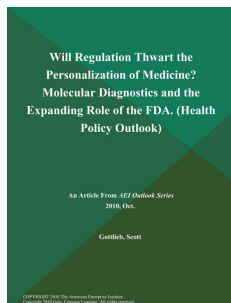


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## WILL REGULATION THWART THE PERSONALIZATION OF MEDICINE MOLECULAR DIAGNOSTICS AND THE EXPANDING ROLE OF THE FDA HEALTH POLICY OUTLOOK EBOOKS 2019



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The FDA recently announced that it will be exerting more regulatory scrutiny over molecular diagnostics. (1) Molecular diagnostics are lab tests that look at individuals' DNA. These tests can measure the expression of individual genes, and they are being used to determine everything from the presence of a disease to the risk of developing one. They can also identify patients likely to benefit from a drug and those most likely to develop a side effect. (2) Molecular diagnostics have become an essential part of clinical practice and of efforts to improve the development and prescription of drugs to make treatments safer and more targeted. The diagnostic field has undergone rapid innovation over the last decade, in part because labs were able to incorporate new information into tests quickly and offer them to patients. The FDA wants to regulate the vast majority of these molecular diagnostics as medical devices, regardless of who is performing the tests and how they are being sold to doctors and patients. Yet when it comes to safety, the industry has a fairly good track record. If the FDA steps in to impose regulations that are too costly, time consuming, or burdensome, it could stall much of the investment and entrepreneurship that have fueled recent innovations. The regulatory regime needs to be matched to the risks and mindful of the opportunities that hang in the balance.

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