

EXHIBIT 1

Based on my review of the reliable and credible publicly available published peer-reviewed scientific literature regarding calcium nutrition, metabolism, and physiology, their interactions with renal physiology and the disease-preventing properties of dietary calcium in the prevention of nephrolithiasis, I conclude that there is significant scientific agreement in support of the following health claim:

- Calcium may reduce the risk of kidney stones.
- Calcium may reduce the risk of urinary stones.

Calcium

I. Intestinal Calcium Absorption and Retention of Ingested Calcium

A. Mechanisms of Calcium Absorption

Calcium in foods occurs as salts or in association with other dietary constituents in the form of complexes of calcium ions. Calcium must be released in a soluble, and probably ionized, form before it can be absorbed (i.e., transferred from the intestinal lumen to the circulatory system). Once in a soluble form, calcium is absorbed by two routes, transcellular and paracellular transport.¹

The saturable, transcellular pathway is a multi-step process, involving the entry of luminal calcium ions across the microvillar membrane into the enterocyte, then movement through the cytosol (i.e., translocation to the basolateral membrane), followed by active extrusion from the enterocyte into the lamina propria and diffusion into the general circulation. The entry of calcium ions across the apical membrane of the enterocyte is favored electrochemically because the concentration of calcium ions within the cell (10^{-7} to 10^{-6} M) is considerably lower than that in the intestinal lumen (10^{-3} M), and the cell is electronegative relative to the intestinal lumen.¹ Therefore, the movement of calcium ions across the apical membrane does not require the expenditure of energy. However, because lipid membranes are impermeable to calcium ions, apical entry must involve the participation of a calcium ion channel or integral membrane transporter residing within the brush border membrane. Evidence suggests that the calcium transport protein, CaT1, may be the putative calcium ion transporter.^{2,3}

The intracellular diffusion of calcium ions is thought to be facilitated by a cytosolic calcium-binding protein, calbindin D_{9K}, whose biosynthesis is dependent on the presence of vitamin D (in the form of 1,25-dihydroxycholecalciferol). Calbindin D_{9K} facilitates the diffusion of calcium ions across the cell by acting as an intracellular calcium ferry or chaperone. The active extrusion of calcium ions at the basolateral membrane takes place against an electrochemical gradient and is mediated primarily by a calcium-dependent ATPase. While each step in the transcellular movement of calcium ions has a vitamin D-

dependent component, the intracellular concentration of active calbindin D_{9K} is believed to be rate-limiting in 1,25-dihydroxycholecalciferol-induced transcellular calcium transport.¹

The paracellular route of calcium absorption involves passive calcium transport through the tight junctions between mucosal cells. Because it does not require a transporter and is driven by the large luminal:serosal calcium concentration gradient, this transport pathway is non-saturable and appears to be independent of nutritional or physiologic regulation (although some limited evidence suggests that it also may respond to 1,25-dihydroxycholecalciferol in an as yet unknown manner).^{1,4}

Most calcium absorption in humans occurs in the lower small intestine, but there is some evidence for a colonic component that may increase total calcium absorption by as much as 10%.⁵ However, the large intestine may represent a site of increased importance for calcium absorption when acidic fermentation takes place. Slightly acidic intracolonic pH increases the efficiency of colonic absorption of calcium.⁶ For example, prebiotics acidify slightly the intracolonic pH (secondary to increased production of short-chain fatty acids as byproducts of increased fermentation) and have been shown to increase the fractional true absorption of ingested calcium in human adolescents, young adults and postmenopausal women.⁶

When dietary calcium is abundant, the paracellular pathway appears to be dominant.⁷ When dietary calcium is limited, the active 1,25-dihydroxycholecalciferol-dependent transcellular pathway increases in importance.⁷ Transmembrane calcium receptors (especially in renal tissues) mediate the conversion of 25-hydroxycholecalciferol to biologically-active 1,25-dihydroxycholecalciferol through regulation of the expression of 25-hydroxycholecalciferol-1 α -hydroxylase and thereby indirectly regulate hormone-mediated up-regulation and down-regulation of calbindin D_{9K} activity in mucosal cells.¹ The beginning of a decline in plasma calcium ion concentration evokes an increase in serum 1,25-dihydroxycholecalciferol concentration, which in turn stimulates increased calbindin D_{9K} biosynthesis in the intestinal mucosa.¹

B. Efficiency of Calcium Absorption

The efficiency of absorption of ingested calcium is inversely proportional to chronic calcium intake. However, this adaptive decrease in the fraction of ingested calcium that does not appear in the feces as calcium intake decreases is not sufficient to offset the decrease in the amount of calcium that is absorbed as a result of a decrease in calcium intake.^{8,9} Regardless of the efficiency of absorption, the amount of calcium that is absorbed is directly proportional to the amount ingested.^{8,9} For example, despite the significantly greater efficiency of absorption when human calcium intake is less than 500 mg/day, the total amount of calcium absorbed from such a low-calcium diet is less than half the amount that is absorbed (even with significantly lower efficiency) from a diet providing 1000 mg/day.^{10,11}

The efficiency of calcium absorption varies throughout the life cycle. It is greatest in infancy, when about 60% of consumed calcium is absorbed,¹² decreases during childhood, and increases again early in adolescence, when about 25% of consumed calcium is absorbed.¹³ The efficiency of calcium absorption remains at about this level into middle adulthood.¹³ As adults age beyond middle adulthood, the efficiency of calcium absorption declines gradually. For example, in postmenopausal women and older men, the efficiency of calcium absorption has been reported to decrease by an average of about 0.2 percentage points annually.^{13,14}

Decreased production of estrogen results in decreased efficiency of calcium absorption in women at any age.^{8,13} For example, the apparent absorption of dietary calcium by premenopausal and perimenopausal women ranges between 17% and 58% and decreases slightly with increasing calcium intake.¹⁵ However, women over 65 years old respond to low calcium intakes with significantly smaller increases in fractional calcium absorption than occur in women 20 to 35 years old consuming the same inadequate amount of calcium.¹⁶ Similarly, amenorrheic young women with hypoestrogenic anorexia nervosa have significantly less efficient calcium absorption than is enjoyed by healthy eumenorrheic young women.¹⁷

Racial differences affect the efficiency of calcium absorption. For example, African American girls exhibit significantly more efficient calcium absorption after menarche than do Caucasian girls.¹⁸ Interestingly, African American adults later exhibit significantly lower rates of bone fractures than do Caucasian adults.^{19,20}

C. Calcium Retention

The retention of ingested calcium within the body reflects the interplay among the amount of calcium consumed, the efficiency of calcium absorption, and urinary excretion of calcium. For example, when a group of healthy adult women reduced their calcium intake from 2000 mg/day to 300 mg/day, although their efficiency of calcium absorption increased significantly, their urinary excretion of calcium decreased significantly, and their efficiency of whole body retention of ingested calcium increased significantly (from 27% to 37%), the overall net result was a significant decrease in the net amount of calcium retained (from 540 mg/day to 111 mg/day).²¹

Amenorrheic young women with anorexia nervosa have significantly greater urinary excretion of calcium than healthy eumenorrheic women; coupled with the reduced absorption efficiency also exhibited by such women, these greater losses produce significantly reduced net calcium retention (evidenced by significantly reduced bone mass).¹⁷ Similarly, in contrast to the generally beneficial effects of moderate exercise on calcium metabolism and skeletal physiology, exercise-induced amenorrhea also produces significantly decreased net calcium retention (and lower bone mass).^{22,23}

Vegetarian diets produce metabolizable anions (such as acetate and bicarbonate) that may increase renal resorption of filtered calcium, decreasing urinary calcium excretion.^{24,25} Consequently, vegetarians may be more efficient retainers of dietary calcium.

