April 2010
• SACGHS releases recommendations on DTC testing, including:
  • FDA and CMS develop guidance and regulations to close gaps in oversight of genetic marketed DTC
  • DTC tests and services and information on analytical and clinical validity should be part of Federal test registry
• HHS-FTC task force to develop guidelines to evaluate DTC company claims
• HHS to identify gaps in research and privacy protections for PHI-generated DTC
• HHS to develop genetics education initiative for consumers and HCPs, including information on DTC genetic testing

May 2010
• Pathway Genomics announces plan to sell genetic tests at Walgreens

May 2010 - May 2011
• FDA sends letters to 24 DTC companies and manufacturers stating that their tests meet the definition of medical devices

July 2010
• GAO report on DTC testing finds that consumers had received test results that had little or no practical use
  • Joint NIH/FDA paper calling for better regulatory pathways and voluntary testing registry
  • FDA holds public meetings on laboratory-developed tests
  • CDRH Director testifies to Congress that due to changes in the nature of tests offered DTC, the FDA is working towards regulation

March 2011
• FDA convenes a two-day meeting of the Molecular & Clinical Genetics Panel for expert opinion and input on scientific issues concerning DTC genetic tests that make medical claims

September 2011
• CDRH held the last of six town hall meetings to "engage in a dialogue about issues of importance to the public" and to present the CDRH FY 2011 priorities