FDA Detects That a Screening Tool for Early Detection of Cancer Types Might Require More Sleuthing

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The Food and Drug Administration recently issued an untitled letter to a medical device company concerning its non-invasive blood test intended for use as a screening tool for the early detection of certain cancer types[1]. FDA said that the product, sold direct-to-consumers, "appears to meet the definition of a device," and recommends the company consult with the agency about potential next steps. This is not the first time FDA has taken exception to such DTC screening tools.

Highlights of Letter

- The product is sold directly to consumers but was not cleared or approved by FDA for marketing.
- FDA could not find any published literature "that this test or any similar test has been clinically validated as a screening tool for early detection of cancer in high risk individuals."
- The agency challenged the company's White Paper, posted on the corporate website, which purported to support the screening claims.
- FDA expressed concern about the company's sale of a "high risk test that has not received adequate clinical validation and may harm public health," particularly as it is sold directly to consumers.

AGG Observations

- FDA expressed concern about the potential public health risk presented by the screening tool, particularly relating to adequate clinical validation.
- FDA did not come straight out and state the product was a medical device (and, thus, this might explain why the letter was not a formal Warning Letter), but the agency said the product "appears" to be a device, namely an in-vitro diagnostic test.
- The cancer detection claims clearly raise the bar on regulatory scrutiny due to the significance of the disease and the large population potentially affected.
- The DTC model is likely another contributing factor to FDA's concern, as there is no healthcare professional intermediary involved.
- FDA attempts seemingly to strike a conciliatory tone at the end of the letter. It noted that it was "committed to working with you as we strive to protect the public health without unnecessarily imposing regulatory burdens on the marketing of products of potential clinical importance." The agency appears to recognize that these types of IVD-like products may provide a medical benefit and does not want its oversight to unduly delay innovation. However, it also wants to ensure that the regulatory process protects the public by ensuring a thorough review of a marketing submission, including validation data.
- More and more clients are approaching us with similar IVD-type, screening tool products to assess their regulatory classification and potential authorization strategy. Intended use claims, technology, public health concerns (such as validation), and sales models (DTC vs. sale to doctors) are only some of the discussion points. Early consultation with outside counsel or consultants, and a possible meeting with FDA, may help minimize regulatory scrutiny and commercial delays and interruptions.

1 The letter can be accessed at www.fda.gov/medicaldevices/resourcesforyou/industry/ucm211866.htm. Incidentally, the company was questioned by FDA in 2010, in a similar type of letter, for a home-use saliva collection kit

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