

ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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The Genomics and Personalized Medicine Act of 2006

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H&O What has spurred your interest in genomics-based medicine?

BO It is clear that genomics is starting to revolutionize the way in which healthcare is practiced. New research findings are being translated into tests and treatments in all areas of medicine. For many types of cancers, genomics-based medicine has already had a major impact on the way in which patients are treated. Trastuzumab (Herceptin, Genentech) therapy for patients with HER2-positive breast cancer is certainly a hallmark in the application of genomics research. Similarly, the development of algorithms to determine which patients receiving warfarin are more likely to experience bleeding, and thus warrant closer monitoring or dose adjustment, is another milestone.

Although the potential benefits of genomics-based medicine cannot be overestimated, there are also a number of potential pitfalls and concerns. There are ways in which federal, state, and local resources can be leveraged to avoid these barriers and to ensure the expansion and acceleration of this field, with appropriate privacy safeguards and consumer protections. With the quantity and quality of research findings now emerging, it seems important to have federal regulations and support firmly in place.

H&O How will the Genomics and Personalized Medicine Act address genomics research?

BO This bill directs the Secretary of Health and Human Services to expand areas of genomics research. In addition, the bill aims to increase coordination and integration of research efforts across various agencies, including the National Institutes of Health (NIH), the Center for Disease Control and Prevention, and the Food and

Drug Administration (FDA). All of these agencies play important roles with regard to accelerating the field of genomics, and this bill includes provisions to ensure that these agencies are leveraging each other's expertise and resources. Moreover, health experts at these agencies will help to determine which diseases and conditions should be prioritized for genomics research. We expect that the federal investment in genomics research will focus on diseases and conditions that have a substantial health impact, whether due to the outcomes of the disease, the number of people affected, the lack of effective treatments, or the side effects associated with currently available therapies.

H&O What types of research would be sponsored by the funds allocated by this Act?

BO This bill supports genomics research broadly, but one area of specific focus is biobanking. The NIH is already working on a large, national biobanking plan, but there are also several local efforts at academic institutions across the United States to collect DNA samples and health information in order to try to understand the correlation between genetic make-up and the onset and outcomes of disease. Some of the goals of biobanking may be best accomplished by large, concerted efforts with the largest sample sizes possible, thereby making any analyses more scientifically rigorous. Therefore, the bill encourages sharing of information learned, if not the actual data, from individual biobanking efforts by establishing a national distributive biobanking database. In this way, findings from biobanking efforts at Northwestern University can contribute to efforts at Duke University, for example, and vice versa. The number of academic institutions developing biobanks is rapidly increasing and all would benefit from greater partnership and collaboration.

Some of the research that would be supported by these biobanking provisions is already exemplified by efforts at Northwestern University and the University of Chicago, as well as elsewhere. Patients come to a clinic and agree to be part of the research initiative by voluntarily submitting DNA samples and having their health information stored in electronic form. These collections of genetic material and health records from cohorts of patients provide researchers with the data needed in order

to understand, say, genetic variations that may affect the onset of diabetes or an individual's response to a particular treatment for diabetes. Cancer registries have been organized with similar goals. Collection of such data makes it possible to begin to understand who is likely to develop a particular type of cancer and who is likely to respond to a particular treatment.

Issues of ethics and privacy are also addressed in the Genomics and Personalized Medicine Act. For-profit companies and academic institutions alike should have independent advisory committees, informed consent protocols, and appropriate expert consultants examining the ethical and legal issues related to genomics research before they get involved in this area of research.

The Genetic Information Nondiscrimination Act is likely to pass the Congress in 2007, which will provide a foundation of protection for patients. This Act is an extremely important first step in ensuring that any information obtained, whether through research or clinical practice, is kept private, and that appropriate safeguards are in place to prevent misuse.

H&O Could you describe further how this bill addresses private sector drug development?

BO This bill includes a modest financial incentive to offset the costs of research and development for tests and treatments prioritized by the Secretary of Health and Human Services. Perhaps even more importantly, this bill focuses on modernization of the FDA and Centers for Medicare and Medicaid Services (CMS) regulatory pathways regarding genomic tests, which hopefully will help to streamline, and provide clarity about federal requirements for development of such tests.

H&O What measures are suggested toward modernization of the FDA and CMS?

BO Currently, new genetic tests either proceed through the FDA's regulatory pathway or are offered by a laboratory meeting the requirements of the Clinical Laboratory Improvement Act (CLIA) at CMS. Test kits produced by diagnostic companies generally need to be cleared by the FDA, which could take some time. By contrast, laboratories at academic institutions and hospitals are permitted to develop genetic tests themselves, and these laboratories are subject only to CLIA requirements at CMS.

With the number of available tests increasing, there is growing concern that the oversight of these products is insufficient, and that the quality of tests and interpretation of results may vary tremendously between institutions. Some advocates have noted that test information is not transparent or readily available for doctors or patients.

These concerns led to the recommendation from several expert groups to examine the entire regulatory process. This bill instructs the Secretary to determine when a test should be reviewed by the FDA or by CMS. This decision would mainly depend on what the test is being used for, the volume of tests performed, the clinical validity and utility of the test, any safety concerns, and the health implications of test results. A test that helps predict response to a drug may warrant a different level of regulatory oversight than one that, for example, may lead to a woman choosing to have a mastectomy. The bill mandates the development of a decision matrix that would provide guidance for developers of these tests about which regulatory requirements, if any, their test would be subject to, and to minimize the regulatory burden in cases where a high level of oversight is not necessarily warranted.

H&O How does this bill address direct-to-consumer marketing?

BO A recent investigation of direct-to-consumer marketing of nutrigenetic tests found that in some cases manufacturers were appropriate, but in other cases the results were being used to recommend the purchase of expensive tests or supplements that were not necessarily needed. Consumer protection should be ensured, particularly as more tests become available. Manufacturers should be required to provide scientific data to back up any recommendation and the response from federal oversight should be effective. The bill directs attention to this issue as well.

H&O What is the status of the bill?

BO The Genomics and Personalized Medicine Act did not pass in 2006 and will be reintroduced with some modifications in 2007. Since the bill was first introduced, my office has been soliciting feedback and comments so that it can be further strengthened and, hopefully, passed into law in 2007.

Suggested Reading

Genomics and Personalized Medicine Act of 2006 (S.3822). Available online: <http://thomas.loc.gov/cgi-bin/query/z?c109:s.3822>. Accessed December 19, 2006.

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