CBTS Call for Proposals
Substandard, Fraudulent, and Counterfeit Illegal Medical Supplies
Opportunities to Near-/ On-Shore High-Risk Pharmaceuticals and Critical Medical Supplies

A. Introduction

To provide capabilities for securing our Nation's supply chain against threats and hazards without compromising the pace and operational structures of commercial enterprises, the Texas A&M University System formed the Cross-Border Threat Screening and Supply Chain Defense (CBTS) Center of Excellence (COE) in partnership with the U.S. Department of Homeland Security (DHS) Science and Technology Directorate (S&T) Office of University Programs (OUP). Critical research activities are needed to assist DHS in balancing the tipping point between trade as a potential source of threat introduction and economic vitality that results from safe borders open to commerce.

This solicitation invites white paper proposals to address two research topics and a selection of subtopics outlined in Section B. Successful proposals should address some, but not all topics or subtopics listed in this call. Although projects may span multiple years, funding is incrementally approved on an annual basis. Proposed projects should achieve measurable results in a 12-month period or less.

In all proposals, it should be clear about how the proposed work can provide new insights, address current DHS gaps and challenges, and how it goes beyond the state-of-the-art. Customer engagement and understanding of operational component needs are key to successful projects. COE leadership and management personnel will engage with DHS customers and sponsors as early and throughout the process.

For all details on submission requirements, please refer to the CBTS website, which contains the call, templates and a proposal guide at https://cbts.tamu.edu/proposals. The deadline for submission is August 27, 2021 at noon Central time. Please send white papers via email to CBTS@ag.tamu.edu

B. Topics:

1. Substandard, Fraudulent, and Counterfeit Illegal Medical Supplies

Background: Continued action needs to be taken to address the ongoing issue of fraudulent, substandard and counterfeit medical supplies as these illegal products harm businesses and put lives at risk. The Department of Homeland Security (DHS) Homeland Security Investigations (HSI) launched Operation Stolen Promise in April 2020 to protect the U.S. from the threat posed by COVID-19-related fraud and criminal activity. One focus of Operation Stolen Promise 1.0 is

to combat the illegal import and sale of counterfeit/substandard personal protective equipment (PPE).

Counterfeit products are "trade in goods that, be it due to their design, trademark, logo, or company name, bear without authorization a reference to a brand, a manufacturer, or any organization for the quality of standard conformity of the goods in such standards." For example, counterfeit respirators are products that are falsely marketed and sold as being NIOSH-certified and may not be capable of providing appropriate respiratory protection. Counterfeit goods can include fake goods, production over-runs, relabeling with newer date codes and/or different product ID or at a higher performance. Definitions may be in 19 CFR § 133.21 – Articles suspected of bearing counterfeit marks. ***Fraudulent*** PPE may involve non-authorized distributors and unauthorized resellers that may ask for unfavorable terms, such as complete payment upfront, letters of intent, or proof of funds. ***Substandard*** PPE may not meet testing specifications or quality standards and provide inadequate protection.

Subtopics and questions of interest:

a. To examine supply chains for specific critical medical products and their precursor components.
b. To examine the current state of quality control, intellectual property, and regulatory processes designed to ensure the integrity of medical products and pharmaceuticals used in the U.S.
c. How can we better address supply/ demand imbalance in PPE, to mitigate distribution and availability issues at the regional and local level?
d. How can we better identify ways in which, or channels through which, counterfeit medical products are purchased and use lessons learned from other supply chains to counter the availability and access to counterfeit and fraudulent products?
e. How do we engage the public in detecting fraudulent, substandard, and counterfeit medical supplies and pharmaceuticals (e.g., vaccines, therapeutics), utilizing the consumer as a partner in preventing the proliferation of these illegal medical supplies?
    i. How can we better educate the consumer on the dangers of substandard, fraudulent, and counterfeit PPE so that they are better equipped to avoid purchasing these products?
    ii. What mechanisms can we draw upon to get the public involved in helping to quickly remove these supplies from the global supply chain?
f. Under what conditions does counterfeiting become attractive (e.g., scarce resources, increased cost, etc.)?
g. How can we better identify and assist those facilities/areas most likely to make these purchases (e.g. border towns/villages with limited access to proper healthcare facilities)?
h. How do we leverage private-public partnerships to address the scope/scale of this issue?
    i. What other critical sectors need to be engaged?

ii. How should consumers/end-users be engaged?

i. Interest in reaching out to collaborators in Mexico for medical supplies and pharmaceuticals and healthcare supplies/COVID19 response. The issues include intellectual property enforcement and coordinating with manufacturing base.
    i. How do we transition from Asia to North America for critical supply commodities?

