



WIB-National Webinar

## "Class II Medical Device Innovation and IP Strategy: Case Study in Women's Health Products"

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Women In Bio is an organization of professionals committed to promoting careers, leadership, and entrepreneurship of women in the life sciences.

**Inviting.  
Supporting.  
Succeeding.**

# About the Speaker

- Over twenty years in medical devices with focus on breast pump industry
- President of Kurtz Consulting Inc., providing sales & marketing solutions to healthcare organizations for over twelve years
- [www.DebraKurtz.com](http://www.DebraKurtz.com)



**Debra Kurtz BA, BS, MBA**

# Objectives

- The history of breast pump innovation
- How these medical devices assist with maternal employment
- Insights on driving product innovation and IP strategy
- Opportunities to improve health products, advance employee benefits, and improve work/life balance for future generations of women

# Breast pumps in ancient times

- For centuries, mothers have used a number of different tools to relieve the pain of engorged breasts, correct inverted nipples, and increase milk production
- Women in Ancient Greece used ceramic cups called gutti (dual purpose pumps and feeding bottles)
- The Romans invented sucking glasses – glassware tools that worked like drinking straws.

<http://artefact.museumofhealthcare.ca/?p=47>



Glass gutti, Roman period, 1<sup>st</sup>-4<sup>th</sup> century CE

Gérard Coulon, *L'enfant en Gaule romaine*, 1994, 2<sup>nd</sup> edition revised and expanded 2004, page 63, <https://www.alimentarium.org/en/magazine/history/history-baby-bottles>

# Breast pipe and nursing bottle



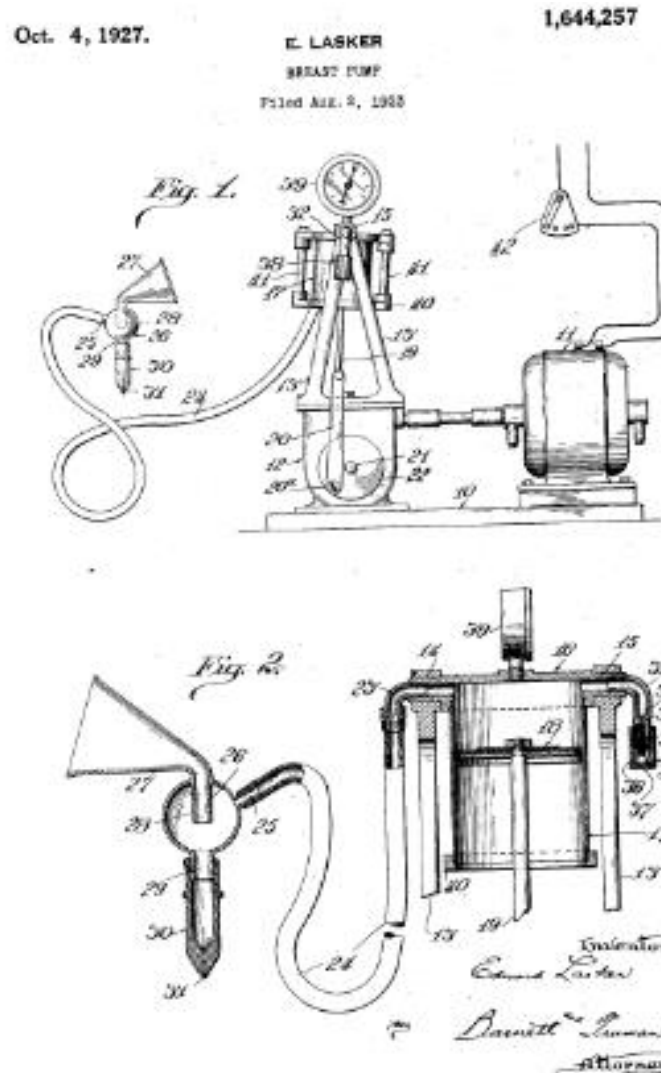
<http://www.phillyarchaeology.net/philly-archaeology/artifactindex/august-2013-artifact-of-the-month/>



# Early US breast pump patents

- In 1921-23, engineer and chess master Edward Lasker produced a mechanical breast pump
- It imitated an infant's sucking action and was regarded by physicians as a marked improvement on existing hand-operated breast pumps

<https://www.google.com/patents/US1644257>



# 1830 breast pump ad



Bettmann/Getty Images

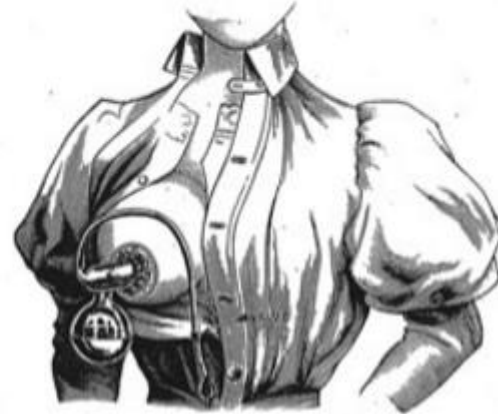
"Pump for extracting breast fluid." Woodcut. 1830.

