FDA approval of 23andMe’s genetic test positive sign for the genomics industry

On February 19, the Food and Drug Administration approved a test made by 23andMe, the Mountain View, Calif.-based personal genetics company, for a gene that can cause a rare disorder called Bloom Syndrome, which causes short stature and a heightened risk of cancer.

This is news not because a new carrier test is important, but because the FDA seems to be using this test as a way to start to think out its plans for regulating new types of genetic tests that are emerging from the revolution in DNA sequencing, the technology that can read out a person’s genetic material at a materials cost of less than $1,000. The news is a positive not only for 23andMe but also for Illumina, the largest maker of DNA sequencing gear, and smaller players like Thermo-Fisher, PacBio, and Oxford Nanopore.

The big question is how the FDA will regulate cases where doctor’s want to sequence all of a patient’s genes, or whole genome sequencing. It is meeting today (February 20) to collect advice from scientists.

The reason the 23andMe approval is exciting is that it represents a baby step into this world. It doesn’t put 23andMe back into the business of selling consumers lots of genetic tests (it will take time even for the company to launch a test that does carrier screening) but it makes it easier to imagine a world where the FDA intelligently regulates genetic data.

Read full, original article: What 23andMe’s FDA Approval Means For The Future Of Genomics