

TAB B

DECLARATION OF K. SHAWN BLOOD, D.V.M.

As a veterinarian licensed in Oklahoma and Kansas, I have practiced food animal medicine, with an emphasis on cattle and swine since 1989. Since 1991, I have served as the consulting/staff veterinarian for Hitch Enterprises, providing oversight of all livestock operations, which consists of three large commercial feedyards. In addition, I provide veterinary consulting services for a 15,000 sow farrow-to-finish pork operation and cow/calf and stocker operations at Hitch Ranch.

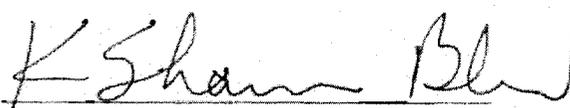
I am active in various associations, including: The American Veterinary Medical Association; Council on Biologic and Therapeutic Agents (COBTA) - member 2001 - present and Animal Agriculture Liaison Committee - COBTA representative 2004 - present; Academy of Veterinary Consultants, Policy and Procedures Committee - member; American Association of Bovine Practitioners, Pharmaceutical and Biologic Issues Committee member 1996 - 2002 and Chairman - 2001 - 2002; Board of Directors-District VII - 2005 - present; American Association of Swine Veterinarians; Oklahoma Veterinary Medical Association; Nebraska Veterinary Medical Association - 1989 - 1999; and the Society for Theriogenology - 1989-1999. I am active in various producer associations including: The National Cattlemen's Beef Association - Associate member; Oklahoma Cattlemen's Association; Nebraska Cattlemen 1990 - 1999, Chairman - Animal Health and Nutrition Committee, Beef Quality Assurance Advisory Board-Member, Board of Directors - Member, Legislative Committee-Member; and the Bureau of animal industries Advisory Committee. I have attached my C.V. for further reference.

I have been asked to provide my opinion of whether an approved generic multi-day enrofloxacin solution will likely be used off label as a high single dose and to discuss the benefits offered by a single dose product that may contribute to off label use.

In my current practice, I oversee cattle in three commercial feedyards, with a capacity of 150,000 head. Baytril 100 is used as a high single dose in all operations that I oversee. In my practice the single dose use is preferred and well accepted. Use of the single high dose leads to better animal welfare and reduced labor. The risk of injury to the animal and the handlers decreases when it is no longer necessary to put the animal through a squeeze chute multiple times. In addition, with the single high dose, compliance improves and as a result efficacy may also increase.

Given the clear benefits, in my operations, 100% of Baytril doses are given as the single high dose. There is no question in my mind that, due to labor, compliance and other economic pressures, an approved multi-day generic will be used off label use as the single high dose.

I make this statement knowing it will be provided in support of a Citizen's Petition to the FDA. I confirm that its contents are true and correct to the best of my knowledge and belief. Executed this 17 day of May, 2006.



K. Shawn Blood, DVM
RR3 Box 32N
Guymon, OK 73942
(580) 338-8575 (O)
sblood@hitchok.com

K.Shawn Blood, DVM

RR3 Box 32N
Guymon, OK 73942
(580) 338-8586 (H)
(580) 338-8575 (O)
(580) 651-3342 (M)
sblood@hitchok.com

Professional Experience

Hitch Consulting Services, Inc

Guymon, Ok

Consulting/Staff veterinarian for Hitch Enterprises- May 1999 thru present

Veterinarian over all livestock operations for Hitch Enterprises. Entities consist of three large commercial feedyards with approximately 150,000 one-time capacity; 15,000 sow farrow-to-finish pork operation, and cow/calf and stocker operations at Hitch Ranch.

Sutton Veterinary Clinic, PC

Sutton & Geneva, NE

Associate Veterinarian- June 1989 thru October 1991

Partner/Owner - October 1991 thru May 1999

Practiced two years as an associate veterinarian in a four person totally food-animal practice with emphasis on swine and cattle. The practice consists of two clinics covering most of a six county area. Became an equal partner in the practice in 1991. My time in the practice evolved into 90% beef cattle with an emphasis on feedlot production medicine.

Licensing and Accreditation

Licensed to practice in Nebraska, Kansas, and Oklahoma.

Accredited in Nebraska, Kansas, and Oklahoma for USDA health programs.

Publications

Cobta publication

"Evaluation of health status of calves and the impact on feedlot performance: assessment of a retained ownership program for postweaning calves"

Fulton RW, Cook BJ, Step DL, Confer AW, Saliki JT, Payton ME, Burge LJ, Welsh RD, Blood KS
The Canadian Journal of Veterinary Research 2002;66:173-180

"Body Weight Change During Respiratory Disease Treatment as a Treatment Success Indicator in Feedlot Cattle"

Published in *Agri-Practice* - May/June 1996. This trial was conducted as a requirement for the Beef Cattle Production Management Series at the UNL-GPVEC at Clay Center, NE.

