CV -91-0506 WEXLER, J.

UNITED STATES DISTRICT COURT
for the
EASTERN DISTRICT OF NEW YORK

Texas Chiropractic Association,
by its members as representatives of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology who reside in the State of Texas, and on behalf of all those so unfortunate as to be denied access to clinical thermography utilizing modern digital thermal imaging technology as a result of the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services,

Plaintiffs,

v.

Office of Health Technology Assessment, United States Public Health Service (OHTA), and Health Care Financing Administration, United States Department of Health & Human Services (HCFA),

Defendants

VERIFIED COMPLAINT

Victor John Yannacone, jr.
YANNACONE & YANNACONE, P.C.
Attorneys for the Plaintiffs
Office & Post Office Address
39 Baker Street
Post Office Drawer 109
Patchogue, New York 11772+0109
(*Area Code* 516) 475-0231

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VERIFIED COMPLAINT

PLAINTIFFS DEMAND TRIAL BY JURY

The plaintiff, **Texas Chiropractic Association**, who bring this action as a representative of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology, and on behalf of all those so unfortunate as to be denied access to clinical thermography utilizing modern digital thermal imaging technology as a result of the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services, sets forth the following as and for a complaint against the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services, jointly and severally, individually and collectively, all as their several interests may appear.

Jurisdiction

1. The jurisdiction of this United States District Court is predicated on the existence of a federal question under 28 U.S.C. §1331. Among the federal statutes, rules, and regulations which are the subject matter of this action are those which regulate the activities of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services, including the *Social Security Act*, Title XVIII, §1862 (a) (I) (A) , and the *Administrative Procedure Act.* The claims made by the representative plaintiffs in this action may also require consideration of the Fifth and Fourteenth Amendments to the Constitution of the United States.

Venue

2. The venue of this action is set in the Eastern District of New York because issues similar to those raised in this verified complaint are already before this Court in *Health Care Professionals United to Protect Patients, &c.* v. *Office of Health Technology Assessment, United States Public Health Service* (OHTA) and the *Health Care Financing Administration, United States Department of Health & Human Services* (HCFA), an action filed as **CV 90-3086** and assigned to the Hon. Leonard Wexler, USDJ, a Judge of this Court.

3. Just as clinical thermography utilizing modern digital thermal imaging technology is well established as a diagnostic procedure relied upon by health care practitioners thoughout the region and is also used by such health care practitioners as a means of monitoring the course of treating their patients, clinical thermography utilizing modern digital thermal imaging technology is similarly well established as a diagnostic procedure relied upon by members of the *Texas Chiropractic Association.*

4. Upon information and belief, thousands of members of the class of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology who reside in the State of Texas and have been or surely will be adversely affected by the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services complained of in this action.

Class Action

5. This action is brought as a Class action, pursuant to the provisions of Rule 23 of the Federal Rules of Civil Procedure, by the plaintiff Texas Chiropractic Association as representative of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology who reside in the State of Texas, and on behalf of all those so unfortunate as to be denied access to clinical thermography utilizing modern digital thermal imaging technology as a result of the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health

Care Financing Administration, United States Department of Health & Human Services who reside in the State of Texas.

6. The claims of the individual patients represented in this action by the representative plaintiff association are typical of the claims of all those so unfortunate as to be denied access to clinical thermography utilizing modern digital thermal imaging technology as a result of the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services (HCFA) who reside in the State of Texas as well as all others so unfortunate as to be similarly at risk.

7. The issues of law and fact determining the claim of the plaintiff class that the Office of Health Technology Assessment report entitled, Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast is unsupported by a fair preponderance of the substantial and credible evidence are common to all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology.

8. The number of individuals so unfortunate as to be adversely affected by the determination of the Office of Health Technology Assessment, United States Public Health Service based on its Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast exceeds one hundred thousand (100,000) individuals throughout the United States.

