

Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Karen Midthun, M.D.		
2. Your Title: Director, Center for Biologics Evaluation and Research (CBER) , FDA		
3. The Entity(ies) You are Representing: CBER		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No
	X	
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2013. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. None		
6. Please attach your curriculum vitae to your completed disclosure form. See attached		

Signature: _____



Date: 11-16- 2015

CURRICULUM VITAE

NAME: Karen Midthun, M.D.

Business address: Center for Biologics Evaluation and Research, FDA
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Silver Spring, MD 20993



PROFESSIONAL EXPERIENCE

- 9/2010-present Director, Center for Biologics Evaluation and Research, FDA
- 3/2009-9/2010 Acting Director, Center for Biologics Evaluation and Research, FDA
- 2004-present Deputy Director (Medicine), Center for Biologics Evaluation and Research, FDA
- 2003-2004 Acting Deputy Director (Medicine), Center for Biologics Evaluation and Research, FDA
- 2000-2003 Director, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA
- 1999-2000 Director, Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, Center for Drugs Evaluation and Research, FDA
- 1997-1999 Chief, Clinical Branch, Division of Vaccines and Related Products Applications, Center for Biologics Evaluation and Research, FDA
- 1993 - 1997 Medical Officer, Division of Vaccines and Related Products Applications, Center for Biologics Evaluation and Research, FDA
- 1993 - 1999 Adjunct Assistant Professor, Department of International Health, Johns Hopkins Bloomberg School of Public Health
- 1987-1993 Assistant Professor, Department of International Health, Johns Hopkins Bloomberg School of Public Health with joint appointment in Department of Medicine, Johns Hopkins University School of Medicine
- 1986-1987 Senior Staff Fellow, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health

EDUCATION AND TRAINING

- | | |
|---------------|--|
| 1975 | B.S., Biology, Massachusetts Institute of Technology |
| 1979 | M.D., George Washington University School of Medicine |
| 1979-1982 | Internship and Residency, Johns Hopkins Hospital, Internal Medicine |
| 1982-1985 | Medical Staff Fellow, Laboratory of Infectious Diseases, National Institutes of Allergy and Infectious Diseases, NIH |
| 1985-1986 | Clinical Fellow, Division of Infectious Diseases, Johns Hopkins Hospital |
| 1982- present | Maryland Medical License, active |
| 1982 | Diplomate in the Specialty of Internal Medicine, American Board of Internal Medicine |
| 1986 | Diplomate in the Subspecialty of Infectious Diseases, American Board of Internal Medicine |

PROFESSIONAL ACTIVITIES

Society membership

Alpha Omega Alpha
American College of Physicians
Infectious Diseases Society of America (fellow)

EDITORIAL ACTIVITIES

Ad hoc reviews of manuscripts submitted for publication to peer-reviewed journals such as Journal of Infectious Diseases and ASM publications.

HONORS AND AWARDS

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|------|--|
| 1977 | Goddard Prize in Pharmacology |
| 1979 | Janet M. Glasgow Award for Outstanding Achievement, American Medical Women's Association; Valedictorian, George Washington University School of Medicine, Class of 1979; Oscar Benwood Hunter Prize in Pathology; John Ordonaux Prize; Alpha Omega Alpha |
| 1989 | Burroughs Wellcome Young Investigators Award in Virology of the Infectious Diseases Society of America. |

