WRITTEN SUBMISSION OF THE NATIONAL FOREIGN TRADE COUNCIL

Comments Regarding the United States-Kenya Strategic Trade and Investment Partnership

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INTRODUCTION

The National Foreign Trade Council ("NFTC") appreciates the opportunity to provide input as the Office of the U.S. Trade Representative ("USTR") works to develop priorities for the US-Kenya Strategic Trade and Investment Partnership ("STIP") negotiations.

In 2020, NFTC strongly supported plans for a US-Kenya Free Trade Agreement that would expand the existing U.S. – Kenya trading relationship. We are pleased the Biden Administration is taking a fresh look at opportunities to strengthen this important trading relationship through the STIP. The priorities provided below reflect NFTC's strong desire for a high-standard agreement that delivers commercially meaningful outcomes for both sides.

About NFTC

NFTC is the premier association for leadership, expertise, and influence on international tax and trade policy issues. We believe trade and tax policies should foster fair access to the opportunities of the global economy and advance global commerce for good. NFTC serves as a nimble and effective forum for businesses to tackle critical and complex issues together and to foster trust with governments to improve policy outcomes in the United States and around the world. Leveraging its broad membership, expertise, and influence, the NFTC contributes to a greater understanding of the critical role an open, rules-based international economy plays in the success of American businesses, entrepreneurs and workers and shared global prosperity.

NFTC PRIORITIES FOR US-KENYA STRATEGIC TRADE AND INVESTMENT PARTNERSHIP

1. General Negotiating Objectives for the Contemplated Agreement

NFTC believes a US-Kenya STIP should aim for the type of high-level commitments achieved in the United States-Mexico-Canada Agreement (USMCA). However, NFTC recognizes the particular challenges faced by developing countries when agreeing to far-reaching trade commitments and therefore suggests that the U.S. explore mechanisms to maximize the ability of Kenya to implement ambitious commitments in the context of the STIP. Provisions regarding technical assistance and support for capacity building are likely to be needed to support a high-standard outcome.

The STIP negotiations should be focused on improving market access and ensuring greater fairness but must not become a pretext for designing new trade restrictions or undermining existing access. Negotiations should seek to achieve state-of-the-art rules on digital trade, customs and trade facilitation, technical regulation, and regulatory coherence to both ensure greater fairness and openness between Kenya and the U.S. and to make the new agreement a better model for future negotiations with other regions.

The STIP also should look for new and creative ways to ensure open markets in digital trade, e-commerce, and other new technologies and modes of commerce that are the future of international trade. It should establish disciplines on state-owned enterprises, which are increasingly involved in commercial activities, and create better opportunities for small and medium-sized enterprises to compete in global commerce.

USTR's Federal Register Notice invited comments on a number of specific topics. We address those topics in detail below.

2. Digital Economy

STIP must help foster an open Internet and include high standard obligations that prevent measures that result in data flows being burdened by unnecessary costs or blocked, or otherwise create unnecessary obstacles to digital trade. Businesses across every industry depend on the Internet and the ability to move and store data across borders to manage operations, reach new customers and become more productive. Effective participation in the global marketplace relies on an underlying public policy framework that facilitates the movement of digital information, Internet-enabled platforms, and the open Internet, as well as the services that the digital economy enables. A framework of rules for digital trade between the U.S. and Kenya will benefit both businesses and consumers and support U.S. economic growth, jobs, and innovation. Almost every sector of the U.S. economy, from manufacturing to services to farming, and including SME's, now depends in large part on digital technology to provide the innovation and efficiency that drives economic growth.

General Digital Trade Provisions. Digital trade disciplines in STIP must ensure open global flows of information and promote an open Internet while regulating appropriately for the public good. Robust, high-standard digital trade commitments would complement the modernized customs and trade facilitation provisions (discussed below) to encourage a suite of policies that enable the global digital economy to function to the mutual benefit of American innovators and Kenya's vibrant startups and other micro and small businesses who use global digital tools to operate their businesses and reach new markets.