9. The prosecution of separate actions by individual members of the class litigating their claim that the Office of Health Technology Assessment report entitled, Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast is unsupported by a fair preponderance of the substantial and credible evidence will create a risk of inconsistent or varying adjudications with respect to individual members of the class.

10. Adjudication of the common issues of law and fact associated with determining that the Office of Health Technology Assessment report entitled Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast is unsupported by a fair preponderance of the substantial and credible evidence will, as a practical matter, be dispositive of similar issues in actions involving individual patients throughout the United States.

11. To the extent that determinations about the effectiveness of clinical thermography utilizing modern digital thermal imaging technology by the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services are persuasive, adjudication of the common issues of law and fact associated with this action will determine similar issues in Canada and Australia as well.

12. The members of the class of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology and who reside in the State of Texas are fairly and adequately represented by the plaintiff Texas Chiropractic Association, as to the common issues of law and fact determining that the Office of Health Technology Assessment report entitled Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast is unsupported by a fair preponderance of the substantial and credible evidence.

13. The common issues of law and fact must be determined by this Court in order to fashion an appropriate equitable remedy for the benefit of the entire class of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology.

The Representative Plaintiff

14. The representative plaintiff, Texas Chiropractic Association, is organized and exists for the purpose, among others, of representing Doctors of Chiropractic in matters concerning the care and treatment of patients in the State of Texas among whom are those individuals who might obtain significant benefit from the use of clinical thermography utilizing modern digital thermal imaging technology in the diagnosis, care, and treatment of injury, illness, and disease.

15. The representative plaintiff, Texas Chiropractic Association, its members and its counsel have no interests adverse to those of any individual who might be a member of the class sought to be represented herein.

The Office of Health Technology Assessment United States Public Health Service

16. The Office of Health Technology Assessment, United States Public Health Service (OHTA) is part of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), Public Health Service, Department of Health and Human Services.

17. The Office of Health Technology Assessment (OHTA) evaluates the safety and effectiveness of new or unestablished medical technologies that are being considered for coverage under Medicare. These assessments are performed at the request of the Health Care Financing Administration (HCFA). They are the basis for recommendations to HCFA regarding coverage policy decisions under Medicare.

18. Questions about Medicare coverage for certain health care technologies are directed to HCFA by such interested parties as insurers, manufacturers, Medicare contractors, and practitioners. Those questions of a medical, scientific, or technical nature are formally referred by HCFA to OHTA for assessment.

19. Upon information and belief, Donald Goldstone, M.D. was the Acting Director of the Office of Health Technology Assessment responsible for approving the publication, distribution, and circulation of the OHTA report entitled, *Thermography for Indications Other Than Breast Lesions*.

20. Upon information and belief, J. Michael Fitzmaurice, Ph.D. was the Director of the National Center for Health Services Research and Health Care Technology Assessment responsible for approving the publication, distribution, and circulation of the OHTA report entitled, *Thermography for Indications Other Than Breast Lesions*.

21. Upon information and belief, the Office of Health Technology Assessment and the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), jointly and severally, individually and collectively made the determination and approved the statement that "Copies [of *Thermography for Indications Other Than Breast Lesions*] may be obtained at no charge from the Publications and Information Branch NCHSR, 5600 Fishers Lane, Parklawn Building, Room 18-12, Rockville, MD 20857.

22. Allegedly OHTA's assessment process includes a comprehensive review of the medical literature and emphasizes broad and open participation from within and outside the Federal Government.

23. However, the OHTA Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, did not include a comprehensive review of the medical literature and emphasize broad and open participation from within and outside the Federal Government.

24. According to the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), a range of expert advice is allegedly obtained by widely publicizing the plans for conducting the assessment through publication of an announcement in the Federal Register and solicitation of input from Federal agencies, medical specialty societies, insurers, and manufacturers.

25. However, in preparing its Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, OHTA solicitated input from Federal agencies, medical specialty societies, and insurers, but did not solicit input from among those who have substantial professional and practical knowledge of clinical thermography utilizing modern digital thermal imaging technology.