- 1996 FDA Commendable Service Award, "for exceptional performance in the review of vaccine trial design and clinical data." (5/10/96)
- 1997 FDA Group Recognition Award as a member of the Supplemental Indications Task Group, "for exceptional effort and coordination in developing documents which enable timely flow of accurate information on new uses of human drugs and biological products." (5/9/97)
- 1997 FDA Group Recognition Award as a member of the COMVAX Licensure Group, "for outstanding performance in conducting the review, lot release, and licensure of COMVAX, an important new combination vaccine."
- 1998 FDA Award of Merit as a member of the Certiva Licensing Group, "for critical and careful review of the acellular pertussis vaccine Certiva for immunization of infants and young children, an important public health measure."
- 1999 FDA Award of Merit as a member of the LYMERix Licensing Group, "for exceptional review of complex manufacturing and clinical data supporting the safety and efficacy of LYMERix, culminating in licensure of the first vaccine to prevent Lyme disease."
- 2001 FDA Award of Merit as a member of the Prevnar Licensure Group, "for exceptional review of manufacturing and clinical data supporting licensure of Prevnar, the first vaccine for prevention of invasive pneumococcal disease in infants and toddlers."
- 2001 FDA Group Recognition Award as a member of the Influenza Virus Vaccine Working Group, "for helping avert a major influenza vaccine shortage and helping PHS agencies, health practitioners, and the general public cope with delayed availability."
- 2003 Center Director's Distinguished Service Award as a member of the Acambis Working Group, "in recognition of efforts to address product development and regulatory issues in a timely manner for the smallpox vaccine manufactured by Acambis, Incorporated."
- 2004 FDA Scientific Achievement Award as a member of the HIV/AIDS Therapeutic Vaccine Review Group, "for exceptional performance reviewing the first phase 3 clinical trial of a therapeutic vaccine designed to prevent progression to AIDS."
- 2004 FDA Award of Merit as a member of the Defense Team for St. Louis University Litigation, "for exceptional performance in response to litigation filed by St. Louis University."
- 2004 FDA Outstanding Service Award as a member of the CBER COOP Development Team, "for outstanding effort in establishing a Continuity

of Operations (COOP) Plan for the Center of Biologics Evaluation and Research.”

- 2005 U.S. DHHS Secretary’s Award for Distinguished Service “for extraordinary efforts to protect the nation’s influenza high-risk population through innovative vaccine acquisition strategies during the 2004-2005 influenza season vaccine shortage.”
- 2005 FDA Award of Merit as a member of the Flu Vaccine Shortage Response Team, “for rapid, innovative responses to a sudden, unexpected shortage of influenza virus vaccine.”
- 2005 FDA Group Recognition Award as a member of the Emergency Use Authorization Review Group, “for exceptional and rapid review of the first Emergency Use Authorization request under the Project BioShield Act of 2004.”
- 2005 FDA Leveraging/Collaboration Award as a member of the European Commission and the European Medicines Evaluation Agency Bilateral Team, “for outstanding commitment to collaboration between FDA and EC/EMA to address public health challenges and further public health goals related to human and veterinary medical products.”
- 2005 FDA Group Recognition Award as a member of the Litigation Document Production Team, “for exceptional, sustained performance regarding complex, voluminous document production request in litigation involving multiple vaccine application files.”
- 2006 U.S. DHHS Secretary’s Award for Distinguished Service “for exceptional expedited review of a new influenza vaccine and remediation of manufacturing problems, leading to a substantial increase in the U.S. vaccine supply.”
- 2006 FDA Group Recognition Award as a member of the Emergency Use Authorization Guidance Team, “for outstanding contribution to the Nation’s counterterrorism preparedness by developing draft guidance for Emergency Use Authorizations of medical products.”
- 2006 FDA Commissioner’s Special Citation as a member of the FDA Hurricanes Katrina/Rita Response Team, “for outstanding service in assisting the State, the FDA/FEMA mission assignments and FDA’s responsibilities in response to the devastation and adverse working conditions as a results of Hurricanes Katrina and Rita.”
- 2006 FDA Commissioner’s Special Citation as a member of the Anthrax Vaccine Final Order Working Group, “for exceptional dedication, expertise, and performance in finalizing and publishing the Efficacy Review for Bacterial Vaccines and Toxoids Order covering anthrax vaccine adsorbed.”
- 2006 FDA Award of Merit “for exceptional outstanding leadership and

accomplishments in successfully meeting urgent public health priorities and assuring our nation's preparedness."

