







Disclosures

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-no relevant financial or non-financial disclosures

Learning Objectives

- 1. Define the importance of breastmilk.
- 2. Summarize how breastmilk is regulated.
- 3. List the risks of improper breastmilk testing.



Human Milk Versus Bovine (Cow) Milk

- Bovine Milk is the perfect food for baby calves.
- Human Milk is the perfect food for human babies.
- Historically, milk from other species caused problems with infants.
 - Modern formulas may mimic the protein, sugar content, casein and whey but cannot match the nutritional quality or immune boosting potential of human milk
 - Most every baby deserves the advantages of human milk



like blood, plasma and other biologics, nature's perfect food is not without risk

The Composition of BREAST MILK

Made for Babies

90% water

10% solids

lactose

protein

fat

vitamins

minerals

enzymes

antibodies

growth factors

probiotics

colostrum

Breast Milk is Living Tissue

200+ components

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Safety from donation, through direct testing of raw and processed milk

Donor Selection Procedure
Donor Screening - Written health screen - Educational material provided
Serological Blood Test HBV-1 & 2, HTLV-I & II, HBV, HCV, and syphilis
Healthcare Professional Medical Release Forms - Donor - Infants
Donor Identification Test DNA profile created when donor applies
Donor Freezer Qualification To determine adequate storage temperature
Donated Raw Milk Is...
Tested for adulteration, nicotine, and drugs of abuse
DNA matched for assured donor identification
Tested using nucleic acid testing for HIV- 1 & 2, HTLV-I & II, HBV, HCV, Syphilis, and ZIKV
Processed Milk Is...
Screened for aerobic count, <i>B. cereus</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas</i> , <i>coliforms</i> , <i>S. aureus</i> , yeast, and mold
Nutritionally standardized to 20 Cal./fl. oz.

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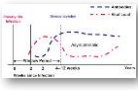
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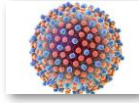
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Why the distinction between Screening and Testing is so important?



Seroconversion



Newly acquired Infections



Harmful chemicals

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"Do you smoke?"

- o All Donor screened via questionnaire for tobacco use
 - o 1 in 5 breastfeeding mothers returned to smoking by 8 weeks post partum¹
 - o 2 in 5 relapsed by 26 weeks¹

And whether a donor is compensated for her donation has NO influence on positivity rates

Test	Non-Paid Donors (n=1537)	Paid Donors (n=4324)	p-Value (Fisher's Exact Test)
Cotinine (Nicotine)	9 (0.59%)	26 (0.60%)	1.0

¹Kendzor DE, et al. (2010) Breast feeding is associated with post partum smoking abstinence among women who quit smoking due to pregnancy. Nicotine Tob Res. Oct 2010; 12(10):983-988

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But pasteurization kills everything anyway, right?

Holder Method of Pasteurization



Used in Albumin production

Incredibly high oversight due to myriad potential fail points

No central guidance as in the FDA's Pasteurized Milk Ordinance (PMO)

Vat Pasteurization



Used in the dairy industry

Detailed guidance on proper performance provided in PMO

Retort processing



Used most commonly in food canning industry

Effective in sterilizing milk, while also destroying any remaining bioavailability

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Which is the best approach? How as Leaders can you Advocate beyond the bedside?



Regulators should have oversight of biological material being fed to preterm infants, just as with any other "medicine". Support legislation at the state and federal level that calls for it.

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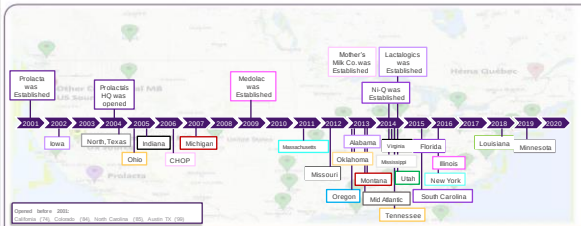
As front-line Advocates, ask questions of all manufacturers. Put them to the test:



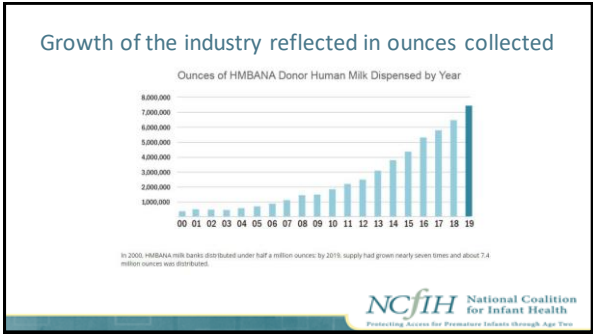
What clinical trials have been conducted in premature infants?
How do they screen donors and test milk?
Do they test milk for drugs and adulterants including THC and Nicotine?
What type of pasteurization is used?
If actual significance, what bioavailability of the fats and proteins are left?
And if that process is used how are heat-resistant THC and enterotoxins addressed?
What does the data say about homogenization and the impact on the bioavailability of fat globules.

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Timeline of the Growth of the Human Milk Industry



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Absence of Basic Safety Standards Poses a Life-and-Death Risk Our Most Vulnerable Citizens

- Human milk can - and does - transmit viruses, bacteria and adulterants
 - Just like blood & plasma
- There are no mandatory safety measures that govern donor human milk
 - Screening isn't Testing
- Variety of Donor Milk Banks Operate in State & Growing
 - Increase of new organizations becoming operational and selling their milk to hospitals across the country
 - Unknown and Undisclosed Process

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