



FDA plays an enormous role in the governance of emerging technologies but the laws that govern FDA's activities, particularly those that govern medical devices, are 40 years old. Much has changed in 40 years that suggest that it is time to take a fresh look at those institutions. Foremost amongst those changes is the internet that has given rise to the information revolution. Where information was costly to obtain, process, and disseminate on virtually anything purchased in 1976, that is no longer the case and information is becoming freely available on medical devices as well. The internet also brings us crowdsourcing innovation that has the ability to promote speedy repair of defects. This type of resiliency fits neatly into our modern understanding that safety, or risk, is not a static concept, but rather a dynamic notion of marginal improvements. Such improvements may also allow for devices that fit individuals desires using their own risk/benefit trade-offs. Finally, we are living in a world of increasing international competition. These new developments compel us to adjust our regulatory system to one that places equal emphasis on what can go right as well as what can go wrong (the latter being weighted much more heavily in our existing system). This paper will examine a role for FDA that fits a 21st century understanding of these issues.