

**Tab D**

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

FEDERAL TRADE COMMISSION,  
Plaintiff,

v.

LANE LABS-USA, INC.,  
CARTILAGE CONSULTANTS, INC.,  
corporations, and  
I. WILLIAM LANE and ANDREW J.  
LANE, individuals  
Defendants.

Hon. Dennis M. Cavanaugh

00CV374 (DMC)

DECLARATION OF CRAIG  
NIEDERBERGER, M.D.,  
F.A.C.S.

I, CRAIG NIEDERBERGER, DO HEREBY DECLARE PURSUANT TO  
28 U.S.C. SEC. 1746, AS FOLLOWS:

Education, Experience and Training

1. As detailed in my *Curriculum Vitae*, attached hereto as Exhibit 1, I obtained my undergraduate Bachelor of Science Degree at Harvey Mudd College in 1982, and my Medical Degree at the University of Pittsburgh in 1986. I completed my Urological residency at the University of Illinois at Chicago in 1991, and fellowship in Andrology (male reproductive medicine and surgery) at Baylor College of Medicine in 1993.

2. I returned as faculty to the University of Illinois at Chicago in 1993, and was tenured in 1999. I serve as Chief of the Division of Andrology in the Department of Urology, where I am currently Interim Head of the Department. As Chief of Andrology, I oversee the Andrology fellowship program, and have mentored 10 fellows, six of whom became faculty at major university urology programs across the country.
3. I authored or co-authored 75 peer reviewed journal articles and 10 book chapters, with areas including male reproductive basic science in animals and humans, clinical male reproductive medicine, the interpretation of laboratory assays including reproductive hormones and the semen analysis, and the analysis of male reproductive data.
4. I am a primary editor of the upcoming fourth edition of the textbook "Infertility in the Male," the infertility editor of the Journal of Urology Survey Section, the infertility editor of Practical Reviews in Urology Infertility, a column editor of the Journal of Andrology, the infertility editor of Urology Times, and a co-moderator of the international Internet user's group "Androlog."
5. My local and national leadership roles include the American Urological Association / American Board of Urology Exam Committee (which creates the tests for Urologic certification), Presidency of the Society for the Study of

Male Reproduction (the Society for male reproductive medicine and surgery within the American Urological Association), Presidency of the Society for Male Reproduction and Urology (the Society for male reproductive medicine and surgery within the American Society for Reproductive Medicine), and Presidency of the Chicago Urological Society.

### Scope of Work, and Conclusions

6. The Federal Trade Commission (FTC) asked me to evaluate, from my perspective as an expert on male reproductive medicine, whether existing data supported claims made by Lane Labs that the product “Fertil Male” (Lepidium Meyenii, Maca Roots) improved male fertility by increasing sperm count, motility, and sperm production. The FTC also asked me to identify what kinds of studies and data would need to be completed in order to support such claims.
7. In order to facilitate these tasks, the FTC provided me with certain materials referring or relating to Fertil Male, including the following: studies published in journals, including animal, human and basic pharmacology studies, unpublished studies, basic pharmacology studies, research reports, abstracts, and miscellaneous materials. Exhibit 2 contains my detailed analyses of these materials from a scientific perspective.

## 8. Studies published in journals:

### 8.1. Animal studies

- 8.1.1. Gonzales GF, Ruiz A, Gonzales C, Villegas L, Cordova A Effect of *Lepidium meyenii* (maca) roots on spermatogenesis of male rats. *Asian J Androl.* 2001 Sep;3(3):231-3.
- 8.1.2. Zheng BL, He K, Kim CH, Rogers L, Shao Y, Huang ZY, Lu Y, Yan SJ, Qien LC, Zheng QY. Effect of a lipidic extract from *lepidium meyenii* on sexual behavior in mice and rats. *Urology.* 2000 Apr;55(4):598-602.
- 8.1.3. Cicero AF, Bandieri E, Arletti R. *Lepidium meyenii* Walpers improves sexual behaviour in male rats independently from its action on spontaneous locomotor activity. *J Ethnopharmacol.* 2001 May;75(2-3):225-9.
- 8.1.4. Gonzales GF, Gasco M, Cordova A, Chung A, Rubio J, Villegas L. Effect of *Lepidium meyenii* (Maca) on spermatogenesis in male rats acutely exposed to high altitude (4340 m). *J Endocrinol.* 2004 Jan;180(1):87-95.

### 8.2. Human studies

- 8.2.1. Gonzales GF, Cordova A, Gonzales C, Chung A, Vega K, Villena A. *Lepidium meyenii* (Maca) improved semen parameters in adult men. *Asian J Androl.* 2001 Dec;3(4):301-3.

- 8.2.2. Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C, Castillo S. Effect of *Lepidium meyenii* (MACA) on sexual desire and its absent relationship with serum testosterone levels in adult healthy men. *Andrologia*. 2002 Dec;34(6):367-72.
- 8.2.3. Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C. Effect of *Lepidium meyenii* (Maca), a root with aphrodisiac and fertility-enhancing properties, on serum reproductive hormone levels in adult healthy men. *J Endocrinol*. 2003 Jan;176(1):163-8.8.3. Basic pharmacology studies
- 8.3.1. Bogani P, Simonini F, Iriti M, Rossoni M, Faoro F, Poletti A, Visioli F. *Lepidium meyenii* (Maca) does not exert direct androgenic activities. *J Ethnopharmacol*. 2006 Apr 6;104(3):415-7. Epub 2005 Oct 18.
- 8.3.2. Piacente S, Carbone V, Plaza A, Zampelli A, Pizza C. Investigation of the tuber constituents of maca (*Lepidium meyenii* Walp.) *J Agric Food Chem*. 2002 Sep 25;50(20):5621-5.

## 9. Unpublished studies:

- 9.1 Cuya MV, Rosado DN, De La Guarda RG, Rosello X, de Boccard GA, Rojas PA. Maca's and Maca-HAI's effect on subfertile males. Submitted 2006.

10. Research reports:

- 10.1. Gonzales GF, Cordova A, Chung A, Villena A, Gonez C, Vega K, Rubio J, Gasco M, Gonales C, Castillo S, Garayar D. Effect of *Lepidium meyenii* (maca) in the form of gelatinized maca tablets, administered to apparently normal adult male subjects. Research Report 2001.

11. Abstracts:

- 11.1. Maca and maca-HAI effect on sperm quality of rats with induced sub-fertility.
- 11.2. Maca and maca-HAI effect on sperm quality and hormone levels of sub-fertile males.
- 11.3. Effect of *Lepidium meyenii* or *Lepidium peruvianum* (maca) administered in form of tablets of gelatinized maca to grown-up male, apparently normal.

12. Miscellaneous Documents:

- 12.1. Maca-HAI study – update email.
- 12.2. Various unpublished and governmental documents pertaining to *Lepidium meyenii* preparations and animal toxicity studies without direct investigation into an effect on male reproductive potential.
- 12.3. A sampling of abstracts and editorial reports concerning the issue of global sperm decline. This is a highly controversial area in which good scientific

evidence exists to support each side of the debate. However, the topic of a possible global sperm decline is not particularly relevant to the issue of the effect of *Lepidium meyenii* on male reproductive potential.

13. My own independent research did not uncover evidence relating to claims of Fertil Male's effect on male fertility beyond those documents provided by the FTC.
14. In brief, I found that while *Lepidium meyenii* (maca) appears to function as a stimulatory agent for sexual behavior in animals and humans, there is no definitive, compelling or analytically suggestive evidence that compounds based on *Lepidium meyenii* (maca) roots improve human male fertility. I understand from conversations with FTC that the FTC standard requires that claims be substantiated by "competent and reliable scientific evidence." It is my opinion, on review of the available evidence, that the claim that *Lepidium meyenii* (maca) improves human male fertility is not supported by competent and reliable scientific evidence.

### Biology of Male Fertility

15. Male fertility in animals and humans is a fairly complex process. Sperm are formed in the testis, which in humans requires an intricate series of tightly controlled steps encompassing approximately two to three months duration.



These steps are orchestrated by chemicals passing between cells in the testis, with the major one being the male hormone testosterone. The amount of testosterone released in the testis is regulated by a chemical released in the brain by the pituitary, lutenizing hormone, which circulates in the bloodstream. Sperm formed in the testis then pass through the epididymis, a small organ attached to the testis containing a highly coiled microscopic tube, in which sperm mature and attain the capacity to fertilize an egg.

16. The most common test of male fertility at present is the semen analysis, in which the volume of liquid (typically more than 2 milliliters), the number of sperm per milliliter (for an average male over 50 to 80 million in each milliliter), and the percentage of sperm that when observed under the microscope appear to be moving forward (typically 50% or more), are recorded. The number of moving sperm in the semen analysis varies considerably in any man from ejaculate to ejaculate.

#### General Requirements for Reliable Scientific Support for Defendant's Claims

17. To demonstrate with reasonable likelihood that compounds based on *Lepidium meyenii* (maca) roots improve human male fertility, the following conditions must be satisfied:

- 17.1. A plausible biological basis for improvements in male fertility be established in animal studies, and
- 17.2. Human studies with sufficient subjects be designed and implemented such that:
  - 17.2.1. Chance effects leading to observed improvements in fertility be excluded, conventionally by the inclusion of a placebo group separate from the treated group,
  - 17.2.2. Biases introduced by the investigators carrying out the trial(s) be excluded, traditionally by a double-blind design, and
- 17.3. Clinically and statistically significant improvements be documented in outcomes that are relevant to an expected improvement in male fertility.
18. No matter what type of outcome for a particular treatment, psychological or biological, a placebo group is conventional in studies for a clear and critical reason. This reason relates to a statistical effect referred to as “regression to the mean.” Given any subjects with measurements related to a biological effect outside of the mean measurement for those subjects, such as a group of infertile men, they are *expected* to improve on subsequent testing simply because it is more likely that the next measurement will approach the mean. The only way to determine if such an improvement was due to chance or to a therapeutic effect is to give placebo to a separate group of subjects, and

compare outcomes of the placebo group to those of the treated group.