Racial differences may affect the efficiency of calcium resorption in the kidneys. For example, African American children aged 9 to 18 years have exhibited significantly less urinary excretion of calcium than similarly-aged Caucasian children.²⁶ In contrast, it was reported that less calcium was excreted in the urine of African American girls before menarche but that urinary calcium excretion was similar in African American and Caucasian girls after menarche.¹⁸

Data from 181 balance studies subjected to nonlinear regression analysis indicate that maximal calcium retention occurs in men and women when dietary calcium intake is 1200 mg/day.²⁷⁻²⁹ Nonetheless, this level of intake may be inadequate for many individuals. For example, a daily intake of 1300 mg of calcium was insufficient to maximize calcium retention in all members of a group of adolescent females.²⁸

II. Nephrolithiasis

Nephrolithiasis (urolithiasis) produces aggregates of crystals mixed with a protein matrix (uroliths; kidney stones; urinary stones) that cause obstruction of urine flow in the renal collecting system, ureters or urethra and cause severe pain, bleeding, or local erosion of renal tissue.³⁰ This condition affects 12% to 20% of men and 5% to 10% of women in the US.³¹ Between 100 and 300 cases occur annually per 100,000 individuals.³² The risk for a second stone within 6 years is 50%.³³ Uroliths can be extremely painful and may require surgical removal.³⁴ Annual costs associated with nephrolithiasis in the US exceed 2 billion dollars.³⁵

The direct cause of urolith formation is unknown and is likely to be multifactorial.³⁴ Etiologic theories have focused on the roles of lithogenic (calcium oxalate) salts, renal tubular dysfunctions, anomalies in cation and anion transport across membranes and cell membrane lipid composition.³⁶ There is evidence that essential hypertension and nephrolithiasis may share a similar defect in calcium physiology.³⁷⁻⁴¹ In any case, it is apparent that dietary calcium restriction increases the risk for nephrolithiasis.⁴²⁻⁴⁴ One reviewer has commented, "a low calcium diet as a treatment for idiopathic calcium nephrolithiasis should be abandoned."⁴⁴

A. Dietary Calcium and Nephrolithiasis

Adequate calcium nutrition reduces the risk for nephrolithiasis.^{42,45,46} In a prospective observational study of 45,619 men, 40 to 75 years of age and without a history of kidney stones at the beginning of the study, after 4 years of observation (a total of over 200,000

person-years of experience⁴⁵), daily dietary calcium intake was significantly inversely associated with the risk of symptomatic kidney stone formation (RR for men consuming more than 1050 mg of calcium daily compared with men consuming less than 500 mg daily: 0.56; 95% CI: 0.43, 0.73).⁴⁶ In a prospective observational study of 91,731 women, 34 to 59 years of age and without a history of kidney stones at the beginning of the study, after 12-years of observation, daily dietary calcium intake was found to be significantly inversely associated with risk for kidney stones (RR for stone formation for women consuming more than 1100 mg of calcium daily compared with women consuming less than 500 mg daily: 0.65; 95% CI: 0.50, 0.83).⁴⁷

Paradoxically, in this study it appeared that dietary supplementation with calcium, even in amounts that resulted in a total daily calcium intake greater than 1100 mg, significantly increased the relative risk for kidney stones (RR: 1.20; 95% CI: 1.02, 1.41).⁴⁷ However, a number of other dietary factors and practices may have artificially inflated the risk associated with supplementation. In particular, if dietary calcium decreases risk for nephrolithiasis by complexing with and preventing the absorption of oxalates within the gastrointestinal tract,^{48,49} then supplemental calcium consumed between meals, as commonly occurs, would not confer this benefit.⁴² Three small groups of postmenopausal women with osteoporosis and without nephrolithiasis appear to have confirmed this surmise.⁵⁰⁻⁵² In three short experiments, daily dietary supplementation with 750 mg of elemental calcium (as calcium carbonate, consumed as 250 mg of elemental calcium with each of three meals) for 3 months did not change any of the biochemical markers for risk for nephrolithiasis and did not increase or decrease risk for kidney stone development.⁵⁰⁻⁵² The addition of either a program of estrogen/medrogestone therapy⁵¹ or dietary supplementation with calcitriol⁵² to this level of dietary calcium supplementation did not alter these findings. One epidemiologic study found a significant inverse relationship between dietary calcium intake and risk for kidney stones;⁵³ another found no relationship (positive or negative) between dietary calcium intake and the incidence of urinary calculi.⁵⁴

III. Bioavailability of Calcium from the Diet and from Dietary Supplements

Calcium absorption efficiency is fairly similar for most foods, including milk, dairy products and grains.²⁹ However, the efficiency of calcium absorption is reduced when the food sources include spinach, sweet potatoes, rhubarb, beans, unleavened bread, seeds, nuts, or soy isolates.²⁹ The fractional absorption of calcium from dietary supplements typically ranges from 25% to 35% (similar to range for calcium in milk).²⁹ In particular, men and women absorb calcium from calcium citrate and calcium carbonate with equivalent efficiency.^{55,56} However, clinical achlorhydria may impair absorption of calcium from calcium carbonate while enhancing the absorption of calcium from calcium citrate.⁵⁷

IV. Amounts of Supplemental Dietary Calcium that Are Effective in Reducing the Risk of Nephrolithiasis

The reliable and credible scientific literature indicates that daily dietary supplementation with calcium-containing compounds in amounts that provide sufficient elemental calcium to allow individuals to achieve daily total calcium intakes consistent with current Institute of Medicine recommendations for gender, age and reproductive status are effective in reducing the risk of nephrolithiasis.

Current recommended daily calcium intakes are 800 mg (4 through 8 years old), 1300 mg (9 through 18 years old), 1000 mg (19 through 50 years old) and 1200 mg (over 50 years old).²⁹ These intakes were chosen in order to ensure maximal skeletal development and duration.²⁹ Importantly, it appears that additional health benefits may occur only at intakes at least equal to the skeletal requirement.

Unfortunately, daily calcium consumption meets or exceeds these amounts in only a small fraction of the population.²⁹ For example, only half of children 4 to 8 years old consume at least 800 mg of calcium daily; less than 25% of boys 9 to 13 years old consume at least 1300 mg of calcium daily; less than 50% of boys 14 to 18 years old consume at least 1300 mg of calcium daily; only about 5% of adolescent girls consume at least 1300 mg of calcium daily; less than 50% of adult men and only about 10% of adult women consume at least 1000 mg of calcium daily; and less than 10% of the population over 50 years old consumes at least 1200 mg of calcium daily.²⁹ Recognizing the limitations of any recommendations that rely solely on the implementation of changes in life-long eating and dietary habits, the Institute of Medicine has suggested that “some seemingly healthy individuals may require higher calcium intakes”⁵⁸ and that for individuals at risk for dietary calcium intakes below recommendations, “use of calcium supplements may be desirable in order to meet [recommendations].”⁵⁹

V. Safety of Dietary Supplementation with Calcium in Amounts that Are Effective in Reducing the Risk of Nephrolithiasis

The US Food and Drug Administration has published its finding that the following calcium-containing compounds are “safe”: calcium carbonate, calcium citrate, calcium glycerophosphate, calcium oxide, calcium pantothenate, calcium phosphate, calcium pyrophosphate, calcium chloride, calcium lactate and calcium sulfate.^{60,61}

The Tolerable Upper Limit of Intake (“the maximal level of nutrient intake that is unlikely to pose risks of adverse health effects to almost individuals in the target group”⁵⁸) for calcium has been set at 2500 mg daily for males and females over 1 year of age,²⁹ providing an ample margin of safety for individuals choosing to improve their

health by supplementing their diets with calcium. This limit is not set lower during pregnancy or lactation and compares favorably with estimates of daily calcium consumption by modern hunter-gatherers.¹³ The Food and Nutrition Board of the Institute of Medicine has stated that “for the majority of the general population, intakes of calcium from food substantially above the UL are probably safe.”²⁹

No adverse events have occurred when adults with chronic renal failure and receiving hemodialysis have consumed up to 8000 mg of calcium carbonate (providing up to 3200 mg of elemental calcium) daily for up to 48 months^{62,63} or when adults with chronic renal failure and not yet receiving hemodialysis have consumed up to 3000 mg of calcium carbonate (providing up to 1200 mg of elemental calcium) daily for 6 months.⁶⁴ In these patients, daily dietary supplementation with calcium produced significant improvements in the clinical hyperphosphatemia caused by chronic renal failure.⁶²⁻⁶⁴ In addition, both dialyzed⁶³ and nondialyzed patients⁶⁴ experienced attenuation of disease-induced secondary hyperparathyroidism and bone resorption. Similarly, adults with chronic renal failure and receiving hemodialysis have consumed an unspecified amount of calcium as calcium acetate for 8 weeks with significant improvements in clinical hyperphosphatemia.⁶⁵ Boys and girls aged 1 month to 16 years with chronic renal failure and undergoing hemodialysis regularly and consuming 10 to 340 mg of calcium carbonate per kg body weight daily (providing 4 to 136 mg of elemental calcium per kg body weight daily, equivalent to a daily intake of 400 to 13,600 mg of elemental calcium by a 100-kg adult) also have exhibited significantly attenuated hyperphosphatemia and secondary hyperparathyroidism without any adverse reactions.⁶⁶

