

A Safer, Healthier Future Through U.S.-Cuba Cooperation

MEDICC White Paper
February 18, 2016

A Safer, Healthier Future Through U.S.-Cuba Cooperation

Many threats to people's health and safety are common to the United States and Cuba—whether the Zika/dengue mosquitoes, hurricanes on the Gulf Coast or ever-higher rates of cancer and diabetes. President Obama's opening to Cuba, including the latest measures, also opens the way for cooperation that can save lives, improve medical care and contribute to better quality of life in both countries.

But more needs to be done. While the U.S. embargo on Cuba still must be lifted, the President has the authority to take the actions outlined below, to make sure it doesn't stand in the way of U.S. institutions and companies that make safeguarding health their business. Both Cuba and the U.S. have expertise and experience to offer each other and to improve health worldwide. There is no time to lose.

Here are the actions the President can take now:

1. Eliminate the extra hurdles for Cuban-developed biotech and other medical innovations, so they can be introduced sooner and more easily into the U.S. regulatory approval process.

Why? Because as the President and Vice President take their "moonshot" against cancer, Cuban biotech has developed therapeutic cancer vaccines already used in many countries, designed to prolong life and quality of life for cancer patients. Because while there are 70,000 amputations per year in the United States due to diabetic foot ulcers, Cuba has a treatment that peer-reviewed journal articles report has reduced relative risk of amputation by over 70 percent. Yet, U.S. embargo obstacles delay and even scuttle FDA trials linked to future marketing (see Appendix).

Presidential action needed:

Issue a general authorization for Cuban-developed pharmaceutical and other medical products to be subject only to the same rigorous regulatory tests as those from other countries, eliminating the extra steps now imposed by the embargo. This should include authorization for U.S. pharmaceutical companies to freely negotiate terms and conditions with the Cuban parties as they do with other foreign institutions, and general post-regulatory approval authorization to market these products in the United States.

2. Eliminate barriers faced by U.S. companies and academic institutions to carry out collaborative research and product development, and to invest in Cuba's pharmaceutical and health sector, including formation of joint ventures.

Why? Because these actions are vital to serious collaboration, bringing new products on board that will add new medications and the latest technologies to doctors' choices for patient care. U.S. companies and other institutions are already interested, and the way should be opened for them.

Presidential action needed:

Issue a general authorization for U.S. entities to pursue research and joint ventures with Cuban entities and, as done in the telecommunications sector, include general authorization for exports to and investment in Cuban health and medical research centers, companies and institutions, as well as permission to establish subsidiaries and offices in Cuba.

3. Allow U.S. companies and institutions to carry out clinical trials in Cuba on medications and medical technologies they develop.

Why? Because Cuba's single, universal health system enables faster identification of people potentially willing to participate in the numbers required, and hence hastens the whole process, obtaining final results sooner for doctors and their patients. Cuba has years of experience with such trials and a regulatory process designed with the FDA in mind, as well as a clinical trials registry accredited by the World Health Organization.

Presidential action needed:

Issue a general authorization for U.S. pharmaceutical and medical equipment companies and U.S. academic institutions to include Cuban medical centers in trials that adhere to U.S. regulatory process standards, including customary payment for services rendered by Cuban health authorities and institutions.

4. Allow U.S. nationals to travel to Cuba for medical treatment.

Why? Because many Cuban medical services and treatments are recognized worldwide, and U.S. patients should be permitted the choice of receiving them in Cuba.

Presidential action needed:

Issue a general authorization for:

- U.S. persons to travel to Cuba for medical treatment they may require; for payment to Cuban medical centers for treatment; and for U.S. insurance companies to cover such costs.
- U.S. companies or other parties to facilitate travel for this purpose, and for travel to organize such patient care and to negotiate and implement contracts with Cuban entities for this purpose.
- U.S. health insurance companies to travel to Cuba, for the purpose of negotiating and implementing contracts with Cuban entities to enable patient reimbursement.

5. Enable more U.S. students in the health professions to study in Cuban academic institutions.

Why? The Association of American Medical Colleges (AAMC) predicts within a decade the U.S. will have a shortage of 46,000 to 90,000 physicians, mainly affecting poor and rural communities. Primary care doctors make up about one third of this shortfall. Cuba's Latin American Medical School (ELAM) has graduated over 25,000 international students on scholarship, including a pipeline of 200 low-income, diverse U.S. students and graduates. They are passing their U.S. medical boards, and keeping their promise to work in medically underserved areas, with 90 percent of those in residency and practice choosing careers in primary care with underserved populations. This U.S. number could increase dramatically, if permitted by U.S. regulations. And other health professionals could also receive the necessary training to build the U.S. health care workforce.