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STRATEGIC SALES & MARKETING SOLUTIONS

# Mid 19<sup>th</sup> Century New Yorker Ad



## BLACK'S AUTOMATIC BREAST PUMP



This Pump is the first perfect instrument of the kind. It is highly endorsed by every physician who has tested it. It has an automatic valve, allowing the patient to produce any degree of tension that may be desired, thus allowing the milk to flow freely, without any pain.

It is especially adapted to cases of inverted nipple.

SENT BY MAIL.

PRICE, 75 CENTS.

MANUFACTURED BY

**BLACK MANUFACTURING CO.**

1015 CHESTNUT STREET, ST. LOUIS, MO.

In Writing to Advertisers, Mention Medical Ref.

**KURTZ CONSULTING INC.**

**STRATEGIC SALES & MARKETING SOLUTIONS**

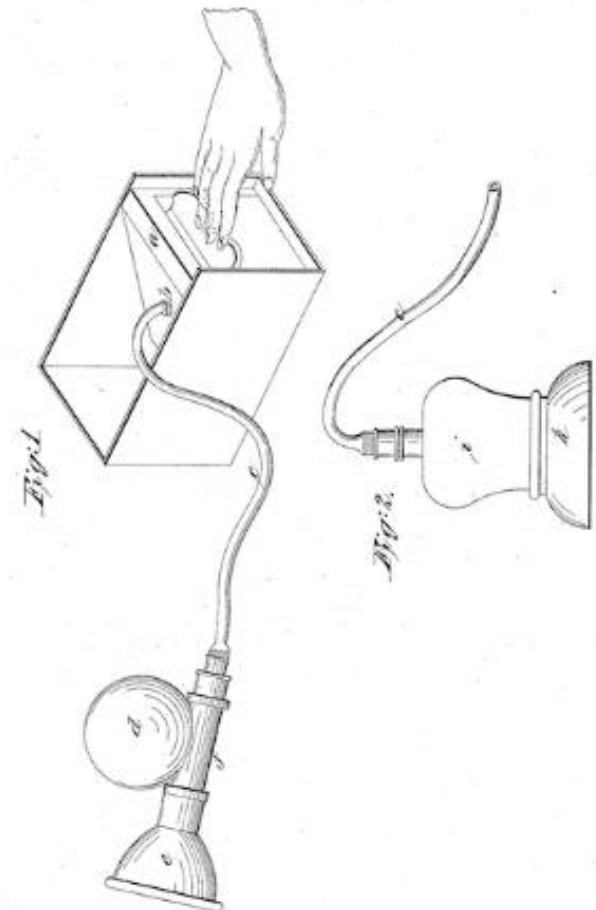
<http://www.newyorker.com/magazine/2009/01/19/baby-food>



# Early US breast pump patents

- On June 20, 1854, the United States Patent Office issued Patent No. 11,135 to O.H. Needham for a breast pump.<sup>1</sup>
- Scientific American (1863) credits L.O. Colbin as the inventor and patent applicant of a breast pump<sup>2</sup>

*O. H. Needham*  
*Breast Pump,*  
*No. 11,135*  
*Patented June 20, 1854.*



1. <http://www.google.com.au/patents/US11135>
2. *Scientific American*, Vol. 8, No. 4, January 24, 1863

# The landmark breast pump study

- In 1956 Einar Egnell published his groundbreaking work, "Viewpoints on what happens mechanically in the female breast during various methods of milk collection"
- This article provided insight to the technical aspects of milk extraction from the breast
- The Egnell SMB breast pump designed through this research is quite robust and many pumps are still in operation today over 50 years after publication



Sven Lakartidn. 1956 Oct 5;53(40):2553-64.Links [Viewpoints on what happens mechanically in the female breast during various methods of milk collection.] [Article in Swedish] EGNELL

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# Public Health Policies Support BFing

- Breastfeeding has health benefits for moms and babies
- The US Dept. of Health & Human Services has breastfeeding objectives for the Nation
- The CDC tracks breastfeeding rates

