send

BILL LOCKYER
Attorney General of the State of California
JOHN H. SANDERS
Lead Supervising Deputy Attorney General
KAREN ACKERSON-BRAZILLE
Deputy Attorney General
State Bar No. 157514
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2448
Fax: (213) 897-2805
Email: Karen.AckersonBrazille@doj.ca.gov

Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

JOHN ALLEN RAINWATER, STEVEN LAWRENCE BURKHART, DOUGLAS ERNEST BADGER, CHARLES CHRISTMAN, STEVE JOSEPH WILLETT, DAVID HUFFMAN, TROY MICHAEL NAYLOR,

Plaintiffs,

v.

JAN MARIE ALARCON, Ph.D.; FREDERICK BANALES, Ph.D.; RONALD LAPP, M.D.; MARY FLAVIN, Ph.D.; ROBERT S. KNAPP, MD., Ph.D.; GLORIA FISCALINI, GABRIEL PALADINO, Ph.D.,

Defendants.

CV 03-8569 R

(~~PROPOSED~~) ORDER RE: STATEMENT OF UNCONTROVERTED FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OR, ALTERNATIVELY FOR SUMMARY ADJUDICATION

Date: March 20, 2006
Time: 11:00 a.m.
Courtroom: 8
Judge: Hon. Manuel L. Real

166

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

JOHN ALLEN RAINWATER, STEVEN LAWRENCE BURKHART, DOUGLAS ERNEST BADGER, CHARLES CHRISTMAN, STEVE JOSEPH WILLETT, DAVID HUFFMAN, TROY MICHAEL NAYLOR,

Plaintiffs,

v.

JAN MARIE ALARCON, Ph.D.; FREDERICK BANALES, Ph.D.; RONALD LAPP, M.D.; MARY FLAVIN, Ph.D.; ROBERT S. KNAPP, MD., Ph.D.; GLORIA FISCALINI, GABRIEL PALADINO, Ph.D.,

Defendants.

CV 03-8569 R

(PROPOSED) ORDER RE: STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OR, ALTERNATIVELY FOR SUMMARY ADJUDICATION

Date: March 20, 2006
Time: 11:00 a.m.
Courtroom: 8
Judge: Hon. Manuel L. Real

The Court having reviewed the [Proposed] Statement of Uncontroverted Facts and finding pursuant to Local rule 56-3, that the Court can assume that material facts claimed and adequately supported by Defendants have been admitted by Plaintiffs because plaintiffs have failed to controvert the material facts by including them in a "Statement of Genuine Issues" hereby orders that these Uncontroverted Facts are binding on all parties.

UNCONTROVERTED MATERIAL FACTS

1. ASH is a maximum security forensic hospital. Forensic mental health care, by definition, involves treatment and management of persons with mental disorders associated with criminality. Psychiatric treatment principles must be merged with effective strategies from police science and personnel management to provide a maximum-security treatment environment responsive to the needs of the patients, the staff, the courts and the California Department of Corrections.

2. The Antiandrogen Workgroup was started at the Direction of the then Clinical Administrator at Atascadero State Hospital (ASH), Dr. Craig Nelson, Ph.D. and the Quality Council in February of 1998. The expressed purpose of the Antiandrogen Work Group was to (1) explore all the relevant world literature on antiandrogens.

3. The original members of the Antiandrogen Workgroup were:

   a. G. Paladino, MD, staff psychiatrist
   b. Federico Banales, MD, staff psychiatrist
   c. Mary Flavin, MD, staff psychiatrist
   d. Mike Groom LCSW, a social worker at ASH
   e. Linda Kocsis, MD, a medical doctor no longer at ASH
   f. Grace Hayes, Pharm. D, a staff pharmacologist at ASH
   g. Bill Walters, MD, staff psychiatrist
   h. Jay Seastrunk, MD, staff psychiatrist. He is now deceased as of 5/05.

4. Dr. Paladino oversees the care and treatment of patients housed in ASH. Also, apart of her duties include administering the antiandrogen therapy program at ASH.

5. Dr. Paladino has received extensive training in the care and treatment of sex offenders. These topics were covered in her Medical school clinical core courses (1988) and in clinical rotations 1989-90 in psychiatry at Camarillo State Hospital totaling 8 months, and in internship and residency (1992-1996 at the University of California at San Francisco). The medical school and residency programs also

included courses on ethics as well as treatment of special populations (including sex offenders). Pharmacology was covered extensively in medical school and in residency. Antiandrogens (and their side effects) were covered extensively in her urology rotation in medical school at Cook County Hospital in Chicago (1990), as well as in internship regarding chemotherapy (Lupron is used for treatment of prostatic carcinoma). Upon Dr. Paladino's arrival at ASH, she attended large numbers of lectures and conferences on the treatment and evaluation of sex offenders, such as Dr. Robert Hare on psychopathy, Dr. Karl Hanson on the static - 99 and the SONAR scale (special scale to evaluate sex offenders), and Dr. Amy Phenix regarding the evaluation of the sexually violent predators (svp) sex offender population. As ASH developed the SOCP (sex offender commitment program) to deal with sexually violent predators (svps) beginning in 1996, seminars were held by Dr. Craig Nelson Ph.D. and Dr. Janice Marquez, previous directors of the SOTEP program and Dr. Paladino attended all of these. Dr. Paladino has been invited to numerous programs each year to update her knowledge in the field of sex offender treatment, usually held at ASH.

6. Antiandrogens are medications that reduce the amount of testosterone produced by the body. Decreased levels of testosterone can help reduce deviant sexual arousal. Antiandrogens may help control obsessive sexual thoughts and compulsive sexual behaviors.

7. Antiandrogen therapy has been used in the treatment of sexual offenders for over 40 years. Sex Offenders taking antiandrogens commonly report that the drive to sexually act out in deviant ways is greatly reduced while they are on antiandrogen therapy.

8. Individuals that may benefit from taking antiandrogens are those who may have sexually arousing fantasies involving: a) Dominating or degrading others, b) Forced sexual activity, and c) Sex with children.

9. Antiandrogens affects the testosterone. The production of testosterone is regulated

by a very complicated process. This process begins with the hypothalamus and pituitary glands in the brain. Testosterone is produced by the testes. Testosterone travels through the blood stream and effects different parts of the body.

10. Testosterone assists in building muscle, increases bone strength, and assists in the production of red blood cells. In the brain, testosterone stimulates sexual interest and is believed to be involved in some obsessive though processes.

11. A dramatic decrease in testosterone levels can lead to a decrease in sexual preoccupation, aggression and deviant sexual arousal. Unlike surgical castration, the effects of antiandrogens are reversible once treatment is stopped.

12. The two antiandrogens currently being used at ASH are Lupron (Leuprolide) and Depo Provera (Medroxyprogesterone Acetate). Lupron and Depo Provera are commonly given in their long-acting or "Depo" forms. Each "Depo" injection is effective for a number of weeks. Lupron can be given monthly, every 3 to 4 months. Depo Provera can be given every one to two weeks.