Conventionally the investigators and the subjects do not know who received placebo and who received the treatment until the end of the trial, a methodology referred to as “double blind” design. When the variability of the outcome measurements is large, such as with semen analysis parameters, a placebo group is absolutely critical, as any chance effect appearing as improvement is likely to be of large magnitude.

19. Pilot studies are conventionally undertaken to determine the number of subjects required to determine a statistically significant difference between a treatment and placebo. If the variability of the outcome measurements is large, such as with semen analysis parameters, calculation of the number of subjects required to discern a statistically significant difference may result in thousands or more. However, scientists commonly balance what is ideal and what is practical, and typically choose 100 subjects in each group if the variance of outcome measurements is large.

Review of the Evidence Does Not Substantiate the Defendant’s Claims that “Fertil Male,” Derived From *Lepidium meyenii* (Maca) Improves Human Male Fertility

20. The majority of the evidence presented in the form of scientific literature reporting outcomes of animal studies focused on sexual behavior, which is

not directly related to spermatogenesis. In effect, animals displaying differing kinds and amounts of sexual behavior cannot be expected to differ in fertility as well: fertility must be investigated by some form of fertility test such as the semen analysis. Where outcomes relating to male fertility were studied in animal models likely to simulate normal adult human male conditions, either statistically or clinically non-significant effects of *Lepidium Meyenii* were reported. For example, in one animal study with a small number of rats, testis and epididymal weight varied by such a small amount that a difference in male fertility would not be expected. Scant animal data relating directly to male fertility was found in the literature, with the majority of scientific studies addressing sexual behavior rather than male fertility.

21. Even if animal studies were to show a definitive spermatogenic effect, human studies are absolutely required, as animals are different than humans. In the human studies, like the animal studies, investigators addressed sexual behavior with substantially greater emphasis than male fertility. Only three studies addressed human sperm parameters in subjects taking Maca. In the single published study, only nine men were given Maca and had their sperm parameters recorded. No placebo group was used. Similarly, in a research report, only nine men taking Maca had sperm parameters reported. In an unpublished study concluding in 2006, 47 infertile men and 12 men with

normal sperm parameters were given Maca and Maca-HAI. Oddly, the investigators refer to a “double blind” design, but they did not include a placebo group, a critical omission. In addition, the human studies did not detect demonstrable changes in reproductive hormones coincident with *Lepidium Meyenii* administration, further lowering expectation that compounds based on this agent would improve male fertility, in that no biological basis for an effect is reasonably posited or apparent.

22. Of greatest concern in the human studies is the lack of a placebo group. A placebo group is central to determining whether a drug is effective or not, and is conventional in science for clear reasons. Subjects cannot be used as their own controls, as it is impossible to disprove regression to the mean as the reason for an observed improvement rather than a drug effect.

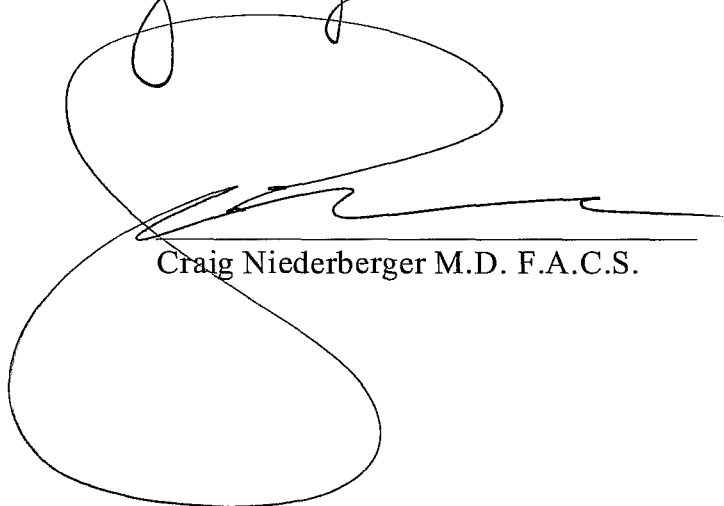
#### Summary of Expert Opinion

23. In summary, the available evidence does not suggest that *Lepidium Meyenii* administration improves male fertility. When outcomes relating to male fertility were studied, subject numbers were small and improvement in male fertility was questionable at best. To demonstrate with a reasonable degree of scientific certainty an effect of *Lepidium Meyenii* administration on human male fertility, larger, better designed trials would be required. However,

based on the available evidence, a reasonable prediction regarding the outcome of larger trials would be that an effect on human male fertility is unlikely to be demonstrated. Of greatest concern is the lack of any human trials with a placebo group. Claims stating that compounds based on *Lepidium Meyenii* improve male fertility thus are not based on competent and reliable scientific evidence.

I declare under penalty of perjury that the foregoing statement is true and correct.

Executed at Chicago, IL on January 8, 2007.



Craig Niederberger M.D. F.A.C.S.

# Exhibit 1

## **Craig Niederberger, M.D.**

Chief, Division of Andrology  
Associate Professor, Department of Urology  
Associate Professor, Department of Obstetrics/Gynecology,  
Associate Professor, Department of Genetics  
**1993 to present**

### **University of Illinois at Chicago College of Medicine**

840 South Wood Street, M/C 955  
Chicago, Illinois, 60612-7316  
(312) 996-2779, Fax: (312) 996-1291  
*Birthplace:* San Diego, California (1960)

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#### **Education**

*Undergraduate:* B.S. 1982 Harvey Mudd College, Claremont, California (Graduation with Distinction, and Honors in the Humanities and Social Sciences, Dual Majors in Chemistry and Theater)

*Graduate:* M.D. 1986 University of Pittsburgh, Pittsburgh, Pennsylvania

#### *Residency:*

-Surgery: 1986-1988: Michael Reese Hospital, Chicago, Illinois

-Urology: 1988-1991: Michael Reese Hospital and University of Illinois at Chicago, Chicago, Illinois

*Fellowship:* Andrology: 1991-1993 Baylor College of Medicine: Houston, Texas

#### **Medical Licensure and Board Certification**

National Board of Medical Examiners: Diplomat 1987

State of Illinois 1988 (036-076974)

State of California 1990 (C 069693)

Board Certified: American Board of Urology, 1995

#### **National and Regional Organizations**

American Urological Association / American Board of Urology

Exam Committee 2004-present

American Urological Association

Audio-Visual committee 2000-present

Internet Advisory committee 2001-present

Research Council committee 2003-present



Society for the Study of Male Reproduction

Secretary 2001-2003  
Vice President 2003-2004  
President 2004-2005

North Central Section

Young Leadership committee Vice Chair 2000-2001  
Young Leadership committee Chair 2001-2002  
Local Arrangements Chair for 2003 Annual Meeting

Chicago Urological Society

Secretary/Treasurer 2003-2004  
Vice President 2004-2005  
President 2005-2006

American Society for Reproductive Medicine

Co-Chair Electronic Communications Resource committee 1998-present  
Continuing Medical Education committee 1997-present

Society for Male Reproduction and Urology

Secretary/Treasurer 2003-2004  
Vice President 2004-2005  
President 2005-2006

**Medical Organizations**

Chicago Urological Society: *Member*  
Chicago Medical Society: *Member*  
Illinois State Medical Society: *Member*  
Illinois State Urological Society: *Member*  
American Medical Association: *Member*  
American College of Surgeons: *Fellow*  
American Urological Association: *Member*  
American Fertility Society: *Member*  
Society for the Study of Male Reproduction: *Member*  
Society for Basic Urologic Research: *Member*  
American Society of Andrology: *Member*  
American Association for the Advancement of Science: *Member*  
American Chemical Society: *Member*  
Endocrine Society: *Member*  
American Society for Cell Biology: *Member*  
Society for Laparoscopic Surgeons: *Member*

## Journal Articles

1. Saslawsky M, Niederberger C, Schacht M, Prinz L, Ross L. Ureterocutaneous fistula: a case report of treatment by subtrigonal injection of polytetrafluoroethylene (Sting procedure). J Urol. 1989 Nov;142(5):1310-1
2. Schacht MJ, Niederberger CS, Garnett JE, Sensibar JA, Lee C, Grayhack JT. A local direct effect of pituitary graft on growth of the lateral prostate in rats. Prostate. 1992;20(1):51-8
3. Niederberger C, Ross LS, Mackenzie B Jr, Schacht MJ, Cho Y. Vasovasostomy in rabbits using fibrin adhesive prepared from a single human source. J Urol. 1993 Jan;149(1):183-5
4. Niederberger CS, Lome LG. Primary malignant melanoma of urinary bladder. Urology. 1993 Jan;41(1):72-4
5. Niederberger C, Ross LS. Microsurgical epididymovasostomy: predictors of success. J Urol. 1993 May;149(5 Pt 2):1364-7
6. Niederberger CS, Lamb DJ, Glinz M, Lipshultz LI, Scully NF. Tests of sperm function for evaluation of the male: Penetrak and Tru-Trax. Fertil Steril. 1993 Aug;60(2):319-23
7. Niederberger CS, Lipshultz LI, Lamb DJ. A neural network to analyze fertility data. Fertil Steril. 1993 Aug;60(2):324-30
8. Niederberger CS, Shubhada S, Kim SJ, Lamb DJ. Paracrine factors and the regulation of spermatogenesis. World J Urol. 1993;11(2):120-8
9. Lamb DJ, Niederberger CS. Artificial intelligence in medicine and male infertility. World J Urol. 1993;11(2):129-36
10. Niederberger CS, Ross LS, Cho Y, Pursell S, Rizvi S, Glinz M, Maislos S, Kim S, Lipshultz LI, Lamb DJ. Genetic Regulation of Spermatogenesis. Molecular Andrology. 1994;6:270-80
11. Qin Y, Lamb DJ, Golden RM, Niederberger C. A Neural Network Predicts Mortality And New Metastases In Patients With Renal Cell Cancer. Proceedings of the First World Congress On Computational Medicine: Public Health And Biotechnology-Building A Man In the Machine: Part III: Series In Mathematical Biology And Medicine: 1994;5:1325-34
12. Niederberger CS, Ross LS, Lipshultz LI, Lamb DJ, Golden R. Artificial Intelligence: The New Frontier of Fertility Data Analysis. ARTA. 1995;7:57-68
13. Niederberger CS. This month in Investigative Urology. Commentary on the use of neural networks in clinical urology. J Urol. 1995 May;153(5):1362
14. Ross LS, Niederberger CS: Male infertility: Diagnosis And Treatment: COMPREHENSIVE THERAPY: 1995 Jun;21: 276-82

