

**Un Futuro Más Seguro Y Saludable
Mediante La Cooperación
Entre Estados Unidos Y Cuba**

White Paper de MEDICC
18 de febrero de 2016

UN FUTURO MÁS SEGURO Y SALUDABLE MEDIANTE LA COOPERACIÓN ENTRE ESTADOS UNIDOS Y CUBA

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Estados Unidos y Cuba enfrentan muchas de las mismas amenazas a la seguridad y la salud de sus pueblos—ya sean mosquitos que transmiten el Zika y el dengue, huracanes en las costas del Golfo o tasas cada vez mayores de cáncer y diabetes. La apertura del Presidente Obama hacia Cuba, incluyendo las últimas medidas, también abre un camino para la cooperación que puede salvar vidas, mejorar la atención médica y contribuir a una mejor calidad de vida en ambos países.

Sin embargo, se necesitan más acciones para lograr una colaboración efectiva. Aunque aún falta levantar el embargo de EEUU a Cuba, el Presidente tiene la autoridad de tomar las decisiones que se esbozan a continuación, al menos para desbloquear el camino de las instituciones y compañías norteamericanas que se dedican a la salud. Tanto Cuba como EEUU tienen conocimientos y experiencia que ofrecerse mutuamente y que pueden mejorar la salud a nivel global. No hay tiempo que perder.

Estas son las acciones que el Presidente puede tomar ahora:

1. **Eliminar los obstáculos adicionales que afrontan las innovaciones biotecnológicas y médicas desarrolladas por Cuba, para permitir que sean introducidas de forma más rápida y más fácil en el proceso regulatorio de aprobación de EEUU.**

¿Por qué? Porque al mismo tiempo que el Presidente y el Vicepresidente han lanzado su ambicioso programa contra el cáncer, la biotecnología cubana ha desarrollado vacunas terapéuticas para esta enfermedad que ya se utilizan en muchos países, diseñadas para prolongar la vida y la calidad de vida de los enfermos. Porque mientras hay 70 000 amputaciones al año en EEUU debido a las úlceras de pie diabético, Cuba tiene un tratamiento que, según estudios publicados en revistas arbitradas, reducen el riesgo relativo de amputación en más del 70%. Pero los obstáculos del embargo de EEUU demoran e incluso sabotean la realización de los ensayos clínicos requeridos por la FDA vinculados a una futura comercialización de estos productos (ver Anexo).

La acción presidencial que se necesita:

Emitir una autorización general para que los productos farmacéuticos y médicos desarrollados por Cuba se sometan solamente a las mismas rigurosas pruebas regulatorias por las que pasan los de otros países, eliminando los pasos extras ahora impuestos por el embargo. Esto debe incluir una autorización para que las compañías farmacéuticas norteamericanas negocien libremente términos y condiciones con las partes cubanas como lo hacen con otras instituciones extranjeras, y una autorización general que automáticamente permita la comercialización en EEUU de estos productos, una vez aprobados por las agencias regulatorias pertinentes.

- 2. Eliminar las barreras que enfrentan las compañías e instituciones académicas norteamericanas para investigar y desarrollar productos conjuntamente con Cuba, así como para invertir en los sectores de la industria farmacéutica y de la salud cubanos, incluyendo la formación de empresas mixtas.**

¿Por qué? Porque estas acciones son vitales para una colaboración seria, incorporando nuevos productos que adicionarán novedosos medicamentos y las últimas tecnologías a las opciones de los médicos para el tratamiento de sus pacientes. Compañías y otras instituciones norteamericanas ya muestran su interés, y se les debe abrir el camino.

La acción presidencial que se necesita:

Emitir una autorización general para permitir a las entidades norteamericanas realizar investigaciones conjuntas y empresas mixtas con entidades cubanas, como se hizo en el sector de las telecomunicaciones. Debe incluir una autorización general para las exportaciones norteamericanas y la inversión en centros de salud e investigación médica, compañías e instituciones de la isla, así como un permiso para establecer subsidiarias y oficinas en Cuba.

- 3. Permitir a las compañías e instituciones de EEUU realizar ensayos clínicos en Cuba de medicamentos y tecnologías médicas que ellos desarrollan.**

¿Por qué? Porque el sistema de salud en Cuba, único y universal, ofrece la posibilidad de identificar con mayor premura a personas que potencialmente estén dispuestas a participar en los ensayos en los números necesarios, acelerando así todo el proceso, para obtener los resultados finales más rápidamente para los médicos y sus pacientes. Cuba tiene años de experiencia con ensayos de este tipo y un proceso regulatorio cuyo diseño ha tomado en cuenta los requisitos del FDA, así como un registro público de ensayos clínicos acreditado por la Organización Mundial de la Salud (OMS).

La acción presidencial que se necesita:

Emitir una autorización general para que las compañías farmacéuticas y de equipamiento médico de EEUU y las instituciones académicas norteamericanas incluyan a los centros médicos cubanos en los ensayos que cumplen con las normas del proceso regulatorio norteamericano, incluyendo el habitual pago por los servicios prestados por las autoridades y las instituciones de salud de Cuba.

