained to custom-tailor radiation to the individual patient. The FDA is an institution with farther reaching regulating powers than the ACR, so there is hope that the proposed initiatives will increasingly insure that only appropriately trained physicians are allowed to perform imaging and radiation dose awareness is enhanced in the entire medical community.

The FDA notes correctly that CT, nuclear medicine, and fluoroscopic imaging have led to early diagnosis of disease, improved treatment planning, and image-guided therapies that help save lives every day. It is also correct that the amount of radiation Americans are exposed to from medical imaging has increased over the past 20 years. It is important to note, however, that an increase in cancer mortality has not been observed. On the contrary, cancer mortality has dramatically decreased over the past decades, in step with increased utilization of medical imaging. According to a recent analysis by the National Bureau of Economic Research (Lichtenberg 2009), life expectancy increased more rapidly in states where the fraction of advanced diagnostic imaging procedures increased more rapidly. While the FDA is right to embark on initiatives to reduce unnecessary radiation exposure, it cannot be overemphasized that there is no evidence suggesting that radiation received from medical imaging, such as computed tomography (CT), increases the risk of developing cancer. All models that have been proposed for calculating the theoretical risks of developing a cancer from radiation at medical imaging is extrapolated from data on WWII atomic bomb survivors in Japan, a sudden cataclysmic exposure to various types of radiation. Whether this data can indeed be used to gauge cancer risk from pure photon exposure during x-ray or CT scan acquisition is highly debatable. Accordingly, the risk of developing a cancer from medical imaging is a remote, stochastic risk. What is often forgotten in this discussion is that serious injury or death, resulting from missing a potentially life-threatening diagnosis if no imaging is performed is a much greater, more imminent, and very real risk.