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**Subject:** THE WHITE HOUSE: FACT SHEET - President Obama's Precision Medicine Initiative

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**From THE WHITE HOUSE:  
Office of the Press Secretary**

**FACT SHEET: President Obama's Precision Medicine Initiative**

January 30, 2015

Building on President Obama's announcement in his State of the Union Address, today the Administration is unveiling details about the Precision Medicine Initiative, a bold new research effort to revolutionize how we improve health and treat disease. Launched with a \$215 million investment in the President's 2016 Budget, the Precision Medicine Initiative will pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients.

Most medical treatments have been designed for the "average patient." As a result of this "one-size-fits-all-approach," treatments can be very successful for some patients but not for others. This is changing with the emergence of precision medicine, an innovative approach to disease prevention and treatment that takes into account individual differences in people's genes, environments, and lifestyles. Precision medicine gives clinicians tools to better understand the complex mechanisms underlying a patient's health, disease, or condition, and to better predict which treatments will be most effective.

Advances in precision medicine have already led to powerful new discoveries and several new treatments that are tailored to specific characteristics of individuals, such as a person's genetic makeup, or the genetic profile of an individual's tumor. This is leading to a transformation in the way we can treat diseases such as cancer. Patients with breast, lung, and colorectal cancers, as well as melanomas and leukemias, for instance, routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

The potential for precision medicine to improve care and speed the development of new treatments has only just begun to be tapped. Translating initial successes to a larger scale will require a coordinated and sustained national effort. Through collaborative public and private efforts, the Precision Medicine Initiative will leverage advances in genomics, emerging methods for managing and analyzing large data sets while protecting privacy, and health information technology to accelerate biomedical discoveries. The Initiative will also engage a million or more Americans to volunteer to contribute their health data to improve health outcomes, fuel the development of new treatments, and catalyze a new era of data-based and more precise medical

treatment.

#### Key Investments to Launch the Precision Medicine Initiative:

Complementing robust investments to broadly support research, development, and innovation, the President's 2016 Budget will provide a \$215 million investment for the National Institutes of Health (NIH), together with the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC) to support this effort, including:

- \$130 million to NIH for development of a voluntary national research cohort of a million or more volunteers to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing.
- \$70 million to the National Cancer Institute (NCI), part of NIH, to scale up efforts to identify genomic drivers in cancer and apply that knowledge in the development of more effective approaches to cancer treatment.
- \$10 million to FDA to acquire additional expertise and advance the development of high quality, curated databases to support the regulatory structure needed to advance innovation in precision medicine and protect public health.
- \$5 million to ONC to support the development of interoperability standards and requirements that address privacy and enable secure exchange of data across systems.

#### Objectives of the Precision Medicine Initiative:

- More and better treatments for cancer: NCI will accelerate the design and testing of effective, tailored treatments for cancer by expanding genetically based clinical cancer trials, exploring fundamental aspects of cancer biology, and establishing a national "cancer knowledge network" that will generate and share new knowledge to fuel scientific discovery and guide treatment decisions.
- Creation of a voluntary national research cohort: NIH, in collaboration with other agencies and stakeholders, will launch a national, patient-powered research cohort of one million or more Americans who volunteer to participate in research. Participants will be involved in the design of the Initiative and will have the opportunity to contribute diverse sources of data—including medical records; profiles of the patient's genes, metabolites (chemical makeup), and microorganisms in and on the body; environmental and lifestyle data; patient-generated information; and personal device and sensor data. Privacy will be rigorously protected. This ambitious project will leverage existing research and clinical networks and build on innovative research models that enable patients to be active participants and partners. The cohort will be broadly accessible to qualified researchers and will have the potential to inspire scientists from multiple disciplines to join the effort and apply their creative thinking to generate new insights. The ONC will develop interoperability standards and requirements to ensure secure data exchange with patients' consent, to empower patients and clinicians and advance individual, community, and population health.
- Commitment to protecting privacy: To ensure from the start that this Initiative adheres to rigorous privacy protections, the White House will launch a multi-stakeholder process with HHS and other Federal agencies to solicit input from patient groups, bioethicists, privacy, and

- civil liberties advocates, technologists, and other experts in order to identify and address any legal and technical issues related to the privacy and security of data in the context of precision medicine.
- Regulatory modernization: The Initiative will include reviewing the current regulatory landscape to determine whether changes are needed to support the development of this new research and care model, including its critical privacy and participant protection framework. As part of this effort, the FDA will develop a new approach for evaluating Next Generation Sequencing technologies — tests that rapidly sequence large segments of a person’s DNA, or even their entire genome. The new approach will facilitate the generation of knowledge about which genetic changes are important to patient care and foster innovation in genetic sequencing technology, while ensuring that the tests are accurate and reliable.
- Public-private partnerships: The Obama Administration will forge strong partnerships with existing research cohorts, patient groups, and the private sector to develop the infrastructure that will be needed to expand cancer genomics, and to launch a voluntary million-person cohort. The Administration will call on academic medical centers, researchers, foundations, privacy experts, medical ethicists, and medical product innovators to lay the foundation for this effort, including developing new approaches to patient participation and empowerment. The Administration will carefully consider and develop an approach to precision medicine, including appropriate regulatory frameworks, that ensures consumers have access to their own health data – and to the applications and services that can safely and accurately analyze it – so that in addition to treating disease, we can empower individuals and families to invest in and manage their health.

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