Specifically, STIP must include the following:

- Ensure that companies and consumers can access and move information freely; prohibit governments from requiring local storage of information, mandating the use of local infrastructure or building redundant data centers, or dictating the location of computing facilities; and ensure that such commitments apply fully to financial services and financial services providers.

- Ensure non-discriminatory treatment vis-a-vis domestic providers, and state-owned enterprises.

- Prohibit the imposition of customs duties on digital products and on the value of electronic transmissions or the value of data being transferred.

- Prohibit the parties from enacting any requirements that force suppliers to share software source code, encryption keys, or proprietary algorithms with foreign governments or commercial competitors.

- Ensure the parties provide technology choice and encourage open architecture. Innovative companies should be able to utilize the technology that works best and suits their needs. Trade agreements should encourage the widespread use of open architectures to drive innovation in key technologies, including cloud computing, Artificial Intelligence and 5G telecommunications and ensure companies can choose their suppliers of choice, irrespective of where they are headquartered.

- Foster innovative encryption products. Encryption is a critical tool to protect privacy and security in the digital ecosystem. Trade agreements should protect innovation in encryption products to meet consumer and business demand for product features that protect security and privacy while allowing law enforcement access to communications consistent with applicable law.

- Prohibit making market access contingent on the forced transfer of technology.

- Include appropriate protections for Internet intermediaries regarding third-party activity that occurs on their networks, platforms, or other services, consistent with U.S. law.

- Provide for use of diverse electronic signature and authentication methods to allow transactions through secure online payment systems.

- Require the parties to promote paperless trading, including the use of customs forms in electronic format.

- Provide that new and innovative digital products and services are protected against future discrimination.

- Encourage governments to develop reasonable and balanced regulations that provide assurance to businesses and consumers that the use of emerging technologies such as Artificial Intelligence are transparent, explainable, and fair.

- Encourage governments to share, in readable and accessible form, data sets for innovative use by the public.

- Create a mechanism under the agreement, such as a U.S. - Kenya Digital Trade Steering Committee, to coordinate approaches to combating digital trade barriers in third-country markets and to advance new rules with respect to third countries and international organizations.

Digital Services Tax. NFTC members have serious concerns with Kenya's Digital Services Tax ("DST"). Kenya's 2021 Finance Act applies a 1.5 percent DST to nonresident businesses. The DST taxes gross revenue accrued through any "digital marketplace," defined as "an online platform which enables users to sell or provide services, goods, or other property to other users." The OECD/G20 Inclusive Framework's October 8, 2021 Statement commits participating governments to provide for the removal of unilateral DSTs for all companies. As part of the STIP, Kenya should commit to removing its DST and endorse the OECD/G20 ongoing framework negotiations as a pre-condition to the initiation of STIP negotiations.

Data Protection Act. NFTC is concerned with Kenya's Data Protection Act passed in November 2019, which includes potentially trade-restrictive measures related to the cross-border transfer of personal information.

Electronic Payments. The STIP should incorporate commitments (similar to those in the USMCA) that ensure a level playing field for domestic and foreign-based suppliers of electronic payment services ("EPS") in both markets. Robust, high-standard commitments for EPS are particularly relevant and necessary in Sub-Saharan Africa, where secure and innovative payment methods offer a key to expand financial inclusion, improve transparency and formalize economy activity, and build trust and security in the financial system. Regulation should account for, and be respectful of, different business models, encouraging a diverse set of players in the payments space. This competition among players will not only result in greater consumer choice, but will also spur innovation, contributing to a more robust payments ecosystem that will allow all market participants to develop and supply a wide range of payment services with differing product features and value propositions. The agreement should also apply digital trade provisions to electronic payment services suppliers. Specifically, digital trade provisions of the agreement should ensure EPS suppliers are able to transfer and store information across borders. It should also prohibit requirements to use or locate computing facilities in a party's territory as a condition for supplying EPS in that territory.