- 2007 FDA Group Recognition Award "for outstanding leadership of the Emergency Use Authorization final guidance working group."
- 2007 FDA Commissioner's Special Citation "for outstanding leadership in developing the FDA Pandemic Influenza Preparedness Strategic Plan."
- 2007 FDA Award of Merit as a member of the Gannon vs. the United States group "for excellence in researching 50 years of documents to respond to multiple complex court ordered requests and assistance in trial preparation regarding oral polio vaccine."
- 2007 Center Director's Public Health Achievement Award as a member of the Influenza Virus Vaccine Manufacturing Remediation Team
- 2009 FDA Commissioner's Special Citation as a member of the Mercury-Based Preservatives Response Group "for exceptional performance and leadership in carrying out FDA's missions to ensure the safety of vaccines and other drug products."
- 2009 FDA Group Recognition Award as a member of the WHO Vaccine Prequalification Working Group "for contributions to global public health by developing the operational framework for FDA to provide regulatory oversight for certain vaccines through the WHO prequalification program."
- 2009 FDA Group Recognition Award as a member of the FDA representatives to the DHHS Enterprise Executive Committee "for support of the Public Health Emergency Medical Countermeasures Enterprise."
- 2009 FDA Commissioner's Special Citation as a member of the Foreign/International Implementation Team
- 2009 FDA Group Recognition Award as a member of the Laboratory Quality Systems Group
- 2009 FDA Leveraging Collaboration Award as a member of the Direct Export Request Team

FDA PRESENTATIONS

"Update on Cholera Vaccines," FDA Vaccines and Related Biological Products Advisory Committee, November 18, 1994, Gaithersburg, MD.

"FDA Perspective on Viral Burden Study of HIV-Immunogen" (in HIV-1 infected

subjects), FDA Vaccines and Related Biological Products Advisory Committee, January 26, 1995, Bethesda, MD.

"FDA Perspective on Dose-Ranging Study of HIV-Immunogen" (in HIV-1 infected subjects), FDA Vaccines and Related Biological Products Advisory Committee, January 26, 1995, Bethesda, MD.

"Clinical issues regarding AMVAX DTaP Product License Application," FDA Vaccines and Related Biological Products Advisory Committee, October 29, 1996, Bethesda, MD.

"Safety assessment of combination vaccines," presented at conference entitled "Preclinical and Clinical Development of New Vaccines" (sponsored by International Association of Biological Standardization at the Institut Pasteur), May 27-30, 1997, Paris, France.

"Correlates of Immunity: a regulatory perspective," presented at The First Annual Conference on Vaccine Research, Washington, D.C., May 30-June 1, 1998.

"FDA perspective: clinical and scientific basis for product labeling: consideration and implications for the recommending bodies," presented at Pediatric Vaccine Forum '98: Optimizing Education, Communication, and Choices. Carmel, California, August 19-21, 1998.

"Combination vaccines: a regulatory perspective," presented at the Second Annual Conference in Vaccinology, Annecy, France, May 29, 2001.

"Adenovirus-vectored vaccine candidates," presented at the Recombinant DNA Advisory Committee (RAC), NIH, Bethesda, MD, June 2001.

"RAC reconsideration of exemption of vaccines from RAC review," presented at the RAC, NIH, Bethesda, MD, November 2001.

"Vaccine development and licensure: an FDA perspective," presented as part of a course sponsored by the Johns Hopkins School of Public Health in vaccine development, Baltimore, MD, December 2001.

"Regulatory issues for new smallpox vaccines," presented at a PAHO-sponsored meeting on smallpox, PAHO, Washington, DC, December 2001.

"Vaccine approval process and counter-terrorism vaccine," presented at the National Health Policy Forum, Atlanta, Georgia, April 2002.

"Markers of protection against smallpox" and "Smallpox vaccines and cell substrate issues," presented at a WHO consultation for revising smallpox vaccine requirements, WHO, Geneva, Switzerland, May 2002.

"Assessing vaccine safety in pre-licensure clinical trials: a regulatory perspective," presented at The Fifth Annual Conference on Vaccine Research, Baltimore, MD, May 2002.

"Combination vaccines: a regulatory perspective," presented at the Third Annual

Conference in Vaccinology, Annecy, France, June 2002.

“Regulatory requirements for historical and new smallpox vaccines: review of U.S. regulation,” presented at the G7+ Workshop on smallpox, Langen, Germany, September 2002.

