



Preventive Oncology International

May 12, 2015

RE: Cervical Cancer Screening Program Sponsorship

Jeffrey Epstein USVI



Dear Mr Epstein,

This request for funding is respectfully submitted to your foundation's interest in early diagnosis.

Preventive Oncology International, a 501(c)(3) Public Charity, was founded in 1997 to blend humanitarian work with good clinical science. The foundation, known as POI, is based in the United States, and has worked with international collaborators in the Dominican Republic, Mexico, Peru, and rural China.

POI's first objective was to define the effectiveness of the technologies that existed; and then improve screening for cervical cancer, a disease that affects 530,000 women worldwide and causes 270,000 deaths annually. We began by working on molecular testing for human papillomavirus (HPV), the virus that is known to cause virtually all cervical cancers. To date, more than 60,000 women have participated in our clinical trials, leading to improved care for millions worldwide. Our trials for cervical cancer screening have been documented in 100+ peer-reviewed scientific publications. See <https://archive.org/details/BelinsonJPubMed22015>. Discoveries include significant breakthroughs in screening technologies and the creation of a functional and streamlined community-based method for reaching underserved populations in rural communities. Our full list of accomplishments in cervical cancer prevention is noteworthy:

1. POI introduced Human Papilloma Virus (HPV) testing to China
 - a. The results of our studies led to CSFDA approval of HPV testing assays in China.
2. POI introduced Liquid-based cytology for cervical cancer screening to China
 - a. The results led to SFDA approval of Liquid-based cytology tests in China, as an alternative to the dry slide-based method of the Pap smear
3. POI accumulated international data that was provided as evidence for HPV tests to be FDA approved in the USA
 - a. POI testified before the FDA committee reviewing the Digene Hybrid Capture Assay. The Digene Assay was the only approved and available HPV test in the USA for more than 15 years.
4. POI tested and validated multiple new HPV test related technologies that are currently available for use
 - a. Sampling devices
 - b. Specimen Transport media
 - c. Multiple new assays

5. POI tested emerging diagnostic imaging technologies for use in cervical cancer screening
 - a. The results led to diagnostic algorithms intended to predict the presence of cervical pre-cancer and cancer
6. POI completed studies resulting in evidence of the inaccuracies of current biopsy protocols based on visualization methods (colposcopy)
 - a. Our studies persuaded leading health organizations (NIH, ASCCP) to question and ultimately study their validation methodologies for cervical cancer screening studies as well as patient care
7. POI began a discovery program in 1997 that focuses on self-collection as a means to reach the worlds medically underserved
 - a. We discovered several ways to improve the accuracy of self-collection for HPV
 - b. We proved that a self-collected sample can be as accurate as a physician obtained specimen
 - c. We developed an inexpensive and cost-effective self-collection kit
 - d. We developed a non-liquid specimen transport system that
 - i. Indicates the presence of the specimen to ensure adequate sampling,
 - ii. renders the specimen non-infectious,
 - iii. provides a stable setting for long-term sample preservation, and
 - iv. Is resistant to unfavorable effects of highly humid environments
 - e. We developed community-based and internet-based models that identify those who test positive in order to “focus the available human and financial assets of resource-poor healthcare systems on the evaluation and management of those who truly need care”
 - f. POI is currently working with technology companies exploring and developing new inexpensive and effective methods for outpatient therapy for women with pre-invasive cervical cancer

We are very proud of our record of discovery and the publications that share and expand the reach of our work. Today, we are in the midst of an explosion of new genomic markers for other cancers and diseases. Using the knowledge gained from our work in cervical cancer, many of these new tests can be adapted to fit our community-based and internet-based self-collection methods for screening large at-risk populations.

Although technologies will continue to improve, we believe that we have great solutions now.

With your help POI can provide cost-effective evidence-based cervical cancer screening to the people who need it most. Our community-based models, combined with self-collection and new specimen transport methods have been proven reliable and effective. High throughput inexpensive cost/case assays are available that allow affordable massive screening programs.

Implementation of our discoveries can transform the health of Nations of Women.

We have now been asked to explore and design a cervical cancer screening program for the Philippines. Cervical cancer is a very serious problem in the Philippines due to its prevalence combined with the countries limited healthcare resources. In addition the logistics of reaching all the people, overwhelms conventional models. Currently 100 million people inhabit over 4000 islands in the Philippines. Using self-collection we believe we can design a system to reach all corners of the Philippines. We are confident although initially designed for cervical cancer, the models can be expanded to many other diseases and conditions amenable to self-collection technologies.

We are hopeful that funding from your foundation will be matched by the Philippines and our collaborating organization (Florence Nightingale Global Health) who asked us to help the people of the Philippines. We are requesting \$100,000 dollars to initiate these efforts. This funding will support local site visits to determine initial target populations, local staff training, sampling kits, sample transport and testing assays.

I would be grateful to continue a dialogue that can result in funding for this important effort.

My sincere appreciation for your review of this inquiry,



Jerome L Belinson MD
President, Preventive Oncology International
www.poiinc.org
Professor of Surgery
Women's Health Institute
Cleveland Clinic Lerner College of Medicine