Increased risk for the development of symptomatic “milk alkali syndrome” (renal impairment, hypercalcemia, alkalosis) may accompany daily intakes of over 4,000 mg of elemental calcium, particularly if accompanied by equivalently large amounts (over 6,000 mg) of carbonate.⁶⁷ However, 4 days of daily supplementation with up to 5200 mg of elemental calcium and up to 7800 mg of carbonate was without adverse effect in young adult men and women⁶⁸ and 4 months of daily supplementation with 3240 mg of carbonate has been without adverse effect in healthy premenopausal women.⁶⁹ Individuals with uremia, hypothyroidism, adrenocortical insufficiency or PTH-secreting tumors may develop clinically relevant hypercalcemia after routine chronic daily consumption of 4,000 mg or more of elemental calcium.⁷⁰

One investigator calculated a Lowest Observed Adverse Effect Level (LOAEL) for calcium for individuals with a history of nephrolithiasis of 1685 mg daily, an amount more than current Institute of Medicine recommendations.⁷¹ The US Food and Drug Administration has concluded that daily intakes of elemental calcium up to at least 1800 mg pose no increased risk for kidney stones among the general population.⁶¹

A characteristic shared by all of the studies cited in this document is the absolute lack of any reports of any clinically-significant adverse reactions that could be attributed to dietary calcium. As noted by the North American Menopause Society in their 2001

Consensus Opinion, “The side effect profile from recommended levels of calcium intake is insignificant. No calcium intervention trials have reported any serious side effect associated with these levels.”⁷²

VI. Additional Literature regarding Relationships between Dietary Supplementation with Calcium and Reduction of the Risk of Nephrolithiasis

This literature review is by necessity brief and targeted to the requirements of the US Food and Drug Administration as concerns a balanced presentation of the published peer-reviewed scientific evidence relevant to the proposed health claim. However, it should be noted that the scientific literature upon which this review relies represents only a small fraction of the total available scientific literature base that may be relevant to the relationships between dietary supplementation with calcium and renal physiology. Literature searches performed on August 26, 2003, on the following topics obtained these numbers of citations:

Calcium and Nephrolithiasis (926 citations)

Calcium and Safety (1511 citations)

While there is some (undetermined) degree of repetition in the citations identified by these somewhat related searches, clearly there are at least 1500 unique citations that could be construed to be in some way relevant to this review. After examination of the 2437 citations listed above, 72 were found to be germane to the claim presented.

Conclusions

- The amount of ingested calcium that is absorbed increases with increasing daily dietary calcium intake.
- Daily dietary calcium intake of at least 1200 mg of elemental calcium is required in order to maximize the retention of absorbed calcium.
- The amount of dietary calcium required daily in order to maximize calcium retention is approximated by the current Institute of Medicine intake recommendations for this nutrient.
- Nephrolithiasis is produced by an abnormality in renal physiology.
- Nephrolithiasis may be associated with chronic secondary hyperparathyroidism.
- Maintaining sufficient dietary calcium intake to reduce oxalate absorption reduces the likelihood of nephrolithiasis.
- Avoidance of the possibility of dietary calcium deficiency reduces the risk for nephrolithiasis.
- Daily intakes of calcium satisfying the current Institute of Medicine intake recommendations for this nutrient reduce the risk for nephrolithiasis.
- Routine chronic consumption of dietary and supplemental calcium in amounts consistent with the current Institute of Medicine recommendations for this nutrient is safe.

Summary Conclusions

In conclusion, I find that there is significant scientific agreement in support of the following health claim:

- Calcium may reduce the risk of kidney stones.
- Calcium may reduce the risk of urinary stones.

/s/ Michael J. Glade¹

Michael J. Glade, Ph.D., F.A.C.N., C.N.S.
(a copy of my CV is attached)

¹ The original signature page is on file with Emord & Associates, P.C., counsel to Marine Bio Inc. Dr. Glade requested that it not be submitted to FDA to avoid having it posted on the internet and available for nefarious use.

Michael John Glade, Ph.D.

8612 Kedvale Avenue, Skokie IL 60076

TEL: (847)-329-9818

e-mail: the_nutrition_doctor@yahoo.com

EDUCATION:

Ph.D., Animal Science - Nutrition 1979
Cornell University, Ithaca, New York

Bachelor of Science, Molecular Biology 1973
Massachusetts Institute of Technology, Cambridge, Massachusetts

PROFESSIONAL AND CAREER OBJECTIVES:

To contribute to the improvement of public health in the areas of nutrition and public health policy through an internationally recognized nutrition program

LICENSES, CERTIFICATIONS, HONORS:

Licensed Dietitian (L.D.), State of Illinois 1995 to present

Certified Nutrition Specialist (C.N.S.) 1993 to present

Fellow, American College of Nutrition (F.A.C.N.) 1992 to present

Honorary Member, Irish Veterinary Medical Association 1988 to present

EXPERIENCE:

Independent Consultant May 1998 to present

Senior Research Analyst, ECRI, Plymouth Meeting, PA 1997 to 1998

Senior Scientist, American Medical Association, Chicago, IL 1990 to 1997

Visiting Scientist/Research Assistant Professor
Northwestern University, Chicago, IL 1986 to 2002

Assistant Professor, University of Maryland, College Park, MD 1981 to 1986

Assistant Professor, Rutgers University, New Brunswick, NJ 1979 to 1981

Michael J. Glade, Ph.D.

Director and Nutritionist Adviser to the Board of Directors
International College of Advanced Longevity Medicine 1998 to present

Member, Advisory Board
Society for Integrative Medicine 1998 to present
National Graves' Disease Foundation 1992 to 2001

Recorder
Nutrition Sciences Education and Research Fund 1997 to present

Designated Representative of the C.B.N.S.
Intersociety Physician Nutrition Education Consortium 1996 to present

Policy Paper Reviewer
Council for Agricultural Science and Technology (CAST). 1996 to present

Lecturer
Capital University of Integrative Medicine, Washington, DC 1999 to present
New York Chiropractic College (Diplomate in Nutrition program) 1998 to present
Northwestern University Medical School, Chicago, IL 1990 to 2002

Part-Time Faculty
Biostatistics, University of Bridgeport, Bridgeport, Connecticut 1993 to present

Adjunct Faculty
Union Institute, Cincinnati, Ohio 2000 to present

Book Review Editor
Nutrition: The International Journal of Applied and Basic Nutritional Sciences 1992 to present

Manuscript Reviewer
The Journal of the American Medical Association, The Journal of the American College of Nutrition, Nutrition, and other peer-reviewed journals 1980 to present

Council Coordinator
American College of Nutrition 1994 to 1998

Certification Board for Nutrition Specialists
Director 1992 to present
Director of Educational Programs 2001 to present
President 1996 to 1999
Vice-President 1992 to 1996
Editor, Certifying Examination, Certification Board for Nutrition Specialists 1992 to 2001
Editor/Author
1996 *Study Guide for the Certifying Examination for Certified Nutrition Specialists* 1996
1996 *Candidate's Guide for Licensure as a Nutrition Counselor, State of Illinois* 1996
1999 *Study Guide for the Certifying Examination for Certified Nutrition Specialists* 1999
Study Guide for the Certifying Examination for Certified Nutrition Specialists,
3rd Edition 2002
Lecturer, "Fundamentals of Human Nutrition" Review Course 2002 to present

Complete Nutrition Expertise

May 1998 to present

8612 Kedvale Avenue
Skokie IL 60076

- technical support
- educational/promotional materials
- seminars and symposia
- publications
- labeling
- regulatory affairs
- scientific product support
- policy development
- research protocol evaluation
- research design/implementation
- data analysis and interpretation
- product formulation

Product formulation and development projects have emphasized the rational combination of select vitamins, minerals, herbs, and phytonutrients and phytomedicines into formulas for individuals who are attempting to quit smoking or who are afflicted with alcoholism, caffeine dependency, colorectal cancer, breast cancer, cardiovascular disease, osteoporosis, arthritis or celiac disease. These projects have included the assembly of scientific substantiation for both product ingredients and product labeling.

