What Makes Medical Technology Work
Prof. Kenneth R. Foster

Abstract:
The complex interplay between the development of technology as seen by engineers, and the medical, regulatory, and economic factors that determine success is frequently overlooked by engineers. And the consequences can be very expensive. I consider three cases that illustrate the problem. The first is infrared imaging of the breast for screening for cancer. The technique provides highly sensitive (in an engineering sense) and detailed thermal images of the breast but, after decades of work and premarket approval by the US Food and Drug Administration (FDA), the technique has never succeeded medically or commercially. The second is the role of smartphone apps in medicine. The FDA has recently stated its intention to regulate some apps as medical devices and subject to the FDA's premarket approval process -- which could introduce a standard of proof of safety and efficacy that few app developers could meet. A final example is the order in September 2013 by the FDA preventing the marketing of a popular genetic testing service (23andme.com). These technologies all work in a technical sense, but making them work in the real world of medicine, regulation, and economics is a different matter entirely.

Biography
Kenneth R. Foster received his PhD in physics in 1971. Since 1977 he has been at the University of Pennsylvania, where he is Professor of Bioengineering. His technical work involves studies on the interaction of nonionizing radiation and biological systems, ranging from biophysical principles of interaction to dosimetry and exposure assessment. A major secondary interest is the interaction of technology and society. For a number of years he has taught a course to biomedical engineers on "what makes medical technology work". In addition to more than 100 articles in peer reviewed journals, he is coauthor or coeditor of two books on risk assessment and the law. He is a fellow of the IEEE and of the Americal Institute for Medical and Biological Engineering and the Editor-in-Chief of BioMedical Engineering Online, and has been involved for many years with evaluating health effects of nonionizing radiation and participating in standards setting committees. Among his other activities, he teaches a course unofficially known as "What Makes Medical Technology Work"
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