"Nebraska Beef Quality Assurance Handbook"

Active in the development and as a contributing editor for the statewide quality assurance program.

Additional Professional Activities

Beef Cattle Production Management Series-April '93 thru April '94

Great Plains Veterinary Educational Center, Clay Center, NE

This series is an intensive series of six 3-day seminars spread over a one-year period. Focus is on non-traditional veterinary medical issues that directly affect the economic success of producers. The curriculum included design and execution of a clinical trial, completion of a SPA-F and SPA-P for a client, starting a client herd on CowCalf computer record systems, nutrition, financial management, and economics. Also included were seminars and projects on genetics, communications, predicting cattle performance, and risk management. Instructors included staff from the GPVEC and UNL as well as OSU, KSU, and NCSU. Guest lecturers from many other states were regular speakers as well.

Professional Memberships

American Veterinary Medical Association
Council on Biologic and Therapeutic Agents(COBTA)-member 2001-present
Animal Agriculture Liason Committee-COBTA representative 2004-present

Academy of Veterinary Consultants
Policy and Procedures Committee-member

American Association of Bovine Practitioners
Pharmaceutical and Biologic Issues Committee member 1996-2002
Chairman-2001-2002
Board of Directors-District VII 2005-present
????biosecurity

American Association of Swine Veterinarians
Oklahoma Veterinary Medical Association
Nebraska Veterinary Medical Association- 1989-1999
Society for Theriogenology

Producer Group Activities

National Cattlemen's Beef Association-Associate member
Oklahoma Cattlemen's Association
Nebraska Cattlemen 1990-1999
Chairman- Animal Health and Nutrition Committee
Beef Quality Assurance Advisory Board-Member
Board of Directors-Member
Legislative Committee-Member
Bureau of animal industries Advisory Committee

Community Activities

Victory Memorial United Methodist Church-Member
Finance Committee-2004 to present
Administrative Council-2003 to present
Confirmation Class Instructor
Guymon Leadership-Class of 2004

Education

Oklahoma State University-College of Veterinary Medicine
Stillwater, OK
Doctor of Veterinary Medicine-May 1989
Emphasis in Food Animal Medicine. All electives focused on beef cattle and swine.

Oklahoma State University-College of Agriculture
Stillwater, OK
Worked toward B.S. degree with a major in animal science/pre-vet

Western Oklahoma State University
Altus, OK
Completed basic curriculum courses with the intention of transfer to OSU after two years.

Mangum High School
Mangum, OK
Graduated from High School in 1981

Personal Information

Married since May 1995. My wife Jennifer and I are the parents of three daughters; Anna, 10; Katie 7; and Hope 4.

DECLARATION OF KELLY F. LECHTENBERG, D.V.M.

I have practiced veterinary medicine, specializing in livestock and research services since 1987. As President and Director of Research, I own and operate Midwest Veterinary Services (MVS), a consulting and contract research organization that provides clinical studies in cattle, swine and chickens. Other business interests include: co-owner of Swine Biomedical Resource Centre, LLC, president and director of research of Central States Research Centre, Inc., and owner of Logan Valley Feeders.

Other associations include: Adjunct Professor at the University of Nebraska, Lincoln; Academy of Veterinary Consultants; Academy of Veterinary Consultants - Board of Directors (1994 - 2002); American Association of Bovine Practitioners; American Association of Swine Practitioners; American Veterinary Medical Association; Nebraska Veterinary Medical Association; American Society of Animal Science; National Cattlemen's Beef Association; Gamma Sigma Delta; Phi Zeta; Oakland Memorial Hospital Board; Federation of Animal Science Societies (FASS). I have advisory board functions with: NCBA Beef Quality Assurance Task Force; ASAS Regulatory Affairs Committee; Elanco Animal Health Advisory Board (Lilly); Intervet Advisory Council; Bayer Health Care Feedlot Advisory Board and; Mercy Medical Trinity Systems Strategic Planning Committee Member. I have attached my C.V. for further reference.

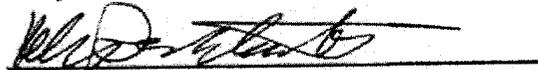
I have been asked to provide my opinion on advantages offered by the use of a high single-dose therapy of Bayer's Baytril 100 Injectable Solution (Baytril) and the likelihood of off label use of an approved generic multi-day enrofloxacin solution. In my current practice, I oversee cattle in three feed yards, totaling 70,000 head. In addition to my veterinary consultation services on the use of antimicrobials, I have an extensive research practice which supports USDA and FDA approvals of biological as well as other livestock products.