15. Spear KA, Niederberger CS. Male Infertility: Evaluation And Treatment. JOURNAL OF UROLOGICAL NURSING. 1996;15:1182-93
16. Meacham RB, Niederberger CS. Use of a moderated international Internet information exchange in the study of male reproduction. Urology. 1996 Jul;48(1):3-6
17. Brown B, Cho L, Golden RM, Hong Y, Michaels EK, Niederberger CS, Ross LS. A Neural Computational Model of Stone Recurrence After ESWL: Proceedings of the International Conference On Engineering Applications of Neural Networks. 1996;423-26
18. Niederberger CS. Is Semen Quality Declining? Contemporary Urology. 1996 Sep;8(9):55-62
19. Niederberger C. Computational tools for the modern andrologist. J Androl. 1996 Sep-Oct;17(5):462-6
20. Krongrad A, Granville LJ, Burke MA, Golden RM, Lai S, Cho L, Niederberger CS. Predictors of general quality of life in patients with benign prostate hyperplasia or prostate cancer. J Urol. 1997 Feb;157(2):534-8
21. Niederberger C, Agulnik AI, Cho Y, Lamb D, Bishop CE. In situ hybridization shows that Dazla expression in mouse testis is restricted to premeiotic stages IV-VI of spermatogenesis. Mamm Genome. 1997 Apr;8(4):277-8
22. Ilekis JV, Gariti J, Niederberger C, Scoccia B. Expression of a truncated epidermal growth factor receptor-like protein (TEGFR) in ovarian cancer. Gynecol Oncol. 1997 Apr;65(1):36-41
23. Ilekis JV, Connor JP, Prins GS, Ferrer K, Niederberger C, Scoccia B. Expression of epidermal growth factor and androgen receptors in ovarian cancer. Gynecol Oncol. 1997 Aug;66(2):250-4
24. Katz D, Niederberger C, Slaughter GR, Cooney AJ. Characterization of germ cell-specific expression of the orphan nuclear receptor, germ cell nuclear factor. Endocrinology. 1997 Oct;138(10):4364-72
25. Michaels EK, Niederberger CS, Golden RM, Brown B, Cho L, Hong Y. Use of a neural network to predict stone growth after shock wave lithotripsy. Urology. 1998 Feb;51(2):335-8
26. Agoulnik IY, Cho Y, Cooney AJ, Kieback DG, Niederberger C. Cloning. Expression Analysis And Chromosomal Localization of The Human Nuclear Receptor Gene GCNF. Febs Letters. 1998 Mar;424:73-8
27. Niederberger CS. The Cell As An Information Machine: The Genetic Code. Contemporary Urology. 1998 Apr;10(4):29-44
28. Bagli DJ, Agarwal SK, Venkateswaran S, Shuckett B, Khoury AE, Merguerian PA, McLorie GA, Liu K, Niederberger CS. Artificial neural networks in pediatric urology: prediction of sonographic outcome following pyeloplasty. J Urol. 1998 Sep;160(3 Pt 2):980-3

29. Scoccia B, Lee YM, Niederberger C, Ilekis JV. Expression of the ErbB family of receptors in ovarian cancer. *J Soc Gynecol Investig.* 1998 May-Jun;5(3):161-5
30. Prins GS, Dolgina R, Studney P, Kaplan B, Ross L, Niederberger C. Quality of cryopreserved testicular sperm in patients with obstructive and nonobstructive azoospermia. *J Urol.* 1999 May;161(5):1504-8
31. Mantz CA, Nautiyal J, Awan A, Kopnick M, Ray P, Kandel G, Niederberger C, Ignacio L, Dawson E, Fields R, Weichselbaum R, Vijayakumar S. Potency preservation following conformal radiotherapy for localized prostate cancer: impact of neoadjuvant androgen blockade, treatment technique, and patient-related factors. *Cancer J Sci Am.* 1999 Jul-Aug;5(4):230-6
32. Habermann H, Seo R, Cieslak J, Niederberger C, Prins GS, Ross L. In vitro fertilization outcomes after intracytoplasmic sperm injection with fresh or frozen-thawed testicular spermatozoa. *Fertil Steril.* 2000 May;73(5):955-60
33. Niederberger C. Neural computation in urology: an orientation. *Mol Urol.* 2001 Winter;5(4):133-9
34. Niederberger C. How Good Is It, Really, Evaluating Diagnostic And Screening Tests? *Contemporary Urology.* 2001 Oct;13(10):76-81
35. Schoor RA, Elhanbly SM, Niederberger C. The pathophysiology of varicocele-associated male infertility. *Curr Urol Rep.* 2001 Dec;2(6):432-6
36. Elhanbly S, Schoor R, Elmogy M, Ross L, Hegazy A, Niederberger C. What nonresponse to intracavernous injection really indicates: a determination by quantitative analysis. *J Urol.* 2002 Jan;167(1):192-6
37. Schoor RA, Elhanbly S, Niederberger CS, Ross LS. The role of testicular biopsy in the modern management of male infertility. *J Urol.* 2002 Jan;167(1):197-200
38. Niederberger C. The adverse effect of sulfasalazine on spermatogenesis and male reproductive potential. *J Androl.* 2002 Mar-Apr;23(2):180
39. Tubb B, Mulholland DJ, Vogl W, Lan ZJ, Niederberger C, Cooney A, Bryan J. Testis fascin (FSCN3): a novel paralog of the actin-bundling protein fascin expressed specifically in the elongate spermatid head. *Exp Cell Res.* 2002 Apr 15;275(1):92-109
40. Schoor RA, Elhanbly SM, Ross LS, Niederberger CS. The influence of obstructive interval on patency rates following microsurgical epididymovasostomy. *World J Urol.* 2002 Apr;19(6):453-6
41. Niederberger C. Cryptorchidism, fertility, and cancer. *J Androl.* 2003 Jan-Feb;24(1):19-20
42. Caroppo E, Niederberger C, Iacovazzi PA, Correale M, Palagiano A, D'Amato G. Human chorionic gonadotropin free beta-subunit in the human seminal plasma: a new marker for spermatogenesis? *Eur J Obstet Gynecol Reprod Biol.* 2003 Feb 10;106(2):165-9

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47. Stuart A, Niederberger C. Current State of Vasectomy Reversal. *A.R.T. & Science.* 2003 Oct;3(3) 5-8
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56. Niederberger C. The clinical conundrum of complete asthenospermia.

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62. Kshirsagar A, Ku J, Lamb D, Liu H, Niederberger C. Computational Models of Intracytoplasmic Sperm Injection Prognosis. Proceedings of the European Society on Artificial Neural Networks. 2005 Apr:115
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65. Kshirsagar A, Seftel A, Ross L, Mohamed M, Niederberger C. Predicting hypogonadism in men based upon age, presence of erectile dysfunction, and depression. Int J Impot Res. 2006 Jan-Feb;18(1):47-51.
66. Hussein A, Ozgok Y, Ross L, Niederberger C. Clomiphene administration for cases of nonobstructive azoospermia: a multicenter study. J Androl. 2005 Nov-Dec;26(6):787-91.
67. Liu H, Kshirsagar A, Niederberger C. The application of Machine Learning Techniques to the Prediction of Erectile Dysfunction. IEEE Fourth International Conference on Machine Learning and Applications. Los Angeles, CA. Dec, 2005. 227-32.
68. Niederberger C, Makhlof AA. Vasectomy reversal in the presence of diminished ovarian reserve: a complex clinical conundrum. J Androl. 2006 Jan-Feb;27(1):3-5.
69. Wald M, Ross LS, Prins GS, Cieslak-Janzen J, Wolf G, Niederberger CS. Analysis of Outcomes of Cryopreserved Surgically Retrieved Sperm for IVF/ICSI. J Androl. 2006

Jan-Feb; 27(1):60-5.

70. Makhlof A, Kshirsagar A, Niederberger C. Phosphodiesterase 11: a brief review of structure, expression and function. *Int J Impot Res*. 2006 Jan 5; [Epub ahead of print]

71. Wald M, Meacham RB, Ross LS, Niederberger CS. Testosterone replacement therapy for older men. *J Androl*. 2006 Mar-Apr;27(2):126-32.