3. **Customs and Trade Facilitation**

The STIP presents an excellent opportunity to speed the flow of trade by improving and harmonizing customs regulations. The U.S. should encourage Kenya to implement high-standard trade facilitation measures and modernize its customs processes. Chapter 7 of the USMCA presents an excellent starting point for negotiating customs and trade facilitation measures with Kenya. The focus of the negotiations should be to streamline and make fully transparent customs procedures and expedite the customs clearance process in order to ensure that the movement of goods between the two countries is efficient and timely. Further, the goal of all improvements in this area should be to provide transparent procedures that require customs authorities to treat products fairly. The STIP should build upon the commitments in USMC and that the U.S. and Kenya have made as signatories to the World Trade Organization ("WTO") Trade Facilitation Agreement ("TFA") and create a "gold standard" set of commitments.

Customs Measures: Specifically, the STIP should address the following:

- All agencies with border responsibilities should provide information online, especially regarding the publication of applicable fees, charges, and quotas.

- Adoption of new regulations should be done via a transparent procedure with stakeholders being given an adequate opportunity to comment on proposed new regulations.

- Provisions regarding advance rulings need to be standardized and improved. The rulings should be issued in a reasonable time frame and should be made publicly available once issued.

- STIP should include provisions to separate the physical release of goods from the duty and tax collection process.

- STIP should provide for a simplified process for the return of domestic origin goods to meet the challenges of e-commerce.

- The parties should work to improve "trusted trader" programs that will better facilitate trade for those who can meet the program requirements.
- Adopt the use of electronic customs forms, electronic signatures, and authentications, and develop secure online payments in both countries.

- Enhance capabilities and use of the single window system in Kenya to allow the trade community to provide the necessary information to satisfy all government agency requirements in a single data transmission. While Kenya does provide the functionality for a single window, the continued use of and reliance on a manual review process for shipments (VO process) makes a single window impossible. In addition, not all Government Departments are fully on board yet. The KENTRADE portal, which includes all other government agencies and importers, could provide the technology to do this.

U.S. businesses of all sizes would benefit from these trade-facilitating changes to customs rules and procedures. In particular, such revisions would also unlock the exporting potential of MSMEs. These businesses often find complex customs procedures and costs to be among the most serious obstacles to trade. Modernization of these provisions would enhance the ability of customs officials to prevent abuses and enable the customs authorities in both countries to cooperate more efficiently to combat duty evasion, counterfeit trade, and other customs offenses. STIP should promote cooperation between the two countries in order to enforce customs laws and regulations, including information sharing as appropriate to pursue investigations of unlawful activities.

Expedited Customs Clearance and De Minimis Thresholds. It is crucial that STIP include an explicit commitment to require expedited customs treatment for certain shipments. Specifically, provisions regarding the streamlining of documentation and the timely release of goods for these shipments should be included. This language should also allow for the immediate release of express shipments upon arrival, provided that all required documentation and data is submitted. Most importantly, the agreement should establish a commercially-meaningful *de minimis* threshold for Kenya, inclusive of duties and taxes. Raising the customs *de minimis* levels contributes to faster and more efficient customs procedures, particularly for international shipments derived from e-commerce, thereby alleviating the workload for the government customs officials charged with targeting and risk analysis. Lastly, there should be a commitment to develop a robust informal entry process that is above the *de minimis* level, but below the formal entry level, that would necessitate less documentation than is required in a formal entry and would also aim to reduce the time, cost, and complexity in trade.

Implementation of these types of provisions would allow Kenya Customs officials to target high-risk imports, such as illegal or illicit material (see below), allowing customs agents to refocus their resources on risk-based targeting and analysis, as opposed to the considerable administrative burdens of clearing small or low-value shipments. Kenya should also be encouraged not to require Harmonized Tariff Schedule codes on imports entering under the new, higher customs *de minimis* levels. Finally, the new, higher customs *de minimis* amount should apply to imports from all origins, and not exclusively goods of U.S.-origin.