Consulting Clinical Nutritionist
North Shore Wellness and Cosmetic Surgery
281 Waukegan Road, Northfield, IL 60093

September 1999 to present

Patient care in the areas of nutritional support for cancer management, restoration of intestinal function, diabetes, chronic fatigue, multiple sclerosis, mental illness, skeletal function, heart disease, chronic fatigue syndrome, fibromyalgia, morbid obesity, yeast infection and smoking cessation.

Nutritionist/Medical Advisor
Lake County Chapter, Celiac-Sprue Association

September 2000 to present

Past consulting projects:

Identification and substantiation of structure/function statements for dietary supplements containing ginseng (prepared for a commercial client).

Substantiation of new health claims for dietary supplements containing folic acid (prepared for a petition submitted to the FDA).

Substantiation of new health claims for dietary supplements containing antioxidant vitamins (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing selenium (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing antioxidant vitamins (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing selenium (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing phosphatidylserine (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing glucosamine (prepared for petitions submitted to the FDA).

Substantiation of new health claims for dietary supplements containing chondroitin sulfate (prepared for petitions submitted to the FDA).

Design of human trials to demonstrate the safety of a new dietary ingredient (prepared for a commercial client).

Preparation of the scientific background for petitions to FDA requesting approval to import new dietary ingredients (prepared for commercial clients).

Comparison of scientific manuscripts in several copyright infringement cases.

Substantiation of structure/function statements made for several dietary supplements (prepared for commercial clients).

Data analysis for the development of normal reference intervals for a series of new diagnostic tests.

Scientific substantiation and validation of a survey instrument for the assessment of overall health.

Scientific substantiation of a dietary supplement formulation for the support of cognitive functions (prepared for a commercial client).

Evaluation of the safety and effectiveness of a dietary supplement formulation for the chelation of heavy metals (prepared for a commercial client).

Evaluation of the safety and effectiveness of a dietary supplement formulation for enlargement of the human female breast (prepared for a commercial client).

Evaluation of the safety and effectiveness of dietary supplement formulations for enhancement of weight loss (prepared for commercial clients).

Evaluation of the safety and effectiveness of dietary supplement formulations for enhancement of sexual function (prepared for a commercial client).

Evaluation of the safety and effectiveness of dietary supplement formulations for enhancement of immune function (prepared for a commercial client).

Evaluation of the safety and effectiveness of dietary supplement formulations for enhancement of sleep (prepared for a commercial client).

Evaluation of the safety and effectiveness of a dietary supplement formulation for reduction of serum total cholesterol concentration (prepared for a commercial client).

Consultations with the Deputy Commissioner of the Food and Drug Administration concerning the scientific substantiation of proposed health claims for dietary supplements.

Presentations since May 1998:

Herbal management of diabetes. Natural Pharmacy East, Arlington, VA, October 1998.

Nutritional support for breaking nicotine addiction. International College for Advancement of Longevity Medicine Fall Symposium, Reno, NV, October, 1998.

Nutritional support for breaking nicotine addiction. Sixth International Congress of the American Academy of Anti-Aging Medicine, Las Vegas, NV, December, 1998.

Nutritional support for breaking nicotine addiction: A randomized, double-blind, placebo-controlled evaluation of a proprietary dietary supplement. American College of Nutrition Annual Symposium, Washington, DC, October, 1999

Efficacy of an enzyme product derived from *Aspergillus niger* and bromelain (AbsorbAid™) in improving protein absorption in nursing home patients on tube feeding. American College of Nutrition Annual Symposium, Las Vegas, NV, October, 2000.

Preventing cancer with nutrition. Prevention Plus, Oak Park, IL, October, 2000.

Celiac disease. Healthy Eating Seminar Series, Lake County Chapter, Celiac-Sprue Association, Waukegan, IL, October, 2000.

Gluten sensitivity and other digestive disorders. Healthy Eating Seminar Series, Lake County Chapter, Celiac-Sprue Association, Deerfield, IL, January, 2001.

Digestive disease; celiac disease; digestive ecology; using diagnostic technology to target trace elements and vitamin therapy. American Naprapathic Association, Countryside, IL, April 22, 2001.

Biomarkers of aging. Chicagoland Anti-Aging Conference, Wilmette, IL, May 19, 2001.

Restoration of digestive ecology. Designs for Health – Advanced Training in Clinical Nutrition, Designs for Health Institute, Boulder, CO, June 30, 2001.

The relationship between digestive tract function and autism. In-service training, Pfeiffer Foundation, Naperville, IL, July 2001.

Nutrition and brain function. Amer, Naprapathic Assoc., Countryside, IL, April 7, 2002.

Fundamentals of Human Nutrition. Two-day Review Course in preparation for the certifying examination of the Certification Board for Nutrition Specialists. American College for the Advancement of Medicine, Ft. Lauderdale, FL, May 15-16, 2002.

Fundamentals of Human Nutrition. Two-day Review Course in preparation for the certifying examination of the Certification Board for Nutrition Specialists. American College of Nutrition, San Antonio, TX, October 2-3, 2002.

Fundamentals of Human Nutrition. Two-day Review Course in preparation for the certifying examination of the Certification Board for Nutrition Specialists. American College of Nutrition, New York, NY. April 5-6, 2003.

Fundamentals of Nutrition. Two-day Review Course in preparation for the certifying examination of the Certification Board for Nutrition Specialists. American College of Nutrition, Miami, FL, April 23-24, 2003.

Upcoming Presentations:

Fundamentals of Human Nutrition. Two-day Review Course in preparation for the certifying examination of the Certification Board for Nutrition Specialists. American College of Nutrition, New York, NY. April 5-6, 2003.

Teaching Lecture Topics since May 1998:

Environmental medicine and detoxification therapy.
Carbohydrate nutrition and nutritional therapy.
Protein nutrition and nutritional therapy.
Nutritional and herbal management of diabetes.
Nutritional therapeutics in cancer.
Nutrition and cancer prevention for consumers.
Celiac disease and its prevention and treatment.
Free radical and antioxidant biology.
Biostatistics for nutritionists (I designed and am teaching this course both in-class and over the internet)

Michael J. Glade, Ph.D.

ECRI

5200 Butler Pike, Plymouth Meeting, PA 19462

August 1997 to May 1998

SENIOR RESEARCH ANALYST
Technology Assessment

Evaluation of medical, nutritional, and technological therapies and diagnostic techniques for human endocrine, metabolic, musculoskeletal, and nutritional diseases.

Quality Assurance Manager, National Guidelines Clearinghouse (with AHCPH)

Participant in database design, National Guidelines Clearinghouse (with AHCPH)

Statistical expert, diagnostic technologies and meta-analysis

Provide in-house expertise to ECRI Management on food, device, drug, agriculture and nutrition-related health, policy, legal, and regulatory matters.

SUPERVISOR: Charles Turkelson, Ph.D.
Chief Research Analyst
Technology Assessment
ECRI

Michael J. Glade, Ph.D.

AMERICAN MEDICAL ASSOCIATION

515 N. State St. Chicago, IL 60610

1993 to 1997

SENIOR SCIENTIST, Technology Assessment & Nutrition Department of Technology Assessment

Evaluation of medical, nutritional, and technological therapies and diagnostic techniques for human endocrine, metabolic, musculoskeletal, and nutritional diseases.