72. El-Latif M A, Makhlof A A, Moustafa Y M, Gouda T E, Niederberger C S, Elhanbly S M. Diagnostic value of nitric oxide, lipoprotein(a), and malondialdehyde levels in the peripheral venous and cavernous blood of diabetics with erectile dysfunction. *Int J Impot Res*. Apr 20 2006; [Epub ahead of print]

73. Makhlof A A, Niederberger CS. DNA Integrity Tests in Clinical Practice: It Is Not a Simple Matter of Black and White (or Red and Green). *J Androl*. 2006 May/June;27(3):316-32.

74. Makhlof A A, Niederberger CS. Ensuring Vasectomy Success: What Is the Standard? *J Androl* 2006 Sep/Oct; 27(5): 637-40.

75. Sun P, Cameron A, Seftel A, Shabsigh R, Niederberger C, Guay A. Erectile Dysfunction An Observable Marker of Diabetes Mellitus? A Large National Epidemiological Study. *J Urol* 2006 Sep;176(3):1081-5.

## **Books**

Associate Editor: *Handbook of Neural Computation*: eds. Fiesler E, Beale R, Axelrod T, Blayo F, Cios KJ, Doerschuk PI, Jain S, Murphy CL, Niederberger C, Torkkola K, Wellekens CJ; IOP Publishing and Oxford University Press: Oxford: 1997

Associate Editor: *Jeyendran RS, Niederberger C, Nani JM, Chen D, Brannigan R, Schoor R, Ross LS, Zhang XJ, Ruiz A: Sperm Collection and Processing Methods. A Practical Guide: Cambridge Press, United Kingdom: October 2002*

*The Urologic Clinics of North America*, Larry Lipshultz, Craig Niederberger: Publisher WB Saunders Co: London: November 2002

## **Book Chapters**

1. Lamb DJ, Niederberger C: *Animal Models That Mimic Human Male Reproductive Defects: Urology Clinics of North America: WB Saunders Co: London: 1994: pp 377-387*

2. Lamb DJ, Niederberger CS, *New statistical techniques that predict medical outcomes in Advances in Urology: volume 9: eds. McGuire EJ, Bloom D, Catalona WJ, Lipshultz LI: Mosby, St. Louis: 1996: pp. 407-426*

3. Niederberger CS, Pursell S, Golden RM: *A neural network to predict lifespan and new metastases in patients with renal cell cancer: in Handbook of Neural Computation: eds. Fiesler E, Beale R, Axelrod T, Blayo F, Cios KJ, Doerschuk PI, Jain S, Murphy CL, Niederberger C, Torkkola K, Wellekens CJ; IOP Publishing and Oxford University Press: Oxford: 1997: pp. G5.4: 1-6*

4. Niederberger CS, Lamb DJ: Spermatogenesis in the adult, in Infertility in the Male: 3rd edition: eds. Lipshultz LI and Howards SS; Mosby: St. Louis: 1997: pp. 106-122
5. Niederberger CS, Meacham R: Reproductive Medicine on the Internet and the World Wide Web: Male Infertility: WB Saunders Co: Philadelphia: 1999: pp. 621-630
6. Niederberger CS, Ridout D: Neural Networks In Urologic Oncology : The Biomedical Engineering Series Editor Michael Newman: Artificial Neural Networks in Cancer Diagnosis: Prognosis, and Patient Management: eds Raouf N.G. Naguib, Gajanan V. Sherbert: Boca Raton : CRC Press, 2001: Chapter 9: pp. 103-113
7. Niederberger CS: Understanding the Epidemiology of Fertility Treatments: Urology Clinics of North America: WB Saunders Co: London: 2002: pp 829-840
8. Land S, Niederberger C: The current role of the urologist in the assisted reproductive technology team: Infertility and Reproductive Medicine Clinics: WB Saunders Co: Philadelphia: 2002: Chapter 13, pp. 791-807
9. Rajasingam JS, Niederberger C: Sperm procurement methods: Sperm and Processing Methods a practical guide: Cambridge University Press: New York: 2002: pp. 11-14
10. Schoor RA, Ross LS, Niederberger C: Clinical sperm collection: Sperm and Processing Methods A practical guide: Cambridge University Press: New York: 2002: pp. 85-104

### **Editorships**

Practical Reviews in Urology Infertility Editor 2004-present

Journal of Urology Survey Section Infertility Editor 2004-present

Journal of Andrology From Androlog Column Editor 2002-present

Androlog Internet Editor 1995-present

Urology Times Infertility Editor 1993-present

### **Grants**

American Fertility Society / Serono Research Grant Recipient, PRINCIPAL INVESTIGATOR Craig Niederberger: 1991-1992

American Urological Association /American Foundation for Urological Disease Research Scholar, PRINCIPAL INVESTIGATOR Craig Niederberger: 1991-1993

NIH R01-HD30155-01: Correlates of Fertility in Spinal Cord Injured Men, PRINCIPAL INVESTIGATOR: LI Lipshultz, DJ Lamb: Co-investigator: Craig Niederberger : 1992-1997



American Urological Association / American Foundation for Urological Disease / Searle  
New Investigator Research Award N194-04, PRINCIPAL INVESTIGATOR Craig  
Niederberger: 1994-1996

Health Foundation of South Florida PRINCIPAL INVESTIGATOR: Arron Kongrad:  
Predictors of psychosocial outcomes in South Florida prostate cancer patients  
CO-INVESTIGATOR Craig Niederberger: 1994-1996

Bayer Corporation - Unrestricted Educational Research Grant: PRINCIPAL  
INVESTIGATOR Craig Niederberger: 1999-2001: \$40,000

UIC Cancer Center- Prostate Cancer Research Grant: PRINCIPAL INVESTIGATOR  
Craig Niederberger: 1999-2000: \$6,000

Burlington Northern Santa Fe Foundation - Research Grant: PRINCIPAL  
INVESTIGATOR Craig Niederberger: 1999-2000: \$5,000

NIH # 99-3-107 Molecular Basis of Male Infertility: PRINCIPAL INVESTIGATOR Craig  
Niederberger: 2000-2004: \$115,064

UIC #01-1-427 Bayer Corporation - Clinical Trial Agreement: PRINCIPAL  
INVESTIGATOR Craig Niederberger: 2000-2002: \$455,315

UIC #01-1-427 Bayer Corporation - Clinical Trial Amendment: PRINCIPAL  
INVESTIGATOR Craig Niederberger: 2001-2002: \$113,863

UIC #04-1-074-1 Eli Lilly - Clinical Trial Agreement: PRINCIPAL INVESTIGATOR Craig  
Niederberger: 2003-2007: \$54,838

American Urological Association / Pfizer/AUA Foundation Fellowship in Urology:  
PRINCIPAL INVESTIGATOR Craig Niederberger: 2006 \$70,000

### **Fellows Mentored**

Ashutosh Kshirsagar, M.D. (2005)  
Kaiser Permanente

Moshe Wald, M.D. (2004)  
Assistant Professor, Chief of Andrology  
University of Iowa, Department of Urology

Spencer Land, M.D. (2002)  
Assistant Professor, Chief of Andrology  
Loyola University Medical Center, Department of Urology

Richard Schoor, M.D. (2001)  
Suffolk Urology Associates

Leonard Kaufman, M.D. (2000)  
University Urologists  
Lake Worth, Florida

Erol Onel, M.D. (1999)  
Assistant Professor of Urology  
Tufts University School of Medicine

Robert Seo, M.D. (1998)  
Dupage Urology Associates

Jerry Yuan, M.D. (1996)  
Urology Associates of North Georgia

Kevin Spear, M.D. (1995)  
Chief of Urology  
Northeastern Ohio Universities College of Medicine

### **M.S./Ph.D. Computer Science Theses (East Campus) Mentored**

Yuan Qin  
Joe Jovero  
Young Hong  
Kai Liu  
Gaurav Bansal  
Hui Liu

### **Book Reviews**

Book Review of: 'WHO Manual for the Standardized Investigation, Diagnosis and Management of the Infertile Male' edited by Rowe, Comhaire, Hargreave and Mahmoud, Urology. 2001 Jan;57(1): 208

### **Special Achievements**

1. In Situ Testis Expression of DAZ and DAZLA in Mouse and Man: Society for Male Reproduction and Urology Prize Paper: 53rd Annual Meeting of the American Society for Reproductive Medicine: October, 1997
2. President Citation for the American Society of Andrology for exceptional contribution in the area of Science Communication: 23<sup>rd</sup> Annual Meeting of the American Society of Andrology: April, 1998
3. First place winner: Jackson Hole Urological meeting: January, 1999

### **Meetings Organized and Hosted**

1. Chicago Urological Society: Male Infertility, February 4, 1998
2. Aging Male Symposium: Galena, Illinois, October 12-14, 2001
3. Perspectives in Men's Health: Chicago, Illinois, September 15, 2002

