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TESTIMONY BILL 106, PANDEMIC AND EMERGENCY PREPARDNESS ACT, 2022

BY
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I have dedicated my entire professional career spanning some forty years to the manufacturing, design, distribution of PPE most notably respirator protection. I acquired the respirator manufacturing operation from my long-time supplier in 2014. This operation was manufacturing NIOSH approved reusable elastomeric respirators, cartridges, and filters for some 75 years. I was their master distributor in Canada since 1987. I believe I am qualified as an expert in the manufacturing of the respirator product category. We are a Canadian family owned and operated business located in Newmarket, Ontario with our respirator manufacturing plant located in Kansas. We are a NIOSH certified operation, and our respirators are Health Canada Approved.

I have worked through all the pandemics since SARS in 2002 and have witnessed firsthand the supply challenges for PPE but respiratory protection in particular. During those pandemics, we experienced sharp increases and declines in cases that did affect the supply chain but not to the extreme we have experienced and continue to experience with COVID-19. At the end of each of the other pandemics, we as a society never took the initiative to prepare for the next one and we must take the initiative to act now to fight through COVID-19 and prepare for the next one.

Over the last two months, I have been involved in meetings with Mr. Tim Manning National COVID19 Supply Coordinator for the White House on preparedness planning for the next waves. In the fall of 2021, I testified in Congressional Hearings to the Small Business Committee chaired by Congresswoman Sharice Davids. The purpose of my testimony was to explain to the committee the challenges that a critical product supplier like our company had to deal with during the COVID crisis. They are trying to prepare additional funding and planning to understand what is needed to ensure proper levels of respiratory protection while the pandemic lingers and what is needed to prepare for the next one.

We have learned that COVID-19 is a particulate aerosol that can travel great distances in many directions. We have examples that nurses walking past COVID patients wearing a loose-fitting surgical mask contracting the virus.

October 2020, the CDC updated their Guidelines for “HEALTHCARE WORKERS Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations Conventional, Contingency, and Crisis Strategies, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>, where they advised not to use a respirator with an exhalation valve when protecting against a deadly virus such as COVID. They also asked the market to create a reusable elastomeric rubber half mask respirator without an exhalation valve with an N95 or higher filter. **This type of respirator did not exist prior to this call to action. They state that when using a filter on a mask of this nature whose filter is encapsulated in a protective housing that allows for decontamination, the filters could last up to a year conservatively when protecting against a virus such as COVID.**

The new messaging in 2021 from health experts and authorities in Canada and the United States was to wear a tight-fitting NIOSH approved N95 respirator as the highest level of protection providing source control.

I have asked both the Provincial and Federal governments for funding to set up manufacturing in Newmarket, Ontario to produce our reusable half mask respirator and replacement filters since early 2021 while communicating with a Mr. B. Whitfield, Central Region, Business Advisory Services as recently as January 2022 through the OTF. On February 22, 2022, I had a virtual

meeting with the head of procurement for the Province Mr. D. Kent and various members of his staff to introduce him to reusable respirators and ask him to consider making them part of the provinces solution to protect our HCW.

While I have been advocating for the use of reusables in Canada for almost two years, the following summarizes the changes in direction for the type of protection that should be provided to healthcare and frontline workers. Reusable respirators must be part of the PPE solution along with disposable respirators.

In March of 2022, 100 health experts who have been advising the White House, including Dr. Osterholm, issued their own pandemic preparedness plan, which they called a “Road Map For Living With Covid”. The group’s leader, Dr. Ezekiel Emanuel, has estimated that it will cost \$100 billion or more to fully prepare the nation for future variants and pandemics moving forward. This link will take you to the entire document. <https://www.covidroadmap.org>. Here are some highlights from the PPE section in chapter 5, page 57.

- **Workers in higher-risk settings need access to reusable respirators.**
- There should be a robust domestic respirator manufacturing industry to ensure sufficient supply for healthcare and other high-risk settings, with capacity to ramp up production during respiratory emergencies such as another pandemic or surge.
- **The national stockpile should be replenished with elastomeric** and powered air purifying respirators for healthcare workers, which must be deployed immediately as future surges or pandemics occur.