“Regulatory processes: impact on vaccine supply,” presented at a Sabin Vaccine Institute sponsored meeting on the vaccine supply, Cold Spring Harbor, New York, October 2002.

“Workshop on non-clinical safety evaluation of preventive vaccines: recent advances and regulatory considerations,” presented at “Workshop on non-clinical safety evaluation of preventive vaccines,” co-sponsored by CBER, the Society of Toxicology, and the FDA’s Office of Women’s Health, Arlington, VA, December 2002.

“SARS vaccine development: an FDA perspective,” presented at the NIH-sponsored meeting on SARS research, Bethesda, MD, May 2003.

“Combination vaccines: a regulatory perspective,” presented at the Fourth Annual Conference in Vaccinology, Annecy, France, June 2003.

“Workshop on the development of a clinical trial plan for pandemic influenza vaccines: regulatory considerations,” presented at the NIAID-sponsored “Workshop on the development of a clinical trial plan for pandemic influenza vaccines,” Rockville, MD, September 2003.

“Biological and chemical threats: FDA’s public health challenge,” presented at the Annual Conference of the American National Standards Institute, Washington, DC, October 2003.

“CBER’s Role in the Regulation of Products Relevant to HIV,” presented at FDA HIV/AIDS Advocates Meeting, Rockville, MD, November 14, 2003.

“CBER: Product Development Challenges for the 21st Century,” presented at the Tenth Biopharmaceutical Applied Statistics Symposium, Savannah, Georgia, December 10, 2003.

“Regulatory Considerations: How Can Vaccine Development Be Accelerated?”, presented at the IOM’s Board on Global Health Forum on Microbial Threats, Washington, DC, February 17, 2004.

“Thimerosal as a Preservative in Vaccines: An FDA Perspective,” presented at EPA/HHS sponsored workshop on “Mercury: Medical and Public Health Issues,” Tampa, FL, April 30, 2004.

“Combination vaccines: a regulatory perspective,” presented at the Fifth Annual Conference in Vaccinology, Annecy, France, May 2004.

“CBER Update,” presented at the 40th DIA Annual Meeting, Washington, DC, June 15, 2004.

“CBER Update: Selected Accomplishments and Major Initiatives,” presented at the Biowest Conference, Denver, Colorado, October 27, 2004.

“Vaccine development and licensure: an FDA perspective,” presented as part of a course on vaccine development at the Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, December 2004.

“Expediting the development, availability, and approval of medical products for counterterrorism,” presented at the Regulatory Affairs Professional Society Annual Conference, Baltimore, MD, October 17, 2005.

“Ensuring a robust U.S. vaccine industry: an FDA perspective,” presented at the BIO2005 Annual International Convention, Philadelphia, PA, June 20, 2005.

“Expediting the development, availability, and approval of medical products for counterterrorism,” presented at the BIO2005 Annual International Convention, Philadelphia, PA, June 20, 2005.

“An FDA Perspective: Facilitating development of new vaccines and cell and gene therapies,” presented at the Phacilitate Cell and Gene Therapies and Vaccines Forum, Baltimore, MD, January 2006.

“CBER Update,” presented at the Food and Drug Law Institute 49th Annual Conference, Washington, DC, April 2006.

“CBER Update 2006,” presented at the BIO2006 Annual International Convention, Chicago, IL, April 2006.

“Vaccine Regulation: FDA’s Role in Facilitating Development of and Access to New Vaccines,” presented at the World Vaccine Congress, Washington, D.C., March 2007.

“CBER Update and Priorities 2007,” presented at National Blood Foundation Leadership forum, San Francisco, CA, April 2007.

CONGRESSIONAL TESTIMONY

FDA witness to Rep. Burton’s hearings on vaccines and autism, Committee on Government Reform, U.S. House of Representatives, April 2001 and December 2002.