13. As with any medication, there are side-effects associated with antiandrogens. These side effects can range from mildly bothersome to potentially serious. Potential side effects include, but are not limited to, 1) easy bruising, 2) weight gain, 3) facial flushing, 4) hot flashes, 5) increased cholesterol, 6) headaches, 7) moodiness, 8) decreased bone density, 9) decreased testicular size, and 10) inability to have or to maintain an erection.

14. Most side effects can be minimized and effectively treated. These side effects are usually reversible when treatment is discontinued.

15. It is important that the patient is aware of any potential side effects and that they inform their physician about any symptoms that they may be experiencing.

16. Once starting antiandrogen therapy, it will take at least one month before a noticeable decrease in testosterone levels will be seen.

17. It is unknown how long an individual will need to remain on antiandrogen therapy. Some individuals continue on antiandrogen therapy for the remainder of their

lives. Other men discontinue antiandrogens once they have received maximum benefit from the treatment.

18. Deviant sexual arousal plays a major role in motivating sexual offenders to commit their crimes. However, deviant sexual arousal is only one reason people sexually offend.

19. Antiandrogens can help control sexual offender's deviant sexual thoughts and can therefore help them to focus on the other areas and phases of treatment.

20. The other important areas of the treatment may include improving social skills, understanding the consequences of their crimes and the effects of those crimes on their victims.

21. Correcting errors in thinking (cognitive distortions) and developing a comprehensive and detailed relapse prevention plan are all very important.

22. Under a doctor's supervision, antiandrogen can be safely used and can play an important role in the treatment of a sex offender.

23. Before introducing the antiandrogen treatment program to the patients at ASH, the Antiandrogen Workgroup reviewed the Physicians Desk Reference on Leuprolide Acetate, the package insert on Leuprolide acetate, and many articles associated with antiandrogen treatment, which included the following studies and/or presentations:

IN HOUSE STUDIES

Leuprolide Acetate for Treatment of Sexual Deviancy
by Eve Smallfield, Pharmacy Intern
1999 Pharmacy Evaluation of Lupron

A-A WORK GROUP
ASH Governing Body Presentation
April 6, 1999

ASH A-A WORKGROUP
Research Article Synopsis
The Paraphiles & Depo Provera: Some Medical, Ethical, and Legal Considerations
by Fred Berlin

RECOMMENDATIONS OF THE A-A WORKGROUP
by Craig Nelson, Ph.D., Clinical Administrator, Gabrielle Paladino, MD, Federico Banales, MD
Co Chairs of the AA Work Group

March 13, 1998

ASH AA WORKRGOUP (Research Article Synopsis)
AA (CYPROTERONE ACETATE) THERAPY IN DEVIANT HPERSUALITY
by Cooper et al
(1972)

ASH AA WORKRGOUP (Research Article Synopsis)
OESTROGEN AND PSYCHOSEXUAL DISORDERS
by L. Howard Whitaker
October 17, 1959

ASH AA WORKRGOUP (Research Article Synopsis)
PHARMACEUTICAL TREATMENT OF THE PARAPHILIAS
by Bradford

ASH AA WORKRGOUP (Research Article Synopsis)
PHARMACOTHERAPY AND OTHER BIOLKOGICAL TREATMENTS OF SEX OFFENDERS - A REVIEW
by Sheila Lynch

ASH AA WORKRGOUP (Research Article Synopsis)
TREATMENT OF MEN WITH PARAPHILIA WITH A LONG ACTING ANALOGUEOF GONADATROPIN RELEASING HORMONE
by Ariel Rosler & Eliezer Witzum

ASH AA WORKRGOUP (Research Article Synopsis)
DOUBLE BLIND PLACEBO CROSSOVER STUDY OF CYPROTERONE ACETATE IN THE TREATMENT OF PARAPHILIAS
by Bradfor et al
1993

ASH AA WORKRGOUP (Research Article Synopsis)
A CLINICAL TRIAL OF CYPROTERONE ACETATE FOR SEXUAL DEVIANCY
by Baron, et al

ASH AA WORKRGOUP (Research Article Synopsis)
47, XYY & 46, XY MALES WITH ANTISOCIAL AND/OR SEX-OFFENDING BEHAVIORS: A-A THERAPY PLUS COUNSELING
by J. Money, et al
1975

ASH AA WORKRGOUP (Research Article Synopsis)
CYPROITERONE ACETATE FOR MALE HYPERSEXUALITY
by Davis, et al
1974

ASH AA WORKRGOUP (Research Article Synopsis)
HORMONE TREATMENT OF THE SEXUAL OFFENDER
By F.L. Golla & Lessions Hodge

AA THERAPY FOR THE SEXUAL OFFENDER - ASH BIBLIOGRAPHY
by Richard Dabell, Ph.D.
February 15, 2002

ARTICLES REVIEWED

ARE SEX OFFENDERS TREATABLE? A RESEARCH OVERVIEW
by Linda S. Grossman, Ph.D.; Brian Martis, M.D., Christopher G. Fichtner, M.D.
Psychiatric Services, March 1999 Vol. 50 No. 3

NEWS OF MEDICINE

PHARMACOTHERAPY AND OTHER BIOLOGICAL TREATMENTS OF SEX OFFENDERS - A REVIEW
by Sheila Lynch, M.D.
UC San Francisco, Fellow in Forensic Psychiatry
June 1996

BUILDING STRONGER BONES
Life Extension Excerpt
March 1999
Used to educate doctors regarding bone density problems

PHARMACOLOGICAL TREATMENT OF THE PARAPHILIAS
by J.M.W. Bradford, M.B., Ch.B., D.P.M., F.F. Psych., F.R.C. Psych., D.A.B.P.N., F.R.C.P.C.

EFFECT OF TREATMENT WITH MPA (PROVERA) ON TESTICULAR FUNCTION
by Marco A. Rivarola, Alvro M. Camacho, and Claude J. Migeon

DEPO-PROVERA CASE REPORTS
USE OF AN ANDROGEN-DEPLETING HORMONE IN TREATMENT OF MALE SEX OFFENDERS.
THE JOURNAL OF SEX RESEARCH
by Money J
August 1970
PHARMACOTHERPY OF SEXUAL OFFENDERS
by Monique Richer and M. Lynn Crismon
1993

LUPRON CASE REPORT
THE MANAGEMENT OF A CASE OF TREATMENT-RESISTANT PARAPHILIA WITH A LONGACTING LHRH AGONIST.
CANADIAN JOURNAL OF PSYCHIATRY
by Dickey R
October 1992

EFFECT OF COMBINED ANROGEN BLOCKAGE WITH AN LHRH AGONIST AND FLUTAMIDE IN ONE SEVERE CASE OF MALE EXHIBITIONISM
CANADIAN JOURNAL OF PSYCHIATRY
by Louis Rousseau, M.D., Marcel Couture, M.A., Andre Dupont, M.D., Ph.D., Fernand Labrie, M.D., Ph.D. and Normande Couture, M.A.
May 1990