Development of Technology Assessments for the AMA *Diagnostic and Therapeutic Technology Assessment (DATTA)* project:

- Diagnostic Value of Plasma Lp(a) Concentrations
- Diagnostic Value of Plasma Apolipoproteins
- Diagnostic Value of Serum Thyroid-Stimulating Hormone (TSH)
- Diagnostic Value of Computerized Dynamic Posturography
- Diagnostic Value of 24-hour Esophageal pH Monitoring
- Therapeutic Value of Peripheral Parenteral Nutrition
- Therapeutic Value of Intraoperative Radiotherapy
- Therapeutic Value of Speech Therapy in Otitis Media
- Therapeutic Value of Recombinant Human Growth Hormone (rhGH) in Children with Short Stature
- Therapeutic Value of Mononuclear Leukocyte ("Buffy Coat") Infusions in Chronic Myelocytic Leukemia
- Therapeutic Value of Medicinal Leeches
- Therapeutic Value of Pedicle Screw Spinal Fixation Systems
- Therapeutic Value of Recombinant Human Growth Hormone (rhGH) in Children with Gonadal Dysgenesis

Related Duties:

Statistician; perform statistical analyses for all physician surveys administered by the *DATTA* project.

Co-Editor of the monthly AMA newsletter, *Technology News*.

Provide in-house expertise to AMA Senior Management on food, device, drug, agriculture and nutrition-related health, policy, legal, and regulatory matters.

Secretary, AMA House of Delegates Reference Committee E (advise AMA policy committees on medicine, nutrition, and public health).

Michael J. Glade, Ph.D.

Publications:

Published In:	No. of Publications:
<i>DATTA</i> Assessments:	13
peer-reviewed journals:	4
Proceedings chapters:	4
book reviews:	11
general public press:	16
peer-reviewed journals (submitted):	5

Original articles published in the monthly AMA newsletter, *Technology News*:

Risk Assessment in the Establishment of Upper Safe Limits for Nutrient Intakes	12/96
Dietary Fat and Cancer: Molecular Mechanisms	10/96
Clinical Significance of Melatonin (with B. Kendler)	9/96
Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	6/96
Dietary Phytochemicals in Cancer Prevention and Treatment	11/95
Electromagnetic Compatibility for Medical Devices: Issues and Solutions	9/95
FDA/NIH-Sponsored Conference: Comparing Treatments: Safety, Effectiveness, and Cost-Effectiveness	5/95
Clinical Significance of Oxidative Stress (with B. Kendler)	11/95
Diet and Cancer: Molecular Mechanisms of Interactions	1-2/95
Management of Disorders of Cholesterol, Triglyceride, and Lipoprotein Metabolism	11/94
AMA Annual Meeting Update (with S. Kalousdian)	7-8/94
Drug and Device-Induced Disease: Developing a Blueprint for the Future	/94
AMA Interim Meeting Update (with S. Kalousdian)	1-2/94
AMA Annual Meeting Update (with S. Kalousdian)	8/93
Breast Cancer Risk and Diet	1/93

Author of AMA policy statements on nutrition issues:

- food irradiation;
- lipoproteinemia;
- bacterial contamination of meat;
- dietary calcium requirements;
- folic acid supplementation to prevent neural tube defects;
- thiamin supplementation of alcoholic beverages to prevent polyneuropathy;
- neonatal hyponatremia from hypo-osmolar bottled water

Michael J. Glade, Ph.D.

Speaking Invitations:

The Dietary Supplement and Health Education Act of 1994. Annual Meeting of the American College of Nutrition, Washington, DC, October, 1995.

Innovation in clinical nutrition. Harvard University, May 6, 1995.

Environmental medicine. New York Chiropractic College, April 29, 1995.

Environmental medicine. New York Chiropractic College, September 11, 1994.

Additional Responsibilities:

Meeting with representatives of the Food and Drug Administration, the US Department of Agriculture, and other federal agencies concerning:

food, device and drug regulation;

food safety;

direct to consumer advertising of medical therapies.

Collaboration with other AMA staff in the development of scripts for television programs aired on American Medical Television.

Represented AMA on "National Educational Forum on Food Safety Issues."

Book Review Editor, *Nutrition: The International Journal of Applied and Basic Nutritional Sciences*.

Reviewed manuscripts submitted to *the Journal of the American Medical Association*, *the Journal of the American College of Nutrition*, and other peer-reviewed journals.

Reviewed advertisements intended for use in AMA publications.

Policy paper reviewer for the Council for Agricultural Science and Technology (CAST).

Invitations to Chair National Meetings:

Invited to chair and organize a session on "Nutritional Controversies" at the 1996 Annual Meeting of the American College of Nutrition, San Francisco.

Invited to serve as co-chairman of a session of the 1994 Malnutrition and AIDS Symposium, Los Angeles.

Invited to serve as co-chairman of a session of the 1994 Annual Meeting of the American College of Nutrition, Atlanta.

SUPERVISOR: Sona Kalousdian, MD, MPH
Department Director, Department of Technology Assessment
American Medical Association
(773) 384-4915

Michael J. Glade, Ph.D.

AMERICAN MEDICAL ASSOCIATION

515 N. State St. Chicago, IL 60610

1990 to 1993

SENIOR SCIENTIST, Endocrinology, Metabolism & Nutrition Department of Drugs

Evaluation of medical and nutritional therapies and diagnostic techniques for human endocrine, metabolic, musculoskeletal, and nutritional diseases.

Extensive revision of chapters in the Congressionally-recognized compendium of FDA-approved unlabeled drug use and nutritional therapy, *AMA Drug Evaluations*:

Fluid, Electrolyte, and Acid-Base Therapy (pp. 865-880*)

Drugs Used for Urolithiasis (pp. 907-924)

Drugs Used in Adrenocortical Dysfunction (pp. 1017-1036)

Drugs Used in Thyroid Disease (pp. 1037-1062)

Vitamins and Minerals (pp. 2283-2306)

Parenteral and Enteral Nutrition (pp. 2307-2362)

Drugs Used in Obesity (pp. 2439-2454)

Treatment of Disorders of Cholesterol and Lipoprotein Metabolism (pp. 2455-2500)

(* page numbers as in the 1995 edition)

Assistant Secretary, AMA House of Delegates Reference Committee E (advise AMA policy committees during development of policies concerning medicine, nutrition, and public health).

Collaboration with other AMA staff in the development of scripts for television programs aired on American Medical Television

Publications:

Published In:	No. of Publications:
<i>AMA Drug Evaluations</i> Chapters:	8
peer-reviewed journals:	12
Proceedings chapters:	6
book reviews:	1
general public press:	6

Speaking Invitations:

A review of hormonal regulation of cartilage growth in foals. Symposium on Equine Osteochondrosis, Cambridge University, United Kingdom, September, 1992.

Marginal copper deficiency as a cause of defective angiogenesis in chondrodysplasia. Symposium on Equine Osteochondrosis, Cambridge University, United Kingdom, September, 1992.

Michael J. Glade, Ph.D.

Endocrine regulation of equine growth plate chondrocytes. Symposium on Equine Osteochondrosis, Cambridge University, United Kingdom, September, 1992.

Equine osteochondrosis as a manifestation of induced episodic "pseudohypothyroidism." Symposium on Equine Osteochondrosis, Cambridge University, United Kingdom, September, 1992.

Insulin and thyroid hormones influence matrix production by chondrocytes. Seminars in Endocrinology, Northwestern University, Chicago, IL, April 2, 1991.

Additional Responsibilities:

Meetings with representatives of the Food and Drug Administration, the US Department of Agriculture, and other federal agencies concerning:

food, device and drug regulation;

food safety;

direct to consumer advertising of medical therapies

Collaboration with Centers for Disease Control in development of recommendations concerning folic acid and the prevention of neural tube defects (*Morbidity and Mortality Weekly*, August 2, 1991, and September 21, 1992).

Author of AMA policy statement on monosodium glutamate.

Provide in-house expertise to AMA Senior Management on food, device, drug, agriculture and nutrition-related health, policy, legal, and regulatory matters.

Represented AMA on "National Educational Forum on Food Safety Issues".

Book Review Editor, *Nutrition: The International Journal of Applied and Basic Nutritional Sciences*.

Review manuscripts submitted to *the Journal of the American Medical Association*, *the Journal of the American College of Nutrition*, and other peer-reviewed journals.

Review advertisements intended for use in AMA publications.

Coordinator, Council on Endocrinology, Bone, and Minerals; American College of Nutrition.

Advisory Board Member, National Graves' Disease Foundation

SUPERVISOR: Joseph Cranston, Ph.D.
Department Director
Department of Drugs
American Medical Association

Michael J. Glade, Ph.D.