Preventing Illicit Trade. The 2022 NTE Report notes that “concerns related to the widespread availability of counterfeit and pirated goods remain.” Kenya has seen a significant influx of counterfeit medicines into the market in recent years. Capacity building is necessary to create systems to prevent counterfeits and trade in other illicit products. The STIP presents an opportunity for the US and Kenya to take steps to collaborate to prevent illicit trade and strengthen capacity and regulatory/legislation frameworks. There is still an absence of law enforcement and/or notification to the Kenyan Pharmacy and Poisons Board (“PPB”) associated with IPR infringement for pharmaceuticals despite multiple efforts at law enforcement training. Specific steps the US and Kenya should take include:

- Implementing the customs notification process between Kenyan Revenue Authority and the rights holder;
- Implementing a customs application procedure;
- Implementing a notification process between law enforcement / PPB and the rights holder or market owner.
- Increasing and strengthening interagency cooperation across the Kenyan government to identify and address trade in illicit products;
- Developing an educational campaign to increase awareness about the risks of illicit products;
- Implementing a process to proactively detect illicit medicines; and
- Creating a surveillance network.

Pre-Import Inspections. Kenya suffers from Customs delays from pre-import inspections, particularly for pharmaceutical products. The STIP should identify measures to improve capacity within the Kenya Revenue Authority (KRA) to eliminate delays related to pre-import inspection for pharmaceuticals, increased training on software, and enhance network capacity.

4. Environment- and Climate Change

As part of the STIP's commitments on environment and climate change-related matters, the US and Kenya should engage on the important role that remanufactured goods can play in environmental protection, conservation, reducing green-house gas emissions, and supporting the sustainable use and management of each country's natural resources.

Remanufacturing returns products at the end of their serviceable lives to same-as-when-new condition. This helps reduce owning and operating costs by providing quality components and equipment at a fraction of the cost of a new product. Remanufacturing reduces waste and minimizes the need for producing new raw materials. Remanufactured goods are entirely or partially composed of recovered materials, have a similar life expectancy to a new product, and have a factory warranty similar to that of a new product.

USMCA contains language that clarifies that remanufactured goods will not be subject to restrictions that apply to used goods. This language sets a strong precedent for the treatment of remanufactured goods in future trade agreements with countries where barriers remain, and should be a priority negotiating objective in every new U.S. trade agreement, including the STIP.

5. Transparency and Good Regulatory Practice

The STIP should include robust commitments to sound regulatory practices, including transparency, impartiality, consultation with affected stakeholders, due process, and impact assessments of proposed measures and consideration of alternatives. The agreement also should provide for coordination among regulators in the U.S. and Kenya to ensure a coherent regulatory approach that enables the cross-border value chains so important to supporting American jobs and exports. The objective of such improved regulatory cohesion should be to facilitate trade between Kenya and the U.S. Regulatory cohesion should not lead to the adoption of unnecessary and unscientific obstacles to trade under the guise of harmonization, but rather to a regulatory environment that is based on a full assessment of relevant and sound scientific evidence and is as least trade restrictive as possible while acknowledging different policy objectives and regulatory preferences that may exist.

In the pharmaceutical sector, Kenya suffers from long medicine registration approval timelines (currently, a three-year backlog). To address this issue and speed the availability of life-saving drugs to patients, STIP measures on regulatory harmonization should include the following measures to address the regulatory review backlog:

- Create an expedited pathway for new molecule approval by implementing regulatory reliance on assessments from FDA or other WHO recognized reference agencies.
- Commit to use transparent metrics of review timelines for all applications, and prioritize applications based on their potential to have the greatest impact to public health issues.
- Implement a risk-based approach for post approval changes.

In addition, Kenya still takes a long time to issue national level approval after harmonized approval is issued through the East African Community ("EAC"). STIP presents an opportunity to continue regional regulatory harmonization in the East African Community with an aim for full continental harmonization. Kenya should prioritize the national review and approval of products already approved through EAC harmonization.

