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Testimony of Mr. Brooke Fishback, MBA, CGBP

International Sales Manager

On behalf of Health Enterprises, Inc.

House Committee on Small Business

Hearing:

READY TO EXPORT: SMALL BUSINESS POLICY RECOMMENDATIONS FOR USTR

June 26, 2013

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Introduction

Chairman Graves, Ranking Member Velazquez and members of the Committee, thank you for the invitation to testify at this hearing of the House Committee on Small Business on the subject of "Ready to Export: Small Business Policy Recommendations for USTR", and for the opportunity to share my views and the experiences of our company, Health Enterprises, Inc., with the members of the Committee.

Witness Background

My name is Mr. Brooke Fishback, and I am the international sales manager for Health Enterprises, Inc. I have over 15 years of international experience working with customers in over 60 countries around the world, and having spent substantial time in almost 50. I hold a Bachelor of Science Degree in International Business and German, a MBA from McGill University, and am a NASBITE "Certified Global Business Professional". I also serve on the U.S. Federal Government Industry Trade Advisory Committee on Small & Minority Business, "ITAC 11", and the Massachusetts DEC (District Export Council).

Health Enterprises is a leading manufacturer and distributor of medical compliance (pill boxes, pill splitters, dosage droppers), 1st Aid, Hot/Cold, Sports Therapy, Home Health, Ear Care, and Head Lice Care products, and is a true American success story. In the early 1970's Arthur Leman founded the company in the basement of his home, and sold products door-to-door to independent pharmacies. Today, still family owned and operated, we sell our products under our Acu-Life brand and as Private Label to over 25,000 retail stores in the U.S., and have exported our products to over 60 countries worldwide. For our commitment to global sales, we were awarded a *Commercial News USA* Consumer Goods "Exporter of the Year" Award, Massachusetts Alliance for International Business "Ambassador's Award" for excellence in international trade, and President's "E Award"; which was presented at a White House ceremony.

Even with all of this growth – domestically and internationally – we are still a "Small Business", with fewer than 50 employees involved in sales/marketing, production, and logistics at our headquarters in North Attleboro, Massachusetts, and the equivalent of 2 full time employees working in exporting. That being the case, and similar to SMEs throughout the U.S., we do not have large legal teams or in-house regulatory departments to navigate complicated international rules for global commerce; instead we rely on the USTR to negotiate beneficial, easy to understand trade agreements, so that we can sell our products to those 95% of consumers that live outside of our domestic market.

Any assistance that the USTR can provide in improving the international trade situation for U.S. companies – primarily through Trade Agreements – is greatly appreciated. SMEs are the engines of export growth; and exporting stimulates the economy and creates good American jobs.

Subject of Testimony

I will discuss action items for USTR to assist U.S. SMEs. The views I express are my own, and are on behalf of Health Enterprises, Inc.

Trade Agreements

Trade Agreements have traditionally focused on reducing tariff rates. In entering into new trade agreements, and reviewing old agreements, a focus needs to be made on removing non-tariff barriers to trade with specific focus on "regulatory cohesion" and "standards harmonization". Our philosophy should be that "if it is legally sold in the U.S., then it should be legally sold in FTA partner countries, without the need for costly and/or time-consuming re-registration with local authorities".

USTR should strive to conclude Trans Pacific Partnership (TPP) negotiations as soon as possible, so that we can begin receiving the benefits of the trade agreement. Currently, around 36% of our export sales are directed to TPP negotiating countries, with Australia being our top market. We are excited about exploring new sales opportunities in Vietnam and Japan, and would estimate the markets worth 10's of 1,000's of dollars per year in new business.

I was pleased to hear the announcement at the G8 meeting of the beginning of talks for a Transatlantic Trade & Investment Partnership (TTIP)! Now USTR should energetically enter into these negotiations. Around 38% of our export sales are directed to EU member states, with the UK being our top market. Tariff rates between the U.S. and EU are already relatively low, and so the key will be to find common ground as it pertains to non-tariff barriers, including standards and regulatory cohesion. We currently encounter issues of costly and time-consuming re-registration with our FDA-registered "Class I Medical Devices" in the European Union. See Appendix I for a copy of a letter that I sent previously in response to a Federal Register notice which details the challenges we encounter trying to sell a simple "finger splint" in the E.U., along with some suggestions as to how to improve the system.

