

Ruthanne Fuller Mayor

City of Newton, Massachusetts

Office of the Mayor

#101-23 Telephone (617) 796-1100 Fax (617) 796-1113 TDD/TTY (617) 796-1089 Email rfuller@newtonma.gov

March 13, 2023

Honorable City Council Newton City Hall 1000 Commonwealth Avenue Newton, MA 02459

To the Honorable City Councilors:

I am pleased to appoint Harry Meade of 62 Grasmere Street, Newton 02458 as a member of the Biosafety Committee. His term of office shall expire on April 18, 2025 and his appointment is subject to your confirmation.

The Biosafety Committee members have three year terms staggered over the three year period. Mr. Meade will be serving the term expiring April 18, 2025.

Thank you for your attention to this matter.

Warmly,

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Ruthanne Fuller Mayor

Newton, MA Boards & Commissions

Application Form

#101-23 Submit Date: Jan 13, 2023

Harry	М	Meade		
irst Name	Middle Initial	Last Name		
armeade@mac.com				
mail Address				
32 Grasmere St.				
lome Address			Suite or Apt	18.0-99-909-909-909-900-91-91-9-909-900-900
Newton			MA	02458
lity			State	Postal Code
What Ward do you live in?	hat Ward do you live in?			
✓ Ward 1				
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Interests & Experiences

Please tell us about yourself and why you want to serve.

Why are you interested in serving on a board or commission?

Contribute to the community

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'Upload a Resume

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Harry Melvin Meade

eRA COMMONS USER NAME (agency login): hmmeade

POSITION TITLE: Chief Scientific Officer IGABIO LLC

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Union College, Schenectady, NY	BS BSEE	06/1969	Chemistry Electrical Engineering
Massachusetts Institute of Technology Cambridge MA	Ph.D.	06/1977	Biology bacterial genetics
Harvard University, Cambridge MA	Postdoctoral Fellow	09/1978	Bacterial genetics

A. Personal Statement

My career has been dedicated to applied research. To this end I have championed the efficient production of pharmaceuticals in the milk of dairy animals. I began this at Biogen in the mid-80s, carried it to Genzyme and was part of the spin-out of Genzyme Transgenics Corp. (GTC) in 1992. This company was acquired by LFB of Paris France in 2010. Throughout this time I have directed the Research programs. This has led to the Regulatory approval of two products, recombinant ATIII, (ATryn) and FVIIa, (Sevenfact).

We produced recombinant proteins under contract, resulting in over a dozen Mabs being produced in transgenic goats at levels of up to 40g/L. Several Biosimilar programs are still under development. The efficient production has also led to programs to prevent viral and bacterial pathogens. To this end, I have set up collaborations with Dr. Lisa Cavacini, (MassBiologics, UMASS Medical, Boston MA) and Dr. Nicolas Mantis, Wadsworth Lab. Albany NY). IgA antibodies were produced in milk that are active toward HIV and Cholera Toxin.

In order to mature the milk production platform, several areas were improved. These include chromosome insulator sequences that provide position independent expression of transgenes and the use of sugar transferases to improve the glycosylation of proteins expressed in the mammary gland. In addition we initiated a cloning program to improve the efficiency of obtaining transgenic founders.

This could be considered a disruptive technology (TED talk, Medicines in Milk <u>https://www.youtube.com/watch?v=aH_SvupfkgU</u>) that continues to progress. Throughout this time I have maintained a personable management style, resulting in loyal, committed lab members.

B. Positions and Honors

- 2020 present Founder and CSO IGABIO LLC
- 2013 2019 Senior VP R&D rEVO Biologics, (LFB-USA), Framingham MA
- 2002 2013 Senior VP Genzyme Transgenics Corp, (GTC), Framingham MA
- 1994 2002 Vice President of Transgenic Research, Genzyme Transgenics Corp.
- 1990 1993 Scientific Fellow, Genzyme, Framingham MA,

- 1981 1990 Scientist and later Senior Scientist at Biogen, Inc. Cambridge MA.
- 1979 1981 Senior Scientist in Development Department, Merck & Co, Rahway, NJ
- 1977 1979 Post doc--Cellular and Development Biology at Harvard University, Cambridge, MA

C. Contributions to Science

2013 – 2019 Senior VP, R&D LFB-USA

1993 – 2013 Senior VP, Research, GTC Biotherapeutics

Production of recombinant proteins in milk

First to demonstrate high level expression of recombinant protein in milk of a transgenic animal Received first patent covering expression in milk (1989)

Directed Research for a company dedicated to the production of recombinant proteins in milk. Improved expression vectors for milk production system.

Modified the mammary gland for expression of glycosylated products.