In my practice, it is my estimate that 100% of Baytril 100 is used as a high single dose and among my clients; this use is well accepted in all categories of livestock growing. Compared to the use of a multi-day treatment, the benefits of a high single dose include less time and labor to treat the animal. In my opinion, less is more: Less handling and less stress leads to faster improvement in health and performance, easier logistics and greater safety to the animals and the individuals handling the animals. In addition, compliance is improved. With multi-day treatments, the opportunity for under dosing increases because once cattle look better, there is always a risk that the three-day dosing will not be completed. This all adds up to greater safety and efficacy with use of a high single dose regimen.

Due to educational efforts over the last few years and the resulting increased awareness of the need for compliance with the use of FQ's, my clients prefer to use the high single dose treatment to eliminate any risk of non-compliance in treatment. In my opinion, there will be many who use a generic multi-day according to label

guidelines, however, I have no doubt there will be tremendous pressure in some organizations to use a less expensive generic off label as a high single dose. In those operations where the generic is used as a high single dose, one will probably find Baytril 100 on the shelf to camouflage the off label use.

I make this statement knowing it will be provided in support of a Citizen's Petition to the FDA. I confirm that its contents are true and correct to the best of my knowledge and belief. Executed this 16th day of May, 2006.



Kelly F. Lechtenberg, D.V.M., Ph.D.
Midwest Veterinary Services, Inc.
1443 Hwy 77
Oakland, NE 68045

Logan Valley Feeders
Commercial Feedlot Operation
Oakland, Nebraska

LVF is a commercial cattle feeding operation that also serves as the site for the conduct of clinical efficacy studies in feedlot cattle. LVF also serves as the production site for our colostrum deprived calf project, in which we produce 300 to 500 animals per year.

1987-Present President and Director of Research
Midwest Veterinary Services, Inc.
Oakland, Nebraska

MVS is the consulting and contract research organization that I started in 1987 upon my graduation from veterinary school. The focus of MVS is to help biological and pharmaceutical manufacturers bring novel animal health product through the approval processes of USDA and FDA. MVS conducts clinical studies in cattle, swine and chickens.

1987-1991 Staff Veterinarian & Feedlot Consultant
Red Barn Veterinary Clinic, P.C.
Oakland, Nebraska (20%)

Research Associate
Kansas State University
Manhattan, Kansas (20%)

President and Director of Research
Midwest Veterinary Research, Inc.
Oakland, Nebraska (60%)

Awards and Honors:

2006 College of Agricultural Sciences and Natural
Resources (CASNR) Alumni Achievement Award
Lincoln, NE

2005 Kansas State University Alumni Fellow
Manhattan, KS

2005 Oakland Chamber of Commerce -- Boss of the Year Award

2004 Oakland Chamber of Commerce Community Service Award

1994 Feedlot Consultant of the Year
Academy of Veterinary Consultants

Professional Associations:

Adjunct Professor at the University of Nebraska, Lincoln
Academy of Veterinary Consultants
Academy of Veterinary Consultants - Board of Directors (1994 - 2002)
American Association of Bovine Practitioners
American Association of Swine Practitioners
American Veterinary Medical Association
Nebraska Veterinary Medical Association
American Society of Animal Science

National Cattlemen's Beef Association
Gamma Sigma Delta
Phi Zeta
Oakland Memorial Hospital Board
Federation of Animal Science Societies (FASS)

Advisory Board Functions:

NCBA Beef Quality Assurance Task Force
ASAS Regulatory Affairs Committee
Elanco Animal Health Advisory Board (Lilly)
Intervet Advisory Council
Bayer Health Care Feedlot Advisory Board
Mercy Medical Trinity Systems Strategic Planning Committee Member

Invited Conference Presentations:

June 9, 2005 – 2005 Summer Summit (Pfizer) – “Innovative Revenue Opportunities”,
Chamberlain, SD; “Application of USDA Challenge Studies Relating to Field Usage”

April 6-9, 2005 - Academy of Veterinary Consultants – Kona, Hawaii – “Review of the
Rumenitis – Liver Abscess Complex in Feedlot Cattle”

Feb 19-23, 2005 Western Veterinary Conference, Las Vegas, NV
Topics – “Acidosis in Feedlot Cattle”; “Feedlot Management – Techniques I – Biosecurity”;
“Feedlot Management – Techniques II – The Environment”; Composting of Carcasses and
Feedlot Waste”

September 21, 2004 – 65th Minnesota Nutrition Conference and Technical Symposium: On the
Cutting Edge of Direct Fed Microbials – “Feedlot Interventions for food safety”.