FDA EX-OFFICIO MEMBER

To the CDC’s Advisory Committee for Immunization Practices (2000-2003)

To the National Vaccine Program Office’s National Vaccine Advisory Committee (2000-2003)

PUBLICATIONS

Journal articles, peer reviewed:

1. Macaluso A, Midthun K, Bender R, Botstein D. Nonsense suppressor mutants of bacteriophage T5. *Virology* 117:275-279, 1982.
2. Greenberg H, Valdesuso J, van Wyke K, Midthun K, Walsh M, McAuliffe V, Wyatt R, Kalica A, Flores J, Hoshino Y. Production and preliminary characterization of monoclonal antibodies directed at two surface proteins of rhesus rotavirus. *J Virol* 47:267-275, 1983.
3. Midthun K, Greenberg HB, Hoshino Y, Kapikian AZ, Wyatt RG, Chanock RM. Reassortant rotaviruses as potential live rotavirus vaccine candidates. *J Virol* 53:949-954, 1985.
4. Hoshino Y, Wyatt RG, Flores J, Midthun K, Kapikian AZ. Serotypic characterization of rotaviruses derived from asymptomatic human neonatal infections. *J Clin Microbiol* 21:425-430, 1985.
5. Flores J, Perez-Schael I, Boeggeman E, White L, Perez M, Purcell R, Hoshino Y, Midthun K, Chanock RM, Kapikian AZ. Genetic relatedness among human rotaviruses. *J Med Virol* 17:135-143, 1985.
6. Hoshino Y, Sereno MM, Midthun K, Flores J, Kapikian AZ, Chanock RM. Independent segregation of two antigenic specificities (VP3 and VP7) involved in neutralization of rotavirus infectivity. *Proc Natl Acad Sci USA* 82:8701-8704, 1985.
7. Flores J, Midthun K, Hoshino Y, Green K, Gorziglia M, Kapikian AZ, Chanock RM. Conservation of the fourth gene among rotaviruses recovered from asymptomatic newborn infants and its possible role in attenuation. *J Virol* 60:972-979, 1986.
8. Kapikian AZ, Flores J, Hoshino Y, Glass RI, Midthun K, Gorziglia M, Chanock RM. Rotavirus. The major etiologic agent of severe infantile diarrhea may be controllable by a "Jennerian" approach to vaccination. *J Infect Dis* 153:815-822, 1986.
9. Losonsky GA, Rennels MB, Kapikian AZ, Midthun K, Ferra PJ, Fortier DN, Hoffman KM, Baig A, Levine MM. Safety, infectivity, transmissibility and immunogenicity of rhesus rotavirus vaccine (MMU 18006) in infants. *Pediatr Infect Dis* 5:25-29, 1986.
10. Midthun K, Hoshino Y, Kapikian AZ, Chanock RM. Single gene substitution rotavirus reassortants containing the major neutralization protein (VP7) of human rotavirus serotype 4. *J Clin Microbiol* 24:822-826, 1986.
11. Hoshino Y, Sereno MM, Midthun K, Flores J, Chanock RM, Kapikian AZ. Analysis by plaque reduction neutralization assay of intertypic rotaviruses suggests that gene reassortment occurs *in vivo*. *J Clin Microbiol* 25:290-294, 1987.
12. Midthun K, Valdesuso J, Hoshino Y, Flores J, Kapikian AZ, Chanock RM. Analysis by RNA-RNA hybridization assay of intertypic rotaviruses suggests that gene reassortment occurs *in vivo*. *J Clin Microbiol* 25:295-300, 1987.
13. Midthun K, Flores J, Taniguchi K, Urasawa S, Kapikian AZ, Chanock RM. Genetic relatedness among human rotavirus genes coding for VP7, a major neutralization