2. Opportunities to on-shore* (*on-shore meaning North America) high-risk pharmaceuticals, critical medical supplies, and the national security implications

Background: The ongoing COVID-19 pandemic has revealed that the U.S. has relied too much on distant and stretched global supply chains. The U.S. needs the capability to make these vital health-care supplies domestically, or within the North American continent. Reshoring of pharmaceuticals, medical device manufacturing, and PPE would save lives, ensure adequate supply, and has the potential to create numerous jobs.

Subtopics and questions of interest:

a. Starting with a list of essential pharmaceuticals and active pharmaceutical ingredients (APIs), how do we best assess and determine which critical resources should be on-shored?
b. What incentives may be needed to on-shore production?
    i. Need to be able to define the economic incentives to facilitate this shift
c. What are the financial and infrastructure requirements for manufacturing the final product and are any of the necessary ingredients within North America?

C. Submission Information

Two-Stage Award Process

In order to minimize the cost and effort for prospective offerors, this solicitation uses a ***two-stage proposal process*.**

Stage One: White Paper

The first stage begins with this open call for ***white papers***. Researchers interested in studying these topics should submit a white paper of no more than five pages (including references, tables, graphs, etc.) in PDF format. White Paper Templates are provided on the CBTS website. Each proposal should describe the research question to be studied, the objective, technical approach/methods, data and methods to be used, milestones and outputs, a bottom-line cost estimate inclusive of directs and indirects, and the composition of the research team that will be carrying out the project. A conflict of interest statement describing any financial or other interests of the research team that might bear on the proposed work should be included.

Proposals that do not address the research priorities listed in the RFP, that do not follow formatting, or page limit requirements will be rejected. Proposals arriving after submission deadlines will not receive funding consideration.

In the **budget estimate**, provide a high-level break-down of direct and indirect costs for your institution and any subawards. Proposed work should be for a 12-month period of performance.

Complete packages (white papers with budget estimate) will be evaluated by a scientific panel of peer reviewers/subject matter experts and by a DHS panel for relevancy as described below (please see Scientific Review and Relevancy Review). A minimum threshold for each score will be determined, and apparent successful offerors will be invited to Stage Two.

Stage Two: Workplan Development

If CBTS and DHS are interested in considering a project based on a selected white paper, CBTS will invite the authors to develop and submit a ***full workplan*** with a detailed ***budget justification***. The elements and requirements of the complete workplan will be shared when the request is made. Full details of the call, CBTS Proposal Guide, and white paper templates may be found on the CBTS Website at https://cbts.tamu.edu/proposals/

Budget and period of performance

CBTS projects selected by DHS are funded using the CBTS cooperative agreement. Project funding is subject to availability of funds. Applicants may propose projects with a duration of up to 12 months. Award amount depends upon availability of funds.

Eligibility Information

Applications will be accepted from accredited U.S. higher education institutions, for-profit organizations, or an organization that meets the definition of non-profit in OMB Circular A-122, relocated to 2 CFR Part 230.

Exceptions

- Non-profit organizations described in Section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities as defined in Section 3 of the Lobbying Disclosure Act of 1995 are not eligible to apply.
- Federally Funded Research and Development Centers (FFRDCs) or laboratories funded by federal agencies are not eligible to apply. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation, regulations, and policies, are not eligible to serve in a principal leadership role and may not receive salaries or in other ways augment their agency's appropriations through awards made by this program.
- Institution partnerships with foreign institutions are permitted but may require special justification and approval from CBTS and DHS.

