One Step Up: U.S. Export Controls for Pharma/Device Companies

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2016 was an active year for U.S. export control developments impacting U.S. pharma/device companies. We expect 2017 also to be busy, especially with the upcoming change in Administrations. This article briefly will review for U.S. pharma/device companies (i) relevant, but general, changes to U.S. export controls; (ii) changes to the Cuba sanctions program; and (iii) changes to the Iran sanctions program. The article also will—very briefly—try to divine potential changes to those programs that may be implemented in 2017.

In terms of general changes, in 2016, the number of people included on the Specially Designated Nationals List (SDN List) pursuant to the Russia/Ukraine-related Designations increased; along with the enforcement of the 50% rule (a rule providing that any business that is more than 50% owned by person(s) on the SDN List in the aggregate is also deemed to be included on that list) this increase expands the universe of sanctioned parties in Russia and parts of Ukraine. This action will increase the compliance burden, at least as far as SDN screening, on U.S. pharma/device companies operating in those jurisdictions.

In 2016, the U.S. sanctions program against North Korea was expanded and strengthened, although few U.S. pharma/device companies have business dealings in that country. The U.S. government instituted new sanctions programs against Burundi and South Sudan, and terminated sanctions programs involving Côte d'Ivoire and Burma.

2016 saw some significant changes to the U.S sanctions program against Cuba, although it is worth nothing that the general U.S. economic embargo against Cuba remains in place. Notwithstanding that general restriction, the Office of Foreign Assets Control at the Treasury Department (*OFAC*) issued a new authorization that allows U.S. pharma/device companies to engage in joint medical research projects with Cuban nationals. This authorization allows for both non-commercial and commercial research.

In addition, OFAC issued a new authorization that would allow U.S. pharma/device companies to engage in transactions incident to obtaining U.S. Food and Drug Administration (FDA) approval of Cuban-origin pharmaceuticals. A separate authorization allows the importation into the United States, and the marketing, sale, or other distribution in the United States, of FDA-approved Cuban-origin pharmaceuticals. U.S. pharma/device companies also may now establish and maintain a physical presence in Cuba, such as an office, warehouse, or retail outlet, to engage in transactions authorized by or exempt from OFAC sanctions.

2016 saw some modest changes to the U.S. embargo against Iran, and the U.S.'s comprehensive sanctions against Iran remains in place. On January 16, 2016 (Implementation Day), the US lifted certain nuclear-related secondary sanctions against Iran. Also on Implementation Day, the United States removed over 400 individuals and entities from the SDN List.

General License H under the Iran sanctions program, issued by OFAC in 2016, would allow U.S.-owned or -controlled foreign entities (such as ex-U.S. affiliates of U.S. pharma/device companies) to engage in transactions with the Government of Iran or any Iranian person or entity that would otherwise be prohibited, except for transactions involving: (i) the direct or indirect exportation or re-exportation of goods, technology, or services from the United States; (ii) any transfer of funds

to, from, or through the U.S. financial system; or (iii) any individual or entity on the SDN List or any activity that would be prohibited by non-Iran sanctions administered by OFAC if engaged in by a U.S. person or in the United States other specifically prohibited transactions. General License H also authorizes U.S. pharma/device companies to establish or alter their operating policies and procedures to the extent necessary to allow that company's ex-U.S. affiliates to to engage in transactions with Iran that are authorized by General License H. In making such changes, and unless authorized by OFAC, U.S. persons employed by or serving on the board of directors of the ex-U.S. affiliate must be recused or "walled off" from all Iran-related business of that affiliate.

For 2017 and beyond, we expect pharmaceutical and medical device companies to remain a focus of export control enforcement efforts by OFAC and other relevant U.S. agencies. We anticipate that the incoming Trump Administration will slow the pace of liberalization of Cuba sanctions regime, but it may have some difficulty in fully reversing that liberalization trend. The Iran sanctions program may be differently situated given the incoming Administration's statements about renegotiating the Iran Joint Plan of Action. On the one hand, certain liberalizations may continue given U.S. commitments under the Iran Joint Plan of Action. We don not expect significant changes to the licensing mechanism under the Trade Sanctions Reform Act of 2000, pursuant to which U.S. pharma/device companies may obtain limited licenses to export pharmaceuticals or medical devices to Iran. However, new or toughened sanctions against Iran are possible with the new Administration.

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