July 1, 2004 – CVM Bactalexin[®] Meeting – Washington, D.C. – “Practical aspects of
conducting studies designed to measure decreases in E. coli 0157:H7 shedding in cattle” -
Alpharma

June 26-29, 2004 – IPVS Seminar – The Importance of Long Acting, Single Injection Therapies
for SRD – Experiences with Draxxin[®] Sterile Solution – Hamburg, Germany

May 18-20, 2004 – Draxxin[®] Meeting Presentation – Trento, Italy

February 19-20, 2004 – Draxxin[®] Launch Meeting presentation – Barcelona, Spain

October 22-24, 2003 – Pfizer Fusobacterium Expert Panel – “Field Perspectives in Control of
Liver Abscess” – Las Vegas, Nevada

Sept 19, 2003 – AABP – Columbus, Ohio – “Managing Mud in the Feedlot”

March 27, 2003 – Ft. Collins, Co – “Colorado Nutrition Roundtable” – “Opportunities with
Water, Including the Potential Administration of Antibiotics and/or Nutrients via Water”

2002 SDSU Advanced Feedlot Cattle Management Shortcourse – June 2002, Brookings, SD

FDA-Veterinary Medical Advisory Committee Meeting – “Pathogen Load” – FDA/Center for Veterinary Medicine - Jan 22-24, 2002, Washington, DC.

NMHCC's Fourth International - “A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for use in Food-Producing Animals”- December 7-8, 1998, Washington, DC – Symposium Faculty

Elanco Feedlot Program – Cattle Team Training – Aug. 3-6, 1998, Toluca, Mexico

USAHA Pharmaceutical Committee – Minneapolis, MN – Oct 6, 1998 – “Antibiotic Resistance And Food Animal Health – Current Status – Panel

American Association Bovine Practitioners – September 24-26, 1998 – Spokane, Washington, “Adding Value and Getting Paid for It”

Farmland Miniversity – Aug 4, 1998, “Metaphylactic Use of Antibiotics in Feedlot Cattle”

World Health Organization – Division of Emerging and Other Communicable Diseases Surveillance and Control –Geneva, Switzerland – Jun 98 – WHO Meeting on the Use of Quinolones in Food Animals and Potential Impact on Human Health – Kelly F. Lechtenberg, Representative of WVA – “Review of the use of quinolones in food animals”.

Nebraska Veterinary Medical Association – Jan 98 – “Acidosis or BRD”

1997 Elanco Cattle Practitioner Seminar – Aug 97 – “Bovine Respiratory Disease Management”

Federation of Animal Science Societies Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching – Purdue University – “Use of Agriculture Guide Panel” – June 1997

G.C. Hanford Foundation – The Council of Clinical Veterinary Services – “The Penicillin Panel” – New York – May 97

1997 Lextron National Sales Meeting – “Confined Feedlot Seminar” – Mahoney State Park

“The Use of an Actinobacillus pleuropneumoniae Challenge Model to Determine the Dose of Enrofloxacin in Pigs” – Quebec, Canada – Mar 97

Elanco Animal Health – Nutritional Consultant Board Meeting – Nov 96 – “Liver Abscess Presentation”.

L.L.Vincent, S.L. Swenson, B.H. Janke, B.M.Lute, K.F.Lechtenberg, J.G. Landgraf, B.J. Schmitt, D.R. Kinker, J.K. McMillen 1996. A comparison of Diagnostic Methods for detection of Swine Influenza Virus in Nasal swabs and Lungs. North Central Conference of Veterinary Laboratory Diagnosticians, June 11-12, Brookings, SD.

L.L. Vincent, S.L. Swenson, B.H. Janke, B.M. Lute, **K.F. Lechtenberg**, J.G. Landgraf, B.J. Schmitt, D.R. Kinker, J.K. McMillen 1996. A comparison of Diagnostic Methods for detection of Swine Influenza Virus in Nasal swabs and Lungs. International Pig Veterinary Society Congress, July 7 - 10, Bologna, Italy.

ASAS Regulatory Agency Committee Meeting, Feb 2, 1996, Rockville, Maryland;
Subcommittee on Health and Environment "Coalition For Animal Health"

Western Veterinary Conference – Las Vegas – "Feedlot Training Programs" – Feb 96.