### **Major Visiting Professorships, Lectureships and Programs**

1. Visiting Professor: University of Kansas, February 4-6, 2000
2. American Urological Association / European Association of Urology Academic Exchange Program, April 8-26, 2000
3. Course Chair: American Urological Association Western Section, Palm Springs, California, November 6, 2000
4. Visiting Professor: Cairo and Mansoura Universities, Egypt, August 30-September 8, 2001
5. Invited Lecturer: The 30<sup>th</sup> Annual Montrose Fall Clinic, Colorado, September 28, 2001
6. Invited Lecturer: Allen Zieger Memorial Lecture Series, Novi, Michigan, November 17, 2001
7. Visiting Professor: University of Denver, Colorado, July 12-14, 2002
8. Invited Lecturer: University of Chicago, October 28, 2002
9. Visiting Professor: University of California at Irvine, December 4-6, 2002
10. Visiting Professor: University of Wisconsin, Madison, May 8, 2003
11. Visiting Professor: University of Denver, Colorado July 18-20, 2003
12. Invited Lecturer: Kansas City Urological Society, September 11, 2003
13. Invited Lecturer: Birmingham Urological Society, November 6, 2003
14. Visiting Professor: Uniformed Services University, Walter Reed Army Medical Center, March 20, 2004
15. Invited Lecturer: Rush University Medical Center/Rush Center for Advanced Reproductive Care and the American Association of Bioanalysts Preserving Fertility Through Advances In Cryobiology Seminar, June 11, 2004
16. Visiting Professor: University of Denver, Colorado, July 9-11, 2004
17. Invited Lecturer: University of Medicine and Dentistry New Jersey Post American Urological Association Course, October 9, 2004
18. Invited Lecturer: Midwest Reproductive Symposium, Chicago, June 5, 2005
19. Invited Lecturer: Turkish Society of Andrology, Izmir, Turkey, June 9-12, 2005
20. Visiting Professor: University of Denver, Colorado, July 21-23, 2005
21. Invited Lecturer: Florida Urological Society, September 4, 2005

22. Postgraduate Course Chair: American Society for Reproductive Medicine, Montreal, Quebec, October 16, 2005
23. Visiting Professor: University of Kansas, February 10-11, 2006
24. Visiting Professor: University of Iowa, March 3, 2006
25. Visiting Professor: University of Massachusetts, June 21-23, 2006

### **Abstracts**

1. Single Tubule Microsurgical Epididymovasostomy: Predictors of Success: Illinois Urological Society Meeting: Bloomington, Illinois, September, 1989
2. Single Tubule Microsurgical Epididymovasostomy: Predictors of Success: 63rd Annual Meeting of the North Central Section of The American Urological Association: Chicago, Illinois, September, 1989
3. Primary Malignant Melanoma of The Bladder: 63rd Annual Meeting of the North Central Section of The American Urological Association: Chicago, Illinois, September, 1989
4. The Technique of Specific Tubule Microsurgical Epididymovasostomy: 64th Annual Meeting of the North Central Section of The American Urological Association: Colorado Springs, Colorado, October, 1990
5. Clinical Experience With The Uni-Flate 1000 Penile Prosthesis: 64th Annual Meeting of the North Central Section of The American Urological Association: Colorado Springs: Colorado, October, 1990
6. Fibrinogen Glue Vasovasostomy: Chicago Urological Society: March, 1991
7. Fibrinogen Glue Vasovasostomy: A No Suture Technique For Vasal Anastomosis: 47th Annual Meeting of The American Fertility Society: Orlando, Florida: October, 1991
8. Fibrinogen Glue Vasovasostomy: A No Suture Technique For Vasal Anastomosis: 65th Annual Meeting of The North Central Section of The American Urological Association: Scottsdale, Arizona, November, 1991
9. A Method For Quantification of Sperm Directed Antibodies Using The Immunobead Assay: 65th Annual Meeting of The North Central Section of The American Urological Association: Scottsdale, Arizona, November, 1991
10. Tests of Sperm Function For The Evaluation of The Male: Penetrak And Tru-Trax: 87th Annual Meeting of The American Urological Association: Washington DC, May, 1992
11. The Neural Network As An Artificial Intelligence Tool In Urology: Plenary speaker: Society For Basic Urologic Research Fall Symposium: St. Louis, Missouri: October, 1992

12. The Association of Antisperm Antibodies And Leukocytospermia In Subfertile Men: 48th Annual Meeting of The American Fertility Society: New Orleans: Louisiana, November, 1992
13. Analysis of Sertoli Cell Gene Expression By In-Situ Hybridization: An Optimized Model System: 48th Annual Meeting of The American Fertility Society: New Orleans, Louisiana, November, 1992
14. An Improved Technique For In-Situ Hybridization: Stage-And Cell-Specific Gene Expression In The Testis: 12th North American Testis Workshop: Tampa, Florida, April, 1993
15. The Neural Network Predicts Gamete Micromanipulation Success: 7th Annual Meeting Society For Basic Urologic Research: San Antonio, Texas, 1993
16. Artificial Intelligence In Urology And The Future of Molecular Probes In Testis Biopsy: 1st Annual Meeting of The Society For The Study of Male Reproduction: San Antonio, Texas, 1993
17. Stage-And Cell-Specific Gene Expression In The Testis: 88th Annual Meeting of The American Urological Association: San Antonio, Texas, 1993
18. The Artificial Neural Network: A Novel And Powerful Method of Fertility Data Analysis: 88th Annual Meeting of The American Urological Association: San Antonio, Texas, 1993
19. The Diagnosis And Treatment of Primary Obstructive Azoospermia: 67th Annual Meeting of The North Central Section of The American Urological Association: Milwaukee, Wisconsin, September, 1993
20. A Neural Network To Predict Gamete Micromanipulation Success: 67th Annual Meeting of The North Central Section of The American Urological Association: Milwaukee, Wisconsin, September, 1993
21. A Neural Network To Analyze Fertility Data And Predict Gamete Micromanipulation Success: 49th Annual Meeting of The American Fertility Society: Montreal, Quebec, October, 1993
22. A Neural Network Predicts Mortality And New Metastases In Patients With Renal Cell Cancer: Society For Basic Urologic Research Fall Symposium: Houston, Texas, December, 1993
23. Testis Biopsies From Infertile Males With High Normal FSH Are Accurately Predicted By A Neural Network: 19th Annual Meeting of The American Society of Andrology: Springfield, Illinois, March, 1994
24. A Neural Network Predicts Mortality And New Metastases In Patients With Renal Cell Cancer: First World Congress On Computational Medicine: Public Health And Biotechnology: Austin, Texas, April, 1994
25. Stage And Cell Specific Expression of Growth Related Genes In The Testis: Society

For Basic Urologic Research Spring Symposium: San Francisco, California: May, 1994

26. A Neural Network Predicts Testis Biopsy Results: 89th Annual Meeting of The American Urological Association: San Francisco, California, May, 1994

27. The Immediate Early Gene Nur77 Is Expressed In A Cell-And Stage-Specific Manner During Spermatogenesis: 89th Annual Meeting of The American Urological Association: San Francisco, California, May, 1994

28. Neural Networks In Diagnosing Male Infertility: Assisted Reproduction In The 21st Century: Chicago, Illinois, May, 1994

29. The Genetic Regulation of Spermatogenesis: Arta Conference: Innsbruck, Austria, July, 1994

30. Artificial Intelligence: The New Frontier of Fertility Data Analysis: Arta Conference: Innsbruck, Austria, July, 1994

31. New Issues In The Management of Infertility And Impotence: Current Topics in Urology: New Directions In The 1990s: Peoria, Illinois, September, 1994

32. Prediction of Mortality And New Metastases In Patients With Renal Cell Carcinoma Using An Artificial Intelligence Program (neUROn): 68th Annual Meeting of The North Central Section of The American Urological Association: Boca Raton, Florida, October, 1994

33. The Genetic Regulation of Spermatogenesis: 68th Annual Meeting of The North Central Section of The American Urological Association: Boca Raton, Florida, October, 1994

34. Analysis of A Neural Network That Predicts Testis Biopsy Results With High Accuracy: 50th Annual Meeting of The American Fertility Society: San Antonio, Texas, November, 1994

35. In-Situ Expression of A-Inhibin In Human Azoospermic Males With Sertoli-Cell Only Histology: 34th Annual Meeting of The American Society For Cell Biology: San Francisco, California, December, 1994

36. Expression of The Immediate Early Gene Nur77 In-Situ In Murine And Infertile Human Testis: 34th Annual Meeting of the American Society For Cell Biology: San Francisco, California, December, 1994

37. Novel Markers of Quality of Life: A Potential Framework For Targeting Prostate Therapies: Va Hsr&D Service Meeting: Washington D.C., February, 1995

38. Human Sertoli-Cell Only Males Display A Characteristic Pattern of Nur-77 Expression In Testis Interstitial Cells: 90th Annual Meeting of The American Urological Association: Las Vegas, Nevada, May, 1995

39. Varicocele Outcomes Are Predicted By A Neural Network: 90th Annual Meeting of The American Urological Association: Las Vegas, Nevada, May, 1995

40. New Frontiers In Male Infertility: Minnesota Urological Society Annual Spring Seminar: Rochester, Minnesota, May, 1995
41. An Internet Program Allowing Global Access To Computational Resources In Urological Decision Making: First Joint Meeting of The European And American Societies of Basic Urological Research: Rotterdam, Netherlands: August, 1995
42. Postmortem Sperm Recovery And Preservation, Technique And Issues For Posthumous Reproduction, 69th Annual Meeting of The North Central Section of The American Urological Association: Minneapolis, Minnesota : K Spears, LS Ross, CS Niederberger, G Prins, B Brown: September, 1995
43. Use of Autologous Fibrin Adhesive In Human Vasovasostomy: 69th Annual Meeting of The North Central Section of The American Urological Association: Minneapolis, Minnesota: P Vidal, LS Ross, CS Niederberger, B MacKenzie, September, 1995
44. A Computer Model That Predicts ICSI And SUZI Outcomes: 51st Annual Meeting of The American Society For Reproductive Medicine: S Ting, LS Cho, J Jovero, Y Qin, V Kutty, K Spear, LS Ross, R Hill LI Lipshultz, DJ Lamb, RM Golden, CS Niederberger: Seattle, Washington, October, 1995
45. Double Fluorescent Stain For Accurate Assessment of Human-Hamster ICSI Outcome: 21st Annual Meeting of The American Society of Andrology: Minneapolis, Minnesota, April, 1996
46. Methods For Global Data Allocation In Infertility: Society for the Study of Male Reproduction: 91st Annual Meeting of The American Urological Association: Orlando, Florida, May, 1996
47. Open Testicular Sperm Retrieval Pre And Post Mortem: Society for the Study of Male Reproduction: 91st Annual Meeting of The American Urological Association: Orlando, Florida, May, 1996
48. Mathematical Modeling of Biological And Clinical Phenomena: Neural Networks: Society For Basic Urological Research: 91st Annual Meeting of The American Urological Association: Orlando, Florida, May, 1996
49. Stone Recurrence After Lithotripsy Is Predicted By A Neural Network 91st Annual Meeting of The American Urological Association: EK Michaels, CS Niederberger, B Brown, L Cho: Orlando, Florida, May, 1996
50. Models of General Quality of Life (QOL) In Prostate Disease: A Pilot Study Using Neural Networks: 91st Annual Meeting of The American Urological Association: Orlando, Florida, May, 1996
51. A Neural Computational Model of Stone Recurrence After ESWL: International Conference On Engineering Applications of Neural Networks (Eann '96): CS Niederberger, EK Michaels, L Cho, Y Hong, B Brown, LS Ross, RM Golden: London, England, June, 1996

