by Jim Finn,
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Made in the USA: The case for reintroducing latex surgical and exam glove production back into the U.S.

Following the AIDS/HIV outbreak, the Centers for Disease Control and Prevention (CDC) published a Universal Precautions (UP) document in 1985-88. These recommendations detailed the practices and procedures necessary to reduce the exposure of healthcare workers to blood-borne pathogens. Every patient was treated as if infected, and therefore precautions were taken to minimize risk. The recommendations included the wearing of non-porous articles such as medical gloves, goggles and face shields. The world today uses 12,000 medical gloves per second.

Prior to the UP publication, U.S. glove production had been satisfied by a number of medical device manufacturers, namely, Safeskin, Ansell, Aladan, Baxter, Smith & Nephew and Johnson & Johnson. In addition, glove imports in the U.S. prior to 1985 were 1 billion pieces. In 1996, imports exceeded 21 billion pieces. By this time, most of the glove manufacturing had moved from the U.S. to Southeast Asia.

The immediate benefits for manufacturers from this move included lower labor costs, non-union facilities and the juxtaposition to the source of natural latex. The move, however, was not without its consequences. The significant increase in demand for gloves undoubtedly led to some changes in manufacturing, particularly in operations that were somewhat inexperienced in glove making protocols. These changes, aimed at increasing output, such as reducing inspection levels, increasing line speeds and "corner cutting" processing procedures, led to an increase in overall glove defects. The reduction of leach or wash times to increase output ultimately led to an increase in protein levels on the gloves, as well. The higher protein levels subsequently produced gloves capable of sensitizing nearly 15% of healthcare workers and other vulnerable individuals to latex protein allergies.

There is no doubt that there was a learning curve to be negotiated, and over time, these deficiencies have been corrected. Southeast Asian operations account for nearly 350 billion gloves annually, and ship 65% of these to the U.S. Estimates for total glove production for 2021-2024 would be in the range of 500 billion pieces.

Medical gloves today are produced from a variety of polymers beyond natural latex. These polymers (acrylonitrile, polyisoprene, polychloroprene and even guayule) offer the manufacturer a broad platform for product specificity.

Recently, Tim Manning, the government's newly positioned COVID-19 supply coordinator and former deputy director of FEMA, indicated that the federal government's focus will be to develop the manufacturing capability for nitrile latex and medical gloves to assure a sustainable source of PPE in the U.S.

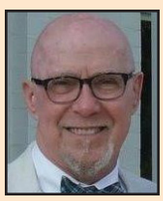
What are the challenges we will face to reintroduce that capability, and can the objective be achieved? Obviously, the Asian producers have a 25-year head start on their glove manufacturing, and they have learned and incorporated the latest innovations in sophisticated glove production and product development during this time. It is estimated that they currently have more than 2,300 production lines up and running.

The U.S. presently has limited capability for the manufacture of medical gloves, with only two manufacturers. The source of nitrile latex, the synthetic polymer used in the majority of exam gloves, is also limited, with only two manufacturers with relatively limited recent experience in these polymer glove formulations. This is not to say that the capability for producing nitrile latex in the U.S. cannot be achieved. It certainly can. Things are happening. The largest manufacturer of nitrile latex in Malaysia recently purchased a latex manufacturer in Ohio, a producer of SBR and NBR polymers. A large chemical firm in Houston completed the purchase of a significant nitrile latex producer, also in Ohio. Couple this with a manufacturer of NBR in Kentucky, and one has the makings of a potentially viable opportunity for nitrile latex growth in the U.S. market.

But we should not forget the impact that natural latex still has on this market. Most of the surgical gloves produced are made of natural latex. It is a softer film, and one that reduces hand fatigue in surgery. Fifteen percent of exam gloves are also made with natural latex. The U.S. presently has significant storage capacity for natural latex, with sources in Thailand, Cameroon and Guatemala. The utilization of natural latex will supplement the alternative synthetic latex supplies.

There are three or four manufacturers of glove dipping lines in Southeast Asia that serve the market. The U.S. has none at this point, but there are U.S. firms with a history of having produced lines years ago. They could work with their U.S. clients to offer assistance and "run interference" for their client partners with engineering firms from Asia and Germany that produce these dipping lines.

Providing the necessary chemicals for the successful processing of the glove polymers will not be a problem. Chemical



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3RW - Latex Today.indd 14 2/22/2021 12:35:50 PM

dispersions, designed for latex glove applications, are presently being manufactured in the U.S. and shipped to Southeast Asia for glove manufacturing there. There is adequate capacity to serve the U.S. market when required.

It is estimated that the level of employment necessary to achieve a 220 billion glove production level for the satisfaction of the U.S. requirement would be 45,000. That is a significant opportunity for employment growth in the U.S. However, it may not be necessary to completely satisfy the total glove requirement in the U.S. Even covering 50% of the requirement would be an admirable goal. In addition, it would ensure that the U.S. has an adequate safety stock of this necessary PPE.

Recent studies have indicated that the production cost per glove in Asia is approximately $0.030 to $0.045 per glove. Comparative costs in the U.S. would be $0.065. However, shipping container costs over the past 18 months have tripled, from $2,800 per container from Malaysia to the U.S., to $9,000. Labor costs, presently representing 9% of the total glove cost in Asia, would be 20% of the glove cost in the U.S. This, however, does not take into account that labor costs are increasing in Asia, coupled with a shortage of available labor for glove manufacturing.

The average selling price for gloves in the U.S. is approximately $0.19 per unit. This does provide some opportunity for a respectable return on investment for those U.S. glove projects.

Lastly, a look at the public benefits derived from U.S. glove projects shows:

- Guaranteed supply of medical grade gloves (this is the most important benefit) so that public and healthcare workers will have reliable access to life saving PPE
- Reduced carbon footprint attached to each glove by manufacturing in the USA
- Direct and indirect employment in the USA
- Research and development; when a product is simply bought and sold on an import basis, there is no opportunity for product development or enhancement
- Entire revenue created by the sale of the gloves remains in the USA
- Manufacturing jobs return to the USA
- Local communities will be involved in the construction, maintenance and operation of company facilities.

It is my belief that we are now in a position to take a serious look at bringing the production of medical gloves back to the United States.

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