North American Veterinary Conference Scientific Program – Orlando, Florida – Jan 96 –
"Management Considerations and Record Systems for Controls of BVD".

"The Role of Disease Modeling in the Development of Efficacy Packages for Cattle & Swine
Biological & Pharmaceutical Products" – Kalamazoo, Michigan – Nov 96

Latin American Swine Training Meeting – Itu, Brazil – Jul 95 – "Swine Gastro-enteric Problems
in the USA".

International Pig Veterinary Society Congress – "Swine Pneumonia Review" – Bangkok,
Thailand – June 94

Lextron Sales Meeting – Omaha – Aug 94 – "Selected Feedlot Topics"

Nebraska Beef Feedlot Roundtable – Grand Island, NE – Aug 94 – "Feedlot Consulting the Art
and Science".

Cargil – Sioux City, Ia – Jul 94 – "Feedlot Calves" – "Handle with Care"

Conference Proceedings and Abstracts

September 21, 2004 – MN Nutrition Conference – St. Paul, MN – "Escherichia Coli 0157:H7 –
Pre-Harvest Intervention Strategies – **Kelly F. Lechtenberg, DVM, Ph.D.**, Marilyn Corbin,
DVM, Ph.D.

Nagaraja, T. G., K. F. Lechtenberg, W. Q. Alali, J. M. Sargeant, W. P. Kautz and J. A. Z. Leedle.
Enterococcus faecium-based direct-fed microbials (DFM) on fecal shedding of E. coli 0157 in
Cattle. Congress of Research Workers in Animal Diseases, Chicago, IL., Nov, 2003. Poster
presented at the Fourth INRA-RRI Symposium on Gut Microbiology: Concerns and responses to
Food safety, Healthy and Environmental Issues, Clearmont-Ferrand, France, June 21-23, 2004

Consortium. 2002. A Report for the Animal Agriculture Alliance (AAA): Criteria for the
Evaluation of Animal Care Guidelines. Federation of Animal Science Societies, Savoy, IL

Vicki J. Rapp-Gabrielson, Ph.D., Linda Gergen, MS, Brad Eddy, BS, Terri Wasmoen, PhD,
Kelly Lechtenberg, DVM, Ph.D., Michael Hanna, DVM; Duration of immunity studies for the
H3N2 fraction of combination swine influenza vaccines; Industrial Partners Session, March 3,
2002 AASV meeting in Kansas City.

K.F. Lechtenberg and G.L. Stokka 1996 Feedlot Health and Management. In **BOVINE RESPIRATORY DISEASE**, Source Book for the Veterinary Professionals, Schering-Plough Animal Health, pp 75-87.

S.L. Swenson, L.L. Vincent, B.H. Janke, D.R. Kinker, **K.F. Lechtenberg** 1996. A comparison of two enzyme immunoassays with egg inoculation for the detection of swine influenza virus from nasal swabs and lungs. American Association of swine practitioners, p 97.

KF Lechtenberg, TG Nagaraja, HW Leipold, Bacteriological and histopathological investigations of liver abscesses, KSU Cattlemen's Day, 1986, Manhattan, KS.

Journal Articles:

Van Baale, M. J., J. M. Sargeant, D. P. Gnad, B., M. DeBey, **K. F. Lechtenberg**, and T. G. Nagaraja. 2004. Effect of forage or Grain Diets with or without Monensin on Ruminant Persistence and Fecal Escherichia coli O157:H7 in Cattle; Applied and Environmental Microbiology, 70: 5336-5342

Lechtenberg, K. F. and T. L. Mader. 2003. Reducing feedlot heat stress. Bovine Veterinarian, May-June 2003.

Hibbard, Beth, Fabian M. Bausch, **K. F. Lechtenberg**, Michael S. Hanna, Edward J. Robb, W. Lawrence Bryson, S. Theodore Chester, Jr, Kenneth J. Dame; Efficacy of ceftiofur sodium for the control of mortality in neonatal pigs orally inoculated with K88+ (F4+) enterotoxigenic Escherichia coli; Journal of Swine Health and Production, Volume 11, Number 1. Journal of Swine Health & Production, 11:1, Jan/Feb 2003

Reddy, J. R., J. Kwang, **K. F. Lechtenberg**, N. C. Khan, B. Prasad Reddy, M. M. Chengappa. 2002. An immunochromatographic serological assay for the diagnosis of Mycobacterium tuberculosis; Comparative Immunology, Microbiology & Infectious Diseases, 25:21-27.