Other opportunities for regulatory harmonization in the pharmaceutical sector under STIP include:

- Creating an expediated pathway for new molecule approval by implementing reliance program from high-standard agencies such as FDA.

- Reversing a new requirement for all imports to have 60% shelf-life remaining. This change was implemented without notice or consultation. Kenya should revert to the previous requirement of 50% shelf-life.

- Creating an abridged assessment/recognition program for products with incomplete dossiers to facilitate registration, approval, and access of older oncology products.

- Improve regulations for prescribing and distributing pharmaceuticals to ensure quality and compliance to prevent:
  - Illegal pharmacies,
  - Distribution of illicit or counterfeit products, and
  - Distribution of partial prescriptions.

6. Measures Related to Micro, Small, and Medium Enterprises

Micro, small and medium-sized business enterprises ("MSMEs") make up an enormous segment of the U.S. and Kenyan economies, representing the overwhelming majority of businesses. One goal of STIP should be to promote and support U.S. and Kenyan MSMEs engaged in global trade and to address barriers that pose a disproportionate impact on small business exports. Such barriers include inaccessible or unduly burdensome trade paperwork, opaque regulatory processes, inefficient customs administration, and delivery issues involving low-value shipments. Modernization of customs provisions (see comment on customs and trade facilitation below), including the establishment of a commercially-meaningful *de minimis* threshold and a robust digital trade chapter (see comment on digital trade above) will provide significant benefits to MSMEs.

In addition, to ensure that MSMEs have access to useful information that will enable them to fully participate in the benefits of trade, STIP measures on MSMEs should require the US and Kenya to create a dedicated website, targeted at MSME users, to provide easily accessible information on bilateral trade to their exporters. This information should include contact information for relevant agencies, information on country-specific standards and regulations, procedures for the protection of intellectual property rights, foreign investment regulations, and business registration procedures.
Further, the United States and Kenya should establish a U.S.-Kenya MSME Working Group, with the goal of exchanging best practices and connecting businesses from our two countries.

7. Worker Rights and Protections

The U.S. government, and USTR in particular, are uniquely positioned to work with our trade partners to advance trade agreements that include international standards and harmonization of labor rights principles that protect workers and promote human rights in global supply chains. The STIP provides an opportunity to collaborate with Kenya in the shared goal of combatting forced labor as a fundamental human rights issue and advance greater government-government action to combat the root causes of forced labor.

The current forced labor obligations of U.S. trade agreements require the parties to prohibit the importation of goods into their territories produced in whole or in part by forced or compulsory labor, but this approach is overly narrow. Most trade agreements also include an obligation to establish cooperative actions to incentivize the implementation of measures to combat forced labor. USTR should leverage incorporate a cooperative actions element into the STIP to incentivize Kenya's implementation of measures to combat forced labor.

Such cooperative actions could incorporate trade and development tools to provide (1) positive and accelerated market incentives and market access for countries making continuous improvements in tackling forced labor and (2) capacity building and foreign assistance packages to address problems in forced labor hot spots. Cooperation and implementation should be targeted at addressing the underlying root causes of forced labor and not just assisting customs authorities in implementing import bans comparable to those in the United States. Rather, USTR should seek to develop a strategic, timely, and coordinated approach that builds on the recently updated U.S. National Action Plan to Combat Human Trafficking and advances prevention, protection, prosecution, and partnerships, including through collaboration with stakeholders that can both address the immediate forced labor indicators and help build long-term solutions.

In addition, USTR should coordinate with interagency counterparts to develop programs that provide rewards for countries that are demonstrating continuous improvement in tackling forced labor (e.g., by moving up on the TIP Report). Incentives could include enhanced or accelerated trade preferences and foreign direct investment.

If USTR pursues new forced labor obligations in trade agreements or preference programs, those obligations should be based on international standards (e.g., UNGP, OECD, ILO), focus on establishing desired outcomes and objectives without including overly prescriptive obligations, and ensure that obligations are feasible, practical, and align with existing regulatory and supply chain disclosure requirements across a diverse range of sectors. Where measures create legal liability for companies, their focus should be on intentional non-compliance or intentional provision of false information.