Initiated Biosimilar programs in the milk production system resulting in expression of versions of Humira, Herceptin, and Erbitux at levels of 20-40g/L

Carried out contract research to produce recombinant proteins in milk of mice, rabbits, cows and goats. Oversaw production of over 100 different proteins in the milk of these transgenic animals. Team member that obtained EMA and FDA approval of first recombinant protein, antithrombin, (ATryn), produced by transgenic animals, (2006, 2009),

A second protein, FVIIa, (Sevenfact) was approved in 2020.

a. Pollock DP, Kutzko JP, Birck-Wilson E, Williams JL, Echelard Y, and <u>Meade HM</u>. Transgenic milk as a method for the production of recombinant antibodies. J Immunol Methods, *231*: 147-57, 1999.
b. Echelard Y, Williams JL, Destrempes MM, Koster JA, Overton SA, Pollock DP, Rapiejko KT, Behboodi E, Masiello NC, Gavin WG, Pommer J, Van Patten SM, Faber DC, Cibelli JB, Meade HM Production of recombinant albumin by a herd of cloned transgenic cattle. Transsgenic Res. 18:361-76, 2009

c. Bertolini, L. R., H. Meade, C. R. Lazzarotto, L. T. Martins, K. C. Tavares, M. Bertolini and J. D. Murray (2016). "The transgenic animal platform for biopharmaceutical production." Transgenic Res 25(3): 329-343. http://www.ncbi.nlm.nih.gov/pubmed/26820414

d. Laible G, Cole S, Brophy B, Maclean P, How Chen L, Pollock DP, Cavacini L, Fournier N, De Romeuf C, Masiello NC, Gavin WG, Wells DN, Meade HM. Transgenic goats producing an improved version of cetuximab in milk. FASEB Bioadv. 2020 Aug 30;2(11):638-652. doi: 10.1096/fba.2020-00059. PMID: 33205005; PMCID: PMC7655094.

2. Anti pathogen and passive immunotherapy

Initiated programs to utilize antiviral moieties to treat viral infections.

Utilized CD4 for anti HIV treatment, both as an IgG and toxin fusion protein. Pro542 and CD4-Exo Produced anti malaria vaccine, using novel modified sequence, that was active in a monkey model Produced IgA antibodies in milk to control HIV and Cholera infection as a passive immunotherapy. Initiated a program to produce an IgA directed toward gram-negative bacteria to use as an oral treatment to prevent NEC, necrotizing enterocolitis, in preterm infants, (current grant application).

a. Tsubota H, G Winkler, <u>H M Meade</u>, A Jakubowski, D W Thomas, N L Letvin, CD4-Pseudomonas exotoxin conjugates delay but do not fully inhibit human immunodeficiency virus replication in lymphocytes in vitro, J Clin Invest. 1990 Nov;86(5):1684-9. doi: 10.1172/JCI114892.PMID: 2243139
b. Stowers AW, Chen Lh LH, Zhang Y, Kennedy MC, Zou L, Lambert L, Rice TJ, Kaslow DC, Saul A, Long CA, <u>Meade HM</u>, and Miller LH. A recombinant vaccine expressed in the milk of transgenic mice protects Aotus monkeys from a lethal challenge with Plasmodium falciparum. Proc Natl Acad Sci U S A, 99: 339-44, 2002.

c. Yu X, Pollock D, Duval M, Lewis C, Joseph K, Meade H, Cavacini L. Neutralization of HIV by milk expressed antibody. J Acquir Immune Defic Syndr. 2013 Jan 1;62(1):10-6. PubMed PMID: <u>23269241</u>
d. Baranova, D., Chen, L., Destrempes, M., Meade, H., & Mantis, N. (2020). Passive Immunity to *Vibrio cholerae* O1 Afforded by a Human Monoclonal IgA1 Antibody Expressed in Milk. *Pathogens and Immunity*, *5*(1), 89-116. doi:<u>http://dx.doi.org/10.20411/pai.v5i1.370</u>.

D. Additional Information: Research Support and/or Scholastic Performance

Publications available NCBI https://www.ncbi.nlm.nih.gov/myncbi/1-Eu6ni-ntz5F/bibliography/public/