NORTHWESTERN UNIVERSITY

303 E. Chicago Avenue, Chicago, IL 60610

1986 to 1990

RESEARCH ASSISTANT PROFESSOR **Department of Pharmacology**

Funded originally as an NIH Senior Fellowship, this position - including both research and teaching - has been continued on a part-time, unpaid basis through the present time as a Visiting Scientist, Department of Molecular Pharmacology and Biological Chemistry

Laboratory and field research; presentation and publication of research findings; fund raising; maintenance of laboratory; practice of safe and proper animal housing and handling; practice of safe handling of hazardous substances.

Concentration on the effects of nutrients, hormones and growth factors on skeletal development and disease.

Guest lectures on pancreatic and thyroid disease and their prevention and medical and nutritional management.

Publications:

Published In:	No. of Publications:
peer-reviewed journals:	11
Proceedings chapters:	8
abstracts:	4
general public press:	98

Speaking Invitations:

Response of arthritic chondrocytes to polysulfated glycosaminoglycans. Skeletal Biology Program, Case Western Reserve University, Cleveland OH, May 14, 1990.

Flora and fauna of Africa and Europe. Department of Pharmacology, Northwestern University, Chicago, IL, February 9, 1989.

Influences of diet and endocrinology on equine developmental orthopedic disease. Department of Animal Sciences, University of Guelph, Ontario, Canada, January 18, 1989.

Diet and growth quality. Equine management class, University of Guelph, Ontario, Canada, January 18, 1989.

Fermentation enhancers. Department of Animal Sciences, University of Guelph, Ontario, Canada, January 17, 1989.

Nitrogen metabolism in the equine. Equine management class, University of Guelph, Ontario, Canada, January 16, 1989.

Michael J. Glade, Ph.D.

Feeding and management of pleasure and show horses. Potomac Horse Club, Silver Spring, MD, October, 1988.

Feeding and management of pleasure and show horses. Potomac Horse Club, Silver Spring, MD, October, 1988.

Homeorrhesis and the growing animal. Biological Sciences Seminar, University College, Dublin, Ireland, October 17, 1988.

Nutrition and developmental disorders of equidae. Department of Zoology, University College, Dublin, Ireland, October 17, 1988.

Nitrogen metabolism in horses. Veterinary College of Ireland, Dublin, Ireland, October 14, 1988.

The role of yeast culture in the nutritional management of young horses. 100th Irish Veterinary Congress, Dublin, Ireland, September 23, 1988.

The role of endocrine factors in equine developmental orthopedic disease. Developmental Orthopedic Disease Panel, American Association of Equine Practitioners Annual Meeting, New Orleans, LA, November 29, 1987.

Diet, chondrodysplasias and animals. Oral Biology Seminar, Northwestern University, Chicago, IL, October 29, 1987.

Effects of yeast culture on nitrogen metabolism in young horses. Alltech Biotechnology Symposium, Lexington, KY, April, 1987.

Bibliometric analysis of research activity in Brazil. Central Intelligence Agency, MacClean, VA, March, 1987.

Bibliometric analysis of research activity in Spain. Ministry of Science and Education, Madrid, Spain, March, 1987.

Cartilage disorders associated with changes in thyroid hormone metabolism. The Chicago Endocrine Society, Chicago, IL, December, 1986.

Dietary causes of osteochondrosis. Pathology Seminar, Northwestern University, Chicago, IL, April, 1986.

Michael J. Glade, Ph.D.

UNIVERSITY OF MARYLAND

College Park, Maryland

1981 to 1986

**ASSISTANT PROFESSOR, Department of Animal Sciences
College of Agricultural Sciences**

Teaching: (Class, laboratory, barn; lecture, hands-on formats)

Animal Husbandry (nutrition, diet formulation, diseases, management, genetics, physiology, functional morphology)

Animal Training (including principles of animal behavior and their application to training)

Safe Animal Handling (including principles of animal behavior and their application to safe practices in handling animals)

Protein Nutrition (graduate course)

Training:

How to Teach and Supervise Animal Training (undergraduate and graduate students; written materials; videotapes)

Laboratory Techniques (undergraduate and graduate students)

Field Research Techniques (undergraduates and graduates)

Dissertation and Scientific Writing

Grant Proposal Preparation

Research:

Animal Nutrition and Physiology Projects, including several in collaboration with the National Zoo, Washington, DC

Publications:

Published In:	No. of Publications:
peer-reviewed journals:	17
Proceedings chapters:	8
abstracts:	8
general public press:	73

Other projects: (in addition to those documented in publications)

hormone secretion rates in pigs

skeletal growth in monkeys

pharmacokinetics of ivermectin in bullfrogs

growth hormone concentrations in horses and zebras

Michael J. Glade, Ph.D.

Invitation to Chair National Meeting:

Invited to serve as co-chairman of a Non-Ruminant Nutrition session at the 1982 meeting of the American Society of Animal Science, Guelph, Ontario, Canada.

Speaking Invitations:

Quality feed management: tips for proper production and storage. Baltimore Horse Seminar, March, 1985.

Dietary carbohydrate induction of the multiple-messenger, inositol-calmodulin pathway. Animal Sciences Seminar, University of Maryland, February, 1985.

The use of ultrasound to monitor neonatal bone development. Invited seminar, Walter Reed Medical Center, Washington, DC, December, 1984.

Mechanisms of dietary induction of osteochondrosis. Invited seminar, Department of Animal Science, University of Alberta, Edmonton, Canada, August, 1984.

The Use of Self-Supervised Activity to Acquaint College Students with the Teacher-Student Dynamic. 10th International Conference, Improving University Teaching, College Park, MD, July, 1984.

Diagnostic ultrasound - a non-invasive method for examining bone. Pediatric Research Conference, University of Maryland School of Medicine, May, 1984.

Electrical stimulation of bone healing. Alice Deal Science Day, May, 1984.

Non-Traditional feeding practices for the performance horse. Maryland Nutrition Conference, Baltimore, MD, March, 1984.

The use of ultrasound. Nutritional Sciences Colloquium, University of Maryland, February, 1984.

Nutrient-hormone interactions and their impact on growth. Nutritional Sciences Colloquium, University of Maryland, February, 1984.

Feeding horses for a lot less money. Eastern Amateur Arabian Horse Show Circuit Fall Meeting, December, 1983.

Equine nutritional requirements. Baltimore Horse Seminar, November, 1983.

The costs of owning a horse, Maryland Society for the Prevention of Cruelty to Animals Field Day, May, 1983.

Ultrasonic measurement of bone strength. Alice Deal Science Day, April, 1983.

Nutritional manipulation of bone and joint development in growing horses. Maryland Nutrition Conference, Washington, DC, March, 1982.

Developmental origins of growth abnormalities. Animal Sciences Seminar, University of Maryland, October, 1981.

Michael J. Glade, Ph.D.

Additional Responsibilities:

Design of Animal Habitats:

Personally redesigned three multi-acre animal housing facilities, and assisted in their physical renovation

Animal Care:

Collaboration with veterinarians in prophylactic and interventive medical care, including personally:

- administering medications by mouth
- injection (intramuscular; intravenous)
- nasogastric intubation; rectal gavage
- bandaging; suturing
- development of growth plate biopsy procedure for ungulates
- necropsy

Animal Management:

Directly responsible for the management, breeding, and training of up to 120 horses residing at multi-building and multi-site facilities whose activities encompassed teaching, research, breeding, continuing adult education, veterinary care, demonstrations

Supervision of Personnel:

Supervision of up to two dozen permanent and temporary full and part time employees and volunteers engaged in animal husbandry

Record Keeping; Budgets:

Directly responsible for planning, developing, administering, and adhering to expense and revenue budgets, and for extensive and comprehensive record-keeping concerning all facets of a major university equine program

Fund-Raising:

Obtaining funds to support all programs and activities

Sources included federal agencies, state agencies, private foundations, private individuals, corporate entities, animal sales, animal rental

RUTGERS UNIVERSITY

New Brunswick, NJ

1979 to 1981

ASSISTANT PROFESSOR, Department of Animal Sciences

Teaching: (Class, laboratory, barn; lecture, hands-on formats):

Animal Husbandry (nutrition, diet formulation, diseases, management, genetics, physiology, functional morphology)

Animal Training (including principles of animal behavior and their application to training)

Safe Animal Handling (including principles of animal behavior and their application to safe practices in handling animals)

Training:

Field Research Techniques (undergraduates and graduates)

Grant Proposal Preparation

Research:

Animal Nutrition and Physiology Projects

Publications:

Published In:	No. of Publications:
Proceedings chapters	1
abstracts	1

Speaking Invitations:

Digestive physiology of the horse. Animal Sciences Seminar, University of Maryland, September, 1980.