26. According to the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), the involvement of these experts helps assure inclusion of the experienced and varying viewpoints needed to round out the data derived from individual scientific studies in the medical literature.

27. Unfortunately, in preparing its Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast the OHTA decision making process lacked the experienced and varying viewpoints needed to round out the data derived from individual scientific studies in the medical literature because OHTA failed to include the positions and viewpoints of those who have substantial professional and practical knowledge of clinical thermography utilizing modern digital thermal imaging technology.

28. According to the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), after OHTA receives information from experts and the scientific literature, the results are analyzed and synthesized into an assessment report.

29. However, the OHTA Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, failed to properly evaluate the results reported in the scientific literature, many of which were ignored or overlooked, while those considered were neither adequately analyzed nor effectively synthesized.

30. According to the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), each report represents a detailed analysis of the safety, clinical effectiveness, and uses of new or unestablished medical technologies considered for Medicare coverage.

31. However, the OHTA Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, does not represent a detailed analysis of the safety, clinical effectiveness, and uses of clinical thermography utilizing modern digital thermal imaging technology.

32. These Health Technology Assessment Reports form the basis for Public Health Service recommendations to HCFA and are disseminated widely.

33. Because the OHTA Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast has been circulated widely and is the basis for United States Public Health Service recommendations to the Health Care Financing Administration, serious, permanent and irreparable damage has already been done, is continuing to be done, and will be done to all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology.

United States Department of Health & Human Services
The Health Care Financing Administration and Thermography

34. Upon information and belief, Robert E. Wren has been employed by the Department of Health and Human Servicessince 1971 and has held his current position since 1984. As Director of the Office of Coverage Policy, he oversees a staff of 70 people whose responsibilities include making national coverage determinations under the Medicare statute.

35. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, under *Title XVIII* of the *Social Security Act*, 42 U.S.C. §1395y (a)(1) (A), commonly referred to as the *Medicare Act*, payment may not be made for any medical services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.", and this provision is the primary statutory basis for determining whether or not a service can be paid for by the Medicare program.

36. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, HCFA has always interpreted this provision to exclude from Medicare coverage medical services that are not generally accepted by the professional medical community as safe and effective treatments for the condition for which they are recommended. New or emerging medical procedures must be demonstrated to

> inflammatory, neoplastic, and hyperplastic lesions can also be covered. Thermography for use in the detection of breast disease is not covered."

48. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, in 1982, several Medicare contractors recommended that HCFA consider limiting coverage for thermography, claiming other diagnostic techniques were available.

49. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, the BPD compiled all available medical and scientific evidence and presented a background paper to the HCFA Physicians Panel and the Panel recommended on May 27, 1982 that OHTA conduct an assessment of the safety and effectiveness of thermography as a diagnostic technique.

50. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, on 21 December 1983, OHTA sent its assessment to HCFA, and based on the OHTA recommendation, HCFA revised its policy to exclude Medicare coverage for thermography for detection of breast cancer. This policy was published as Section 50-5 of the *Medicare Coverage Issues Manual* and became effective on July 20, 1984.

51. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration on March 21, 1985, OHTA issued a second assessment covering the use of thermography for conditions other than breast disease, but this assessment was withdrawn by OHTA after it received additional Scientific data.

52. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990,

> "[HCFA has] received comments questioning the effectiveness of thermography in general. Many of these commentors believe that more precise diagnostic techniques than thermography have been developed for diagnosing disease."

53. Upon information and belief, the sources of the comments allegedly received by the Health Care Financing Administration are special interest groups and lobbyists representing insurance carriers and other third party payment sources with a declared policy of opposition to the use of thermography in the clinical practice of the healing professions,

and certain medical specialty groups similarly opposed to clinical thermography utilizing modern digital thermal imaging technology largely as a result of their lack of familiarity and understanding of the physiological basis of clinical thermography and technology of digital thermal imaging.