<https://www.cdc.gov/breastfeeding/data/ifps/index.htm>



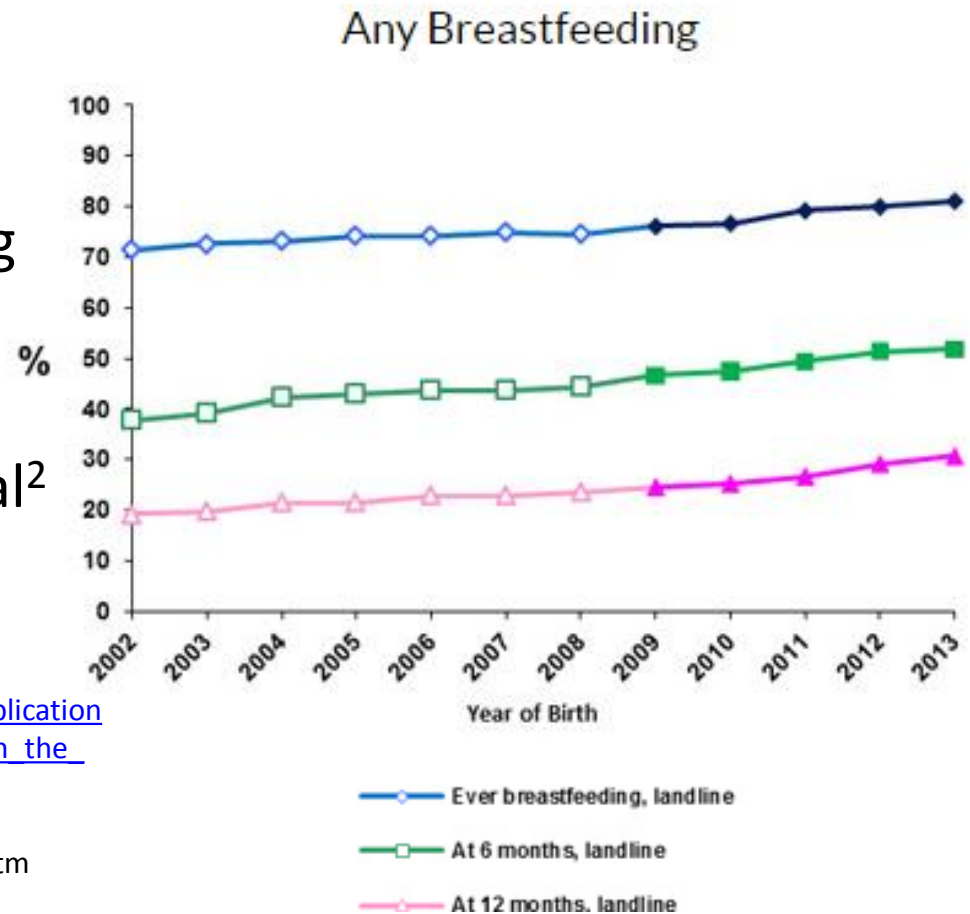
Healthy People 2020 Breastfeeding Objectives	
Objectives	
MICH-21: Increase the proportion of infants who are breastfed	
MICH-21.1	Ever
MICH-21.2	At 6 months
MICH-21.3	At 1 year
MICH-21.4	Exclusively through 3 months
MICH-21.5	Exclusively through 6 months
MICH-22: Increase the proportion of employers that have worksite lactation support programs.	
MICH-23: Reduce the proportion of breastfed newborns who receive formula supplementation within the first 2 days of life.	
MICH-24: Increase the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies.	

<https://www.cdc.gov/breastfeeding/policy/hp2020.htm>



# Breastfeeding is on the rise but still falls short of national objectives

- Public health campaigns began in the early twentieth century to increase US breastfeeding rates<sup>1</sup>
- In 1970, bfing initiation was only 26.5% in hospital<sup>2</sup>
- The CDC reports a rise in recent bfing rates<sup>3</sup>



1. [https://www.researchgate.net/profile/Jacqueline\\_Wolf/publication/8979698\\_Low\\_Breastfeeding\\_Rates\\_and\\_Public\\_Health\\_in\\_the\\_United\\_States/links/55d1ca7008ae3dc86a4f2f61.pdf](https://www.researchgate.net/profile/Jacqueline_Wolf/publication/8979698_Low_Breastfeeding_Rates_and_Public_Health_in_the_United_States/links/55d1ca7008ae3dc86a4f2f61.pdf)
2. <http://kellymom.com/fun/trivia/ross-data/>
3. [https://www.cdc.gov/breastfeeding/data/nis\\_data/index.htm](https://www.cdc.gov/breastfeeding/data/nis_data/index.htm)

# Employment Impacts Breastfeeding

- Employment is the norm for U.S. women of childbearing age.
- In 2015, 54% of all mothers with children younger than 12 months were employed, and 73% of those employed worked full-time
- Employed women currently are less likely to initiate breastfeeding, and they tend to breastfeed for a shorter length of time than women who are not employed.