William E. Beschorner, M.D., Debra L. Sudan, M.D., Stanley J. Radio, M.D., Tianyu Yang, M.D., Kenneth L. Franco, M.D., Arthur C. Hill, M.D., C. Carson Shearon, M.S., Scott C. Thompson, B.A., R. Steven Dixon, D.V.M., Noel D. Johnson, D.V.M., Charles C. Kuszynski, Ph.D., Ronald J. Rubocki, Ph.D., **Kelly F. Lechtenberg, D.V.M., Ph.D.**, Aurelio Matamoros, Jr., M.D., Timothy C. Goertzen, M.D., Ira J. Fox, M.D., and Alan N. Langnas, D.O.; (Annals of Surgery status = submitted for publication); Heart Xenograft Survival with Chimeric Pig Donors and Modest Immune Suppression; study funded in part by a Small Business Innovation Research grant from the National Institutes of Health, DK58701.

Lechtenberg, K. F., T. G. Nagaraja, and M. M. Chengappa. 1998. Antimicrobial susceptibility of *Fusobacterium necrophorum* isolated from bovine hepatic abscesses in cattle. Amer. J. Vet. Res., 59:44-47.

Reddy, J. R., J. Kawng, Ogi Okalmumba, S. Kapil, T. M. Loughin, **K. F. Lechtenberg**, M. M. Chengappa and H. C. Minocha 1997. Application of recombinant bovine viral diarrhea virus proteins in the diagnosis of bovine viral diarrhea infection in cattle. Vet. Microbiol., 51: 119-133

Saginala, S., Nagaraja, T. G., **Lechtenberg, K. F.**, Chengappa, M. M., Kemp, K. E., Hine, P. M. 1997. Effect of *Fusobacterium necrophorum* leukotoxoid vaccine and resistance to experimentally induced liver abscesses in cattle. *J. Anim. Sci.* 75: 1160-1166.

Saginala, S., Nagaraja, T. G., Tan, Z. L., **Lechtenberg, K. F.**, Chengappa, M. M., Kemp, K.E., Hine, P. M. 1996. Serum-neutralizing antibody response and protection against experimentally induced liver abscesses in steers vaccinated with *Fusobacterium necrophorum*. *Amer. J. Vet. Res.*, 57:483-488.

Saginala, S., Nagaraja, T. G., Tan, Z. L., **Lechtenberg, K. F.**, Chengappa, M. M., Kemp, K. E., Hine, P. M. 1996. Serum-neutralizing antibody response to *Fusobacterium necrophorum* leukotoxoid and protection against experimentally induced hepatic abscesses. *Vet. Res. Commun.* 20:493-504.

Lechtenberg, K. F. 1995. The Influence of melengestrol acetate on heifers implanted with trenbolone acetate and testosterone-estradiol, *Agri-Practice*, 16 (5): 20 -22.

Lechtenberg, K. F., T. R. Shryock, G. Moore, 1994. Characterization of an *Actinobacillus pleuropneumoniae* seeder pig challenge-exposure model. *Amer. J. Vet. Res.*, 55: 1703-1709

Tan, Z. L., **K. F. Lechtenberg**, T. G. Nagaraja, M. M. Chengappa and R. T. Brandt, Jr., 1994. Serum neutralizing antibodies against *Fusobacterium necrophorum* Leukotoxin in cattle with experimentally induced or naturally developed hepatic abscesses, *J. Anim. Sci.*, 72: 502-508.

Lechtenberg, K. F. and T. G. Nagaraja. 1991. Hepatic ultrasonography and blood changes in cattle with experimentally induced hepatic abscesses. *Amer. J. Vet. Res.*, 52:803-809.

Swenson, S., L. L. Vincent, B. M. Lute, B. H. Janke, **K. F. Lechtenberg**, J. G. Landgraf, B. J. Schmitt, D. R. Kinker, J. K. McMillen. A Comparison of Diagnostic Assays for the Detection of Swine Influenza Virus from Nasal Swabs and Lungs. International Pig Veterinary Society Congress. Bologna Italy, July 7-10, 1996

Roder, B. L., M. M. Chengappa, **K. F. Lechtenberg**, T. G. Nagaraja, and G. A. Varga. 1989. *Fusobacterium necrophorum* and *Actinomyces pyogenes* associated facial and mandibular abscesses in Blue Duiker. *J. Wildlife Dis.*, 25: 370-377.

Lechtenberg, K. F., T. B. Avery, T. G. Nagaraja, and G. H. Hartke, 1989. Ultrasound-guided, percutaneous catheterization of the portal vein in cattle. *Agri-Practice*, 10:2, 41-44.