NFTC outlined its recommendations for a trade policy to combat forced labor in greater detail in our recent submission to USTR on this issue.

8. Standards Collaboration

The STIP should aim to ensure that technical standards do not become barriers to trade by including commitments that the setting of technical standards, conformity assessment procedures and technical regulations will be developed in a fair and transparent manner and not in a way that favors domestic industry. The TBT chapter of the USMCA provides new features that build on the WTO TBT Agreement and should be incorporated into the STIP. These include new transparency requirements; provisions to ensure that information on regulatory decision-making is publicly available; and important assurances regarding the conformity assessment process.

Further, we recommend consideration of using annexes for TBT provisions regarding specific products including cosmetics: medical devices and pharmaceuticals; information and communications technology products; wine and distilled spirits; formulas for food products; and organic products. These annexes promote a common regulatory approach and should be incorporated into the STIP to enable producers in the two countries to benefit from the efficiencies generated by common, harmonized standards.

9. Agriculture/Sanitary and Phyto Sanitary Measures

The STIP agriculture commitments should address sanitary and phytosanitary ("SPS") measures and provide rules that ensure that SPS measures are science-based and developed and implemented in a transparent, predictable and non-discriminatory manner by the parties.

The rules should also preserve the ability of regulatory agencies in these countries to take necessary steps to ensure food safety and protect plant and animal health. The SPS chapter from the USMCA provides important new features which could be incorporated into the STIP and would enhance the ability of U.S. food and agricultural exporters to gain market access and create a strong template for future U.S. trade agreements. Specifically, the STIP should include provisions that promote the use of risk analysis to improve the scientific basis of SPS regulations; require the publication of SPS regulations for public comment; require that importers and exporters be notified expeditiously if shipments are detained for SPS concerns; and establish procedures for the parties to quickly resolve unwarranted SPS barriers that block the export of U.S. food and agricultural products.

10. Anti-Corruption

USTR's 2022 National Trade Estimate reports that "corruption remains a substantial barrier to doing business in Kenya." Fair, competitive, rules-based trade and investment through the STIP has the potential to diminish that corruption, to the benefit of both parties. However, to realize that potential it is important that the STIP contain strong enforceable provisions on anti-corruption, building on commitments in past agreements such as USMCA.

11. Other Measures or Practices That Undermine Fair Market Opportunities

Border Taxes: Kenya currently levies a 2% import declaration fee ("IDF") on all imports destined for consumption in Kenya and a 1.5% railway development levy ("RDL") (to raise funds for the Nairobi-Mombasa railway funded, which is built and operated by Chinese agencies) on imports destined for consumption in Kenya. Kenya currently exempts imports from its trading partners in the EAC and in the Common Market for Eastern and Southern Africa ("COMESA") from these two border taxes. The STIP should include provisions exempting imports from the United States from these two border taxes as well.

Express Delivery Services Annex: STIP should incorporate an express delivery services annex comparable to those included in other U.S. trade agreements. The Annex should require fair, non-discriminatory treatment of delivery service providers by addressing the unique challenges associated with postal operators through the inclusion of a delivery services sectoral annex in the agreement to ensure that U.S. and Kenya consumers and businesses retain access to world-class delivery service options. The annex should be based on the Delivery Services Annex in the USMCA, but at the very least should: (1) prohibit Postal Corporation of Kenya from cross-subsidizing from non-competitive services (or "exclusive services" as they are also called in Kenya) to fund services it provides in the competitive environment (e.g., courier services); (2) require that the regulator of delivery services (currently, Communications Authority of Kenya) be independent of the Postal Corporation of Kenya in all respect; (3) prohibit the assessment of fees or other charges on delivery service suppliers in order to fund the supply of universal service; and (4) eliminate any other market-distorting laws, regulations, or policies that grant advantages to Postal Corporation of Kenya over private operators in the provision of competitive services.