54. Upon information and belief, not-for-profit organizations such as the Academy of Neuro-Muscular Thermography, the American Academy of Thermology, the American Board of Clinical Thermology, the American Chiropractic Association College of Thermology, the American Herschel Society, the International Academy of Clinical Thermology, the International Thermographic Society, and the National Academy of Thermology, are restricted from lobbying and are therefore extremely limited in the extent of their advocacy on behalf of patients before administrative agencies of the federal bureaucracy such as the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services.

55. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990,

> "As a result of these comments, [HCFA] instituted a review process which"

purported to involve

> "a compilation of the latest medical and scientific evidence on thermography."

56. Upon information and belief, the asserted compilation of what was claimed to be the "latest medical and scientific evidence on thermography" failed to include more than 40 recent articles and papers supportive of thermography as a reliable clinical procedure in the diagnosis and management of a number of disabling conditions, and failed to consider the vast international literature on thermography that has led to its unquestioned acceptance by the health care professions in many advanced industrial nations including Great Britain, France, Italy, and Japan.

57. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990, the asserted compilation of what was claimed to be the

> "latest medical and scientific evidence on thermography ... was then presented to the Health Care Financing Administration's (HCFA) Physicians Panel for its review.
>
> The HCFA Physicians Panel is an internal organization composed of physicians and other health professionals in HCFA's Central Office, and their counterparts from the Public Health Service (PHS). The Panel recommended that OHTA [Office of Health Technology Assessment] (a component of PHS) conduct an assessment of the safety and effectiveness of thermography for indications other than breast disease.
>
> This PHS assessment involved the publication by OHTA of a Federal Register notice announcing that an assessment of thermography was being undertaken and soliciting comments from interested parties. As part of this process, OHTA sought information and advice from other government agencies such as the National Institutes of Health, and the Food and Drug Administration."

58. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990, the Office of Health Technology Assessment

> "also solicited advice from the following medical societies to determine whether a consensus exists on the safety and effectiveness of thermography:
>
> American Thermographic Society
> American Medical Association
> AMA Council of Medical Specialties
> American Osteopathic Association
> American College of Osteopathic Surgery
> American Academy of Orthopedic Surgeons
> American Physical Therapy Association
> Emergency Care Research Institute
> Association for Advancement of Medical Instrumentation
> American Academy of Family Physicians
> American Rheumatism Association
> American College of Physicians
> American Academy of Neurology
> Health Industry Manufacturer's Association"

59. Upon information and belief, the Office of Health Technology Assessment did not at any time solicit advice from the "American Thermographic Society", an organization the proper name of which is the

American Academy of Thermology, the only organization on the OHTA list with any significant experience in the clinical practice of thermography.

60. Upon information and belief, none of the medical societies listed by OHTA professes to have any significant professional experience as an organization with the clinical practice of thermography nor is the clinical practice of thermograpy a matter of general and regular consideration by these organizations, although the American Medical Association did evaluate thermography as an element of the clinical practice of medicine and issued a report in December 1987 which supports the use of thermography in the diagnosis and treatment of pathologic conditions other than breast disease.

> "Thermography is a safe adjunctive physiological procedure which may be useful in the diagnosis of selected neurological and musculoskeletal conditions."

According to the Office of General Counsel of the American Medical Association, in a letter dated 29 March 1989,

> "Currently, the report is considered a 'state of the art' scientific report on the safety and efficacy of the use of infrared thermography as a diagnositic adjunctive procedure in the diagnosis of selected neurological and musculoskeletal conditions."

61. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990,

> "OHTA also conducted an exhaustive search of the published medical and scientific literature. The findings of all relevant studies and reports were carefully analyzed. OHTA then synthesized all the available information in developing the PHS recommendation. This process involved the summarization of all pertinent information (including expert opinions), the weighting of the various sources of information according to their comparative validity and significance, the development of conclusions regarding the safety and effectiveness of thermography, and the development of OHTA's policy recommendations to HCFA regarding the appropriateness of Medicare coverage of thermography for indications other than breast disease."

