

## **MAMMOGRAPHY CONTROVERSY: WHO IS RIGHT?**

The U.S. Preventive Services Task Force (USPSTF) is sponsored by the Agency for Healthcare Research and Quality, a subset of the U.S. Department of Health and Human Services. According to the views expressed by the sponsoring agency (AHRG 2010) the recommendations of USPSTF are considered to be “gold standard” for clinical preventive services. The most recent recommendations of the USPSTF on breast cancer were published in recently (USPSTF 2009). Immediately after the publication of the report, the preverbal “the-hell-broke-loose” happened. Virtually every media outlet had extensive coverage of the subject including *Wall Street Journal* (Anonymous. 2009; Wang et al. 2009) *Washington Post* (Stein 2009) and *New York Times* (Belluck 2009).

The coverage was not limited to public media. The *Journal of American Medical Association* had extensive coverage of the topic (Berg 2010, Murphy 2010, Woloshin and Schwartz 2010, Woolf 2010) and the subject was important enough that the Editor of that journal chose to discuss the subject (DeAngelis and Fontanarosa 2010). Similarly *Science* had a rather lengthy report on the issue (Marshall 2010)

Given the media coverage, the Secretary of Health and Human Services (HHS), and even the White House had to get involved. Although some organizations were supportive of the recommendations others opposed them and some used strong words in their opposition. During the passage of the healthcare bill with the awkward title: “Health Care and Education Affordability Reconciliation Act of 2010”, there was extensive discussions including expression of outrage about the recommendations of the USPSTF. What was the reason for what happened and could the problem have been avoided?

The book “Best Available Science: Fundamental Metrics for Evaluations of Scientific Claims”(BAS/MESC) and its previous edition (Moghissi et al. 2008, Moghissi et al., 2010) attempt to address how a contested area of science can be logically managed. In particular, the BAS/MESC recognizes that science is continuously evolving and decisions based on a specific area of science must take the level of maturity of science into consideration. There are areas of science that are proven and everyone with relevant competency and appropriate equipment and facilities can reproduce them. Conversely there are areas that contain uncertainties, some insignificant and other very significant. Therefore the decision maker must consider them. For example, the so-called “rationalized science” uses proven science but relies upon assumptions that may prove to be right or wrong. And then, there are scientific judgments that are no more than educated guesses. The USPSTF is likely to have recognized that the underlying science ranged from rationalized science to scientific judgment. However, the panel chose to use science with various degrees of maturity, including highly uncertain science to draw firm decisions. For example, the risk vs. benefit on performing a mammography once a year vs. once every second year is associated with large uncertainties and yet the panel chose to provided recommendations despite this uncertainty.

A key reason for problems caused by USPSTE recommendations was the misunderstanding on its role as a scientific panel vs. areas that are inherently outside the purview of science. William Ruckelshaus (1983), the founding administrator of the U.S. Environmental Protection Agency (EPA) provided guidance to regulators by stating that:

“...all scientists must make it clear when they are speaking as scientists – *ex cathedra* - and when they are recommending policy they believe should flow from scientific information.... What we need to hear more of from scientists is science.”

The National Research Council (NRC 1983) of the National Academy of Sciences published a landmark report, known as the “red book”, on risk assessment and risk management (NRC 1983). The red book provided guidance to the Food and Drug Administration (FDA), and by implication, to other federal agencies on risk analysis. According to NRC, whereas risk assessment (one component of risk analysis) is a scientific process, and thus the domain of the scientific community, risk management (another component) is the domain of policy (HHS). By implication risk management is not within the purview of science. The red book became the foundation of a number of laws, regulatory decisions, and many other activities. The red book, the Ruckelshaus Effect, and many subsequent decisions made a clear and unambiguous distinction between science (risk assessment) and governmental and other societal decisions (risk management) that in turn used Science (characterized risk) as its foundation.

The USPSTF consisted of a number of distinguished scientists including medical professionals who were highly qualified to evaluate the scientific foundation of the subject. In its report, the Panel includes quantitative data on the value of mammography (including film and digital); breast self examination (BSE); clinical breast examination (CBE); various other techniques such as MRI; and lives saved as a consequence of using these technologies. In addition, the panel addresses the impact of false positive results (detecting a potential cancer when it does not exist). Clearly, the report is an outstanding compilation of scientific information.

It would have been desirable to convert these data to a quantitative risk assessment and characterize each segment to be provided to the HHS. Instead the USPSTF panel chose to be the risk manager, a task that is outside the purview of science. There is every reason to believe that once the risk is properly characterized and presented in a language that understandable to the decisions makers, the responsibility to manage the risk rests with the policy makers. What should have been the process that could have avoided such an outcry and dissention? There is a well-established and routinely used process that could have been used by the USPSTF:

The USPSTF should have been charged with performing risk assessment of various options including the contentious area of frequency of mammography. In doing so the level of maturity of underlying science should have been emphasized. Much like the practice of the National Academies, the USPSTF report should have been subjected to independent peer review. No risk management (recommendations on the acceptability of various options) should have been included in the report. The outcome of this effort should have been a report describing the scientific foundation of the anticipated decisions. It would have been difficult for anyone to disagree with the results of such an effort. The Secretary of HHS should then have prepared potential options on risk management including the desirability and frequency of mammography, the desirability of BSE, the consequences of false positive results of mammography, and many other related issues. These should have been provided to the public for comment, a well-established process used by many agencies such as Environmental Protection Agency.

The process used by USPSTF is often used by various agencies. The scientific including the medical and engineering communities like the process because it makes them feel good and important. The government agencies like it too because they can hide behind science. However, as the example of USPSTF demonstrates it is not only inconsistent with established requirements but it often causes significant and unnecessary problems.

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- Note: An abbreviated version of this document was submitted as a Letter to the Editor to the Journal of American Medical Association. As the Journal chose not to publish it, the original version is provided to the public.*

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