SERZONE SHOWS PROMISE FOR PARAPHILIA TX
CLINICAL PSYCHIATRY NEWS

by Bruce Jancin
December 1997

EFFECT OF A LONG-LASTING GONADOTROPHIN HORMONE-RELEASING HORMONE AGONIST IN SIX CASES OF SEVERE MALE PARAPHILIA
ACTA PSYCHIATRICIA SCANDINAVICA
by Thibaut F. Cordier B. Kuhn J-M.
1993

A COMPARISON OF TREATMENT OF PARAPHILIAS WITH THREE SEROTONIN REUPTAKIE INHIBITORS: A RETROSPECTIVE STUDY
BULL AM ACAD PSYCHIATRY LAW
by David M. Greenberg, MMed, John M.W. Bradford, MB, Susan Curry, BA, and Annice O'Rourke
1996

TREATMENT OF THE PARAPHILIC DISORDERS: A REVIEW OF THE ROLE OF THE SELECTIVE SEROTONIN REUPTAKE IHIBITORS
SEXUAL ABUSE: A JOURNAL OF RESEARCH AND TREATMENT
by David M. Greeberg and John M.W. Bradford
1997

EFFECT OF PROGESTAGENS ON ANDROGEN METABOLISM
RAVEN PRESS, NEW YORK
by A. Louis Southern, Gary G. Gordon, Jozef Vittek, and Kurt Altman
1977

ENDOCRINE CHANGES IN MALE SEXUAL DEVIANTS AFTER TREATMENT WITH A-A, OESTROGENS OR TRANQUILLIZERS
DEPARTMENT OF HUMAN ANATOMY: UNIVERSITY OF OXFORD
by M.A.F. Murray, J.H.J. Bancroft, D.C. Anderson, T.G. Tennent and P.J. Carr
1975

SPECIAL REPORT: PSYCHOPHARMACOLOGY
PSYCHIATRIC TIMES
June 1996

PHARMACOLOGICAL TREATMENT OF DEVIANT SEXUAL BEHAVIOUR
by J.M.W. Bradford & D.M. Greenberg

THE EROTICIZED VIOLENT CRIME: A PSYCHIATRIC PERSPECTIVE WITH SIX CLINICAL EXAMPLES
THE JOURNAL OF SEXUAL ADDICTION AND COMPULSIVITY
by Fred S. Berlin, M.D., Ph.D., Gregory K. Lehne, Ph.D., H. Martin Malin, Ph.D., Wayne P. Hunt, Ed.D, Kathryn Thomas, R.N., Ph.D., Joseph Fuhrmaneck, M.A., Ps.A.
1997

PHARMACOLTHERAPY, A PATHOPHYSIOLOGIC APPROACH
by Joseph T. DiPiro, PharmD, FCCP, Robert L.Talbert, PharmD, FCCP, BCPS, Gary C. Yee, PharmD, FCCP, Gary R. Matzke, PharmD, FCP, FCCP, Barbara G. Wells, PharmD, FASHP, FCCP, L. Michael Posey, RPh
Third Edition

REFLECTIONS FROM DEATH ROW
by Micael B. Ross #127404
Death Row - Northern

GERMAN ARTICLES

ERFAHRUNGEN UBER DIE BEEINFLUSSUNG DER SEXUALITAT DURCH CYPROTERONACETAT
by M. Appelt und L. Floru
1974

DIE BEHANDLUNG VON SEUALDELINQUENTEN MIT CYPROTERONACETAT INSTITUT FUR GERICHTLICHE PSYCHOLOGIE UND PSYCHIATRIE DER UNIVERSITAT DES SAARLANDES
by Hans J. Horn
April 22, 1971

KLINISCHE PRUFUNG VON CYPROTERONACETAT BEI SEUALDEVIATIONEN – GESAMTAUSWERTUNG LIFE SCIENCES
by Christine Mothes, Jutta Lehnert, Farhang Samimi und Joachim Ufer
August 13, 1971

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
Treat of Sex Offenders with Depo Provera
by Theodore Kiersch, MD
Bull Am Acad. Psychiatry Law, Vol. 18, No. 2, 1990

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
Antiandrogens in the Treatment of Sexual Deviations of Men
by Ursula Laschet & Leonhard Laschet
Journal of Steroid Biochemstry, 1975. Vol.6 821-826

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
Depo Provera Treatment of Sex Offending Behavior: An Evaluation Outcome
by Walter J. Meyer, et al.
Bull Am Acad Psychiatry Law, Vol. 20, No.3, 1992

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
Sadistic Homosexual Pedophilia: Treatment with Cyproterone Acetate:
A Single Case Study
Can. J. Psychiatry Vol.32. February 1987

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
A Placebo-Controlled Trial of Antiandrogen Cyproterone
Acetate in Deviant Hypersexuality
by Alan J. Cooper
Comprehensive Psychiatry, Vol. 22, No. 5 (Sept./Oct.) 1981

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis

Danish Experiences Regarding the Castration of Sexual Offenders
by Louis Le Maire
1956

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
Treatment of Sex Offenders with Medroxyprogesterone Acetate
by Pierre Gagne
Am J Psychiatry 138:5, May 1981

ASH ANTIANDROGEN WORK GROUP
Research Article Synopsis
The Effects of Cyproterone Acetate on Sleeping and Waking Penile Erections in Pedophiles: Possible implications for Treatment
by A.J. cooper, M.D. and Z. Cernovosky, Ph.D
Can. J. Psychiatry vol.37, February, 1992

Articles Reviewed:

News of Medicine: ***Supplement Alert***
by Susan Parrott, AP

EFFECTS OF PROGESTATIONAL COMPOUNDS ON THE REPRODUCTIVE PROCESSES OF THE HUMAN MALE
by Carl G. Heller, et al.
Annals New York Academy of Sciences Vol. 71, Article 1958

NEUROBIOLOGICAL CORRELATES OF MASCULINE SEXUAL BEHAVIOR
by Manuel Mas
Neuroscience and Biobehavioral Reviews, Vol. 19, No.2, pp 261-277, 1995

AROUSAL REDUCTION IN SEXUAL OFFENDERS: A REVIEW OF ANTIANDROGEN INTERVENTIONS
by Rober A. Prentky
Sexual Abuse: A Journal of Research and Treatment, Vol. 9, No. 4, 1997

SEX PREDATOR COMMITMENT LAWS: CONSTITUTIONAL BUT UNWISE
by Eric S. Janus
Psychiatry and the Law June 2000

SENTENCING MALE SEX OFFENDERS TO THE USE OF BIOLOGICAL TREATMENTS - A CONSTITUTIONAL ANALYSIS
by Daniel L. Icenogle, M.D., J.D.
The Journal of Legal Medicine, 15: 279 - 304 1994.

