



Testimony of Leigh O'Donnell, Executive Director of
The Handcrafted Soap and Cosmetic Guild, Inc.
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Hearing: Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety
Energy and Commerce subcommittee on Health

Good morning, Chairman Pallone, Ranking Member Walden and the members of the subcommittee on Health, Chairman Eschoo and Ranking Member Burgess. Thank you for this opportunity today. I am honored to offer this testimony on behalf of the handcrafted soap and cosmetic industry. My name is Leigh O'Donnell, I am the Executive Director of The Handcrafted Soap and Cosmetic Guild (HSCG), a registered non-profit trade association representing the handcrafted soap and cosmetic industry in the United States.

The HSCG has been representing the businesses of the handcrafted soap and cosmetic industry since 1998, by providing business services, legal compliance training, certification, education, an industry conference and more. By using data from our industry suppliers, we estimate that there are over 350,000 small businesses making and selling handcrafted soap and cosmetics in the United States. A large majority of these businesses are women owned and operated.

The handcrafted industry supports updating The Food, Drug and Cosmetic Act of 1938, and supports FDA's oversight of cosmetics and ingredients. We support FDA having recall authority and mandatory adverse event reporting. Most important, the industry supports safe cosmetics, truth in labeling and protecting consumers of personal care products.

The handcrafted industry supports the FDA identifying ingredients of concern. If an ingredient is deemed to be unsafe, the handcrafted industry does not want to use it in the products that they make.

What makes the handcrafted industry unique is the hands-on procedures that are used to produce some of the safest soaps and cosmetics on the market. The entire process is overseen by a maker using hand mixing and pouring, each ingredient is chosen carefully and scrutinized. Many handcrafters that start making these products do so to use and highlight high quality ingredients like olive oil, coconut oil, avocado oil, and more. Batches of handcrafted soap and cosmetics are not measured in the millions or even the hundreds, rather a typical sized batch is around 20 units. Batches are mixed in bowls and hand poured into molds or containers. A lot of thought, care and pride goes into every batch that is made. One of the main advantages to making products by hand is to control the entire process from start to finish. Handcrafters thrive on their ability to change ingredients to meet a customer's needs, make the product seasonal or react to changes in the availability and cost of ingredients. The final product is labeled by hand in accordance with current labeling laws, boxed or bagged and sold at local farmers markets, craft shows, small storefronts and online. Being an entrepreneur gives people freedom on many fronts, whether it is just to supplement an income on up to completely supporting a family. Entrepreneurs create local jobs and have very positive impacts on their local communities.

The handcrafted soap and cosmetic industry does not support ingredient and batch reporting for small businesses with annual gross sales less than \$1M. Requiring handcrafters to register and report all ingredients or batches would result in hundreds to thousands of reports to FDA about mostly food grade ingredients per company per year. This requirement is especially burdensome to small businesses that are just getting started. They do not have employees or professionals on retainer to assist with these filings. This

requirement, without a small business exemption level, would not improve consumer safety. Handcrafted products are unique in the marketplace both for the way they are made and for the use of high quality, food grade ingredients and consumers want access to them.

The handcrafted soap and cosmetic industry does not support requiring small businesses to provide safety substantiation and verification of foreign ingredient imports. This burden should be on the actual importers of the ingredients, the companies that supply raw ingredients to the industry. These supplier companies are much larger with gross annual revenues much higher than \$1M. They have the infrastructure, time and employees necessary to be responsible for these requirements.

The handcrafted soap and cosmetic industry does not support assessing a user fee on small businesses below \$1M in annual gross sales. With over 350,000 small handcrafted businesses in the United States, even a nominal fee of \$250 would mean a disproportionate share of user fees would be from the sector of the industry with the smallest market share of total cosmetic sales. Furthermore, every dollar counts to a small business, they operate under very tight margins for the first several years of existence.

