

# Investing in Cuban Health Care Biotech Industries

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## Summary

The Obama Administration made significant new regulatory changes to allow certain investment opportunities in the Cuban health care and biotech industries. While many barriers remain, US firms in the health care industry have opportunities to invest in the Cuban market.

## In Depth

The Obama Administration made significant new regulatory changes to allow certain investment opportunities in the Cuban health care and biotech industries. While many barriers remain, US firms in the health care industry can now begin investing in the Cuban market. Many companies, hospitals and universities are already seeking strategic relationships with Cuban drug producers, medical service providers and biotech firms to create research and business opportunities.

The United States government is encouraging US companies to seek opportunities in Cuba within the legal limitations still imposed and the Cuban government is cautiously welcoming foreign investment in the health care and biotech industries. US companies interested in exploring these opportunities must understand the parameters of relevant US laws and regulations, Cuban foreign investment law and the economic environment on the island.

## ***Compliance with US Laws and Regulations***

### ***Cuban Sanctions Regulations and Export Controls Regulations***

The Obama Administration has issued new and amended regulations that have significantly relaxed the broad prohibitions and restrictions on US trade with, and investment in, Cuba. However, the trade embargo is still in place and will remain so until the US Congress amends or repeals certain laws. The US government continues to prohibit exporting to Cuba, importing from Cuba, investing in Cuba, and engaging in transactions involving property in which Cuba or a Cuban national has an interest without either a general or specific license from the US Department of Treasury's Office of Foreign Asset Control (OFAC).

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The regulatory and policy initiatives of OFAC and the US Department of Commerce's Bureau of Industry and Security (BIS) have eased certain restrictions that apply to travel, trade and financial dealings with Cuba. Under a series of new general licenses (e.g., requiring no application or preapproval), OFAC now allows US persons and companies to travel to Cuba for several specified reasons (e.g., professional research and meetings), to export and import certain goods and services, to establish a physical presence for certain business and to make certain investments in Cuba. OFAC also has become more open to considering applications for specific licenses for certain activities and transactions that otherwise remain prohibited.

Most recently, on October 14, OFAC made additional regulatory changes to allow US persons to engage in joint medical research projects with Cuban nationals. This general license expands the scope of joint research projects to allow both non-commercial and commercial medical research.

OFAC also now authorizes transactions incident to obtaining approval from the US Food and Drug Administration (FDA) of Cuban-origin pharmaceuticals. The general license includes discovery and development, pre-clinical research, clinical research, regulatory review, regulatory approval and licensing, regulatory post-market activities and the importation into the United States of Cuban-origin pharmaceuticals. The regulations also authorize the importation into the United States, and the marketing, sale or other distribution in the United States, of FDA approved Cuban-origin pharmaceuticals.

For several years preceding the recent US-Cuba normalization initiative, BIS has maintained a favorable policy of approving export license applications for exports of medicine and certain medical equipment. BIS also allows for the export and re-export of "items intended to improve the living conditions" of the Cuban people under the new license exception "Support for Cuban People," under which exports of certain medical goods may qualify. Further, BIS now has a case-by-case policy of favorable consideration for exports to Cuba of items for education, food processing, disaster preparedness, relief and response, public health and sanitation, wholesale and retail distribution for domestic consumption by the Cuban people and construction of facilities for treating public water supplies. Other exports that directly benefit the Cuban people or facilitate the Cuban private sector are also viewed favorably.

OFAC also blocks US persons from dealing with certain Cuban persons and entities. For example, US persons may not engage in transactions with certain Cuban military and government officials. The recent liberalization of US policy has not loosened these restrictions. Investors should screen all business transactions against OFAC's lists before moving forward with any deal.

### ***Travel and Engagement***

Under OFAC general licenses, US persons may travel to Cuba without preauthorization if they are doing so under any of 12 categories. These categories include several that are relevant to the health care industry: professional research and professional meetings; educational activities; support for the Cuban people; humanitarian projects; and activities of private foundations or research or educational institutes. As a practical matter, trade delegations most regularly travel to Cuba under the "professional research and professional meetings" category. These delegations may engage in preliminary talks with potential partners and, under a new general license, may even enter into contracts that are expressly contingent on obtaining necessary licenses or the future removal of the embargo. Entering into contracts that do not include such contingencies remain prohibited without a specific license.

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## ***Investment Opportunities***

While Cuba's economy remains a tightly controlled state economy, the Cuban government is looking for strategic partners in certain sectors. Every November, Cuba issues a "Portfolio of Opportunities for Foreign Investment," which advertises various investment opportunities in Cuba being offered by the Cuban government, including opportunities in the health care and biotech sectors. The following is a sampling of the investments offered in the 2016 portfolio:

- A \$90 million investment to build a new industrial biotechnological facility to produce antibodies for therapeutic use in cancer and other chronic non-transmissible diseases;
- A \$70 million investment to build a new biotech facility to produce recombinant proteins for treating cancer and other chronic non-transmissible diseases;
- An \$11 million investment in a sports medicine facility;
- An \$1.5 million investment in a medical tourism center;
- A plant to manufacture oral biological medicines with the potential for producing anti-salmonella vaccines and cholera probiotics;
- An \$113 million investment to produce 100,000 liters of plasma per year;
- A \$40 million plant to produce solid forms from natural products for the Cuban and Latin American markets;
- An \$120 million investment to produce antibiotics and similar drugs; and
- Investments in auxiliary services to support the drug industry, including labs, engineering, treatment plants, expendable medical materials and warehousing services.

## ***Cuban Foreign Investment Law***

Cuba significantly revised its foreign investment laws in April 2014 to expand investment opportunities and simplify regulations. Under the new law, investment is allowed in all economic sectors, including biotechnology and health care (although not in public health institutions for Cuban citizens). The law also provides for investments in stocks, other securities or bonds that do not fit the definition of direct investment.

After the revisions, investments may now take the form of joint ventures, international economic association agreements, or wholly owned foreign entities, whereas before wholly owned entities were largely prohibited. The Cuban government also reduces taxes for foreign investments. It reduces taxes on profits from 30 percent to 15 percent and eliminates taxes on labor costs entirely.

The Cuban government still controls investment targets and vets all proposals. It will approve a foreign investment with an "authorization" issued, depending on its content and extent, by the Council of State, the Council of Ministers or another authority appointed by the latter. As a practical matter, the Cuban government only approves well-funded foreign investments.

## **Conclusion**

As the title of this article indicates, while much is possible in the Cuban health care and biotech space, investing in Cuba is not easy and restrictions remain under the US embargo. Investing in Cuba requires strict care in complying with relevant US and Cuban laws. Moreover, in Cuba, after decades of isolation, building relationships and trust is critical. Cuba is looking for long-term agreements with trusted partners. Therefore, it is important to start building the relationships long before a deal is signed.

US health care enterprises, including service providers and drug and device developers, have a long history of engaging in the international marketplace. As with many new markets, success requires effective engagement to both develop useful relationships and identify market opportunities. While opportunities remain limited by the embargo, the policy changes of both the US and Cuban governments, together with the Cuban government's regular publication of potential investments, create an opening and opportunity to take the first step in identifying opportunities.

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