Other Initiatives

USTR should actively review and seek out new opportunities for free trade agreements. For example, late last year, the President introduced his "Doing Business in Africa Campaign". Sounds good. We currently sell a mix of our products in South Africa, and are trying to grow this business. The EU has a trade agreement with South Africa giving them preferential duty rates Vs. our products and making their prices more competitive. If the U.S. is promoting a "Doing Business in Africa Campaign", should we also have a trade agreement with South Africa and other African nations?

USTR needs to ensure that countries to whom we grant preferential duty rates to enter our market – under the Generalized System of Preferences (GSP) or other programs - also grant U.S. exporters equitable access to their markets. Brazil, for example, represents the largest market in Latin America, and should theoretically be a good market for U.S. exporters. Problem is, they have high duties/taxes, regulatory and other non-tariff barriers to keep U.S. exports out. Appendix II compares the duties/taxes levied by Brazil on imports from the U.S. for a set of products that we would like to sell in Brazil with the duties/taxes levied by the U.S. on imports from Brazil for the same products. The data is from 2010-11, but would be similar today. Note also that the mix of products that we would like to sell would also require registration with their health authority, ANVISA – a process which costs thousands of dollars and which I am told can take years.

Recommendations

1) **Free Trade** - USTR needs to maintain an aggressive trade agenda to assist SMEs in growing their international business;

2) **Trade Promotion Authority (TPA)** – the President needs TPA for "good faith" trade negotiations with other countries – trade agreements should not be renegotiated when sent to Congress, but be subject to an "up or down" vote;

3) **Exporter Education** – ensure sufficient funding for the SBA's Small Business Development Centers so that they can provide export education for U.S. small businesses. In conjunction, we support your Committee's work in exploring additional opportunities for coordinating state and federal trade agencies to assist small businesses;

4) **Export Promotion** – ensure sufficient funding for the US Commercial Service – and in particular their overseas offices which provide the "boots on the ground" support that we need for market information, and which perform the Gold Key match-making service; which arranges meetings for U.S. companies with pre-screened potential partners in foreign countries. Ensure that costs for U.S. Commercial Service services – like their Gold Key - remain affordable, so that small businesses can participate.

Thank you again for the opportunity to testify, I look forward to your questions.

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APPENDIX I

October 19, 2012

Mr. David Weiner, Deputy Assistant U.S. Trade Representative for Europe
Office of the United States Trade Representative for Europe
600 17th Street, N.W.,
Washington, DC 20508

Comments in Response to Request for Public Comment:
U.S. – E.U. Regulatory Compatability

Docket Number: USTR-2012-0028

Dear Mr. David Weiner,

Our company, Health Enterprises, is a SME currently selling our ranges of consumer health products in the E.U. In general, our products are considered to be "Class I Medical Devices (non sterile, non measuring)" – the safest category for Medical Devices (for example, a low cost "Finger Splint" – the kind that you would buy in the 1st Aid aisle of a CVS Pharmacy for a few dollars) – and they are registered with the FDA (in their Medical Device database @ www.fda.gov) under our "Owner Operator Number: 9022512", for your reference.

U.S. and E.U. regulators have a similar degree of consumer safety (the purpose of regulating Medical Devices is "safety") in mind when regulating Medical Devices, and the philosophy should be "if a Medical Device is legally sold in the U.S., then it should also be legally sold in the E.U." (and vice versa). Let us start with "Class I Medical Devices (non sterile, non measuring)" – the safest category for Medical Devices – as a "test case" to get this process started.

Specific to your questions:

1) Regulatory agencies involved are the FDA in the U.S., and various Ministries of Health in the E.U. Note that the way it is supposed to work is that if you have a medical device legally registered with a Ministry of Health in an E.U. member country, then the medical device is legally sold throughout the E.U. However, in practice different E.U. member countries often require re-registration.