62. There is no evidence contained in any document published by or under the auspices of the Office of Health Technology Assessment

indicating that OHTA or its consultant, Harry Handelsman, D.O. conducted an exhaustive search of the extant published medical and scientific literature.

63. On the contrary, the published Health Technology Assessment Report, *Thermography for Indications Other Than Breast Lesions*, clearly establishes that OHTA failed to conduct an exhaustive search of the extant published medical and scientific literature, much less did OHTA or its consultant, Harry Handelsman, D.O., demonstrate that, "The findings of all relevant studies and reports were carefully analyzed" or that "OHTA then synthesized all the available information in developing the PHS recommendation" which was eventually officially cleared, released, and published by the United States Department of Health & Human Services, National Center for Health Services Research and Health Care Technology Assessment as, *Thermography for Indications Other Than Breast Lesions* in Health Technology Assessment Reports, 1989, Number 2.

64. According to Robert E. Wren, Director, Office of Coverage Policy, Health Care Financing Administration, OHTA issued its revised assessment on January 26, 1989, which recommended that HCFA cancel coverage for diagnosis of conditions other than breast disease.

65. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990,

> "On January 26, 1989, HCFA received OHTA's Assessment on Thermography for Indications Other than Breast Lesions which recommended that [HCFA] discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast.
>
> This assessment, while compiled and written by a member of OHTA represents the analysis and review of all relevant medical and scientific literature, studies and reports available at that time. The assessments conducted by OHTA represent an institutional viewpoint and are not reflective of one individuals opinion."

66. The purported analysis conducted by or on behalf of the Office of Health Technology Assessment was incomplete, seriously flawed, and lacked substantive basis from which to draw a conclusion. The OHTA conclusions were not consistent with and, in some cases, were unsupported by data which it cited. In other cases, OHTA cites findings

favorable to Thermography, but fails to discuss or incorporate such findings in its conclusions.

67. According to Kathleen A. Buto, Director, Bureau of Policy Development, Health Care Financing Administration of the United States Department of Health & Human Services, in a letter dated May 24, 1990,

> "We [Health Care Financing Administration] are currently drafting a proposed notice for publication in the Federal Register in the near future. The notice will propose changes in HCFA's policy that will, in effect, withdraw the coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast."

68. It is this proposed notice which was published in the *Federal Register* on 9 October 1990 at page 41140, and which is unsupported by a fair preponderance of substantial credible scientific evidence, and more particularly the legally insufficient and intellectually flawed OHTA report on which it is based, that is the subject matter of this action.

69. As a result of this proposed action, federal and state agencies, as well as third party payers have declined to pay for clinical thermography utilizing modern digital thermal imaging technology.

Health Care Financing Administration Evaluation Criteria

70. According to information published in 54 *Fed. Reg.* at 34,581 (1989), the Health Care Financing Administration (HCFA) currently provides Medicare coverage for Thermography in connection with the following conditions:

- Peripheral vascular disease including thrombophlebitis, arterial insufficiency, and deep vein thrombosis (DVT);
- Musculoskeletal injury involving musculoligamentous soft tissue or discogenic conditions;
- Extra-cranial vessel disease diagnosis upon demonstration of central nervous system (CNS) symptoms such as carotid insufficiency; and
- Diagnosis of inflammatory, neoplastic, and hyperplastic lesions.

71. The Health Care Financing Administration has established certain fundamental tests for Medicare coverage which include effectiveness, appropriateness, clinical acceptance, safety, and cost-effectiveness.

72. According to information published in 54 *Fed. Reg.* at 4307 (1989), the Health Care Financing Administration has proposed criteria for Medicare coverage decisions which will determine "effectiveness" by reference to a number of factors which will include

- indications for use,
- effectiveness for each indication,
- expected effect on patient outcome,
- accuracy and availability compared with alternatives,
- invasiveness,
- limitations on restrictions on use,
- source and nature of supporting evidence,
- confidence in conclusions,
- FDA review and approval, and
- NIH advice.