Government Procurement. To truly achieve the Administration's goal of creating commercially-meaningful obligations, STIP should include engagement to increase opportunities for U.S. goods and service providers to participate in procurement opportunities by Kenya's government agencies and state-owned public infrastructure and utility enterprises. USTR's 2022 National Trade Estimate report notes that "US firms have had very limited success bidding on government tenders in Kenya," and describes certain Kenyan initiatives that favor domestic products in government and state enterprise procurement. Procurements of medicines procurement   STIP should include the development of a value-based procurement system that uses objective criteria for the procurement of medicines and eliminate the 15% price preference in tenders for locally manufactured pharmaceutical products.

Failure to negotiate procurement commitments that exempt U.S. products from those local content requirements will put U.S. goods and services at a significant disadvantage to both Kenyan firms and firms from third countries like China that might invest in Kenya or partner with a Kenyan firm. Many procurement opportunities exist in areas such as infrastructure and transportation, information technology equipment, engineering, health equipment and supplies, and professional services, where U.S. companies are world leaders, but compete against other countries' national champions that can enjoy preferential access to procurement as well as more generous export financing.

In that context, it is notable that USTR has not yet explicitly identified government procurement as one of the priority areas it intends to negotiate with Kenya. Kenya is not a member of the WTO Agreement on Government Procurement (GPA); therefore, U.S. exporters will rely on the STIP to provide market access to the large segment of the Kenyan economy represented by procurement by government agencies and corporations.

Committing in STIP to clear, transparent, predictable, and non-discriminatory rules for procurements will ensure U.S. exporters have timely information available on upcoming procurements, that technical specifications are fair and non-discriminatory, that tender procedures are transparent, and that adequate time is provided for foreign bidders to participate. It will also help enhance transparency and competition in Kenyan Government procurement, increasing value for Kenyans and promoting development.

Trade and Health Measures. The STIP should include several key provisions regarding trade in pharmaceutical products, including small molecule drugs and biologics. These include:

- **National IP Committee:** The US and Kenya should use STIP to create a national IP committee within the government framework to develop and implement a national IP strategy to create a comprehensive and strong IP system in Kenya working with the U.S. government on capacity-building and best practices to promote innovative, live-saving pharmaceutical products.

- **Weak enforcement of parallel importation guidelines:** To strengthen disciplines surrounding parallel imports of pharmaceutical products, the STIP should include provisions designed to:

- Enforce and adhere to government parallel trade guidelines and revise existing guidelines to require that a company must have a marketing authorization to import the product.
    - Create an interagency working group to address illicit trade that occurs specifically through parallel trade.
    - Ensure that market authorization owner receives the certificate with all demands for parallel including quantities and patch numbers.

- **Pharmaceutical pricing and reimbursement:** STIP should promote value-based reimbursement systems & decisions with the objective of transforming National Reimbursement systems to ensure improve the sustainability of health systems and patients' access to evidence-based medicines. Kenya should also implement a pricing framework that includes mark-up caps.

- **Regulatory data protection:** Kenya currently provides no regulatory data protection. STIP should include obligations to provide regulatory data protection for both small molecule and biological pharmaceutical products.

- **Patent linkage system.** STIP should include provisions that implement an early notification system or some other form of patent linkage.

CONCLUSION

NFTC supports the goal of the U.S. to negotiate a STIP and looks forward to a commercially-meaningful outcome enhance and build upon the existing U.S.–Kenya trading relationship. These negotiations should result in a strengthening of our trade ties with Kenya and not introducing further impediments into the trading relationship. We see important gains to be made by including commitments in the STIP that mirror those achieved in the context of other recently-concluded trade agreements, most notably the USMCA. Adopting measures such as those described in this submission will provide greater fairness and openness in trade between Kenya and the U.S. and help to ensure U.S. exporters are guaranteed the ability to compete fairly in Kenya against third country competitors.

Thank you for the opportunity to present our comments. If you have any questions regarding our comments, please contact Tiffany Smith, Vice President of Global Trade (tsmith@nftc.org).