Presidential action needed:

Issue a general authorization for U.S. persons to travel to Cuba for a degree-granting program of study (undergraduate or post-graduate training) in the health professions, including all necessary payments to Cuban academic institutions and for other expenses incident to this travel. Authorize the U.S. National Health Service Corps to issue scholarships for medical students enrolled at Cuban universities, under

the same conditions as study in U.S. academic centers, further contributing to address the doctor shortages in disadvantaged communities.

6. Enable health and medical-related assistance to be provided (including but not limited to teaching and other services) between the two countries and their governmental agencies, companies and personnel.

Why? U.S. innovations and expertise could contribute to advances in patient care and capacity-building of Cuban health professionals, and the same is true of innovations and expertise that may be useful to U.S. efforts to improve patient outcomes (Cuba's Tropical Medicine Institute, for example, is the WHO Collaborating Center in Dengue). Bidirectional assistance can benefit the health systems and patients in both countries.

Presidential action needed:

Order the negotiation of a bilateral agreement required by statute for U.S. government assistance in this field.

7. Enable greater bilateral cooperation to address health emergencies in the U.S., Cuba and globally.

Why? Because both the U.S. and Cuban health systems have historically contributed to addressing the most pressing health problems globally, including HIV/AIDS, Ebola and natural disasters worldwide. Fostering greater cooperation between the two countries, planned and regular communications and joint endeavors, can lead to earlier, more effective and efficient handling of these emergencies, saving countless victims' lives and protecting those in danger.

Presidential action needed:

Authorize U.S. federal agencies to actively seek and regularize communication and collaboration with Cuba that would enable timely and effective joint action in the face of local, national or global health emergencies. This includes a general authorization for U.S. federal employees to travel to Cuba for this purpose, and a commitment to expedite visas for travel to the U.S. of Cubans involved in efforts to address such emergencies.

These measures, taken together, will ensure cooperation between U.S. and Cuban medical and public health institutions—vital to a safer and healthier future for us all.

A Safer, Healthier Future Through U.S.-Cuba Cooperation

Appendix

Legal Authority and Precedents

Under the U.S.'s embargo regulations — the Cuban Assets Control Regulations (“CACR”) and the Export Administration Regulations (“EAR”) — the President has the authority to license U.S. companies, institutions and individuals (collectively, “persons”) to engage in categories of transactions, or specific transactions, that are otherwise prohibited by the embargo. There is no statutory restraint on the President’s licensing authority other than in four areas, none of which constrain the President’s discretion in ways relevant here.

Since his December 17, 2014 decision to restore diplomatic relations with Cuba, President Obama has amended the U.S. embargo regulations to authorize numerous categories of transactions because they benefit the U.S. or Cuban people — or both. He can exercise the same, ample legal authority to authorize collaboration, for example, in the fight against cancer, diabetes and other life-threatening diseases; for protection of the public’s health; and improved medical services.

In adding medical innovations and public health to the areas of permissible collaboration, President Obama would be building upon his recent breakthrough amendments of January 27, 2016 to the embargo regulations, as well as administrative precedent that goes back to President George W. Bush.

The January 27, 2016 amendments recognize, more emphatically than ever before, that authorizing U.S. persons to collaborate with Cuban government institutions is essential to achieving mutual benefits for both the Cuban and U.S. people in a wide variety of areas: environmental protection, safe and secure aviation, and clean and efficient generation of energy, among others.

The January 27, 2016 amendments also recognize that authorizing U.S. collaboration in the creation and development of certain categories of new products — and not merely the sale and purchase of existing products — makes sense in many fields.

The logical, next step is for the Administration to authorize U.S. persons — companies, not-for-profits and individuals — to collaborate in the development and delivery of medical products and health care services.

U.S. companies and not-for-profits, as well as individuals, are already poised to utilize such openings in the embargo, and recent experience indicates they are eager to move forward with specific projects given the chance.

The current status of U.S. regulations, additional background, and legal action the President can take to further open the door to cooperation in the field of health are outlined below:

The application process is slow, wasting precious time for people in the United States suffering from cancer, diabetes, and other diseases for which Cuban products have been designed to save and prolong lives, and improve quality of life.

I. Authorization for FDA-authorized trials and sales of Cuban-developed medical innovations

Importantly, the Administration's policy to date has been for OFAC only to license clinical trials, without concurrently licensing sales in the event that the trials are successful and FDA approval is obtained. And, even with respect to clinical trials, the Administration's policy has been for OFAC to refuse authority for U.S. pharmaceuticals and not-for-profits to freely negotiate terms and conditions with the Cuban institutions.

The result, predictably, has been that Cuban-developed drugs have not been introduced into the U.S., even though U.S. companies and medical institutions, as well as a substantial body of U.S. medical expert opinion, believe they hold great promise.

