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Humanitarian Licensing: U.S. Government Licensing of Drugs and Medical Technologies to International Organizations

- With more than \$30 billion in annual spending, NIH is the world's largest funder of medical R&D. Each year NIH grants make key, early-stage contributions to the medicines and medical technologies of the future, including high risk and health needs-driven investments that industry is hesitant to make. Directly through its own work and through grants to universities and other research centers, NIH research spending leads to thousands of patentable inventions.
- Under existing law, NIH has authority to issue licenses to those inventions to international organizations and foreign governments, whether or not it owns the patent rights. Pursuant to 35 USC Sec 202 (c) (4) of the Bayh-Dole Act (for public grants leading to patented inventions) or under 37 CFR 404.7 (for government owned inventions), the U.S. Government has an irrevocable, royalty-free right to practice and have the subject invention practiced on its behalf and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.
- In other words, the U.S. government has the right to license the patented medical inventions it has financially supported to international organizations, at any time, to help meet humanitarian needs. For example, the U.S. government could choose to license medicines in which it maintains rights to the World Health Organization or other international organizations.
- The NIH took an important step in the right direction by licensing its interest in the antiretroviral (ARV) darunavir to the UNITAID-funded Medicines Patent Pool in 2010.
- An example of the benefits of a humanitarian licensing policy: The U.S. has rights in the important Sickle Cell Disease medicine (Aes-103) currently in Phase II clinical trials at the Food and Drug Administration. Despite the U.S. government funding research which led to the discovery of the key compound in Aes-103 as well as Phase I and II clinical trials, currently, the drug is exclusively controlled by Baxter International Inc. If Aes-103 were licensed to international organizations, once approved, it could be made more broadly available in Africa, where Sickle Cell Disease causes the equivalent of 5% of under-five deaths.
- Candidate Obama pledged to “support the adoption of humanitarian licensing policies that ensure medications developed with U.S. taxpayer dollars are available off-patent in developing countries.” ¹

¹ Available at <http://change.gov/pages/the-obama-biden-plan-to-combat-global-hiv-aids>.