52. Testicular Sperm Extraction (TESE) Is An Effective Adjunct To Vasal And Epididymal Reconstruction For Obstructive Azoospermia: 70th Annual Meeting of The North Central Section of The American Urological Association: Journal of Urology: J Yuan, LS Ross, CS Niederberger, G Prins, R Dolgina, P Studney: Tucson, Arizona, October, 1996
53. Identification of Four Novel Genes And One Not Previously Localized To Testis That Are Differentially Expressed During Spermatogenesis: 52nd Annual Meeting of The American Society For Reproductive Medicine: JJ Yuan, KA Spear, SE Pursell, SA Gennette, LS Ross, CS Niederberger: Boston, Massachusetts, November, 1996
54. Cryopreservation of Sperm Collected By TESE Provides Adequate Post-Thaw Viability And Successful IVF-ICSI Pregnancies: 22nd Annual Meeting of The American Society of Andrology: R. Dolgina, G Wolf, P Studney, B Kaplan, C Niederberger, L Ross, GS Prins: Baltimore, Maryland, February, 1997
55. Like Human Sertoli-Cell Only Males: C-Kit Mutant Mice Over-Express Nur-77 In Testis Interstitial Cells: 92nd Annual Meeting of The American Urological Association: CM Lash, Y Cho, LS Ross, C Niederberger, L Lipshultz, DJ Lamb: New Orleans, Louisiana, April, 1997
56. Routine Testicular Sperm Extraction (TESE) During Microsurgical Vasal And Epididymal Reconstruction Is Safe And Effective: 92nd Annual Meeting of The American Urological Association: LS Ross, CS Niederberger: New Orleans, Louisiana, April, 1997
57. In Situ Testis Expression of DAZ and DAZLA In Mouse And Man: 53<sup>rd</sup> Annual Meeting of The American Society For Reproductive Medicine: C Niederberger, Al Agulnik, Y Cho, D Lamb CE Bishop: Cincinnati, Ohio, October, 1997
58. Autologous Fibrin Adhesives in Human Vasovasostomy: 53rd Annual Meeting of The American Society For Reproductive Medicine: Cincinnati, Ohio, October, 1997
59. Observation of Telomere Lengths in Abnormal and Normal Human Sperm: IFFS '98 16<sup>th</sup> World Congress On Fertility And Sterility 54<sup>th</sup> Annual Meeting of the American Society for Reproductive Medicine: RM Seo, CS Niederberger, LS Ross, GS Prins, R Dolgina, A Zalensky, A Kozik: San Francisco, CA, October, 1998
60. Local Anesthetics Impair Human Sperm Motility: 23<sup>rd</sup> Annual Meeting of The American Society of Andrology: Long Beach, California, April, 1998
61. A Novel Technique For Assessing Ischemia-reperfusion Injury Using Autoradiography And Computer Enhanced Image Processing. 94<sup>th</sup> American Urological Association Meeting Dallas, TX: May, 1999: Journal of Urology: RV Patel, JR Unnerstall, CS Niederberger, W Cromie: April, 1999
62. Varicocele Surgery Improves Sperm-Egg Penetration as Demonstrated by Sperm Penetration Assay (SPA) 94<sup>th</sup> American Urological Association Meeting Dallas, TX: May 1999: Journal of Urology: E Onel, S Kwak, CS Niederberger, LS. Ross: April, 1999
63. Expression of a Putative Negative Regulator of Epidermal Growth Factor Receptor



is Reduced in Prostate Cancer. Endocrine 81st Annual Meeting: JV Ilekis, CS Niederberger, LS Ross: San Diego, CA, June, 1999

64. Erb-B Receptors Activation Increases the Mitogenic Response and Metastatic Potential in Androgen Independent LnCap Variants: 75<sup>th</sup> Annual Meeting of The Western Section American Urological Association: Monterey, California: DR Ridout, CS Niederberger, LS Ross, JV Ilekis: September, 1999

65. Androgen Insensitive Prostate Cancer Cell Lines Androgen Sensitive in the Presence of Growth Factors: 73th Annual Meeting of The North Central Section of The American Urological Association: Chicago, IL: D Ridout, CS Niederberger, JV Ilekis, September, 1999

66. Vaso-Epididymal Non-Union Syndorome (Venus): Results of Microsurgical Reconstructive and Testicular Biopsy: North Central Section 73<sup>rd</sup> Annual Meeting: Chicago, IL, E Onel, H Habermann, Kannan Manickam, CS Niederberger, LS Ross: September, 1999

67. Expression of The Apoptotic Regulators Bax And Bcl 2 During Murine Spermatogenesis. North Central Section 73<sup>rd</sup> Annual Meeting: L. Kaufman, L. Wang, A. Hussein, K. Manickam, Y. Ozgok, R. Meacham, L. Ross, C. Niederberger : Chicago, IL: September, 1999

68. Modeling IUI Outcomes Using a Neural Network: A Large-Scale Retrospective Analysis: American Society of Reproductive Medicine And Canadian Fertility And Andrology Society Meeting: Toronto, Canada: BN Hendin, A Agrwal, DR Nelson, T Falcone, E Onel, R Golden, AJ Thomas Jr., C Niederberger, September, 1999

69. Successful use of Cryopreserved Sperm Obtained by Electroejaculation for IVF/ISCI: American Society of Reproductive Medicine And Canadian Fertility And Andrology Society Meeting: Toronto, Canada: R Dolgina, GS Prins, LS Ross, CS Niederberger: September, 1999

70. The Role of Diagnostic Testis Biopsy in the Modern Treatment of the Azoospermic Patient: American Society of Reproductive Medicine And Canadian Fertility And Andrology Society Meeting: Toronto, Canada: E Onel, CS Niederberger, LS Ross: September, 1999

71. Expression of The Apoptotic Regulators Bax And Bcl 2 During Murine Spermatogenesis. American Urological Association Annual Meeting: Atlanta GA: L. Kaufman, L. Wang, A. Hussein, K Manickam, Y Ozgok, R. Meacham, L. Ross, C. Niederberger, May, 2000

72. Neural Computational Modeling of Electroejaculation Outcomes: Chicago, IL; Houston, TX American Urological Association Annual Meeting: Atlanta GA, L Kaufman, A. Hussein, E. Onel, D. Sobel, N. Chulamorkodt, Y Hong, L. Ross, E Orejuela, L. Lipshultz, D. Lamb, C. Niederberger: May, 2000

73. Testicular Pathology Discovered In Candidates For Testicular Extraction of Sperm. Fertility And Sterility: Chicago, IL, L. Kaufman, C. S. Niederberger, L. S. Ross, September, 2000

74. Quantitative Assessment of Vascular Flow In Testes of Infertility Patients With Varicocele Using Power Doppler And Image Analysis: Chicago, IL and Denver, CO. Fertility And Sterility, L. Kaufman, J. Drose, L. S. Ross, C. S. Niederberger , R. Meacham: September, 2000
75. Andrology Laboratory Issues In The Era of Icsi: Mesa And Tese: American Society For Reproductive Medicine Meeting: San Diego, CA, October, 2000
76. In Vitro Fertilization Outcomes After Intracytoplasmic Sperm Injection With Fresh Or Frozenthawed Testicular Spermatozoa. Helga Habermann, North Central Section AUA: Robert Seo, Jeanine Cieslak, Craig Niederberger, Gail S. Prins, and Lawrence Ross: October, 2000
77. A World Wide Web And Palmos<sup>tm</sup> Device Converts Ct-Measured Stone Size To That Expected By Kub, American Urological Association Meeting: Joanna Togami, Eli Michaels, Lawrence S. Ross, Craig S. Niederberger : June, 2001
78. Evaluating The Azoospermic Man: A New Algorithm Based On Roc Analyses of Diagnostic Parameters. American Urological Association Meeting: Samir M Elhanbly, Richard A. Schoor, Craig Niederberger, Lawrence Ross: June, 2001
79. A Fresh Look At A Frozen Issue: Ivf Outcomes Using Fresh Vs Frozen-Thawed Testes Sperm. Richard A Schoor, Jeanine Cielak, Brian Kaplan, Samir M. Elhanbly, Lawrence S. Ross, Craig Niederberger. American Urological Association Meeting: Richard A Schoor, Jeanine Cielak, Brian Kaplan, Samir M. Elhanbly, Lawrence S. Ross, Craig Niederberger: June, 2001
80. Robotic Assisted Microsurgical Vasal Reconstruction In A Model System. Richard A Schoor, Lawrence S. Ross, Craig Niederberger. American Urological Association Meeting: Richard A Schoor, Lawrence S. Ross, Craig Niederberger: June, 2001
81. Neural Computational Modeling of Prostate Cancer Detection Outcomes: American Urological Association Meeting: Joanna Togami, Lawrence S. Ross, Craig S. Niederberger: June, 2001
82. A Large Multi-Center Study of The Electroejaculation Procedure: American Society of Reproductive Medicine Annual Meeting: RI Pagani, DJ Lamb, I. Lipshultz, CS Niederberger , September, 2001
83. Duration of Obstructive Interval Negatively Impacts Successful Microsurgical Epididymovasostomy, American Society of Reproductive Medicine Annual Meeting, RA Schoor, SM Elhanbly, CS Niederberger, LS Ross: September, 2001
84. Attempting To Improve Sperm Retrieval Rates Through Testicular Microdissection, The University of Illinois Intital Experience. American Society of Reproductive Medicine Annual Meeting, RA Schoor, SM Elhanbly, CS Niederberger, LS Ross: September, 2001
85. Cigarette Smokingpenile Hemodynamic Changes Resulting In Erectile Dysfunction. American Society of Reproductive Medicine Annual Meeting: SM Elhanbly, RS Schoor,