The Administration of President George W. Bush took a more liberal position than the Obama Administration to date. It concurrently licensed a U.S. pharmaceutical company both to conduct FDA-authorized clinical trials of a Cuban-developed cancer vaccine and sell the vaccine in the U.S. and elsewhere in the world, assuming the trials were successful and the FDA authorized the vaccine for use. Further, the Bush Administration authorized the U.S. company to license the vaccine from the Cuban developer on freely negotiated terms and conditions.

The President has the authority to amend the embargo regulations to provide a general authorization ("General License") for U.S. pharmaceutical companies, research centers and not-for-profits to license drugs and medical treatments, developed by Cuban research entities, for FDA-authorized clinical trials and sales in the U.S., on terms and conditions freely negotiated with the Cuban party involved.

There is no reason this step forward should be delayed any longer. The specific license granted by the first Bush Administration provides administrative precedent. Going forward, a General License, as distinct from requiring applications for specific licenses, would cement this step far more securely in U.S. regulations and policy. It also would avoid needless red tape that hinders timely review of products that can bring potentially life-saving drugs to the U.S. public.

That Cuban institutions might obtain a return on their substantial investment in developing innovative medicines and treatments is hardly reason to hesitate giving U.S. physicians and patients additional options in treating cancer and other serious medical conditions — particularly when the January 27, 2016 and other Obama Administration amendments authorize far more significant flows of hard currency to Cuba.

2. Authorization to carry out collaborative research and product development, and to invest in Cuba's pharmaceutical and health sectors

Using the President's legal authority to license categories of transactions, the Obama Administration has issued a General License authorizing U.S. companies to collaborate and invest in Cuba's development of its telecommunications infrastructure and facilities (31 C.F.R. 515.542). The authorized collaboration and investment can take the form of joint ventures with the Cuban party, as well as any other form of business relationship. In the January 27, 2016 amendments, President Obama has similarly allowed U.S. companies to collaborate in and finance Cuban government institutions' production of music, movies, television broadcasts, art and books (31 C.F.R. 545).

The President has the authority to issue a comparable General License authorizing U.S. pharmaceutical companies to collaborate with and invest in Cuban health and medical research centers, companies and institutions, including the formation of joint ventures with their Cuban counterparts.

The reasons to authorize transactions for the discovery, development, production and sale of improved treatments for cancer and other serious diseases are surely no less compelling than those the Administration has found sufficient to authorize collaboration and investment in the telecommunications and music industries.

3. Authorization for U.S. companies and institutions to carry out clinical trials in Cuba

The President has exercised his legal authority to license transactions incident to U.S. persons carrying out professional research in Cuba (31 C.F.R. 515.564), humanitarian medical and health-related projects there (31 C.F.R. 515.575), and joint academic research projects (31 C.F.R. 515.565).

The President can exercise the same legal authority to license U.S. pharmaceutical companies, research centers and other institutions to utilize Cuban hospitals and health centers for clinical trials, coordinate with Cuban regulatory agencies to do so, and make the customary payments associated with such activities.

4. Authorization for U.S. nationals to travel to Cuba for medical treatment

The President's authority to license travel to Cuba for humanitarian reasons encompasses travel to Cuba for medical treatment.

A General License authorizing treatment in Cuba, as well as any necessary payments, will enable U.S. physicians to include Cuban treatments in therapy options for their patients, some of which are unique and as yet unavailable in the United States.

5. Enable more U.S. students in the health professions to study in Cuban academic institutions

The President has the legal authority to issue a General License authorizing U.S. students to enroll in Cuba's Latin American Medical School ("ELAM") and other Cuban academic institutions that train health professionals.

A General License already authorizes U.S. undergraduate or graduate students to pursue formal courses of study at Cuban academic institutions. However, the General License's requirement that the students receive credit towards a degree at a U.S. institution for their Cuban studies (31 CFR 515.565 (a)(3), makes the General License inapplicable to ELAM and other Cuban health profession schools. U.S. medical and other health profession schools do not enroll students who will be trained mostly or entirely in a foreign institution. The General License's credit requirement should be eliminated for study at ELAM and other degree-granting Cuban health profession schools.

There would be no danger in diluting standards. U.S. graduates of ELAM or other Cuban medical schools must pass the U.S. Medical Licensing Exams and apply for residency positions, the same career path required of all other medical graduates seeking to practice in the United States. Similar U.S. licensure requirements apply to other health professions, such as nursing and allied health workers.

OFAC has previously issued specific licenses authorizing some U.S. students to study at ELAM, although not to pay tuition. A General License is necessary to expand opportunities to enroll at ELAM, by authorizing the payment of tuition and removing the formidable and needless barrier of students having to apply for specific licenses. A General License would also authorize enrollment at other Cuban medical and health profession schools.

6. Enable health and medical-related assistance to be provided (including but not limited to teaching and other services) between the two countries and their governmental agencies, companies and personnel

(a) OFAC's overly restrictive interpretation of existing General Licenses makes them inapplicable to U.S. institutions, including foundations and not-for-profits, wishing to make grants to Cuban medical and public health institutions.