- For-Profit organizations intending to apply may not include profit margins in their cost.
- CBTS is unable to fund Federal Government Agencies

Available Funding

CBTS projects are funded through the CBTS Cooperative Agreement. Project funding is subject to availability of funds. The CBTS is responsible for administering funding to all projects within the Center's portfolio. DHS may allocate up to $250,000 per year (two year maximum) for each selected research project, with a total budget for all projects of $1.5 million. CBTS is responsible for administering funding to all projects within its portfolio. For those proposals that are pursued further, sub-recipients will need to submit a detailed workplan to be subsequently approved, and agree to the terms and conditions of the cooperative agreement between DHS and Texas A&M University (TAMU). CBTS is required to flow down all DHS – TAMU Cooperative Agreement Terms and Conditions with all sub-awardees. A copy of the Terms and Conditions is available upon request.

Scientific Review

The scientific reviews of proposals sent to CBTS will be conducted by panels of peer reviewers who will generally use the following questions and weighted scoring to assess the merits of the proposed work. In addition to the narrative responses, reviewers will rate each of the four review elements on a scale from 1 to 5 (where 5 is the best/highest ranking). Reviewers will apply the percentage weighting factor as indicated below for an overall rating.

1. **Scientific Merit and Originality/Innovation (Rating 1–5) (45%)** – Does the project use appropriate theoretical concepts, technologies, or methodologies, or improve upon existing methods? Does the research have the potential to generate influential publications or lead to new discoveries? Are graduate education and workforce development aspects included in this proposal?

2. **Proposed Approach/Methods and Risks (Rating 1–5) (25%)** – Are the goals clear and supported by evidence or sound theory? Are the methods clear and appropriate to test the hypothesis? Has the team defined metrics or targets appropriate for the stated goals? Are data generation/collection approaches appropriate? Are risks identified with proposed mitigation strategies?

3. **Qualification of Personnel and Suitability of Facilities (Rating 1–5) (20%)** – Does the team have the breadth of qualifications to conduct and complete the proposed work? Does the team have prior expertise in similar areas? Are the facilities suitable for the proposed research?

4. **Budget and Schedule (Rating 1–5) (10%)** – Are the costs appropriate and reasonable? Is the budget proportional to the work being performed and the resources used? Does the team demonstrate an ability to deliver products within the proposed budget and on schedule?

Scientific Reviewer Selection

Researchers may submit list of potential reviewers for CBTS's consideration in the scientific review of their proposal. The list must include specific names with titles, and complete contact information including the potential reviewers' e-mail addresses. This list is not required, but if submitted should be submitted with the proposal by the submission date.

In addition:

1. Researchers should ensure there are no conflicts of interest between the recommended reviewers and the PI's and Co-PI's listed on the proposal. Reviewers will also be asked to ensure there are no conflicts of interest with the PI'S and Co-PI's
2. Reviewers will know the names of the researchers, but the names of the reviewers used will not be shared with a proposal's author(s)
3. CBTS reserves the right to send the proposal to the most qualified reviewers and may or may not use names from the list provided by the researchers
4. In some cases, reviewers will be asked to sign non-disclosure agreements prior to receiving the proposals for review.

Proposals that successfully meet the requirements of the scientific review process will be submitted to the CBTS DHS Program Manager and reviewed for relevance to the DHS mission and objectives. Proposals identified as relevant will be ranked and considered for funding.

Relevancy Review

Following the Scientific Quality Review, DHS &T University Programs will coordinate a Relevancy Review of proposals conforming to the criteria as outlined in this funded solicitation. Reviewers will be asked to rate how the proposal addresses the following criteria, posed as questions. Reviewers will rate applications using numerical ratings of 1 to 5 (poor to excellent) and apply the percentage-weighting factor as indicated for an overall rating.

1. **Mission Relevance (Rating 1-5) (75%) –**
   - Does the proposed project address one or more of the first six research questions as described within the **White Paper Goals** section?
   - Does the proposed project complement (and not duplicate) – existing research and development programs sponsored by DHS, CBP and the National Targeting Center?
   - Does the proposal sufficiently describe the potential research deliverables and users of the research?
   - Does the proposal have a clear pathway to transition from research to acquisition according to DHS mission needs and demonstrate an expectation to publish results in peer reviewed outlets that will contribute to the relevant academic literature?

2. **Communicating/Transitioning Results (Rating 1-5) (25%) –**

- Does the applicant have a record of accomplishment of effectively communicating or successfully transitioning research results to appropriate stakeholders, specifically?
- Does the proposal demonstrate the implementation of an appropriate knowledge transfer process (i.e., models from case studies to other areas, patents, etc.) from academic to government end-users and other DHS customers?