- The supply chain of respirator manufacturing must be considered a national and economic security priority. Where necessary, domestic manufacturing capacity for respirators must be assured.
- The Department of Health and Human Services or an appropriate federal agency must be directed to conduct a thorough assessment of domestic respirator manufacturing supply and needs for the immediate and long-term future.
- Healthcare workers with direct patient care responsibilities should top the priority list for personal protective equipment. They must be provided reusable respirators such as elastomeric half-mask respirators for the remainder of the pandemic.
- Next on the priority list are people who work in non-healthcare high-risk settings like emergency services, meat packing, poultry, food processing, corrections, grocers, and warehousing. These are followed by workers in moderate-risk settings such as restaurants, retail, and transportation. Both sets of workers should be provided respirators by employers and fit-tested in the context of comprehensive respiratory programs.
- Most of the focus has been on filtering facepiece style respirators. Innovative designs of elastomeric respirators are available, many without exhalation valves. These should be made available to more workers and required in healthcare settings. NIOSH and OSHA should undertake the research and regulatory changes needed to encourage the development and deployment of reusable respirators for both source control and personal protection.

All of these recommendations lead to providing a reusable elastomeric rubber respirator like our Comfort-AirNx®. We have just completed our last shipment for the US Government order that is issuing our respirator to 125,000 masks healthcare and frontline workers along with and 500,000

replacement filters. Our respirators have been issued to healthcare and frontline workers to introduce them to this type of respirator. The response to our product has been overwhelming with hospitals converting completely to our reusable solution.

A reusable elastomeric rubber half mask without an exhalation valve such as our Comfort-AirNx® series respirator provides the following advantages versus disposable style respirators. Please note there are only three NIOSH approved respirators of this nature. Our product is the only product that provides all of the following features and benefits.

- **Safer** because it provides an airtight seal providing 100% source control and can be fit checked each time you don the respirator before exposure.
- **Less expensive** to use than disposable respirators because the replaceable filters can last up to a year conservatively when protecting against a virus such as COVID according to CDC.
- **The environmental savings is enormous** due to the reduced filter consumption. Not only will we reduce the waste that is sent to the landfill, but it will also reduce the carbon emissions by reducing transportation costs because of the reduced consumption of filters.
- **Far more comfortable** than using a disposable respirator. Feels great against the skin.
- Will not cause face rash or mask acne associated with wearing a disposable respirator.
- Will not fog glasses,
- Will fit under any medical shield.
- Esthetically pleasing making the HCW patient interaction more pleasing.
- Complete communication between the HCW and the patient.

- Will reduce costs by hundreds of millions of dollars annually
- Will reduce waste by millions and millions of pounds annually.

To demonstrate the cost savings and waste reduction, the chart on the next page lists the number of healthcare and frontline workers as per 2021 statistics in Ontario. The top chart shows the reduction based on a 90-period allowing for only one N95 disposable respirator per person per day versus issuing the entire population with our Comfort-AirNx® respirator. The bottom half of the chart shows the real usage per day per person of an N95 disposable respirator being at least five. In either case, the reduction in cost and waste savings is incredible and it is real.

ONE PER PERSON PER DAY

90 days - \$8,010,400 - 286,465 lbs

365 days - \$32,041,600 – 1,145,860 lbs

FIVE PER PERSON PER DAY

90 days - \$65,685,280 - 1,432,323 lbs

365 days - \$262,741,120 – 4,583,440 lbs

COMFORT-AIRNx RESPIRATOR USAGE COMPARISON VS DISPOSABLE N95															
	IMPACT	USAGE	COST	ENVIRONMENTAL IMPACT (WASTE REDUCTION LBS.)											
				90 DAY SAVINGS	286,465										
				FULL YEAR SAVINGS	1,145,859										
TOTAL DOCTORS, NURSES,PARAMEDICS, FIREFIGHTERS															
COMFORT-AIRNx															
DISPOSABLE N95 RESPIRATORS															
	Users	Weight In G	Cost	Per Day	Days	Total Usage	Total Cost	Total Wght LB (453g/lb)	Weight In G	Cost	Per Day	Days	Total Usage	Total Cost	Total Wght LB (453g/lb)
Nurses	104,980	9	\$1.00	1	90	9,448,200	\$9,448,200	187,713	2.5	\$40.00	0	0	209,960	\$4,199,200	-
Doctors	14,962	9	\$1.00	1	90	1,346,580	\$1,346,580	26,753	2.5	\$40.00	0	0	29,924	\$598,480	-
Paramedics	9,300	9	\$1.00	1	90	837,000	\$837,000	16,629	2.5	\$40.00	0	0	18,600	\$372,000	-
Firefighters	30,966	9	\$1.00	1	90	2,786,940	\$2,786,940	55,370	2.5	\$40.00	0	0	61,932	\$1,238,640	-
Total	160,208	9	\$1.00	1	90	14,418,720	\$14,418,720	286,465	2.5	\$40.00	0	0	320,416	\$6,408,320	-
40' CONTAINERS	Units Per	303,600													
	Number of containers	47		SAVINGS											
				14,098,304											
				4400%											
				125%											
COMFORT-AIRNx															
DISPOSABLE N95 RESPIRATORS															
	Users	Weight In G	Cost	Per Day	Days	Total Usage	Total Cost	Total Wght LB (453g/lb)	Weight In G	Cost	Per Day	Days	Total Usage	Total Cost	Total Wght LB (453g/lb)
Nurses	104,980	9	\$1.00	5	90	47,241,000	\$47,241,000	938,563	2.5	\$40.00	0	0	209,960	\$4,199,200	-
Doctors	14,962	9	\$1.00	5	90	6,732,900	\$6,732,900	133,766	2.5	\$40.00	0	0	29,924	\$598,480	-
Paramedics	9,300	9	\$1.00	5	90	4,185,000	\$4,185,000	83,146	2.5	\$40.00	0	0	18,600	\$372,000	-
Firefighters	30,966	9	\$1.00	5	90	13,934,700	\$13,934,700	276,848	2.5	\$40.00	0	0	61,932	\$1,238,640	-
Total	160,208	9	\$1.00	5	90	72,093,600	\$72,093,600	1,432,323	2.5	\$40.00	0	0	320,416	\$6,408,320	-
40' CONTAINERS	Units Per	303,600													
	Number of containers	237		SAVINGS											
				71,773,184											
				22400%											
				1025%											
				1,432,323											