The number of these businesses in operation in the United States and their overall success demonstrates consumer's appetite for handcrafted soap and cosmetic products. Overreaching and burdensome regulations on this industry would devastate the businesses by forcing them to close and deterring others from starting. It would also remove these safe products from consumers who clearly want them in the market.

In order to give you some practical information and to demonstrate how proposed provisions would affect handcrafters, here are some stories from entrepreneurs that have businesses of various sizes. This gives a good cross section of the types and sizes of businesses that make up the handcrafted soap and cosmetic industry.

Sister Cathleen is a nun that resides at The Benedictine Sisters of Perpetual Adoration Monastery in Clyde, Missouri. Sister Cathleen started her business, Monastery Creations, in 2000, in order to meet one of the needs of the organization to "live by the work of their hands". The revenue that is generated by her nearly two decades old soap business is used to pay the bills of the monastery as they are not financially supported by the diocese. Sister Cathleen currently has two employees working in her shop, they make all of the soaps, scrubs and lotions by hand, adding a few drops of holy water to each product, fulfilling another one of their missions, to give back to the community. A loss of the revenue that the monastery brings in from the sales of their handcrafted soap and cosmetic products would be devastating to the financial health of the organization.

Julie is from Fond-du-lac, Wisconsin and started her business, Kreative Kraftwerks in 2002. She is a retired, divorced woman in her sixties. Julie makes soap, lotion, candles and sugar scrubs from a workshop located on her property behind her house. A retired Executive Assistant at the local police department, Julie planned her business to supplement her retirement income. The revenue that her business generates pays for her health insurance and her mortgage. A loss of this revenue would force Julie back into the workplace and have negative implications for her future plans.

Charlene from Hot Springs, Arkansas, started her business, Bathhouse Soapery & Caldarium, in her home in 2000. She grew the business slowly, selling her products at local farmers markets and craft shows, until she had outgrown her home. In 2009, she opened her first brick and mortar store in Hot Springs. She now has 60 employees and five different retail locations in three different states. Her company will do over \$4.2M in gross revenue this year. Her retail locations have revitalized four downtowns and their main street locations and has provided funds to several local charities. This is a great example of how much a successful business contributes to the local economy. Charlene's company would have to comply fully with the new requirements, she is ready to do so and has the infrastructure, revenue and employees necessary to comply.

The handcrafted industry supports having meaningful small business provisions to allow small businesses, like the ones profiled here, to enter the industry, grow and thrive. Each of these businesses currently has the opportunity to be the next Burt's Bees or Aveda, both of which started in someone's home. Burdensome registration requirements and reporting would be devastating to these fledgling businesses who spend their most precious

resource, time, on developing, making and introducing their products into the marketplace.

To protect the handcrafted soap and cosmetic industry and allow small businesses to continue to thrive in the United States, we must have meaningful thresholds for exemption be considered for registration, ingredient reporting and user fee requirements. A small business that has grown to the level of achieving \$1M in annual gross sales likely has employees to assist in new compliance requirements and is no longer operating out of a personal residence. This is the level that would protect the handcrafted soap and cosmetic industry and the small businesses that make it up. Businesses under this threshold should be exempted from burdensome registration requirements, batch reporting, ingredient reporting, safety substantiation, foreign ingredient verification and user fees. FDA has supported exemptions for small business in other regulations that have recently been enacted, the Food Safety Modernization Act (FSMA) contains an exemption for small businesses with less than \$1M in annual gross sales. The handcrafted soap and cosmetic industry should be afforded the same level.

Starting a small business and becoming an entrepreneur is part of the American Dream. There is something truly special about the entrepreneurial spirit and the freedom that it gives to all kinds of Americans and their communities and families.

Thank you again for inviting me to testify on behalf of the handcrafted soap and cosmetic industry, it has been a privilege and an honor.

Sincerely,

A handwritten signature in black ink, appearing to read "L. O'Donnell". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Leigh O'Donnell
HSCG Executive Director