

Direct-to-consumer pharmacogenetic reports

December 2018—The FDA has granted 23andMe de novo authorization to offer direct-to-consumer reports on pharmacogenetics. The authorization allows 23andMe to report variants in multiple genes that are associated with how an individual may metabolize some medications. The report enables the company to provide customers with information on whether they are predicted to be fast or slow metabolizers based on their genetics, but it does not describe associations between any detected genetic variants and any specific medication. The new regulation will allow for future FDA submissions to seek authorization to report whether an individual with certain genetic variants may experience reduced efficacy or increased chance of side effects from certain medications, when supported by appropriate clinical evidence.

[23andMe](#), 800-239-5230