# CLIENT ALERT

## FDA Promotes Evolving Regulation of Medical Device Materials

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In a statement released on March 15, 2019, the United States Food and Drug Administration (FDA) announced new efforts to evaluate the long-term safety and efficacy of materials used in the manufacture of implantable medical devices.

Specifically, FDA is focused on the health risks certain materials may pose to a small subset of the patient population. Although FDA acknowledges that "[t]he vast majority of patients implanted with medical devices have no adverse reactions," the agency appears motivated by what it calls "a growing body of evidence suggest[ing] that a small number of patients may have biological responses to certain types of materials in implantable or insertable devices." Because these idiosyncratic responses may not manifest for several years following implantation, FDA opines that they may go undetected even in comprehensive, long-term clinical trials. Citing its mandate to ensure the safety and efficacy of medical devices by weighing the probable benefits against the probable risks, FDA concludes that its regulation of medical device materials must evolve "[a]s we learn more about long-term effects of materials and as materials science advances and new innovations become a reality." FDA hopes that "[m]ore closely evaluating the potential for certain materials to cause immune/inflammatory reactions in a small number of patients may improve our understanding of materials, help uncover ways to identify patients predisposed to these reactions and improve overall safety and performance of medical devices."

But FDA does not intend to undertake this effort alone. The agency calls on industry and other stakeholders to help determine the current state of the science, identify critical gaps in the existing science, and develop approaches to further understand medical device materials and improve patient safety.

Certain materials were clearly at the forefront of FDA's mind. FDA highlighted its ongoing effort to evaluate a potential link between materials used to manufacture breast implants and the onset of breast implant-associated anaplastic large cell lymphoma. The agency also announced that it would soon be publishing draft guidance on the use of nitinol in medical devices and that it is currently working to develop new standards for the evaluation and testing of metal-on-metal hip replacement products. And FDA described the efforts that are required to understand the risks and benefits of devices manufactured from animal-derived materials and other "innovative materials," such as graphene.

The takeaway for industry is this: FDA is interested in "[m]odernizing the regulatory framework pertaining to FDA's review of medical device materials." Modernization, in this sense, appears to require regulation that looks beyond the risks and benefits of medical device materials to the patient population as a whole. Apart from that initial risk/benefit analysis, FDA believes that it has a continuing obligation to account for the risks posed to "certain small subsets of patients who exhibit sensitivities to select materials." For those few patients, FDA seeks to "determine what additional actions [it] should take to make sure they are protected and understand the unique risks they may encounter." The agency looks to industry to help make that determination.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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