- Tsubota H, G Winkler, <u>H M Meade</u>, A Jakubowski, D W Thomas, N L Letvin, CD4-Pseudomonas exotoxin conjugates delay but do not fully inhibit human immunodeficiency virus replication in lymphocytes in vitro, J Clin Invest. 1990 Nov;86(5):1684-9. doi: 10.1172/JCI114892.PMID: 2243139
- 2. <u>Meade H</u>, Gates L, Lacy E, and Lonberg N. Bovine alpha S1-casein gene sequences direct high-level expression of active human urokinase in mouse milk. Biotechnology (N Y), 8: 443-6, 1990.
- DiTullio P, Cheng SH, Marshall J, Gregory RJ, Ebert KM, <u>Meade HM</u>, and Smith AE. Production of cystic fibrosis transmembrane conductance regulator in the milk of transgenic mice. Biotechnology (N Y), 10: 74-7, 1992
- 4. Rybak SM, Hoogenboom HR, <u>Meade HM</u>, Raus JC, Schwartz D, and Youle RJ. Humanization of immunotoxins. Proc Natl Acad Sci U S A, 89: 3165-9, 1992.
- Ebert KM, DiTullio P, Barry CA, Schindler JE, Ayres SL, Smith TE, Pellerin LJ, <u>Meade HM</u>, Denman J, and Roberts B. Induction of human tissue plasminogen activator in the mammary gland of transgenic goats. Biotechnology (N Y), *12*: 699-702, 1994.
- Gutierrez A, <u>Meade HM</u>, Ditullio P, Pollock D, Harvey M, Jimenez-Flores R, Anderson GB, Murray JD, and Medrano JF. Expression of a bovine kappa-CN cDNA in the mammary gland of transgenic mice utilizing a genomic milk protein gene as an expression cassette. Transgenic Res, *5*: 271-9, 1996.
- 7. Gutierrez-Adan A, Maga EA, <u>Meade H</u>, Shoemaker CF, Medrano JF, Anderson GB, and Murray JD. Alterations of the physical characteristics of milk from transgenic mice producing bovine kappa-casein. J Dairy Sci, 79: 791-9, 1996.
- 8. <u>Meade HM</u>. Dairy gene. Sciences (New York), 37: 20-5, 1997.
- Gavin WG, Pollock D, Fell P, Yelton D, Cammuso C, Harrington M, Lewis-Williams J, Midura P, Oliver A, Smith TE, Wilburn B, Echelard Y and <u>Meade H</u>. Expression of the Antibody hBR96-2 in the Milk of Transgenic Mice and Production of hBR96-2 Transgenic Goats. Theriogenology Vol 47, Number 1 214-219 (1997).
- 10. Edmunds T, Van Patten SM, Pollock J, Hanson E, Bernasconi R, Higgins E, Manavalan P, Ziomek C, <u>Meade H</u>, McPherson JM, and Cole ES. Transgenically produced human antithrombin: structural and functional comparison to human plasma-derived antithrombin. Blood, *91*: 4561-71, 1998.
- 11. Young MW, <u>Meade H</u>, Curling JM, Ziomek CA, Harvey M. Production of recombinant antibodies in the milk of transgenic animals. Res Immunol. 1998 Jul-Aug;149(6):609-10.
- 12. Meade HM and Ziomek C. Urine as a substitute for milk? Nat Biotechnol, 16: 21-2, 1998
- 13. Young MW, <u>Meade HM</u>, Curling JM, Ziomek CA, and Harvey M. Production of recombinant antibodies in the milk of transgenic animals. Res Immunol, *14*9: 609-10, 1998.
- 14. Baguisi A, Behboodi E, Melican DT, Pollock JS, Destrempes MM, Cammuso C, Williams JL, Nims SD, Porter CA, Midura P, Palacios MJ, Ayres SL, Denniston RS, Hayes ML, Ziomek CA, <u>Meade HM</u>, Godke RA, Gavin WG, Overstrom EW, and Echelard Y. Production of goats by somatic cell nuclear transfer. Nat Biotechnol, 17: 456-61, 1999.
- 15. Newton DL, Pollock D, DiTullio P, Echelard Y, Harvey M, Wilburn B, Williams J, Hoogenboom HR, Raus JC, <u>Meade HM</u>, and Rybak SM. Antitransferrin receptor antibody-RNase fusion protein expressed in the mammary gland of transgenic mice. J Immunol Methods, *231*: 159-67., 1999.
- 16. Pollock DP, Kutzko JP, Birck-Wilson E, Williams JL, Echelard Y, and <u>Meade HM</u>. Transgenic milk as a method for the production of recombinant antibodies. J Immunol Methods, 231: 147-57, 1999.
- 17. Behboodi E, Groen W, Destrempes MM, Williams JL, Ohlrichs C, Gavin WG, Broek DM, Ziomek CA, Faber DC, <u>Meade HM</u>, and Echelard Y. Transgenic production from in vivo-derived embryos: effect on calf birth weight and sex ratio. Mol Reprod Dev, 60: 27-37, 2001.
- 18. Echelard Y and Meade HM. Toward a new cash cow. Nat Biotechnol, 20: 881-2, 2002.
- 19. Stowers AW, Chen Lh LH, Zhang Y, Kennedy MC, Zou L, Lambert L, Rice TJ, Kaslow DC, Saul A, Long CA, <u>Meade HM</u>, and Miller LH. A recombinant vaccine expressed in the milk of transgenic mice protects

Aotus monkeys from a lethal challenge with Plasmodium falciparum. Proc Natl Acad Sci U S A. 99: 339-44. 2002.

