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HHS' Free Genetic Testing Opinion Raises Questions For Cos.

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On April 11, the U.S. Department of Health and Human Services' Office of Inspector General posted Advisory Opinion No. 22-06, regarding a biopharmaceutical company's arrangement to provide free genetic testing and genetic counseling services to patients meeting certain specified eligibility criteria.

The genetic test can detect gene mutations associated with a genetic disorder that presents in various bodily systems, including the heart. This disorder of the heart is characterized by a disease, for which the requestor has two U.S. Food and Drug Administration-approved drugs indicated for patients with either the spontaneous or hereditary forms of the disease.

The OIG concluded that it would not impose administrative sanctions in connection with the arrangement under the Anti-Kickback Statute. An arrangement between testing and counseling vendors in accordance with the OIG's opinion would have to follow strict guardrails around patient eligibility, promotion, marketing and data privacy, which often already form the substance of many company policies and standard operating procedures.

This decision is unique, however, because of its focus on the requestor-presented facts about the disease state and medical treatment landscape and thus warrants a closer look at the OIG's analysis to determine whether and to what extent other diseases and accompanying genetic tests might receive a similar determination by the OIG.

The disease in this case results from genetic mutations and presents in both spontaneous and hereditary forms in various bodily systems. At issue here is cardiac myopathy, which can lead to death.

Diagnosis of the disease requires two key components: (1) diagnostic testing (i.e., invasive procedures, such as a cardiac biopsy, or a noninvasive test, such as nuclear scintigraphy) to confirm the disease within the heart tissue itself, and (2) additional clinical testing to rule out similar cardiomyopathies.

Nonspecific symptomology and disease rarity can result in long delays in diagnosis and treatment, leading to ineffective and potentially inappropriate treatments of the disease. This, in turn, can lead to unnecessary negative patient outcomes.

The disorder and, ultimately, the disease in the heart, can result from more than 120 mutations of one responsible gene. The genetic testing at issue can identify mutations but does not constitute a diagnosis, which, as mentioned above, requires specific clinical confirmation. The OIG focused on three patient groups that

could benefit from genetic testing:

1. For patients already diagnosed with the disease, genetic testing can (1) show if the patient has the hereditary or spontaneous disease, and (2) elucidate expected disease progression, as the hereditary disease tends to progress faster than the spontaneous disease.

2. For patients with disease symptoms but no confirmed diagnosis, genetic testing in parallel with confirmatory clinical testing can provide information about the hereditary or spontaneous forms, further elucidating expected disease progression.

3. For asymptomatic patients related to someone diagnosed with the disease, genetic testing can (1) increase awareness and monitoring for signs and symptoms of the disease, and (2) shorten the time to diagnosis, should the patient later present with symptoms.

It is not only that testing cannot constitute a diagnosis — there is a great deal of attenuation between the disease diagnosis and what the genetic testing actually shows from a clinical perspective.

For example, one mutation in the gene at issue causes a majority of spontaneous cases of the disease, but only 10%-20% of those with the mutation will ultimately develop the disease.

Moreover, and perhaps most clinically relevant, presence of the gene mutation without a confirmatory clinical diagnosis as outlined above (i.e., invasive and noninvasive procedures) is not a basis for prescribing the requestor's products.

The requestor's products are not indicated for prevention of the disease, and it would be medically inappropriate and not within the standard of care for a physician to prescribe the products for prevention of the disease. One might assume that the requestor's drug labels say nothing about genetic testing at all.

This attenuation between what the genetic test shows and how the disease is diagnosed appears to be the most important factor in the OIG's analysis. Indeed, the OIG stated that:

Based on these facts, the nexus between the [free genetic testing and counseling services] and ordering or purchasing Requestor's products is attenuated. We caution that we would likely reach a different conclusion with respect to the risk presented by this type of arrangement if any of these facts were different and there were a more direct nexus between the remuneration and ordering or purchasing the manufacturer's products.

The OIG has drawn a line in the sand on this issue of potential overutilization or inappropriate utilization of the drug products by federal health programs.

Of course, the OIG is concerned about a drug manufacturer using free genetic testing and counseling as a means to have federal health programs cover more prescriptions, but the disease diagnosis and treatment landscape in this case did not appear to lend itself to a high risk of such an outcome because the genetic test formed such a small part of the patient's diagnostic journey.

In two of the patient groups outlined by the OIG, this genetic testing would, at best, only be confirmatory on the type of disease (i.e., spontaneous or hereditary) at or near the final step in the patient's journey to a final

diagnosis. The three groups could also benefit from testing, whether it be reducing time to diagnosis or negative outcomes from unnecessary treatments — all facts cited by the OIG.

However, the OIG's opinion raises a number of questions for manufacturers considering free genetic testing for patients.

For example, what if disease diagnosis in this case required a positive finding of a genetic mutation? Genetic conditions vary on the positive predictive value of genetic testing, but for a disease state where a positive finding would lead to a strong presumption of disease — at least more than the 10%-20% in this case — it stands to reason that the OIG may have come to a different conclusion.

What if there were little to no benefits of genetic testing, such as shortening time to diagnosis or avoiding negative patient outcomes?

Could a similar result be reached if the medical community was generating data or standards of care suggesting that the products could be used in a preventative manner, i.e., a manner potentially inconsistent with the FDA-approved labeling? What if ongoing and/or completed studies were showing that using the products for preventative use lead to better patient outcomes, with low safety concerns?

The OIG highlighted that no medical data supported use of the products for the treatment of undiagnosed patients, and that according to the medical community, it would be inappropriate and not standard of care to prescribe the products for preventative use.

However, data and medical opinions shift over time — with or without the help of the drug industry. Products on the market today are always being studied for new uses, and companies invest heavily in exploring these new uses in various ways, such as clinical trial programs, investigator-initiated studies and real-world data analyses.

These questions illustrate the unsteady ground that the OIG's opinion rests upon and underscore how much the facts matter. Companies contemplating the provision of free genetic testing and counseling services may thus want to carefully consider the medical landscape of the disease state for which their products are indicated.

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