- protein, and its application to serotype identification. *J Clin Microbiol* 25:1269-1274, 1987.
14. Green KY, Midthun K, Gorziglia M, Hoshino Y, Kapikian AZ, Chanock RM, Flores J. Comparison of the amino acid sequences of the major neutralization protein of four human rotavirus serotypes. *Virology* 161:153-159, 1987.
 15. Green KY, Sears JF, Taniguchi K, Midthun K, Hoshino Y, Gorziglia M, Nishikawa K, Urasawa S, Kapikian AZ, Chanock RM, Flores J. Prediction of human rotavirus serotype by nucleotide sequence analysis of the VP7 protein gene. *J Virol* 62:1819-1823, 1988.
 16. Friedman MG, Galil A, Sarov B, Margalith M, Katzir G, Midthun K, Taniguchi K, Urasawa S, Kapikian AZ, Edelman R, Sarov I. Two sequential outbreaks of rotavirus gastroenteritis: evidence of symptomatic and asymptomatic reinfections. *J Infect Dis* 158:814-822, 1988.
 17. Flores J, Daoud G, Daoud N, Puig M, Martinez M, Perez-Schael I, Shaw R, Greenberg HB, Midthun K, Kapikian AZ. Reactogenicity and antigenicity of rhesus rotavirus vaccine (MMU-18006) in newborn infants in Venezuela. *Pediatr Infect Dis J* 7:776-780, 1988.
 18. Halsey NA, Anderson EL, Sears SD, Steinhoff M, Wilson M, Belshe RB, Midthun K, Kapikian AZ, Chanock RM, Samorodin R, Burns B, Clements ML. Human-rhesus reassortant rotavirus vaccines: safety and immunogenicity in adults, infants, and children. *J Infect Dis* 158:1261-1267, 1988.
 19. Flores J, Perez-Schael I, Blanco M, Vilar M, Garcia D, Perez M, Daoud N, Midthun K, Kapikian AZ. Reactions to and antigenicity of two human-rhesus rotavirus reassortant vaccine candidates of serotypes 1 and 2 in Venezuelan infants. *J Clin Microbiol* 27:512-518, 1989.
 20. Kapikian AZ, Flores J, Hoshino Y, Midthun K, Gorziglia M, Green KY, Chanock RM, Potash L, Sears SD, Clements ML, Halsey NA, Black RE, Perez-Schael I. Prospects for development of a rotavirus vaccine against rotavirus diarrhea in infants and young children. *Rev Infect Dis* 11(3):S539-546, 1989.
 21. Midthun K, Valdesuso J, Kapikian AZ, Hoshino Y, Green KY. Identification of serotype 9 human rotavirus by enzyme-linked immunosorbent assay with monoclonal antibodies. *J Clin Microbiol* 27(9):2112-2114, 1989.
 22. Taniguchi K, Nishikawa K, Urasawa T, Urasawa S, Midthun K, Kapikian AZ, Gorziglia M. Complete nucleotide sequence of the gene encoding VP4 of a human rotavirus (strain K8) which has unique VP4 neutralization epitopes. *J Virol* 63(9):4101-4106, 1989.
 23. Midthun K, Pang L, Flores J, Kapikian AZ. Comparison of immunoglobulin A (IgA), IgG, and IgM enzyme-lined immunosorbent assays, plaque reduction neutralization assay, and complement fixation in detecting seroresponses to rotavirus vaccine candidates. *J Clin Microbiol* 27:2799-2804, 1989.