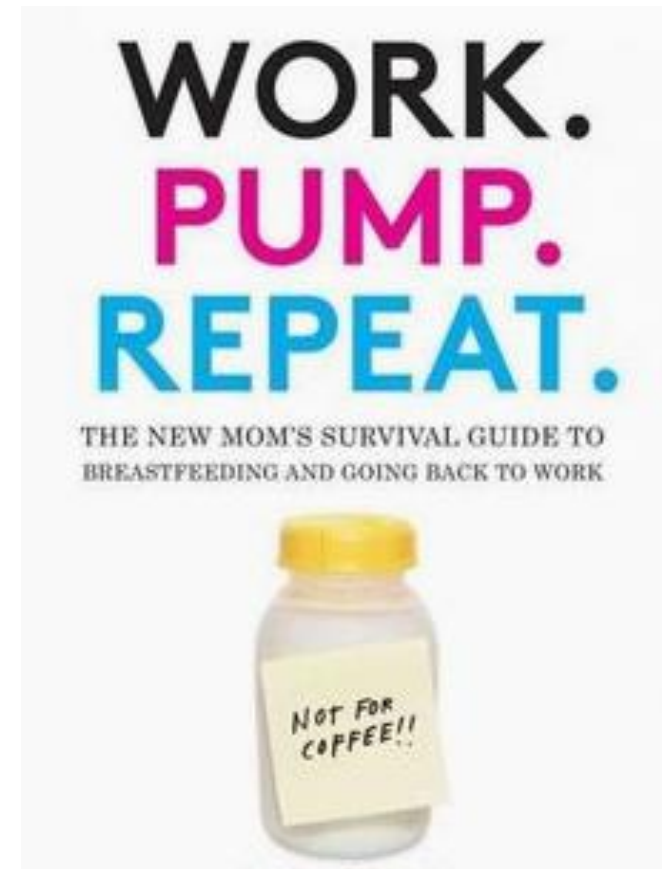


Photo credit: <https://wallethub.com/edu/best-states-for-working-moms/3565/>

<https://www.cdc.gov/breastfeeding/promotion/employment.htm>

# Why Working Moms Need Pumps

- The 1993 Family and Medical Leave Act guarantees only twelve weeks of (unpaid) maternity
- To follow the American Association of Pediatrician's Guidelines to nurse the first year of life, a woman who returns to work twelve weeks after childbirth has to find a way to feed her baby her own milk for another nine months
- Our nation suffers, in short, from a Human Milk Gap.
- There are three ways to bridge that gap: longer maternity leaves, on-site infant child care, and pumps.



# Working moms need a pump & A place to pump

<http://www.dailymail.co.uk/femail/article-2628142/Would-eat-toilet-Powerful-new-ad-series-shows-nursing-mothers-confined-bathroom-stalls-bid-break-taboo-public-breastfeeding.html>

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Behind closed doors: A new ad series shows mothers feeding their babies in bathroom stalls in bid to change negative attitudes towards breastfeeding in public

**WIB**  
Women In Bio



# Healthcare Reform Helped BFing

The ACA included a singular clause that is specific to breastfeeding and covers:

- lactation support and counseling, such as lactation education and consulting services;
- equipment and supplies, such as pumps;
- infrastructure, such as pump rooms and break time



[https://www.washingtonpost.com/news/parenting/wp/2017/01/24/what-does-the-aca-have-to-do-with-breastfeeding-a-lot-but-more-is-needed-not-less/?utm\\_term=.f8eee7a4c530](https://www.washingtonpost.com/news/parenting/wp/2017/01/24/what-does-the-aca-have-to-do-with-breastfeeding-a-lot-but-more-is-needed-not-less/?utm_term=.f8eee7a4c530)

But  
working  
moms still  
have  
barriers to  
pumping

**Table 7.11. Percent of mothers who experienced each problem combining breastfeeding and work by infant age<sup>1, 2</sup>, among mothers who breastfed and worked during the past 4 weeks**