THE TREATMENT OF SEXUAL OFFENDERS - CASTRATION AND ANTIHORMONE THERAPY
by Jorgen Ortmann
International Journal of Law and Psychiatry, Vol. 3 pp 443 - 451. 1980

EVALUATION OF SERUM TESTOSTERONE AND LUTEINIZING HORMONE LEVELS IN SEX OFFENDERS
by Harold Seim, M.D., M.P.H., and Margretta Dwyer, M.A.
Family Practice Research Journal, Vol. 7, No. 3, Spring 1988.

GERMAN STUDIES:

CYPROTERONACETAT IN DER BEHANDLING VON SEXUALDEVIATIONEN
by E. Fahndrich
1974

ENDAST FARMAKOLOGISK BEHANDLING HJALPER
1994

24. In June of 1998, the Antiandrogen Workgroup released its findings, which were that a review of the literature revealed that surgical castration or antiandrogen therapy were very helpful in reducing deviant sexual urges.

25. The hospital then approved the use of antiandrogen therapy (but not physical castration), so long as the application was done by the medical consultants from the Medical Review Committee (MRC) and approved by the Medical Director. The patient had to have a diagnosis of Pedophilia, must be voluntary, and had to have been recommended by the treating psychiatrist. There had to be a signed consent by the patient in the chart before starting the medication.

26. The Medication Review Committee (MRC) is the Committee at ASH that reviews the use of all psycho tropic medications. It is made up of psychiatrist consultants who routinely review medication regimes for safety and applicability. It is a committee of the Department of Psychiatry. For purposes of paperwork, the Antiandrogen Workgroups became a subcommittee of the MRC; all of its consultations and proposals had to be approved by the MRC.

27. The Workgroup reported to the MRC and to the Quality Council. There were certain policies and procedures implemented by the Antiandrogen Workgroup, which were:

a. Requirement of bone density, scans before or soon after starting of antiandrogen therapy (as the bone scans were done off site, there was usually some lag time before the ordering of the scan. Bone scans are done once a year by protocol (approved by the Medication Review Committee). Baseline Serum Testosterone was also done.

b. Monitoring labs such as fasting. Lipid panel and serial serum testosterone levels were done regularly through the Antiandrogen Clinic. This clinic was started right away upon starting these first patients on antiandrogen treatment. This clinic meets once a week in the med-surgical clinic and sees at least 6 patients a week. Dr. Paladino, Dr. Grace Hayes, and Dr. Susan Smith (a non-psychiatric medical doctor) are all present in the clinic, which now handles 70 patients who are released by their doctors. These people (the majority of them have a history of using Lupron for prostrate cancel, or had incidental osteoporosis discovered upon a routine X-ray. Patients are followed (seen) at least quarterly.

28. ASH uses a variety of Relapse Prevention strategies in the comprehensive treatment of sexual offenders.

29. In combination with these Relapse Prevention strategies, antiandrogens can reduce a individuals chances of sexual re-offense.

30. Each patient who consented to antiandrogen treatment was given a handout entitled "Antiandrogen Comparison" before their treatment began. This handout compares the use of the drug Depo Provera versus Lupron. The comparison handout also indicates the possible side effects, including decreased bone density, and the advantages and disadvantages in taking each drug.

31. In addition, a Medication Management Class was taught from 1998-2000 and then from 2003 to the present. This class is for patients of the sexually violent predator (SVP) commitment to learn about all different types of medications used to treat patients, including psycho tropic and medical usages. There is a section on antiandrogen medications as well as treatment of osteoporosis. Plaintiffs, Mr. Christman is in the class now and, along with Mr. Rainwater, took it in 1998 when it was first offered.

32. The Antiandrogen Workgroup first discovered full fledged osteoporosis in January of 2002 when a previously healthy patient who had a normal bone density scan in June of 2001 was found to have osteoporosis. At that point the Antiandrogen

Workgroup at the Medication Review Committee immediately started addressing the issue with the Antiandrogen Clinic becoming the Bone Density Clinic, and all patients either previously or currently on the antiandrogen were notified of this side effect of osteoporosis potentially developing fast - as in 6 months.

33. It was not initially suspected or thought that Lupron could reduce bone density so quickly. The cancer specialists consulted by Dr. Paladino never mentioned it. Of interest, when ASH would receive results of bone density testing on various patients, the recommendation on the report was "follow up in 3-5 years." !!

34. Upon discovery, the following programs were implemented:

An Osteoporosis Wellness Group that is held 5 times a week and is run by the Rehabilitation Therapist, Britney Craig-Harris. All patients in the clinic are invited to this, as ASH's research revealed that good regular non impact exercise can promote good bone growth; patients were given the opportunity to take Fosamax. It is an oral agent that is given at a dose of 70 mg. once a week. It's biggest side effect is esophagel reflux - a person has to stand upright after administration for 30 minutes. It can be given indefinitely. It is a bone rebuilding agent. Also, Fosteo was started at ASH in early 2003. It became available in the USA in early 2003. It is daily subcutaneous injectable. It cannot be used by anyone who had has radiation treatment. In trials rats (which have different bone structure than humans) developed Osteosarcoma, a cancer of the bone, after 2 years of high dose use. So, the FDA limits its use to 2 years total in any given human. There have never been any cases of Osteosarcoma in humans due to Fosteo. In addition, vitamin D (cholecalciferol) calcium supplements, and multivitamins were made available to ASH's patients because it was found to promote bone growth, thanks to literature provided to the Antiandrogen Workgroup by Dr. John Cannel, staff psychiatrist at ASH. The Bone Density Clinic monitors 25 hydroxy vitamin D levels as a low level of vitamin D (another name for vitamin D is cholecalciferol) will impede the absorption of calcium into the body. The world literature supports using vitamin D and calcium

supplementation for the treatment of osteoporosis - this is the gold standard of treatment.

35. The Physician's Desk Reference shows a recommendation for the use of Lupron. It should be noted that for some people, such as those with prostrate cancer, these individuals might have to take Lupron for years. ASH had and still does have multiple patients on Lupron for prostrate cancer. Of note, their treating oncologists never recommended bone density scans to us because the doctors told us, "Most of the people who have prostrate cancer have no choice - it's either Lupron or a recurrence of prostrate cancer."

36. Patients also were monitored and given feedback by the clinic as to the risks and benefits. Ultimately, when it proved that most of the SVPS were going to stay at ASH for years, it was recommended that they get off the Lupron and, if they wished, restart it if they are entering the community as yet another level of protection.

37. None of the committee doctors ever expected the swift and early onset of osteoporosis, nor were they warned about it in the literature of by doctors who routinely used Lupron. However, using Depo Provera, the alternative, proved unsatisfactory due to its many, many side effects such as diabetes, deep vein thrombosis, feminization and weight gain. Lupron has a clean profile, with generally "Hot flashes" and bone loss as its main side effects.

38. Also the SVP patients make up a small but very dangerous segment of the sex offender population - people who started acting out in their teenage years and have spent a lot if not the vast majority of their adult lives behind bars because they could not control their sexual urges. Lupron, according to the patients (Christman and Rainwater), as noted in the Physicians' Progress Notes, helped to significantly decrease their sexual preoccupation, and perhaps give them a chance of life in the free world.