2) Pertinent directives are the FDA Medical Device Directives here in the U.S., and European Medical Devices Directive 93/42/EEC.

3) For "Class I Medical Devices (non sterile, non measuring)", the laws are similar and require that companies pay a nominal fee and self-register the product in a central database (FDA Medical Device database here in the U.S., and the database for the Ministry of Health in a given E.U. member state). So, as a U.S. company we register our products with the FDA. To sell in the E.U., we also need to register our products with a Ministry of Health (possibly more than one!) for an E.U. member state. To do this, we need to first appoint a "European Authorized Representative" or EAR (a legal corporate entity with a physical office in the E.U.). This can take a number of forms, but in our case we contracted the work of an EAR to whom we pay a few thousand dollars per year + hourly fees (which is at the low end of the price spectrum for these services). We then have to pay our EAR an hourly fee to register our products with the Ministry of Health, and pay the Ministry of Health a fee per item and annual fee to maintain the database.

4) "Class I Medical Devices (non sterile, non measuring)" are considered generally safe. Allow companies in the U.S. and E.U. to register their products with the Ministry of Health for their home country. These are public databases that anyone can access to track a product and confirm that it is registered – the purpose of these databases is traceability; knowing which products are on the market and which companies produce them, so that in the event of a problem with a product, the manufacturer can be easily found and contacted. Instead of requiring double registration (both in the U.S. and the E.U.) where the costs involved add no value to a manufacturer, require that companies maintain sufficient product liability coverage (perhaps US$2,000,000) to cover any product issues. Again, we are talking about simple products, like a low cost "Finger Splint" – the kind that you would buy in the 1st Aid aisle of a CVS Pharmacy for a few dollars.

5) Medical Device directives in the U.S. and E.U. need to be harmonized, and currently have many issues, aside from double registration, and including different standards used in certifying products. Best is to start with "Class I Medical Devices (non sterile, non measuring)", as they are simple products which are self-registered as a "test case" of how regulatory cohesion can begin, then move on to more sophisticated Medical Devices.

6) Allowing U.S. companies to simply register their "Class I Medical Devices (non sterile, non measuring)" only with the FDA, and E.U. companies only with their in country Ministry of Health will have the immediate, guaranteed impact of saving companies money; which can be used to actually market or sell their products! For example, a U.S. company that wants to sell the simple "Finger Splint" mentioned above in the E.U. currently has to pay several thousand dollars for the rights to do this, even though the product is already registered in the FDA database (again, a public database that provides the traceability that both the U.S. and E.U. want), and this money would be better spent on promoting the product and generating Export Sales (which increase incomes, add to the U.S. tax base, and create jobs)!

I am happy to provide additional information and insights.

Thank you in advance for working to make "Class I Medical Devices (non sterile, non measuring)" a "test case" for U.S.-E.U. regulatory cohesion for Medical Devices!

Sincerely yours,

Brooke Fishback

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APPENDIX II

HEALTH ENTERPRISES, INC - www.healthenterprises.com
PRODUCT COSTING - SALES TO BRAZIL

Item #	Description	Country of Origin	HTS Code	Brazilian import Duties/Taxes on . shipments from U.S. (U.S. Exports) Landed Cost	Duties + Taxes %	Duties + Taxes $/unit	Vs.	U.S. import duty on shipments from Brazil (Brazilian Exports)
400733	Ear Irrigator	U.S.A.	3824.90	$8.86	61.5%	$3.41		6.5%
400775	After Swim	U.S.A.	3005.90	$3.42	68.8%	$1.07		0.0%
700398	Lice Cure	U.S.A.	3305.10	$6.27	51.5%	$3.04		0.0%
400595	Ear Syringe	U.S.A.	3926.90	$4.94	56.8%	$2.13		4.2%
MC12	Lice Comb	U.S.A.	9615.19	$4.40	56.8%	$1.90		11.0%