Infant Feeding Practices Study II

	Month 3	Month 6	Month 9	Month 12
A coworker made negative comments or complained to me about breastfeeding	4.3	3.3	3.6	3.9
My employer or my supervisor made negative comments or complained to me	1.6	3.0	1.8	2.2
It was hard for me to arrange break time for breastfeeding or pumping milk	30.2	31.6	29.6	21.0
It was hard for me to find a place to breastfeed or pump milk	19.5	16.8	18.2	11.0
It was hard for me to arrange a place to store pumped breast milk	5.5	3.7	5.4	4.4
It was hard for me to carry the equipment I needed to pump milk at work	10.1	6.8	5.1	4.4
I felt worried about keeping my job because of breastfeeding	4.1	2.6	3.0	1.8
I felt worried about continuing to breastfeed because of my job	17.7	14.0	9.6	8.4
I felt embarrassed among coworkers, my supervisor, or my employer because of breastfeeding	8.2	4.4	5.1	4.0
N	515	429	337	228

<sup>1</sup> Table is based on variables: M3H15A-I, M6H21A-I, M9H22A-I, MWH21A-I

<sup>2</sup> Column percentages do not add up to 100% because mothers could choose all that apply

# Practice falls short of healthcare policy

In 2009, the Society for Human Resource Management reported that only 25 percent of companies surveyed had lactation programs or made special accommodations for breastfeeding

www.shrm.org/  
Research/SurveyFindings/  
Articles/Documents/09-  
0295\_  
Employee\_Benefits\_Surve  
y\_Report\_spread\_fnl.pdf.  
Accessed July 21, 2010.

**Table 7.9. Percent of mothers indicating each level of breastfeeding support from their place of employment<sup>1</sup>, among mothers who worked during the past 4 weeks**

**Infant Feeding Practices Study II**

	<b>Month 3</b>	<b>Month 6</b>	<b>Month 9</b>	<b>Month 12</b>
Not at all supportive	8.0	8.0	10.0	8.6
Not too supportive	11.3	12.3	10.5	12.5
Somewhat supportive	30.6	31.9	31.3	32.4
Very supportive	50.1	47.8	48.2	46.6
Total (%)	100	100	100	100
N	902	927	913	865

<sup>1</sup> Table is based on variables: M3H12, M6H18, M9H19, MWH18

[https://www.cdc.gov/ifps/pdfs/data/ifps2\\_tables\\_ch7.pdf](https://www.cdc.gov/ifps/pdfs/data/ifps2_tables_ch7.pdf)

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# Breast pump Product Classification

- Product Classification
- Regulation Description Powered breast pump
- Review Panel Obstetrics/Gynecology
- Product Code HGX
- Premarket Review Office of Device Evaluation (ODE)
- Submission Type 510(k)
- Regulation Number 884.5160
- Device Class 2
- Total Product Life Cycle (TPLC) TPLC Product Code Report
- GMP Exempt? No
- Implanted Device? No
- Life-Sustain/Support Device? No



# Recent innovation

Benefit	Feature
Efficacy	“More power”, presumably greater levels of negative pressure
	Customizable settings – suction & cycles
Convenience	Integrated milk coolers – avoids the company frig
	Operates hands-free, one-handed, or under your shirt
	Battery and vehicle lighter power
	Nightlights to minimize sleep disruption for the family
	Lightweight
	Quiet operation – hydraulic instead of diaphragm or piston operation
	Integrated collection/feeding systems with one single pouch to pump, store, warm, and feed including milk warming options
Smart Pump/Apps	Technology that records the date, time, and duration of each session
Comfort	Flange enhancements like silicone-hugging to the skin for comfort & leakage

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**"If we have seen further, it is by standing on the shoulders of giants"**

**~Sir Isaac Newton**

# How to Help

- Roles in innovation
- Lactation support in the workplace



**Investing in Workplace  
Breastfeeding Programs and Policies**

<https://www.businessgrouphealth.org/pub/f2ffe4f0-2354-d714-5136-79a21e9327ed>



# How to Help

- Societal
  - Participate in community and peer programs
  - Encourage child care centers to support lactation
  - Assist in breastfeeding awareness education
  - Support families in their feeding choices
- Health Policy
  - WIC breastfeeding support for disadvantaged women
  - Support the lactation provision of the Affordable Care Act
    - Provision 207 coverage for pumps, lactation services & pumping time/space at work

# Help Working Moms Who Breast Pump! - Keep Provision 207 in Affordable Care Act



Priya Nembhard New York, NY

## Sign this petition

14,403 supporters

597 needed to reach 15,000

<https://www.change.org/p/help-working-moms-who-breast-pump-keep-provision-207-in-affordable-care-act>



# Thank you!

**Debra Kurtz**

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