Similarities between effects of dexamethasone on growing cartilage and osteochondrosis dissecans. Animal Science Seminar, University of California at Davis, April, 1980.

Osteochondrosis dissecans and growth suppression in dexamethasone treated horse foals. American Association of Equine Practitioners Annual Meeting, Miami Beach, December, 1979.

Effects of dexamethasone on calcium metabolism of pony foals. Animal Sciences Seminar, Rutgers University, May, 1979.

Michael J. Glade, Ph.D.

Additional Responsibilities:

Design of Animal Habitats:

Personally redesigned a multi-acre animal housing facility, and assisted in its physical renovation

Animal Care:

Collaboration with veterinarians in prophylactic and interventive medical care, including personally:

- administering medications by mouth
- injection (intramuscular; intravenous)
- nasogastric intubation; rectal gavage
- bandaging; suturing; necropsy

Animal Management:

Directly responsible for the management, breeding, and training of up to 11 horses residing at multi-building and multi-site facilities whose activities encompassed teaching, research, continuing adult education, veterinary care, demonstrations

Supervision of Personnel:

Directly responsible for the supervision of two permanent part time employees and a dozen or so volunteers engaged in animal husbandry

Record Keeping; Budgets:

Directly responsible for planning, developing, administering, and adhering to expense and revenue budgets, and for extensive and comprehensive record-keeping concerning all facets of a major university equine program

Fund-Raising:

Obtaining funds to support all programs and activities

Sources included federal agencies, state agencies, private foundations, private individuals, corporate entities, animal sales, animal rental

Refereed Journal Articles:

1. Glade, M.J. The effects of gestation, lactation, yeast culture and maternal calcium intake on the mechanical strength of equine bone. *Journal of Equine Veterinary Science*: submitted for publication.
2. Heimbürger, D.C., and the Intersociety Professional Nutrition Education Consortium. 2002. Training and certifying gastroenterologists as Physician Nutrition Specialists. *Journal of Clinical Gastroenterology* 34:505-508.
3. Glade, M.J., D. Kendra and M.V. Kaminski, Jr. 2001. Improvement in protein utilization in nursing-home patients on tube feeding supplemented with an enzyme product derived from *Aspergillus niger* and bromelain. *Nutrition* 17:348-350.
4. Heimbürger, D.C., and the Intersociety Professional Nutrition Education Consortium. 2000. Physician-nutrition-specialist track: If we build it, will they come? *American Journal of Clinical Nutrition* 71:1048-1053.
5. Glade, M.J. 1997. Intake of dietary calcium to reduce the incidence of osteoporosis. *Archives of Family Medicine* 6:491-494.
6. Glade, M.J. 1995. Management of disorders of cholesterol, triglyceride, and lipoprotein metabolism. *Archives of Family Medicine* 4:869-878.
7. Glade, M.J. 1995. Continuous ambulatory esophageal pH monitoring. *Journal of the American Medical Association* 274:662-668.
8. Glade, M.J., Y.S. Kanwar and P.H. Stern. 1994. Insulin and thyroid hormones alter chondrocyte metabolism in cell culture independently and in combination. *Connective Tissue Research* 31:37-44.
9. Glade, M.J. 1993. The effects of gestation, lactation, and maternal calcium intake on the mechanical strength of equine bone. *Journal of the American College of Nutrition* 12:372-377.
10. Glade, M.J. 1992. Effects of *Yucca shidigera* extract on feed utilization by equine weanlings. *Journal of Equine Veterinary Science* 12:93-98.
11. Letcher, J. and M.J. Glade. 1992. Efficacy of ivermectin as an anthelmintic in leopard frogs. *Journal of the American Veterinary Medical Association* 200:537-538.
12. Glade, M.J., Y.S Kanwar and T.J. Hefley. 1991. Enzymatic isolation of chondrocytes from immature rabbit articular cartilage and their maintenance of phenotypic expression in culture. *Journal of Bone and Mineral Research* 6:217-226.
13. Glade, M.J. 1991. Timed administration of leucine, isoleucine, valine, glutamine, and carnitine to enhance athletic performance. *Equine Athlete* 4:1-10.
14. Glade, M.J. 1991. Effects of dietary yeast culture supplementation of lactating mares on the digestibility and retention of the nutrients delivered to nursing foals via milk. *Journal of Equine Veterinary Science* 11:323-329.

Michael J. Glade, Ph.D.

15. Glade, M.J. 1991. Dietary yeast culture supplementation of mares during late gestation and early lactation. 3. Effects on mare and foal plasma metabolite, amino acid and endocrine profiles. *Journal of Equine Veterinary Science* 11:167-175.
16. Glade, M.J. 1991. Dietary yeast culture supplementation of mares during late gestation and early lactation. 2. Effects on milk production, milk composition, weight gain and linear growth of nursing foals. *Journal of Equine Veterinary Science* 11:89-95.
17. Glade, M.J. 1991. Dietary yeast culture supplementation of mares during late gestation and early lactation. 1. Effects on dietary nutrient digestibilities and fecal nitrogen partitioning. *Journal of Equine Veterinary Science* 11:10-16.
18. Glade, M.J. and M.D. Sist. 1990. Supplemental yeast culture alters the plasma amino acid profiles of nursing and weanling horses. *Journal of Equine Veterinary Science* 10:369-379.
19. Glade, M.J. and N.K. Luba. 1990. Benefits to foals of feeding soybean meal to lactating broodmares. *Journal of Equine Veterinary Science* 10:422-428.
20. Glade, M.J. and M. Campbell-Taylor. 1990. Effects of dietary yeast culture supplementation during the conditioning period on equine exercise physiology. *Journal of Equine Veterinary Science* 10:434-443.
21. Glade, M.J. 1990. Polysulfated glycosaminoglycan (PSGAG) accelerates the synthesis of collagen and glycosaminoglycans by arthritic equine cartilage tissues and chondrocytes. *American Journal of Veterinary Research* 51:779-785.
22. Sist, M.D., Youngblood, M.A., Williams, J.F. and Glade, M.J. 1988. Salivary and serum estrone sulfate levels in pregnant mares. *Journal of Equine Veterinary Science* 8: 164-167.
23. Glade, M.J. and M.D. Sist. 1988. Dietary yeast culture supplementation enhances urea recycling in the equine large intestine. *Nutrition Reports International* 37: 11-19.
24. Wright, L.L., M.J. Glade and J. Gopal. 1987. The use of transmission ultrasonics to assess bone status in the human newborn. *Pediatrics Research* 22:541-544.
25. Glade, M.J. and N.K. Luba. 1987. Serum triiodothyronine and thyroxine concentrations in weanling horses fed carbohydrate by direct gastric infusion. *American Journal of Veterinary Research* 48:578-582.
26. Glade, M.J., N.K. Luba, and H.F. Schryver. 1986. Effects of age and diet on the development of mechanical strength by the cannon bones of young horses. *Journal of Animal Science* 63:1432-1444.
27. Glade, M.J. and L.M. Biesik. 1986. Changes in serum hormone concentrations in weanling horses following gastric infusion of sucrose or casein. *Nutrition Reports International* 33:651-659.
28. Glade, M.J. and L.M. Biesik. 1986. Enhanced nitrogen retention in yearling horses supplemented with yeast culture. *Journal of Animal Science* 62:1633-1640.

Michael J. Glade, Ph.D.