- 20. Echelard Y, Meade, HM. Protein Production in the milk of transgenic animals. In "Gene Transfer and Expression in Mammalian Cells", edited by S. C. Makrides, New Comprehensive Biochemistry Vol. 38, General Edidtor: G. Bernardi. Elsevier BV. 2003
- 21. Behboodi E, Memili E, Melican DT, Destrempes MM, Overton SA, Williams JL, Flanagan PA, Butler RE, Liem H, Chen LH, Meade HM, Gavin WG, Echelard Y. Viable transgenic goats derived from skin cells. Transgenic Res 13:215-224, 2004
- 22. Behboodi E, Ayres SL, Memili E, O'Coin M, Chen LH, Reggio BC, Landry AM, Gavin WG, Meade HM, Godke RA. Echelard Y., Health and reproductive profiles of malaria antigen-producing transgenic goats derived by somatic cell nuclear transfer. Cloning Stem Cells. 7:107-18, 2005.
- 23. Echelard Y, Williams JL, Destrempes MM, Koster JA, Overton SA, Pollock DP, Rapiejko KT, Behboodi E, Masiello NC, Gavin WG, Pommer J, Van Patten SM, Faber DC, Cibelli JB, Meade HM Production of recombinant albumin by a herd of cloned transgenic cattle. Transsgenic Res. 18:361-76, 2009
- 24. Yu X, Pollock D, Duval M, Lewis C, Joseph K, Meade H, Cavacini L. Neutralization of HIV by milk expressed antibody. J Acquir Immune Defic Syndr. 2013 Jan 1;62(1):10-6. . PubMed PMID: 23269241
- 25. Bertolini, L. R., H. Meade, C. R. Lazzarotto, L. T. Martins, K. C. Tavares, M. Bertolini and J. D. Murray (2016). "The transgenic animal platform for biopharmaceutical production." Transgenic Res 25(3): 329-343. http://www.ncbi.nlm.nih.gov/pubmed/26820414
- 26. Baranova, D., Chen, L., Destrempes, M., Meade, H., & Mantis, N. (2020). Passive Immunity to Vibrio cholerae O1 Afforded by a Human Monoclonal IgA1 Antibody Expressed in Milk. Pathogens and Immunity, 5(1), 89-116. doi:http://dx.doi.org/10.20411/pai.v5i1.370
- 27. Gavin W, N Buzzell S Blash L Chen, N Hawkins, K Miner, D Pollock C Porter, D Bonzo, H.Meade, Generation of goats by nuclear transfer: a retrospective analysis of a commercial operation (1998-2010) Transgenic Res. 2020 Jul 1. doi: 10.1007/s11248-020-00207-w. Online ahead of print. PMID: 32613547

Issued Patents

4,873,316 (1989) Isolation of exogenous recombinant proteins from the milk of transgenic mammals 5.168.049 (1992) Production of streptavidin-like polypeptides 5,272,254 (1993) Production of streptavidin-like polypeptides 5,688,677 (1997) Deoxyribonucleic acids containing inactivated hormone responsive elements 5,750,172 (1998) Transgenic non human mammal milk 5,827,690 (1998) Transgenic production of antibodies in milk 5,843,705 (1998) Transgenically produced antithrombin III 5,849,992 (1998) Transgenic production of antibodies in milk 6,441,145 (2002) Transgenically produced Antithrombin III 6,528,699 (2003) Transgenically produced non-secreted proteins 6,548,653 (2003) Erythropoietin analog-human serum albumin fusion. 6.593,463 (2003) Modified MSP-1 nucleic acid sequences and methods for increasing mRNA level 7,019,193 (2006) Treatments using transgenic goat produced antithrombin III 7,101,971 (2006) Erythropoietin analog-human serum albumin fusion 7,354,594 (2008) Merozoite surface protein 1 lacking glycosylation sites 7,501,553 (2009) Non-human transgenic mammal comprising a modified MSP-1 nucleic acid 7,550,263 (2009) Method for the production of fusion proteins in transgenic mammal milk 7,632,980 (2009) Modified nucleic acid sequences and methods for increasing mRNA levels and p 7,928,064 (2011) Transgenically produced antithrombin III 8,173,860 (2012) Non-human transgenic mammal expressing a human FcRn on its mammary gland cells and expressing a transgenic protein-human Fc-domain fusion 10,034,921 (2018) Proteins with modified glycosylation and methods of production thereof 10,174,110 (2019) Highly galactosylated anti-TNF-alpha, antibodies and uses thereof