24. Reves RR, Hossain MM, Midthun K, Kapikian AZ, Naguib T, Wyatt RG, Zaki, AM, DuPont HL. An observational study of naturally acquired immunity to rotaviral diarrhea in a cohort of 363 Egyptian children: calculation of risk for second episodes using age-specific person-years of observation. *Am J Epidemiol* 130:981-8, 1989.
25. Midthun K, Garrison L, Clements ML, Farzadegan H, Fernie B, Quinn T, and the NIAID AIDS Vaccine Clinical Trials Network. Frequency of indeterminate Western blot tests in healthy adults at low risk for human immunodeficiency virus infection. *J Infect Dis* 162:1379-82, 1990.
26. Viscidi R, Garrison L, Ellerbeck E, Midthun K, Clements ML, Clayman B, Fernie B, Smith G, and the NIAID AIDS Vaccine Clinical Trials Group. Characterization of serum antibody responses to recombinant HIV-1 gp160 vaccine by enzyme immunoassay. *AIDS Res Hum Retroviruses* 6:1251-56, 1990.
27. Dolin R, Graham BS, Greenberg SB, Tacket CO, Belshe RB, Midthun K, Clements ML, Gorse GJ, Morgan BW, Atmar RL, Karzon DT, Bonnez W, Fernie BF, Montefiore DL, Stablein DM, Smith GE, Koff WC, and the NIAID AIDS Vaccine Clinical Trials Network. The safety and immunogenicity of a human immunodeficiency virus type 1 (HIV-1) recombinant gp160 candidate vaccine in humans. *Ann Intern Med* 114:119-27, 1991.
28. Midthun K, Ellerbeck E, Gershman G, Calandra G, Krah D, McCaughy M, Nalin D, Provost P. Safety and immunogenicity of a live attenuated hepatitis A virus vaccine in seronegative volunteers. *J Infect Dis* 163:735-739, 1991.
29. Midthun K, Halsey NA, Jett-Goheen M, Clements ML, Steinhoff MC, King JC, Karron R, Wilson M, Burns B, Perkis V, Samorodin R, Kapikian AZ. Safety and immunogenicity of human rotavirus vaccine strain M37 in adults, children, and infants. *J Infect Dis* 164:792-796, 1991.
30. Graham BS, Belshe RB, Clements ML, Dolin R, Corey L, Wright PF, Gorse GJ, Midthun K, Keefer MC, Roberts NJ Jr, Schwartz DH, Agosti JM, Fernie BF, Stablein DM, Montefiore DL, Lambert JS, Hu S-L, Esterlitz JR, Lawrence DN, Koff WC, and the NIAID AIDS Vaccine Clinical Trials Network. Vaccination of vaccinia-naive adults with human immunodeficiency virus type 1 gp160 recombinant vaccinia virus in a blinded, controlled, randomized clinical trial. *J Infect Dis* 166:244-52, 1992.
31. Ellerbeck EF, Lewis JA, Nalin D, Gershman K, Miller WJ, Armstrong ME, Davide PJ, Rhoad AE, McGuire B, Calandra G, Provost PJ, Midthun K. Safety profile and immunogenicity of an inactivated vaccine derived from an attenuated strain of hepatitis A. *Vaccine* 10:668-672, 1992.
32. Dagan R, Kassis I, Sarov B, Midthun K, Davidson BL, Vesikari T, Sarov I. Safety and immunogenicity of oral tetravalent human-rhesus reassortant rotavirus vaccine in neonates. *Pediatr Infect Dis J* 11:991-6, 1992.
33. Yolken RH, Peterson JA, Vonderfecht SL, Fouts ET, Midthun K, Newburg DS. Human milk mucin inhibits rotavirus replication and prevents experimental gastroenteritis. *J Clin Invest* 90:1984-91, 1992.