29. Glade, M.J. 1986. Estimation of urine flow rate in weanling and yearling horses. *American Journal of Veterinary Research* 47:2151-2156.
30. Glade, M.J. and T.H. Belling. 1986. A dietary etiology for osteochondrotic cartilage. *Journal of Equine Veterinary Science* 6:151-154.
31. Glade, M.J. 1986. The control of cartilage growth in osteochondrosis. *Journal of Equine Veterinary Science* 6:175-187.
32. Glade, M.J. 1986. "Social Sleeping" among confined horses. *Journal of Equine Veterinary Science* 6:155-157.
33. Glade, M.J. and R.A. Salzman. 1985. Effects of hoof angulation on hoof growth and contraction in the horse. *Journal of Equine Veterinary Science* 5:45-50.
34. Glade, M.J. and T.J. Reimers. 1985. Effects of dietary energy supply on serum thyroxine, tri-iodothyronine and insulin concentrations in young horses. *Journal of Endocrinology* 104:93-98.
35. Glade, M.J., D. Beller, J. Bergen, D. Berry, E. Blonder, J. Bradley, M. Cupelo and J. Dallas. 1985. Dietary protein in excess of requirements inhibits renal calcium and phosphorus reabsorption in young horses. *Nutrition Reports International* 31:649-659.
36. Glade, M.J. 1985. Stimulation of electromagnetic osteogenesis in healthy growing yearlings. *Journal of Equine Veterinary Science* 5:149-153.
37. Glade, M.J. 1985. Overfeeding energy to horses. *Journal of Equine Veterinary Science* 5:95.
38. Glade, M.J., S. Gupta and T.J. Reimers. 1984. Hormonal responses to high and low planes of nutrition in weanling Thoroughbreds. *Journal of Animal Science* 59:658-665.
39. Glade, M.J. and T.H. Belling. 1984. Growth plate cartilage metabolism, morphology and biochemical composition in over- and underfed horses. *Growth* 48:473-482.
40. Glade, M.J. 1984. Feeding innovations for the performance horse. *Journal of Equine Veterinary Science* 4:165-168.
41. Glade, M.J. 1984. "Social sleeping" behavior in young horses. *Equine Practice* 6:10-14.
42. Glade, M.J. 1984. The influence of dietary fiber digestibility on the nitrogen requirements of mature horses. *Journal of Animal Science* 58:638-646.
43. Belling, T.H. and M.J. Glade. 1984. A non-destructive biopsy method allowing the rapid removal of live growth plate cartilage. *Veterinary Medicine/Small Animal Clinician* 79:528-531.
44. Glade, M.J. 1983. Nitrogen partitioning along the equine digestive tract. *Journal of Animal Science* 57:943-953.
45. Glade, M.J. 1983. Nutrition and performance of racing Thoroughbreds. *Equine Veterinary Journal* 15:31-36.

Michael J. Glade, Ph.D.

46. Glade, M.J., L. Krook, H.F. Schryver and H.F. Hintz. 1982. Morphologic and biochemical changes in cartilage of foals treated with dexamethasone. *Cornell Veterinarian* 73:170-192.
47. Glade, M.J., L. Krook, H.F. Schryver and H.F. Hintz. 1982. Calcium metabolism in glucocorticoid-treated foals. *Journal of Nutrition* 112:67-76.
48. Glade, M.J. and L. Krook. 1982. Glucocorticoid-induced inhibition of osteolysis and the development of osteopetrosis, osteonecrosis and osteoporosis. *Cornell Veterinarian* 72:76-91.
49. Glade, M.J., L. Krook, H.F. Schryver and H.F. Hintz. 1981. Growth inhibition induced by chronic dexamethasone treatment of foals. *Journal of Equine Veterinary Science* 1:198-201.
50. Matteo, C.M., M.J. Glade, A. Tanaka, J. Piret and A.L. Demain. 1975. Microbiological studies on the formation of gramicidin S synthetases. *Biotechnology and Bioengineering* 17:129-142.

Abstracts and Proceedings:

1. Glade, M.J., Kendra, D., Kaminsky, M.V., Jr. 2000. Efficacy of an enzyme product derived from *Aspergillus niger* and bromelain (AbsorbAid™) in improving protein absorption in nursing home patients on tube feeding. *Proceedings, Annual Meeting of the American College of Nutrition*, Las Vegas, NV, October.
2. Heimburger, D., and IPNEC. 2000. Training the Physician Nutrition Specialist (PNS). *Proceedings, Annual Meeting of the American College of Nutrition*, Las Vegas, NV, October.
3. Glade, M.J. 1998. Nutritional support for breaking nicotine addiction. *Proceedings, Sixth International Congress on Anti-Aging and Biomedical Technologies* (American Academy of Anti-Aging Medicine), Las Vegas, NV, December, p. unpagged.
4. Glade, M.J. 1998. Nutritional support for breaking nicotine addiction. *Proceedings, International College for Advancement of Longevity Medicine Fall Symposium*, Reno, NV, October, unpagged.
5. Glade, M.J. 1998. Herbal management of diabetes. *Proceedings, Second Annual Natural Pharmacy East Conference*, Arlington, VA, October, unpagged.
6. Glade, M.J., and M.E. Allen. 1996. Assessment of skeletal development in leopard geckos. II. Long bone morphometry and breaking strength. *Proceedings, Ninth Dr. Scholl Nutrition Conference*, Chicago, IL, October, unpagged.
7. Glade, M.J. 1995. The Dietary Supplement and Health Education Act of 1994. *Proceedings, Annual Meeting of the American College of Nutrition*, Washington, DC, October, p. 557.
8. Glade, M.J. 1993. CuSO₄ and chelated copper are bioequivalent when added to the diets of nursing foals. *Proceedings, Annual Meeting of the American College of Nutrition*, Chicago, October, p. 589.
9. Glade, M.J. 1993. CuSO₄ and chelated copper are bioequivalent when added to the culture medium of cartilage tissue and cells. *Proceedings, Annual Meeting of the American College of Nutrition*, Chicago, October, p. 589.
10. Glade, M.J. 1992. Equine osteochondrosis as a manifestation of induced episodic "pseudohypothyroidism." *Proceedings, Symposium on Equine Osteochondrosis*, Cambridge University, United Kingdom, September, p. 44.
11. Glade, M.J. 1992. Endocrine regulation of equine growth plate chondrocytes. *Proceedings, Symposium on Equine Osteochondrosis*, Cambridge University, United Kingdom, September, pp. 42-43.
12. Glade, M.J. 1992. Marginal copper deficiency as a cause of defective angiogenesis in chondrodysplasia. *Proceedings, Symposium on Equine Osteochondrosis*, Cambridge University, United Kingdom, September, pp. 30-31.

Michael J. Glade, Ph.D.

13. Glade, M.J. 1992. A review of hormonal regulation of cartilage growth in foals. *Proceedings, Symposium on Equine Osteochondrosis*, Cambridge University, United Kingdom, September, pp. 19-20.
14. Glade, M.J. 1992. The effects of gestation, lactation, and maternal calcium intake on the mechanical strength of equine bone. *Proceedings, Annual Meeting of the American College of Nutrition*, San Diego, October, p. 600.
15. Glade, M.J. 1992. Marginal copper deficiency as a cause of defective angiogenesis in chondrodysplasia. *Proceedings, Annual Meeting of the American College of Nutrition*, San Diego, October, p. 600.
16. Glade, M.J., C. Cahill and M. Campbell. 1989. Effect of exercise on plasma growth hormone concentrations in foals. *Proceedings, Equine Nutrition and Physiology Society*, pp. 63-64.
17. Glade, M.J. 1989. Effects of specific amino acid supplementation on lactic acid production by horses exercised on a treadmill. *Proceedings, Equine Nutrition and Physiology Society*, pp. 244-251.
18. Glade, M.J. 1989. Undergraduates and publishable equine research. *Proceedings, Equine Nutrition and Physiology Society*, pp. 233-235.
19. Glade, M.J. 1989. Supplemental yeast culture alters the plasma amino acid profiles of weanling Quarter horses. *Proceedings, Equine Nutrition and Physiology Society*, pp. 119-123.
20. Campbell, M. and M.J. Glade. 1989. Effects of dietary yeast culture supplementation during the conditioning period on heart rates and lactic acid production by horses exercised on a treadmill. *Proceedings, Equine Nutrition and Physiology Society*, pp. 72-78.
21. Glade, M.J. and P.H. Stern. 1988. Effect of polysulfated glycosaminoglycan (PSGAG) on monolayer cultures of articular chondrocytes. *Journal of Bone and Mineral Research*: 3: Suppl. 1:465.
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