- A recently-adopted General License authorizes U.S. persons to make "donative remittances" in any amount to any Cuban institution, as well as any Cuban individual (31 C.F.R. 515.570 (b)). However, OFAC has interpreted this General License to apply only to gifts that are made without any strings attached — and therefore to exclude almost all grant-giving because of the obligations normally imposed on grantees to use grants for their intended purposes and to report on project implementation.
- A recently adopted General License authorizes "transactions, including" travel-related transactions, related to "humanitarian projects" in Cuba, and specifically "medical and health-related projects" (31 C.F.R. 515.575). However, OFAC has interpreted this provision to authorize only travel to Cuba and transactions by the traveler while in Cuba — not, for example, authorizing a foundation grant to a Cuban medical institution.

By amendment of these General Licenses, or formal re-interpretation, the Obama Administration can authorize U.S. persons to make grants to Cuban medical and public health institutions. Any grants, of course, would have to conform to U.S. laws regarding charitable activity, and the grantors' own characters.

(b) Similarly, OFAC's overly restrictive interpretation of the General License for humanitarian projects (31 C.F.R. 515.575), has made it inapplicable to the training and other services that are the most important.

To illustrate: it has been OFAC's interpretation that the General License authorizes U.S. physicians to treat Cuban patients as part of a humanitarian project, but does not authorize them to train Cuban physicians at a Cuban hospital or clinic to treat Cuban patients in new or improved ways.

This distinction reflects the prior U.S. premise that humanitarian efforts can and should bypass Cuban government institutions and, instead, provide support directly to the Cuban people. In contrast, the January 27, 2016 amendments reject this premise in numerous areas. Surely, the health and medical fields should be among them.

By amendment of the General License, or formal re-interpretation, the Obama Administration can permit U.S. charities, medical and public health schools and volunteer health professionals to provide services — including training — to Cuban medical and health institutions.

(c) Issuance of a General License authorizing Cuban medical or health institutions to purchase training or other assistance from U.S. persons, and not merely seek foundation or other humanitarian support, would be consistent with the policy reflected in recent amendments to the embargo regulations.

In those amendments, the Obama Administration has established a policy of permitting sales to Cuban government institutions that will enable them to better serve the Cuban public in a variety of ways, such as food production, water treatment, energy, and environmental protection. Health and medical care is clearly no less important.

(d) The President's authority extends to licensing U.S. persons to obtain Cuban services, as shown by the recent amendments authorizing U.S. persons to obtain the services of independent Cuban entrepreneurs (31 C.F.R. 582).

The President can issue a General License authorizing U.S. persons to obtain training and other services from Cuban governmental institutions in the medical and public health fields. This would allow the U.S. to obtain the benefit of Cuban experience and expertise in these areas.

(e) The Administration can provide U.S. Government assistance in the form of training or otherwise to Cuban medical and health institutions. Section 620(t) of the Foreign Assistance Act, 22 USC 2370(t), provides that no "assistance" may be provided under the Foreign Assistance Act or "any other Act" to a country that has severed diplomatic ties with the U.S., or with which the U.S. has severed diplomatic ties, unless: (a) diplomatic relations have been restored – which is the case

with Cuba; and (b) "agreements for the furnishing of such assistance ... have been negotiated and entered into after the resumption of diplomatic relations with such country."

The U.S. Administration can negotiate an agreement with Cuba for the provision of assistance in such areas and in such forms as the two governments may jointly decide.

7. Enable greater bilateral cooperation to address health emergencies in the U.S., Cuba and globally

The President can issue a General License authorizing all transactions incident to bilateral cooperation to address health emergencies in the U.S., Cuba and globally, including transactions by the U.S. Government's Centers for Disease Control and the health units of the U.S. military. A specific license regime is too slow and cumbersome to deal with health emergencies.

Whatever U.S. Government assistance, if any, might be needed for bilateral cooperation to be effective can be authorized by the General License, provided a bilateral agreement on assistance is reached with Cuba. (See above). Travel to Cuba on official business is already authorized by General License.

Clearing the way by General License to effective collaboration is particularly important, given the increase in natural disasters reported throughout the world, and due to the growing threat of emerging and re-emerging infectious diseases such as Ebola, SARS, Zika and others. Such cooperation would enhance not only bilateral, but also global response, to health emergencies, potentially coupling U.S. technological and logistical capabilities with the several thousand Cuban medical personnel posted worldwide and their specialized training in disaster management.

The President has already established the mechanisms for bilateral and multilateral cooperation in other areas, such as oil spills from deep-water drilling in the Caribbean. There is every reason to authorize effective collaboration in responding to health emergencies.



Medical Education Cooperation with Cuba
1814 Franklin St, Ste. 820
Oakland, CA 94612
www.medicc.org