34. Kapikian AZ, Flores J, Green KY, Hoshino Y, Gorziglia M, Chanock RM, Vesikari T, Madore HP, Midthun K, Davidson B, Perez-Schael I. Evaluation of attenuated rotavirus (RV) vaccines for the prevention of severe diarrhea in infants and young children. *Vaccine* 10:272, 1992.
35. Lanata CF, Black RE, Burton B, Midthun K, Davidson B. Safety, immunogenicity and efficacy of one or three doses of the rhesus tetravalent rotavirus vaccine in Lima, Peru. *Vaccine* 10:273, 1992.
36. Midthun K, Greenberg HB, Kurtz JB, Gary GW, Lin F-Y C, Kapikian AZ. Characterization and seroepidemiology of a type 5 astrovirus associated with an outbreak of gastroenteritis in Marin County, California. *J Clin Microbiol* 31:955-962, 1993.
37. Ceyhan M, Kanra G, Secmeer G, Midthun K, Davidson BL, Zito ET, Vesikari T. Take of rhesus-human reassortant tetravalent rotavirus vaccine in breast-fed infants. *Acta Paediatr* 82:223-227, 1993.
38. Midthun K, Kapikian AZ. Rotavirus vaccines: an overview. *Clin Microbiol Rev* 9:423-434, 1996.
39. Lanata CF, Midthun K, Black RE, Butron B, Huapaya A, Penny ME, Ventura G, Gil A, Jett-Goheen M, Davidson BL. Safety, immunogenicity, and protective efficacy of one or three doses of the tetravalent rhesus rotavirus vaccine in infants from Lima, Peru. *J Infect Dis* 174:268-275, 1996.
40. Henchal LS, Midthun K, Goldenthal KL. Selected regulatory and scientific topics for candidate rotavirus vaccine development. *J Infect Dis* 174:S112-S117, 1996.
41. Midthun K, Horne AM, Goldenthal KL. Clinical safety evaluation of combination vaccines. *Developments in Biological Standardization* 95:245-249, 1998.
42. Clements-Mann ML, Makhene MK, Mrukowicz J, Wright PF, Hoshino Y, Midthun K, Sperber E, Karron R, Kapikian AZ. Safety and immunogenicity of live attenuated human-bovine (UK) reassortant rotavirus vaccines with VP7-specificity for serotypes 1, 2, 3 or 4 in adults, children, and infants. *Vaccine* 17:2715-2725, 1999.
43. Bernier B, Midthun K. Getting the science right and doing the right science in vaccine safety. *AJPH* 94:914-917, 2004.
44. Ellenberg SE, Foulkes MA, Midthun K, Goldenthal KL. Evaluating the safety of new vaccines: summary of a workshop. *AJPH* 95:800-807, 2005.
45. Brigitte Autran, Edwin J Asturias, Stephen Evans, Kenneth Hartigan-Go, Gregory Hussey, T Jacob John, Paul-Henri Lambert, Barbara Law, Karen Midthun, Hanna Nohynek, Stefania Salmaso, Peter G Smith, Patrick LF Zuber, Adwoa Bentsi-Enchill, Aleksandra Caric, Dina Pfeifer, Philippe Duclos and David Wood. Global safety of vaccines: strengthening systems for monitoring, management and the role of GACVS. *Expert Review of Vaccines* 8:705-715, 2009.

Books, monographs, chapters:

1. Greenberg H, Midthun K, Wyatt R, Flores J, Hoshino Y, Chanock R, Kapikian A. Use of reassortant rotaviruses and monoclonal antibodies to make gene coding assignments and candidates. In: Chanock R, Lerner R, eds. Modern Approaches to Vaccines: Molecular and Chemical Basis of Virus Virulence and Immunogenicity, Cold Spring Harbor Laboratory, New York, pp. 319-327, 1984.
2. Kapikian AZ, Midthun K, Hoshino Y, Flores J, Wyatt RG, Glass RI, Askaa J, Nakagomi O, Nakagomi T, Chanock RM, Levine MM, Clements ML, Dolin R, Wright PF, Belshe RB, Anderson EL, Potash L. Rhesus rotavirus: a candidate vaccine for prevention of human rotavirus disease. Cold Spring Harbor Conference 1984. In: Lerner R, Brown F, Chanock R, eds. Vaccines 85: Modern Approaches to Vaccines: Molecular and Chemical Basis of Resistance to Viral, Bacterial, and Parasitic Diseases, Cold Spring Harbor Laboratory, New York, pp. 357-367, 1985.
3. Greenberg HB, Midthun K. Norwalk and other small round viruses. In: Tzipori, S, et al., eds. Infectious Diarrhoea in the Young. Strategies for Control in Humans and Animals, Elsevier Science Publishers B.V., New York, pp. 240-247, 1985.
4. Wyatt RG, Kapikian AZ, Hoshino Y, Flores J, Midthun K, Greenberg HB, Glass RI, Askaa J, Levine M, Black RE, Clements ML, Potash L, London WT. Development of Rotavirus Vaccines. In: Control and Eradication of Infectious Diseases: An International Symposium. PAHO Copublication Series No. 1. Pan American Health Organization, Washington, D.C., pp. 17-28, 1985.
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United States Patent (19) (11) Patent Number: 4,571,385
Greenberg, et al. (45) Date of Patent: Feb. 18, 1986
(54) GENETIC REASSORTMENT OF ROTAVIRUSES FOR PRODUCTION OF
VACCINES AND VACCINE PRECURSORS
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(54) VACCINE AGAINST ROTAVIRUS DISEASES
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