39. A moratorium was ordered by the Acting Medical Director, Dr. Garcia, with the approval of the medical staff at ASH because a higher than expected incidence of

osteoporosis was found. Until this incidence could be further evaluated the decision was made to put a moratorium on the use of antiandrogens. The date was approximately September 2003 that this occurred. The antiandrogen program at ASH has never been stopped. There are at least ten patients on this medication (Lupron) and all are carefully followed by the bone density clinic. None wished to stop this medication for fear of acting out their sexuality.

40. Dr. Paladino was the treating psychiatrist for Mr. David Huffman from October 22, 1997 to October 16, 2003.

41. Mr. Huffman was committed to ASH pursuant to the Sexually Violent Predator Statute, Welfare & Institutions Code section 6600.

42. Mr. Huffman has a long history of sex offending, highest possible recidivism rate for hands on sex offenders is for homosexual boy object pedophiles (50% recidivism plus), which is Mr. Huffman's history.

43. Also, by 1998, Mr. Huffman and a peer had gotten involved and were seen in a lot of questionable places together (such as in the bathroom of unit 24, which are very small and can only fit one patient at a time.) This was noted in a forensic report written by Dr. Paladino on July 20, 1998. And, doctor's progress note dated February 11, 1998 noted he was having a sexual relationship with a peer.

44. Mr. Huffman, at the time, was also actively involved in sex offender treatment and thus understood that treatment for sex offenders is multifaceted in that one needs cognitive behavioral treatment first and foremost, and antiandrogen treatment as a possible valuable adjunct treatment modality.

45. Mr. Huffman underwent penile plethysmography in 1998. Penile plethysmography is the use of a strain gauge whereby the offender voluntarily views various visual stimuli, such as pictures of young boys, and the response to such is measured by the gauge. His penile plethysmography showed a deviant profile emphasizing underage males. That report recommended evaluation for antiandrogen therapy.

46. Dr. Paladino had a very positive relationship with Mr. Huffman at the time he started antiandrogen treatment because she had been his treating psychiatrist since 1997.

47. Mr. Huffman was advised of the possible side affects of taking Lupron, including receiving a Comparison handout.

48. Mr. Huffman gave informed, signed consent to take Lupron on April 3, 2001.

49. Dr. Paladino was also Mr. Huffman's treating psychiatrist at the time the consultation request was made by her to the Medication Review Committee. On April 6, 2001, this request to start antiandrogen therapy was approved by Dr. Marlene Cordero M.D., staff psychiatrist, a member of the Medication Review Committee. This consultation was approved by the Medical Director who signed it.

50. On April 9, 2001, Mr. Huffman received a medication consultation by Dr. Cordero based on the request made by Dr. Paladino on April 4, 2001. In this request Dr. Paladino also mentioned the fact that she had advised Mr. Huffman of the possible benefits and adverse effects of antiandrogen medications.

51. Following the consultation, Mr. Huffman was seen by Dr. Paladino again on April 11, 2001 and May 17, 2001, to discuss the antiandrogen therapy and to initiate the protocol process.

52. In a another meeting with Mr. Huffman on May 18, 2001, Dr. Paladino further discussed the antiandrogen therapy with him, including the side effects. She specifically explained hot flashes and bone demineralization as possible side effects of taking the Lupron.

53. Furthermore, she documented that she had informed and taught Mr. Huffman regarding the side effects of antiandrogen therapy on May 18, 2001 as noted in the Interdisciplinary Patient/Family Health Education Record.

Mr. Huffman's first Lupron injection occurred on May 18, 2001 at a dose of of 7.5 mg 1M per month was started for Mr. Huffman.

54. Lupron was prescribed because Mr. Huffman wanted a long acting agent to assist him in the community without daily administration

55. Mr. Huffman's first Bone Density Study occurred on June 20, 2001.

56. Mr. Huffman was diagnosed with severe osteopenia and bordering on frank osteoporosis on his first bone density study, which implied that he already had a bone density consistent with osteopenia since the Lupron had only been in his system for 32 days by this first bone density study.

57. As soon as the ASH doctors were notified of the June 20, 2001 findings, Dr. Paladino sat down with Mr. Huffman on June 25, 2001, and explained the results, which could not have come from Lupron. This is because bone loss, even in people taking Lupron, is a gradual process, usually taking years. Mr. Huffman had preexisting pathological risk factors consisting daily of heavy daily smoking starting before he was a teenager, white/anglo heritage, and a slight build. On that same date, he was started on the bone rebuilding agent, Fosamax, calcium, as well as multivitamins. He was also advised to start a regimen of nutritional and exercise support.

58. An order was placed on August 13, 2003, by Dr. Paladino to have a follow up bone density study scan done to see if the Fosamax had improved Mr. Huffman's bone density.

59. Plus a follow up bone density study was conducted on Mr. Huffman on September 25, 2003. This study indicated that Mr. Huffman was borderline osteoporosis.

60. In total, Mr. Huffman received one 7.5 mg Lupron injection only. As soon as it was noted that Mr. Huffman had a low bone mass, Lupron was discontinued and Pharmacy was contacted (see Physicians Progress Note dated June 25, 2001.) Dr. Paladino also started him on Zyban (otherwise known as Wellbutrin, with Mr. Huffman's written consent on June 25, 2001. Zyban is a long acting antidepressant that is FDA approved to assist with smoking cessation. However, by July 7, 2001,

Mr. Huffman discontinued the Zyban, and continued to smoke.

61. Mr. Huffman was told what the bone scan was for, that it was non invasive, and that it was part of the antiandrogen monitoring proposal. This was all done by me upon starting the medication Lupron on May 18, 2001.

62. At all times, Mr. Huffman as well as the other patients knew what the Antiandrogen Workgroup knew. The members of Antiandrogen Workgroup were always aware of possible side affects of Lupron, and all patients were informed of them before signing the consent forms. However, the members did not know how rapidly some of the effects would occur, i.e. bone density loss. The members first discovered full fledged osteoporosis in January of 2002 when a previously healthy patient who had a normal bone density scan in June of 2001 was found to have osteoporosis. At that point the Antiandrogen Workgroup at the Medication Review Committee immediately started addressing the issue with the Antiandrogen Clinic becoming the Bone Density Clinic, and all patients either previously or currently on the antiandrogen notified of this side effect of osteoporosis potentially developing fast - as in 6 months.

63. Mr. Huffman, like all the patients with a history of exposure to Lupron or documented bone loss, is followed by the Bone Density Clinic at ASH. This clinic was started on June 12, 2003. Mr. Huffman refuses to come physically to the clinic but is followed by Dr. James Dietch, his treating psychiatrist on unit 23. His last bone density scan was September 25, 2002, a request for a repeat scan has been turned in and should be done at any time. He does take Fosamax, Vitamin D, a multivitamin, and calcium. His last 25 Hydroxy Vitamin D level was well above normal at 75 (within normal limits is ideally 50+; 75 is excellent!)