BREATHING RESISTANCE TESTING VS NIOSH VS N95 DISPOSABLES

BREATHING RESISTANCE TESTING & COMPARISON					
NIOSH REQUIREMENT @ 85 LPM	MMWC Inhalation	MMWC Exhalation	% Diff Vs NIOSH Inhale	% Diff Vs NIOSH Exhale	
N95	35	25			
Dentec Comfort-Ease AD2N95 N95 Disposable	6.9	5.5	80%	78%	
Dentec Comfort-Ease AD4N95 Flat Fold N95 Disposable	8.1	8.7	77%	65%	
Dentec Comfort-Ease AD2P95 Cup Shape P95 Disposable	19.5	9.23	44%	63%	
COMFORT-AIR Nx N95 Nx Cover	4.2	3.5	88%	86%	
COMFORT-AIR Nx P100 Cartridge	6.2	5	82%	80%	

INTERNAL MASK TEMPERATURE RECORDING DURING PATIENT INTERVIEW

COMFORT-AIRNx® REUSABLE VS DISPOSABLE RESPIRATORS

RESPIRATOR TYPE			SITTING			Walking Fast	Hard Breaths	Sitting	Sitting
	TEMP	Room Temp	15 sec	45 sec	2 min	500 Paces	20	5 min	10 min
Respirator									
3 Ply Mask	C	24.5	25.7	27.1	29.7	30.6	31.3	31.6	32.1
N95 Disposable Leading Competitor	C	23.5	26.5	28	30.3	32.5	32.6	33.1	33.6
Dentec Comfort-Ease N95 W/O Ex Valve	C	23.5	25.9	27.7	30.2	32.2	32.5	33.3	33.5
COMFORT-AIRNx W/O Ex Valve	C	23.5	27.4	30.2	33	32.9	33.3	33.6	33.7
COMFORT-AIRNx P100 W/O Ex Valve	C	22.4	24.8	28.8	30.4	31.2	32.2	32.9	33.2
COMFORT-AIR N95 W/ Ex Valve	C	24	25.9	27.5	29.2	29.2	29.6	29.9	29.9

INTERNAL MASK TEMPERATURE RECORDING DURING LONG DISTANCE CYCLING

COMFORT-AIRNx® REUSABLE VS DISPOSABLE RESPIRATORS

26-Oct-20		CELCIUS TEMPERATURE RECORDINGS - CYCLIST TRAINING								
Time		Ambient	At Start	15 sec	1 min	2 min	5 min	10 min	18M 15 Sec	
Respirator									Average Temp	Avg Diff Vs Nx
Tested #1 Blue Medical Mask		21.3	21.8	25.1	28.5	29.3	29.9	29.9	26.54	0.33
Test #2 Dentec Comfort-Ease Disposable N95		20.7	21.5	25.4	30.8	32.2	33.2	33.3	28.16	-1.29
Test #3 Dentec Comfort-AirNx N95		21.2	21.4	24.4	28.5	29.5	31.2	31.9	26.87	
Test #4 Dentec Comfort-Air Silicone N95 W/EX Valve N95 Temperature Difference vs N95		20.1	20.7	23.5	26.5	28.1	28.9	29.1	25.27	-2.89

We must make reusable elastomeric respirators a primary product to protect the lives of those that protect others.

Thank you,

A handwritten signature in black ink, appearing to read 'Claudio Dente', with a stylized flourish at the end.

Claudio Dente
President