

“Advancing new drug development tools, like biomarkers, cannot be the sole responsibility of FDA, NIH, or industry alone.”

Senior FDA Staff, *Clinical Pharmacology & Therapeutics*, July 2015

Everyone will be a patient someday.

We live in an era of breathtaking medical breakthroughs. Diseases that were once death sentences can now be managed or cured. The powerful combination of advances in biotechnology and precision medicine promises even more.

“Biomarkers” can provide keys to our individual biology, guiding specific treatments to those who can benefit from them. They are already helping us win our battles against cancer and HIV – and are vital to better treatments for millions of patients battling diabetes, Alzheimer’s, and Parkinson’s.

A new era in science and medicine calls for a new approach at the federal Food and Drug Administration, which determines whether any new treatment is safe and effective.

Every American has a stake in this change – because everyone will be a patient someday.

Congress should lay the foundation for a 21st century FDA by creating an external advisory network drawing on the expertise of the scientific and patient communities to assist the FDA in setting standards for how biomarkers can be better integrated into the drug development process.

This is a call for collaboration on an unprecedented scale to help the FDA chart a safe path for advancing biomarkers from discovery in a lab to your doctor’s office. We echo previous recommendations made by the President’s Council of Advisors on Science and Technology, the National Institutes of Health, a report from the National Research Council – and senior staff at the FDA itself.

There are those who believe the FDA should be siloed away from the doctors, patients, scientists and innovators who are at the forefront of developing cutting edge treatments. However, in order to bring lifesaving therapies to patients, we must fully empower the FDA to embrace precision medicine and promote a culture of collaboration with the broader scientific and patient communities.

A new golden age of medicine is within our grasp. We believe now is the time to seize it.

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