64. Mr. Huffman continues to smoke. Again, he does not truly cooperate with treatment. He continues to smoke despite having been offered Zyban and the nicotine patch. He refuses to go to the Bone Density Clinic; he is followed by his attending psychiatrist and Dr. Paladino checks his chart periodically to make sure he is being

offered all available treatment. Multivitamin and Calcium were started on February 4, 2002.

65. Dr. Banales has been trained in the care and treatment of sex offenders. These topics were covered in Medical school clinical core courses and in clinical rotations 1987-91 in psychiatry at Camarillo State Hospital and Peveral Psychiatric Hospital, Exxex County, United Kingdom, and in internship and residency (1992-1996 at the Maricopa Medical Center in Arizona. The medical school and residency programs also included courses on ethics as well as treatment of special populations (including sex offenders). Pharmacology was covered in medical school (didactic and clinical rotations)and in residency. Antiandrogens (and their side effects) were covered various clinical rotation in medical school at (Peversal, Camarillo, Rancho Los Amigos), as well as in internship regarding and residency. At ASH, I attended large numbers of lectures and conferences on the treatment and evaluation of sex offenders, such as Dr. Robert Hare on psychopathy, Dr. Karl Hanson on the static - 99 and the SONAR scale (special scale to evaluate sex offenders), and Dr. Amy Phenix regarding the evaluation of the svp sex offender population. Beginning in 1996, seminars were held by Dr. Craig Nelson Ph.D. and Dr. Janice Marquez, previous directors of the SOTEP program and I attended all of these.

66. Dr. Banales reviewed the declaration of Gabrielle Paladino, M.D., which relates to the antiandrogen therapy program at ASH. He agrees with her representations in that declaration.

67. Dr. Banales was a member of the Antiandrogen Workgroup.

68. Dr. Banales was the treating psychiatrist for Mr. Charles Christman from approximately September 17, 1997 to May 1999.

69. Mr. Christman was committed to ASH on pursuant to the Sexually Violent Predator Statute, Welfare &69. Mr. Christman was committed to ASH on pursuant to the Sexually Violent Predator Statute, Welfare & Institutions Code section 6600.

70. Mr. Christman, as a repeat sex offender, is in that category of hands-on sex

offenders with the highest recidivism rate, as he is a boy object pedophile. His sex offending began early (age 14 years old), suggesting highly entrenched deviant behaviors. The target for offenses are males, between 9 and 15 years old.

71. Mr. Christman also has historically made it clear he needs supervision while out in the community. Lupron and Depo Provera are the only two true antiandrogens whose levels can be directly monitored via lab values. Also, Depo Provera has multiple side effects, such as liver pathology diabetes and deep vein thrombosis that Lupron does not have. Because all of these factors, Lupron was considered to be the drug of first choice for Mr. Christman.

72. On June 2, 1997, Mr. Christman was interviewed regarding his request for information regarding Depo-Provera and Leuprolide therapy for sexual impulse control. In this interview, "Mr. Christman appeared well-prepared with questions and seemed able to understand the information given to him. He was given a handout, and told he could review it and discuss later that evening with the interviewer if he wished."

73. On September 24, 1998, Mr. Christman signed a consent to take Leuprolide (Lupron). He had saved the consent form for antiandrogen treatment.

74. On November 3, 1998, Mr. Christman's Application for Antiandrogen Treatment was submitted by him.

75. Also on November 3, 1998 Mr. Christman's consultation was approved by the MRC.

76. Mr. Christman received his first dose of Lupron given November 16, 1998.

77. On November 21, 1998, September 3, 1999, October 1, 1999, and January 7, 2000, Mr. Christman received additional teaching on the side effects of Lupron.

78. Also on April 8, 1999, Mr. Christman signed an additional Informed Consent Form, indicating at the bottom that "with Lupron medication I am not having deviant fantasies or arousals to anyone."

78a. Then on May 24, 1999, Mr. Christman was given his first bone density scan at

Beyond Imaging, which indicated that his bone mineral content was average for his.

79. Mr. Christman's follow up bone density scan examination occurred on August 7, 2000 at Raytel Medical Imaging. This examination indicated "The patient's T-score of -2.04 is consistent with the category of low bone mass. No frank osteoporosis is identified at this time."

80. Mr. Christman was placed on Fosamax on November 1, 2000.

81. Because of the side effects he experienced, which included weight gain plus decrease bone density, Mr. Christman was followed by the Antiandrogen Clinic.

82. On December 7, 2000, Mr. Christman attributed his progress to the Lupron. He reported that over time his aggressiveness dissipated and his impulsive behavior was down. He felt more in control and had no sexual impulses.

to the Lupron. He reported that over time his aggressiveness dissipated and his impulsive behavior was down. He felt more in control and had no sexual impulses.

84. Mr. Christman received annual QCT bond density scans to follow up with his status.

85. Each bone density scan required an consent and authorization by Mr. Christman.

86. On September 14, 2001, Mr. Christman received another QCT Bone Mineral Densitometry examination. This examination indicated "The patient's bone density is fairly stable with a T-score of -2.07 is consistent with moderate osteopenia.

87. On May 24, 2002, Mr. Christman renewed his consultation for antiandrogen therapy even after he was clearly aware that he had bone loss. On the Medication Consultation Form the doctor quoted Mr. Christman as stating: "It reduces my sexual urges and thinking. Sexual thing." "Side effects are very bad Osteoporosis. My bones are weak. I'm in the smoking cessation program." "No depression." The doctor also indicated that Mr. Christman was calm and articulate. Mr. Christman wanted to continue antiandrogen therapy. Mr. Christman perceives benefit from antiandrogen therapy. He denies other side effects other than osteoporosis. He

participates in smoking cessation program. In that May 24, 2002 meeting the doctor made a recommendation to continue the antiandrogen therapy, repeat bone densitometry, encourage smoking cessation and follow lab results/protocol.

88. On December 6, 2002, Mr. Christman was taken off Lupron.

89. On April 24, 2003, Mr. Christman received another QCT Bone Mineral Densitometry examination. This examination indicated "Bone mineral density of the patient is 1.8 standard deviations below average normal in the age group. T-score indicative of osteoporosis.

90. On March 11, 2004, Mr. Christman was seen in the Bone Density Clinic. His bone density scan was on April 24, 2003. He quit the Bone Density Group (exercise) saying he already exercises too much. Still smoking, but does not know how much (but is willing to count his cigarettes). Complained of muscle cramps since starting Forteo. Will switch to Calcium Carbonate to Chelaled calcium with magnesium. Will increase 25 Hydroxy Vitamin D as last result was in August.

91. On March 11, 2004 a repeat bone density scan was ordered by Dr. Paladino.

92. On March 14, 2004, Mr. Christman was seen by his doctor. He was confronted about stopping all activities re: osteoporosis and it was explained to him that he appears to be sabotaging his treatment by not attending any physical activity group.

