

Personalized Medicine: The Future Is Now

Margaret A. Hamburg, M.D., Commissioner, FDA



The difference between science and science fiction is a line that seems ever harder to distinguish, thanks in part to a host of astonishing advances in medical science that are helping to create a new age of promise and possibility for patients.

Today cancer drugs are increasingly twinned with a diagnostic device that can determine whether a patient will respond to the drug based on their tumor's genetic characteristics; medical imaging can be used to identify the best implantable device to treat a specific patient with clogged coronary arteries; and progress in regenerative medicine and stem cell therapy using a patient's own cells could lead to the replacement or regeneration of their missing or damaged tissues. Given these trends, the future of medicine is rapidly approaching the promising level of care and cure once imagined by Hollywood in futuristic dramas like Star Trek.

But these examples are not science fiction. They are very real achievements that demonstrate the era of "personalized medicine" where advances in the science of drug development, the study of genes and their functions, the availability of increasingly powerful computers and other technologies, combined with our greater understanding of the complexity of disease, makes it possible to tailor treatments to the needs of an individual patient. We now know that patients with similar symptoms may have different diseases with different causes. Individual patients who may appear to have the same disease may respond differently (or not at all) to treatments of that disease.

FDA has been playing a critical role in the growth of this new era for a number of years. Even before I became FDA Commissioner the agency was creating the

Personalized Medicine: The Future Is Now

Published on Medical Design Technology (<http://www.mdtmag.com>)

organizational infrastructure and putting in place the regulatory processes and policies needed to meet the challenges of regulating these complex products and coordinating their review and oversight. It has been my pleasure to serve at FDA during this next exciting period and to help ensure that the agency continues to prioritize this evolution by anticipating, responding to, and encouraging scientific advancements.

I am very pleased to be able to present a new report by FDA as part of our ongoing efforts in this field. [Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development](#) [1] (.PDF) describes many of the exciting developments and looming advances in personalized medicine, lays out the historical progress in this field, and examines FDA's regulatory role: from ensuring the availability of safe and effective diagnostic devices, to addressing the challenges of aligning a drug with a diagnostic device, to post-market surveillance.

Outside collaboration and information sharing is essential for this field to flourish. On Tuesday, the American Association for Cancer Research and AdvaMedDX held a fruitful daylong conversation on personalized medicine to treat cancer. I was one of the speakers, participating in a conversation with Dr. Francis Collins, the head of the National Institutes of Health. Our discussion focused in part on current status of drug and diagnostic co-development and the challenges and potential of whole genome sequencing, where data can be collected on a patient's entire genetic makeup at a reasonable cost in a reasonable amount of time.

FDA is committed to fostering these cooperative efforts, as it will require the full force of government, private industry, academia and other concerned stakeholders to maximize our efforts and fully realize the promise of personalized medicine. Our new report outlines that commitment, and helps chart the way forward so that more people can live long and prosper.

This blog originally appeared at the FDA Voice blog. You can find it by [clicking here](#) [2].

Source URL (retrieved on 10/31/2014 - 11:43am):

<http://www.mdtmag.com/blogs/2013/11/personalized-medicine-future-now>

Links:

[1] <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf>

[2] <http://blogs.fda.gov/fdavoce/index.php/2013/11/personalized-medicine-the-future-is-now/>