Lechtenberg, K. F., T. G. Nagaraja, H. W. Leipold, and M. M. Chengappa, 1988. Bacteriologic and histological studies of hepatic abscesses in cattle. *Amer. J. Vet. Res.*, 49: 58-62.

Seminars:

GLPs and GCPs in Target Animal Studies Training
March 1 & 2, 2006
Central States Research Centre, Inc.
Oakland, NE

Declaration of Steve Lewis, D.V.M.

As a licensed practicing veterinarian, I am Manager and Senior Partner of the Hereford Veterinary Clinic, Hereford, Texas. I established this practice, specializing in beef cattle consultation, equine and food animal research, and other areas, in 1982. Ninety percent of my practice consists of beef cattle consultation. Currently, I provide professional services for over thirty background and finishing feed yards with yearly capacities of approximately 1.7 million head of cattle.

I am cofounder and stockholder of Veterinary Research Associates, PLLC, which represents more than 6 million head of cattle annually. My involvement in professional associations includes: Past President and Director, Academy of Veterinary Consultants; Board of Directors, District 8, American Association of Bovine Practitioners; American Veterinary Medical Association; Texas Veterinary Medical Association; Regulatory Committee and Board of Directors, Texas Cattle Feeders Association; National Cattlemen Beef Association and several feed yard Advisory Boards. My C.V. is attached for further information.

I have been asked to provide my opinion on advantages offered by the use of a high single-dose therapy of Bayer's Baytril 100 Injectable Solution (Baytril) and the likelihood of off-label use of an approved generic multi-day enrofloxacin solution.

My veterinary consultation services on the use of antimicrobials extend to all phases of beef cattle production including, cattle on feed, feeders and beef

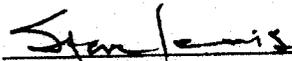
cows, and calves and replacement heifers. While the majority of doses of Baytril are used in confined feeders, in my practice, nearly ninety-five percent of the doses are given as a high single-dose in all these classes of livestock. When Bayer came to market with its approved high single-dose therapy, it was my observation that acceptance and conversion to this regimen was immediate.

As compared to a multi-day treatment, the benefits of a high single dose are obvious and include reduced animal handling, which not only improves economics, but also decreases disease pressure and improved response rates to treatment are observed due to reduced stress of repeat animal handling. Sick animals can be treated with a single high dose and then be quickly returned to "home" pens. On the other hand, multi-day treatment requires retention of sick animals in "sick" pens, thereby increasing exposure to other sick animals and increasing the risk of relapse or opportunistic infection. Animals that are kept on pasture must be roped for multiple days of treatment. As a result, animals that actually receive the three required doses are rare. Clearly we observe better compliance and as a result, better response rates to the single high dose treatment in these pasture animals.

There has been some previous bias among livestock veterinarians that severely ill animals respond better to multi-day treatment. However, performance data from single dose use (Mc6 Feeders, Field Trial Report 03-01) demonstrates the single dose to be equal, if not better than the multi-day.

In my opinion, it is reasonable to conclude that any generic approved for the multiple-day dosing regimen would likely be used as a high single dose. I have gone to great lengths to educate my clients on the proper use of antimicrobials in food animals and on the clear advantages of Baytril single dose use. If a generic multi-day enrofloxacin solution is approved, consulting veterinarians, such as me, are the only ones who could attempt to "police" off-label use and that would only be possible in confined feeding operations and not in stockers and animals on pasture. I know my clients and would expect to hear the question, "Is it the same drug?" There is no question, that a generic multi-day enrofloxacin will be used extra-label as the protected single high dose regimen.

I make this statement knowing it will be provided in support of a Citizen's Petition to the FDA. I confirm that its contents are true and correct to the best of my knowledge and belief. Executed this 26 day of April, 2006.



Steve Lewis, D.V.M.

P.O. Box 119

Umbarger, Texas 79091

May 23, 2006

Steve Lewis, D.V.M.

Current:

Manager and Senior Partner with Mike Mimms, D.V.M. in Hereford Veterinary Clinic, Hereford, Texas. This General Practice was established by myself in November, 1982. There are currently 3 Associate Veterinarians employed. All veterinarians contribute to practice of General Medicine and Surgery with individuals specializing in Beef Cattle Consultation, Equine and Food Animal Research, Embryo Transfer, Equine Surgery, and Orthopedic Surgery.

Personal practice consists of 90% Beef Cattle Consultation and 10% Equine Medicine and Surgery. Currently on some form of retained professional services with over 30 Background or Finishing Feedyards with yearly capacities of approximately 1.7 Million head.

Responsible for Business Management of Practice.