93. On June 3, 2004, Mr. Christman was seen at the Bone Density Clinic. His QCT of May 10, 2004, showed significant improvement from before. Now he has a T-score of -1.82 and a z-score of 0.02.

94. Dr. Banales is also familiar with Mr. John Rainwater. He was Mr. Rainwater's treating psychiatrist on his treatment unit from approximately July 2, 1998 to March 22, 2000.

95. Mr. Rainwater was committed to ASH pursuant to the Sexually Violent Predator Statute, Welfare & Institutions Code section 6600.

96. Mr. Rainwater was an excellent candidate for antiandrogen treatment because he was a repeat boy object pedophile (these offenders have the highest level of sex

offences with regard to offenders with hands-on sex offenders - the recidivism is at least fifty per cent).

97. Mr. Rainwater was actively engaged in sex offender treatment. There were routine lectures conducted in his phase group about potentially considering antiandrogen therapy as a possible adjunct treatment modality. Mr. Rainwater was aware that antiandrogen therapy could potentially help sex offenders. Mr. Rainwater had an active sexual relationship with a peer which involved overt acting out in the hospital main courtyard captured on videotape (see 90 Day Treatment Plan Conference Report dated 6/4/03); as well as other overt sexual activities (see Interdisciplinary Note dated 9/8/98 where Mr. Rainwater was observed by staff wrapping his arms around a peer's neck.

98. In addition, the Antiandrogen Work Group had been exploring different medications, such as Triptorelin (not available in the USA), Cyproterone Acetate (CPA. This drug used to be available in the USA, but has not been available in this country for at least 10 years), and Depo Provera (utilized worldwide for sex offender treatment. Depo Provera has the largest body of information of any of the antiandrogens). Also, Selective Serotonin Reuptake Inhibitors (SSRI's) were and are investigated at ASH. The world literature, especially the Bradford articles, were carefully explored. There are two main drawbacks to SSRI therapy. One is that there are no documented and agreed upon serum levels for any of the SSRI's (to ensure compliance) and the SSRI's do not directly reduce testosterone; they only are capable (and not in all cases) of reducing libido. Also, in the case of Mr. Rainwater, who has a documented mental illness besides his paraphilia, an antidepressant could potentially increase irritability, an already prominent problem for him.

99. On August 12, 1998, Mr. Rainwater made a request to Dr. Banales for Antiandrogen/Leuprolide treatment. The consultation was submitted to Medication Review Committee (MRC) for approval of antiandrogen therapy by Dr. Banales, Mr. Rainwater's treating psychiatrist at the time. As a result Dr. Cordero conducted a

consultation. In the consultation she reported that "Mr. Rainwater requested Leuprolide to decrease his sex drive. He indicated that he has learned about this medication through discussions with his team psychologist and psychiatrist and that he wishes to take the medication to help him through his treatment to prevent further sexual acting out behavior. ... Patient was initially guarded and suspicious, but became open and cooperative as the interview unfolded. He was alert and oriented, speech was clear and coherent. Mood was mildly anxious. Affect was appropriate. Thought processes were organized and goal directed. No delusion expressed. Patient was aware of the possible benefits/side affects of Leuprolide. This is his choice on Depo Provera because of lower side effect profile. He stated his willingness to switch to Depo Provera if a 6 month trial on Leuprolide will not be successful."

100. Also on August 12, 1998, Mr. Rainwater met with his unit psychiatrist and psychologist. ... "Patient discussed treatment about risks, benefits, alternatives of treatment with antiandrogen and the fact that he was specifically interested in taking Leuprolide."

101. On September 11, 1998, Mr. Rainwater was interviewed about the antiandrogen treatment, including the risks, alternatives, and benefits were discussed.

102. Then on September 14, 1998, Mr. Rainwater was seen by Dr. Cordero and his chart was reviewed to evaluate his request for Leuprolide treatment. Mr. Rainwater again indicated his goal was to decrease his sexual drive. The doctor indicated that he had good knowledge of possible benefits/side effects of the medication and that he gave full consent to be medicated.

103. On September 16, 1998 an Application for Antiandrogen Treatment was prepared on Mr. Rainwater. The two targets of treatment were 1) sexual preoccupation and erections interfering with treatment, and 2) Engaged in treatment and does not want to act sexually during this hospitalization.

104. Mr. Rainwater gave informed consent utilizing a signed consent form approved by Medical Director on September 18, 1998.

105. Mr. Rainwater had a deviant penile plethysmograph on October 19, 1998 with a deviant preference directed towards prepubescent and pubescent males (his preferred victim range).

106. Mr. Rainwater started Lupron on November 11, 1998. He was regularly followed by the Antiandrogen Clinic. After that, at least initially monthly at the clinic.

107. On November 18, 1998, Mr. Rainwater received additional teaching on the side effects of Leuprolide treatment.

108. On May 2, 1999, Mr. Rainwater requested an increase in the Leuprolide to 7.5 mg because he was still having deviant thoughts.

109. Mr. Rainwater's first bone density scan done May 21, 1999 was already slightly low but read "average for age".

110. Again on June 4, 1999, Mr. Rainwater requested an increase in the Lupron because he reported fantasizing about children and adults.

111. On August 12, 1999, Mr. Rainwater reported "I haven't had any deviant sexual fantasies... I attribute it to the Lupron... ."

112. Again on October 1, 1999 and April 14, 2000, Mr. Rainwater received additional teaching on the side effects of Leuprolide treatment.

113. On February 14, 2000, Mr. Rainwater denied having sexual fantasies, again attributing this fact to his Lupron treatment.

114. On August 31, 2000,114. On August 31, 2000, Mr. Rainwater received an Antiandrogen Consultation with Dr. Paladino. Mr. Rainwater indicated that he still had some deviant fantasies and he wanted an increase in Lupron. Dr. Paladino also ordered a repeat Bone Density Scan pursuant to MRC protocol.

115. Also on August 31, 2000, Mr. Rainwater was given a referral for a repeat bone scan pursuant to the MRC guidelines.

116. On September 28, 2000, Mr. Rainwater was interviewed. He stated that he now had acceptable (non deviant) ... fantasies.

117. On October 3, 2000, Mr. Rainwater underwent another QCT Bone Mineral Densitometry. The bone scan indicated that "This patient's bone density value corresponds to the category of low bone mass (i.e. A T-score of -1 to -2.5).

118. On October 28, 2000, Mr. Rainwater was seen and his most recent bone density scan results were reviewed by Dr. Paladino. She indicated that the results reported on October 3, 2000 revealed low bone density, which suggests a progression in decrease bone density. She indicated that she would refer Mr. Rainwater's case to medical consultant as to whether to start calcitonin or Miacalcin or Fosamax. Mr. Rainwater was informed and agreed.

119. Next scan was October 3, 2000 bone density scan which was notable for "low bone mass". On October 28, 2000, this writer requested consultation of Dr. Linda Kolsis, ASH's non psychiatric medical specialist consultant for Bone Density/Antiandrogen Clinic, who recommended Fosamax (which had been started January 18, 2000).