CS Niederberger, M Elmogy, A Hegazy, LS Ross: September, 2001

86. Feature Extraction of A Neural Computational Model Which Predicts Prostate Cancer Outcomes. American Urologic Association 97<sup>th</sup> Annual Meeting Orlando, FL: Pankaj Kalra, Alan Partin, Michael Braver, Richard J Babaian, Lawrence S Ross, Craig S Niederberger: May, 2002

87. Erectile Dysfunction Patient Characteristics And Attitudes Based On A Largescale Male Health Study Conducted In Us, Europe, Mexico And Brazil. American Urologic Association 97<sup>th</sup> Annual Meeting: Orlando, FL: Craig Niederberger, Jeremy Lonsdale: May, 2002

88. Sexual Development: From Ancient Beliefs To Sry And Beyond American Urologic Association 97<sup>th</sup> Annual Meeting: Orlando, FL: Spencer Land, Pankaj Kalra, Craig Niederberger, Lawrence Ross: May, 2002

89. Testicular Microdissection: The University of Illinois At Chicago Experience An Update. American Urologic Association 97<sup>th</sup> Annual Meeting: Orlando, FL: Spencer Land, Richard Schoor, Lawrence Ross, Craig Niederberger: May, 2002

90. A Neural Computational Model of ICSI outcomes from Sperm Source and Other Features: American Society of Reproductive Medicine Annual Meeting : Spencer Land, Lata Murthy, Delores Lamb, Larry Lipshultz, Lawrence Ross, Craig Niederberger: October, 2002

91. Is Microsurgical Reconstruction Following Failed Vasectomy Reversal Effective in the Era of Intracytoplasmic Sperm Injection? American Society of Reproductive Medicine Annual Meeting : Spencer Land, Craig Niederberger, Lawrence Ross: October, 2002

92. Vardenafil Improved Patient Satisfaction With Erection Hardness, Orgasmic Function, And Sexual Experience In Men With Erectile Dysfunction: American Urological Association 98<sup>th</sup> Annual Meeting: Chicago, IL: Craig Donatucci, Peter Pommerville, Craig Niederberger, Marc Thibonnier, Thomas Segerson, Kevin T McVary, Wayne Hellstrom: May, 2003

93. Viable Sperm In The Ejaculate of Infertile Men With Bilateral Cryptorchidism Corrected Peripubertally: Richard Schoor, Ettore Caroppom Andrea Stuart, Samir El Hanbly, Lawrence S. Ross, Craig Niederberger: American Urological Association 98<sup>th</sup> Annual Meeting: Chicago, IL: May 2003

94. Vardenafil Improved Patient Satisfaction with Erection Hardness, Orgasmic Function, and Sexual Experience in Men with ED: 2nd International Consultation On Erectile And Sexual Dysfunction: Paris, June, 2003

95. Eardley I, Rosen R, Fisher W, Niederberger C, Sand M, Attitudes toward treatment of erectile dysfunction: results from the Males study. Eur. Urol 2003; Suppl 2(1):97: EAU-2003

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Among Men With Erectile Dysfunction. Progrès en Urologie 2003; 13 (Suppl 2)(3):32 (abs 102): Second International Consultation on Erectile and Sexual Dysfunction: Paris: June, 2003

97. Fisher W, Eardley I, Rosen R, Niederberger C, Sand M, The Men's Attitudes to Life Events and Sexuality (MALES) Study-II. Understanding Treatment-Seeking Patterns Among Men With Erectile Dysfunction. Progrès en Urologie 2003; 13 (Suppl 2)(3):32 (abs 101): Second International Consultation on Erectile and Sexual Dysfunction : Paris : June, 2003

98. Meuleman E, Eardley I, Rosen R, Fisher W, Niederberger C, Sand M, Attitudes Toward Treatment of Erectile Dysfunction: Results from the MALES (Men's Attitudes toward Life Events and Sexuality) study. ASSIR - 2003

99. Rosen R, Fisher W, Eardley I, Niederberger C, Sand M, The Men's Attitudes to Life Events and Sexuality (MALES) Study-II: Correlates of Self-Reported Disease Severity Among Men With Erectile Dysfunction. Asia-Pacific Society for Impotence Research, October, 2003, Chibou, Philippines 2003; Asia-Pacific Society for Impotence Research, October, 2003, Chibou, Philippines

100. Rosen R, Fisher W, Eardley I, Niederberger C, Sand M, The Men's Attitudes to Life Events and Sexuality (MALES) Study-II. Understanding Treatment-Seeking Patterns Among Men With Erectile Dysfunction. Asia-Pacific Society for Impotence Research, October, 2003, Chibou, Philippines

101. Desai R, Sigman M, Jarow J, Ross L, Niederberger C. Computational Models For Detection of Endocrinopathy In Subfertile Men. American Urological Association 99<sup>th</sup> Annual Meeting. San Francisco, CA. May, 2004

102. Parekattil S, Kuang W, Kolettis P, Pasqualitto F, Nangia A, Niederberger C. Multi-institution testing of Vasectomy Reversal Predictor. American Sexual and Reproductive Medicine 2004 Annual meeting. Philadelphia, PA. October, 2004

103. Wald M, Ross L, Cieslak-Janzen J, Wolf G, Niederberger C. Analysis of outcomes of Cryopreserved Surgically Retrieved Sperm For IVF/ICSI. American Sexual and Reproductive Medicine 2004 Annual meeting. Philadelphia, PA. October, 2004

104. Kshirsagar A, Seftel A, Ross L, Niederberger. Using Depression, Age, And Erectile Dysfunction To Predict Hypogonadism. American Urological Association 100<sup>th</sup> Annual Meeting. San Antonio, TX. May, 2005

105. Kshirsagar A, Murthy L, Chelu L, Lamb D, Ross L, Niederberger C. Predicting Outcomes For Intracytoplasmic Sperm Injection. American Sexual and Reproductive Medicine 2005 Annual meeting. Montreal, Canada. October, 2005

106. Makhlouf A, Wald M, Cieslak-Jansen J, Chernoff A, Niederberger C. Fresh Versus Cyro-Preseved Sperm In Same Couples Undergoing IVF/ICSI. American Urological Association 101 Annual Meeting. Atlanta, GA. May, 2006

# Exhibit 2

Exhibit 2: Detailed Scientific Comments on Data Presented for Effects of  
Lepidium Meyenii (Maca) Roots on Male Fertility  
Craig Niederberger M.D. F.A.C.S.  
Chief, Division of Andrology, University of Illinois at Chicago

Numbering of these analyses refers to the same format in my declaration.

Basic pharmacology studies are not included, as they are not relevant to the claim that Maca improves male fertility.

8.1. Animal studies

8.1.1. Gonzales GF, Ruiz A, Gonzales C, Villegas L, Cordova A Effect of  
Lepidium meyenii (maca) roots on spermatogenesis of male rats.

Asian J Androl. 2001 Sep;3(3):231-3.

The study can be considered a small pilot for the effects of *Lepidium meyenii* (maca) roots on murine spermatogenesis. Subjects included two groups of 10 rats, control and oral administration of *Lepidium meyenii*. Main outcome measures included testicular weight, epididymal weight and proportion of various stages within rat seminiferous epithelium. While testicular weight and epididymal weight were significantly different between the two groups by Student's t-test, the actual weights were highly similar (testis 1.52 g versus 1.59 g, and epididymis 0.40 g versus 0.46 g.) Thus, while testis and epididymal weights may have been statistically different, questions remain regarding the biological significance of the observed statistical difference. Due to sampling difficulties, it is difficult to

interpret changes in patterns of seminiferous epithelium, and while differences may be intriguing, they cannot be considered highly informative. A reasonable conclusion from this study is that in a small pilot, small biological differences were observed between controls and animals treated with *Lepidium meyenii*, and that a larger trial is warranted. Such a trial would be designed based on statistical observations in this small pilot (e.g. number of subjects would be determined from power calculations based on differences observed in testis and epididymal weights.)

8.1.2. Zheng BL, He K, Kim CH, Rogers L, Shao Y, Huang ZY, Lu Y, Yan SJ, Qien LC, Zheng QY. Effect of a lipidic extract from *lepidium meyenii* on sexual behavior in mice and rats. *Urology*. 2000 Apr;55(4):598-602.

This is a controlled study of *Lepidium meyenii* on murine sexual behavior. Main outcome measures include frequency of intromission and erectile latency. Animals treated with *Lepidium meyenii* were observed to have a higher frequency of intromissions, and a reduced latent period of erection, variates associated with increased sexual behavior.