Co-founder/Stockholder of Veterinary Research Associates, PLLC. All Stockholders are Stocker/Feedyard Consultants which represent more than 6 million head of cattle annually.

P.O.Box 119 • Umbarger, Texas 79091
Phone 806.499.3773 • Fax 806.499.3774 • Email: slewis@arn.net

May 23, 2006

Background and Education:

Born May 13, 1955, in Plainview, Texas.

Raised on irrigated farm with cow-calf and feedyard entities in Olton, Texas (50 miles South of Hereford, Texas).

Education

Olton High School, Salutatorian, 1973

West Texas A&M University, Canyon, Tx., 1973-1976

College of Veterinary Medicine, Texas A&M University,

B.S. Veterinary Medicine, 1977

Doctor of Veterinary Medicine, Cum Laude, 1976-1979

Family:

Wife: Sally Ann - born October 21, 1957

Son: Dustin Lee - born April 10, 1980

Son: Kody Dale - born October 3, 1983

Daughter: Augusta Marie- born December 19, 1990

Practice Experience:

1979-1982

Muleshoe Animal Clinic, Muleshoe, Texas

Jerry Gleason, D.V.M. and Barry Cowart, D.V.M.

1979-Current

Ranch, Stocker, and Feedyard Consultation, Equine and Food Animal Research, and Equine Medicine and Surgery.

P.O.Box 119 • Umbarger, Texas 79091
Phone 806.499.3773 • Fax 806.499.3774 • Email: slewis@arn.net

May 23, 2006

Research Experience:

GLP Studies

- Swine Coccidiostat Dose Titration Study- MoBay
- Quinalone Efficacy Study - Pfizer
- Quinalone Safety Study - Pfizer
- Quinalone Reproductive Safety in Pregnant Bovine and Offspring - Pfizer
- Nuflor Efficacy Study - Schering
- Naxcel Dose and Comparison Efficacy - Upjohn
- Pharmaceutical Dose and Comparison Efficacy (New Formulation) - Upjohn
- Naxcel Foot Rot Efficacy – Upjohn
- New Formulation Antibiotic – Blue Ridge Pharm.
- Baytril Metaphylaxis Comparison – Bayer
- Prellim Treatment Comparison - Pharmacia

Clinical Trials

- Regumate Efficacy Trial - Hoescht Roussel
- Effects of Ozonated Water on Health Parameters in High Risk Calf Receivals
- Micotil Metaphylaxis Trial - Elanco
- Comparative Nuflor - Micotil Treatment Trial - Schering
- Comparative Pasteurella Bacterin Trial - Corporate In House
- Bovine Oral Vitamin/Trace Mineral 3X and 5X Toxicity Trial
- BRSV Vaccine Efficacy Trial - Norden

P.O.Box 119 • Umbarger, Texas 79091
Phone 806.499.3773 • Fax 806.499.3774 • Email: slewis@arn.net

May 23, 2006

Organizations and Boards:

First United Methodist Church, Canyon, Texas
Academy of Veterinary Consultants
Past President
Director 5 years
American Association of Bovine Practitioners
Board of Director – District 8
American Association of Equine Practitioners
American Veterinary Medical Association
Texas Veterinary Medical Association
Texas Cattle Feeders Association
Regulatory Committee
Board of Director
National Cattlemen Beef Association
Hereford Country Club Board of Directors
Feedyard Advisory Board - Pfizer
Feedyard Advisory Board - Elanco
Feedyard Advisory Board - Bayer
Feedyard Advisory Board - Pharmacia & Upjohn
Feedyard Advisory Board - Hoffman La Roche
Hereford State Bank-First Financial Bankshares (Abilene)
Board of Director

P.O.Box 119 • Umbarger, Texas 79091
Phone 806.499.3773 • Fax 806.499.3774 • Email: slewis@arn.net

May 23, 2006

Professional Activities:

CVM/FDA Workshop II on Flexible Labeling: Provided a practicing veterinarian's critique.

Schering/Plough's Hospital Management Video: Provided outline information for partial content.

Texas Dept.of Health/Texas Board of Vet.Examiners /Pharmacy Board/Texas Cattle Feeders: Provided input in purchase order/prescription guidelines.

Eastern States Veterinary Conference: presented 4 hours.

Western States Veterinary Conference: presented 4 hours.

Practice Veterinarians:

Partner: Mike Mimms, D.V.M., Texas A&M University

Associate: Clay Rollins, D.V.M., Texas A&M University

Associate: Les Mayes, D.V.M., Colorado St. Univer.

Associate: Kynan Sturgess, D.V.M., Oklahoma St. Univ.