120. Mr. Rainwater's Fosamax treatment was started November 28, 2001. (He was on Lupron at the time) with the hope this would augment bone mass substantially enough to offset Lupron's bone demineralization side effect.

121. There was sexual acting out directed towards staff on the part of Mr. Rainwater on January 6, 2001, when he took off all his clothes in front of (an unwilling) female staff.

122. Plaintiff Rainwater requested to stay on Lupron. Lupron, according to the Mr. Rainwater, helped to significantly decrease his sexual preoccupation, and perhaps give him a chance of life in the free world.

123. On September 25, 2002, Mr. Rainwater requested Lupron therapy via implant. As a result his chart was reviewed. The reviewing doctor indicated that he/she would not recommend antiandrogen continuation due to significant decrease in bone mineralization despite Alendronate and Calcium supplements.

124. Notwithstanding on October 3, 2002, Mr. Rainwater consented to receiving a

Viadur implant.

125. Lupron was discontinued on plaintiff Rainwater on or about August 2003.

126. Mr. Rainwater was never entirely cooperative with treatment for improving bone density. He remains a heavy smoker, despite numerous attempts by a number of doctors to assist him in " Stop Smoking" classes or Nicotrol inhalers or the nicotine patch (see doctor's order dated November 22, 2000 for the Nicotrol inhaler); eventually all of these modalities were discontinued (only to be tried again) because Mr. Rainwater would smoke even when on the patch, a very potentially dangerous thing to do as it can cause fatal arrhythmias. His smoking despite using the patch was documented in many notes, especially 90 Day Team Conference Summary Report on September 1, 2004, and 90 Day Team Conference Summary Report.

127. On December 2, 2004 noted he had been smoking 30 cigarettes a day. Many behavior notes for smoking in bathroom (example 12/22/04) or refusing to come out of the courtyard after a smoke break (same day).

128. Mr. Rainwater also would refused to go to Bone Density Clinic at regular scheduled appointments, as documented in Team Conference Summary Report dated December 2, 2004.

129. There were multiple trials of nicotine patch/nicotrol inhaler in 2001, August of 2002, July of 2002 (very comprehensive note written by Dr. Belanger, non psychiatric physician, done July 11, 2002) that document 10-20 attempts at quitting smoking, and that was in 2002! He was also placed on patch (by Dr. Belanger) on April 29, 2004 and 2005 last tried (and failed) patch October 31, 2005. His is still actively smoking.

130. Mr. Rainwater has also been non compliant with taking Fosamax and the other bone density augmentation medication (see doctor's progress notes written by Dr. Belanger September 10, 2004 where Dr. Belanger said Mr. Rainwater is "aware of the consequences" of continued smoking.

131. Mr. Rainwater also repeatedly refused Fosamax treatment, even though he was advised about the inadvisability of doing so. Such refusals, which also included

refusing cholecalciferol (26 refusals in 10/03) and calcium (21 refusals in 10/02) made treating Mr. Rainwater very problematic.

132. In 2003, the new, highly efficient drug Forteo, came on the market, and Mr. Rainwater was given one of the first opportunities to use it, which, he did from August 8, 2003 to October 6, 2004. He then went back on Fosamax, as he preferred a drug with oral administration (Fosamax) rather than injectable (Forteo).

133. Mr. Rainwater's most recent bone density scan was April 12, 2004 and was read as "bone mineral content average for age", showing that despite his lack of cooperation and motivation, the Bone Density Clinic has been able to turn around his previous condition of osteoporosis (as noted in bone density scan of 10/9/02).

IT IS SO ORDERED.

March 20, 2006

Hon. Manuel L. Real
United States District Court Judge

Respectfully submitted

March 13, 2006

BILL LOCKYER, Attorney General
of the State of California
JOHN H. SANDERS, Lead Supervising
Deputy Attorney General

By: _____
KAREN ACKERSON-BRAZIELLE
Deputy Attorney General
Attorneys for Defendants

DECLARATION OF PERSONAL SERVICE

Case Name: **JOHN ALLEN RAINWATER, STEVEN LAWRENCE BURKHART, DOUGLAS ERNEST BADGER, CHARLES CHRISTMAN, STEVE JOSEPH WILLETT, DAVID HUFFMAN, TROY MICHAEL NAYLOR v. JAN MARIE ALARCON, Ph.D.; FREDERICK BANALES, Ph.D.; RONALD LAPP, M.D.; MARY FLAVIN, Ph.D.; ROBERT S. KNAPP, MD., Ph.D.; GLORIA FISCALINI, GABRIEL PALADINO, Ph.D.**

No.: **CV 03-8569 R**

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 300 South Spring Street, Suite 1702, Los Angeles, CA 90013. On March 13, 2006, I served the following documents:

(PROPOSED) ORDER RE: STATEMENT OF UNCONTROVETED FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OR, ALTERNATIVELY FOR SUMMARY ADJUDICATION

on the parties through their attorneys of record, by placing true copies thereof in sealed envelopes addressed as shown below for service as designated below:

(A) **By First Class Mail:** I caused each such envelope to be placed in the internal mail collection system at the Office of the Attorney General with first-class postage thereon fully prepaid in a sealed envelope, for deposit in the United States Postal Service that same day in the ordinary course of business.

(B) **By Messenger Service:** I caused each such envelope to be delivered by a courier employed by Ace Messenger & Attorney Service, with whom we have a direct billing account, who personally delivered each such envelope to the office of the address on the date last written below.

(C) **By Overnite Mail:** I caused each such envelope to be placed in a box or other facility regularly maintained by the express service carrier, or delivered to an authorized courier or driver authorized by the expresses service carrier to receive documents, in an envelope or package designated by the express service carrier with delivery fees paid or provided for.

(D) **By Facsimile:** I caused such document to be served via facsimile electronic equipment transmission (fax) on the parties in this action by transmitting a true copy to the following fax numbers listed under each addressee below.

(E) **By Personal Service:** I caused each such envelope to be served via personal deliver to the following person(s) at the address(es) as follows:

//

TYPE OF SERVICE	ADDRESSEE
E	**JOHN ALLEN RAINWATER** AT#047958-4 Atascadero State Hospital P.O. Box 7001/Unit 30 10333 El Camino Real Blvd. Atascadero, CA 93423-7001
E	**DAVID HUFFMAN** AT#047243-1 Atascadero State Hospital P.O. Box 7001/Unit 23 10333 El Camino Real Blvd. Atascadero, CA 93423-7001
E	**CHARLES CHRISTMAN** AT#045785-3 Atascadero State Hospital P.O. Box 7001/Unit 34 10333 El Camino Real Blvd. Atascadero, CA 93423-7001

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on March 13, 2006, at Los Angeles, California.

Norma L. Herrera-Orr
Declarant

Norma L. Herrera-Orr
Signature

60131875.wpd