8.1.3. Cicero AF, Bandieri E, Arletti R. *Lepidium meyenii* Walpers improves sexual behaviour in male rats independently from its action

on spontaneous locomotor activity. J Ethnopharmacol. 2001  
May;75(2-3):225-9.

This is a controlled study of *Lepidium meyenii* on murine sexual behavior. Main outcome measures include mounting, intromission, ejaculation and postejaculatory latencies, intercopulatory interval and copulatory efficacy. Animals treated with *Lepidium meyenii* were observed to have reduced mounting and intromission latencies and intercopulatory interval, and changes in the other parameters measured depending on dose and chronicity.

8.1.4. Gonzales GF, Gasco M, Cordova A, Chung A, Rubio J, Villegas L.  
Effect of *Lepidium meyenii* (Maca) on spermatogenesis in male rats  
acutely exposed to high altitude (4340 m). J Endocrinol. 2004  
Jan;180(1):87-95.

This is a controlled study of *Lepidium meyenii* on murine spermatogenesis in animals exposed to high altitude. Main outcome measures included pattern of spermatogenic stages, body weight, testosterone, and epididymal sperm count. Changes were noted in the pattern of murine spermatogenic stages, serum testosterone and epididymal sperm count, however, body weight was significantly reduced in the control animals compared to the treated animals, and spermatogenesis, which is exquisitely sensitive to overall systemic health, is likely to have been affected on that basis alone.



## 8.2. Human studies

- 8.2.1. Gonzales GF, Cordova A, Gonzales C, Chung A, Vega K, Villena A. *Lepidium meyenii* (Maca) improved semen parameters in adult men. *Asian J Androl.* 2001 Dec;3(4):301-3.

This is an uncontrolled study of nine men (12 at onset with 3 subject attritions) treated with *Lepidium meyenii* (maca) roots. The central flaw of the study is its lack of control: based on regression to the mean, we expect sperm parameters to generally improve in a sample of men in whom parameters are initially below means. A second flaw is the choice of a probability threshold p-value of 0.05: with 8 observed endpoints, such a threshold is expected to indicate differences where there are none. Main outcome measures included semen analysis parameters. Sperm concentration was not observed to be significantly different, and the majority of the difference pre- and post-treatment is explained by changes in volume, typically a collection artifact. A reasonable conclusion drawn from this study is that in a very small uncontrolled pilot, some differences in the semen analysis based on a generous probability threshold were observed, and that a larger, controlled trial is warranted. As in the murine study, design would be based on statistical observations in this small pilot.

- 8.2.2. Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C, Castillo S. Effect of *Lepidium meyenii* (MACA) on sexual desire and

its absent relationship with serum testosterone levels in adult healthy men. *Andrologia*. 2002 Dec;34(6):367-72.

This is a double blind, placebo controlled trial of 57 subjects, 45 of whom were administered two differing preparations of *Lepidium meyenii*, and the remainder placebo, for 12 weeks. Main outcome measures included a non-validated sexual desire psychometric, the Hamilton depression and anxiety rating scales, and serum testosterone and estradiol. As the focus of this consultation is on reproductive function, attention is primarily paid to those outcome measures that relate directly to male reproductive potential. Data is analyzed in a logistic regression model predicting psychometric outcomes, for which testosterone and estradiol were not found to be significant covariates. A reasonable conclusion drawn from this trial is that if *Lepidium meyenii* functions as a mild stimulant, the biological basis of the effect is not due to changing testosterone or estradiol levels.

8.2.3. Gonzales GF, Cordova A, Vega K, Chung A, Villena A, Gonez C. Effect of *Lepidium meyenii* (Maca), a root with aphrodisiac and fertility-enhancing properties, on serum reproductive hormone levels in adult healthy men. *J Endocrinol*. 2003 Jan;176(1):163-8.

This is a double blind, placebo controlled trial of men administered differing preparations of *Lepidium meyenii* or placebo for 12 weeks. Main outcome measures included endocrine parameters 17-hydroxyprogesterone, testosterone,

estradiol, LH, FSH, and prolactin. No significant differences were noted between controls and treated subjects in the endocrine parameters studied.

## 9. Unpublished studies:

9.1 Cuya MV, Rosado DN, De La Guarda RG, Rosello X, de Boccard GA, Rojas PA. Maca's and Maca-HAI's effect on subfertile males.

This is a study that was submitted for publication in 2006. It is primarily considered as a draft: due to incomplete translation into English, it is difficult to comprehend the study in its entirety. It is expected that this manuscript would undergo substantial line editing before it is found to be accepted for publication in an English language journal.

The study involves 47 infertile men with semen analysis abnormalities who were divided into two groups, one group receiving Maca, and the other Maca-HAI.

Final values were reported in 19 men receiving Maca, and 20 Maca-HAI.

Although it is unclear from the manuscript, it thus appears that in final analysis, 39 men were included in the treated group. The investigators also include 25 normozoospermic men, who they refer to as a "control group," but it is unclear how these men are treated in the study, if at all. Endocrine parameters and semen analyses are reported after 3 and 6 months of treatment. The authors report increases in motility, morphology, total count and total motile count compared to baseline in the treated groups, but without changes in testosterone, LH and FSH.

The main design flaw inherent in the study is the lack of a placebo group. The investigators incorrectly refer to their study as “double-blind,” as this label applies to designs that include placebo and treated groups where both the investigators and the subjects do not know which subjects have received placebo, and which received the intended treatment. Instead, it appears that the investigators randomized the two treated groups, Maca and Maca-HAI, and blinded the investigators and the subjects as to which individuals received what type of treatment. Thus, regression to the mean cannot be excluded as the primary source of improvement in any measured seminal parameters. That the measured endocrine parameters did not change, and that the subjects were not chosen on the basis of abnormal endocrine parameters, further calls into question that changes from baseline in seminal parameters were due to treatment with Maca or Maca-HAI.

#### 10. Research reports:

- 10.1. Gonzales GF, Cordova A, Chung A, Villena A, Gonez C, Vega K, Rubio J, Gasco M, Gonzales C, Castillo S, Garayar D. Effect of *Lepidium meyenii* (maca) in the form of gelatinized maca tablets, administered to apparently normal adult male subjects. Research Report 2001.

This is a trial of four groups of men treated with placebo and three varying concentrations of *Lepidium meyenii* for 12 weeks. Main outcome measures

included morphometric measurements, psychological parameters including depression scales, libido, erectile function, anxiety and stress, endocrine parameters and semen analyses. Unfortunately, while the remainder of the study included a placebo arm, the semen analyses were only performed on a subgroup of subjects treated with *Lepidium meyenii* without a control group, represented treatment for only 4 weeks, and are thus generally uninterpretable.

As the focus of this consultation is on reproductive function, attention is primarily paid to those outcome measures that relate directly to male reproductive potential. However, the remainder of the variates measured suggests that the main effect of *Lepidium meyenii* is as a mild central nervous stimulant similar to caffeine.

Three major analytical flaws are evident throughout the report. The first is that with the large number of outcome variates studied, a probability threshold of 0.05 is too generous. With a p-value of 0.05, one in 20 differences identified would be expected to be by chance. In other words, if 100 measurements were taken, five would be incorrectly attributed to a biological effect whereas they would actually be statistical anomalies. With the hundreds of measurements contained in the report, many such errors are expected at a probability threshold of 0.05. The second analytical flaw is the common use of percentages and ratios, which serve to increase apparent differences. Generally, statistical methods are not used to describe differences in ratios for this reason, however, when ratios are employed in

a rigorous scientific fashion, lower probability values are chosen based on a mathematical argument presented in the report. No such argument is offered, and the high probability threshold of 0.05 is erroneously applied to ratios. This consultation will thus generally ignore all data presented as ratios, as the results are uninterpretable. The final major analytical flaw is to confuse type I and II statistical error: because a type I test did not demonstrate a statistical difference does not prove that the outcomes considered are similar. Rather, a type II analysis is required. This misconception renders safety analyses in the study unusable. For erectile function, two outcome variates were employed, a variant of the non-validated but widely used Sexual Encounter Profile Question 3, and a non-validated metric of the investigators' invention relating to the frequency of morning erections. No significant differences were noted in the latter. Interestingly, for libido, a non-validated metric of the investigators' invention was used, but clear statistically significant differences were noted between *Lepidium meyenii* treated subjects and controls, congruent with a mild stimulatory effect. For endocrine parameters, raw measures of 17-hydroxyprogesterone, testosterone, estradiol (with the exception of a single outcome measure, *Lepidium meyenii* treatment group three at four weeks, highlighting the problem of using a p-value of 0.05 in an analysis where many variates are considered,) LH, FSH, and prolactin were all non-significant when differences between *Lepidium meyenii* treated

subjects and controls were analyzed. Such an analysis does not prove that the groups are similar; a type II analysis would be required. A reasonable conclusion is that no differences were observed in reproductive hormones in the males treated with *Lepidium meyenii* compared to the control subjects.

The study on semen parameters was uncontrolled and with only nine subjects, and were only for four weeks. As human spermatogenesis is expected to require two to three months, treatment duration of four weeks is insufficient. Without a control group, with such a small number of subjects, and with such a limited duration of treatment, no conclusions on the effect of *Lepidium meyenii* on human semen may be drawn. A casual analysis, however, reveals the expected very high standard error in sperm parameters (approximately 100 to 200 million,) and the baseline and the four week outcomes are within similar range.

No evidence is derived from this study that suggests an effect on male reproductive potential by *Lepidium meyenii*, which appears to function primarily as a central nervous system stimulant.