- 4. Permitir a los ciudadanos norteamericanos viajar a Cuba para recibir tratamiento médico.**

¿Por qué? Porque muchos de los servicios y tratamientos médicos cubanos son reconocidos mundialmente, y a los pacientes norteamericanos se les debe permitir la oportunidad de recibirlos en Cuba.

La acción presidencial que se necesita:

Emitir una autorización general para que:

- Personas norteamericanas puedan viajar a Cuba para recibir el tratamiento médico que requieren; puedan efectuar los pagos asociados a los centros médicos cubanos correspondientes; y las compañías de seguro de EEUU puedan cubrir tales costos.
- Compañías norteamericanas u otras entidades faciliten tales viajes a Cuba; puedan viajar a la isla para organizar la atención de estos pacientes; y negocien e implementen contratos con las entidades cubanas para estos fines.
- Compañías norteamericanas de seguro médico viajen a Cuba con el fin de negociar e implementar contratos con las entidades cubanas para posibilitar el reembolso a los pacientes.

5. Posibilitar que más estudiantes norteamericanos puedan estudiar carreras relacionadas con la salud en instituciones académicas cubanas.

¿Por qué? La Association of American Medical Colleges (asociación de las universidades médicas norteamericanas, AAMC) plantea que EEUU enfrentará un déficit de 46 000 a 90 000 médicos en la próxima década, afectando principalmente las comunidades pobres y rurales. Un tercio serán médicos necesitados en la atención primaria. En Cuba, la Escuela Latinoamericana de Medicina (ELAM) ha graduado a más de 25 000 estudiantes internacionales en régimen de becas. Entre ellos, se destacan 200 estudiantes y egresados norteamericanos de bajos ingresos y de las comunidades más diversas, que están obligados a aprobar los mismos exámenes que otros graduados para obtener sus licencias a ejercer en EEUU. Así lo están haciendo, manteniendo a su vez su compromiso de trabajar en zonas carentes de servicios médicos: hoy día, el 90% de los que están ejerciendo la profesión han escogido especialidades asociadas a la atención primaria y la mayoría están trabajando con poblaciones marginadas. Este número pudiera incrementarse de forma dramática si lo permiten las regulaciones del gobierno de EEUU. Y otros profesionales de la salud pudieran también recibir su educación en Cuba, para desarrollar los recursos humanos en salud en EEUU.

La acción presidencial que se necesita:

Emitir una autorización general para que los norteamericanos viajen a Cuba para estudiar carreras en ciencias de la salud (tantos de pre- como de post- grado) y recibir los títulos correspondientes, incluyendo todos los pagos necesarios a las instituciones académicas cubanas y para otros gastos asociados. Autorizar al U.S National Health Service Corps a que emita becas para estudiantes de medicina matriculados en universidades cubanas, bajo las mismas condiciones que los que estudian en centros académicos de EEUU, contribuyendo así a mitigar el déficit de médicos en las comunidades desfavorecidas.

6. Posibilitar la asistencia técnica en materias de salud y medicina (incluyendo pero no limitada a la capacitación y otros servicios) entre los dos países y sus agencias, compañías y personal gubernamental.

¿Por qué? Las innovaciones y los conocimientos técnicos de EEUU pueden contribuir a los avances en la atención al paciente y el desarrollo de capacidades de los profesionales de la salud cubanos, y lo mismo se aplica a las innovaciones y los conocimientos técnicos cubanos que

pueden ser de utilidad a los esfuerzos de EEUU por mejorar los resultados de sus pacientes (el Instituto de Medicina Tropical de Cuba, por ejemplo, es Centro Colaborador de la OMS/OPS para el Dengue). La asistencia bidireccional puede beneficiar a los sistemas de salud y los pacientes de ambos países.

La acción presidencial que se necesita:

Ordenar la negociación de un acuerdo bilateral, como lo exige la ley, para la colaboración del gobierno de EEUU en este campo.

7. Facilitar una mayor cooperación para hacer frente a las emergencias en salud en EEUU, Cuba y el mundo.

Por qué? Porque históricamente, los sistemas de salud de EEUU y Cuba han contribuido a enfrentar los problemas de salud más apremiantes a nivel global, incluyendo el VIH/SIDA, Ebola y los desastres naturales en el mundo entero. Promover mayor colaboración, incluyendo las comunicaciones regulares y planificadas, así como acciones en conjunto, puede conllevar a un manejo más efectivo y eficiente de estos desastres, salvando **incontables** vidas y protegiendo aquellas en peligro.

La acción presidencial que se necesita:

Autorizar a las agencias federales norteamericanas a buscar de forma activa y a regularizar la comunicación y la colaboración con Cuba que permitiría una acción conjunta a tiempo y efectiva en el enfrentamiento a las emergencias de salud locales, nacionales o globales. Esto incluye una autorización general a los empleados federales de EEUU para viajar a Cuba con este propósito, y un compromiso de facilitar las visas de forma expedita para que viajen a EEUU los cubanos involucrados en los esfuerzos para manejar tales emergencias.

Estas medidas, tomadas de forma conjunta, asegurarán la cooperación entre las instituciones médicas y de salud pública de EEUU y Cuba—algo vital para un futuro más seguro y saludable para todos nosotros.

Para más información sobre la Autoridad Legal y Precedentes, ver el Anexo que se adjunta en inglés.

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 H.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.

1. 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 H.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 charters.

(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.



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