73. Clinical thermography utilizing modern digital thermal imaging technology satisfies the fundamental tests for Medicare coverage established by the Health Care Financing Administration.

74. According to *Thermography in Neurological and Musculoskeletal Conditions* Informational Report of the Council on Scientific Affairs, American Medical Association, December 1987,

> "Thermography is a safe adjunctive physiological procedure which may be useful in the diagnosis of selected neurological and musculoskeletal conditions."

75. Clinical thermography utilizing modern digital thermal imaging technology satisfies the criteria for coverage under Medicare, because it is "reasonable and necessary for diagnosis or treatment of illness or to improve the functioning of a malformed body member" as required by the *Social Security Act*, Title XVIII, §1862 (a) (I) (A) .

76. Clinical thermography utilizing modern digital thermal imaging technology meets the fundamental tests of safety, clinical effectiveness and cost effectiveness under the criteria proposed by Health Care Financing Administration for national Medicare coveage decisions regarding

diagnostic imaging technology as published in 54 *Fed. Reg.* at 4305 (1989).

Recent Health Care Financing Administration Action

77. That on or about 2 October 1990, the Health Care Financing Administration caused to be published in the *Federal Register* a certain notice bearing file code designation "[BPD-645-PN] RIN: 0938-AF18" which announced

> "the *Medicare* program's proposal to withdraw Medicare coverage of thermography for all indications.

for the stated reason that

> "Evidence suggests that thermography is not a useful diagnostic modality. Therefore it does not meet HCFA's criteria for effectiveness."

78. That the regulation proposed by the Health Care Financing Administration was initiated "Early in 1982, [by] contractors who process Medicare claims [and who] recommended that HCFA limit coverage of thermography. Their recommendation was based on the belief that more precise techniques have been developed, since the advent of thermography, for diagnosing disease. Moreover, the contractors believed that thermography was ineffective as a diagnositic technique."

79. Upon information and belief, the contractors who process Medicare claims are private insurance carriers organized and existing as private business corporations under and by virtue of the laws of one or more of the United States or certain foreign countries, and purported to be regulated to some extent by the laws of the states in which they conduct business.

80. Upon information and belief, the contractors who process Medicare claims exist to earn a return on the investment of the stockholders or, in the case of mutual insurance associations, their members, and that this return on investment, is nothing more than what the general business community and its accountants refer to as profit.

81. Upon information and belief, the actions of the Health Care Financing Administration and the work of the Office of Health Technology Assessment by which it is allegedly justified were instigated and have been taken at the instance of and for the benefit of the private insurance carriers who are the contractors which process Medicare claims.

Texas Industrial Accident Commission Action

82. The Texas Industrial Accident Commission has taken action limiting the access of Doctors of Chiropractic and other health care professionals to clinical thermography utilizing modern digital thermal imaging technology largely based on the regulations proposed by the Health Care Financing Administration (HCFA) of the United States which regulations were improperly based upon a document prepared by the Office of Health Technology Assessment of the United States Public Health Service.

83. As a result of the OHTA Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast the HCFA action, the Texas Industrial Accident Commission has taken action to effectively preclude Doctors of Chiropractic throughout the State of Texas from utilizing clinical thermography utilizing modern digital thermal imaging technology in the diagnosis and treatment of patients who are victims of industrial accidents and occupational disease.

84. In addition, the Texas Industrial Accident Commission accepted – without opportunity for cross-examination – testimony from individuals and representatives of certain groups all of whom, upon information and belief, were contributors to the HCFA's proposed regulation and whose oppositIon to the use of clinical thermography utilizing modern digital thermal imaging technology as a means of observing and monitoring the activity of the human autonomic nervous system were unsupported by a fair proponderance of the substantial credible, scientific, technical and medical evidence.

Thermography

85. Clinical thermography utilizing modern digital thermal imaging technology is a technique used to quantitatively and qualitatively measure and map variations in skin temperature.

86. Clinical thermography utilizing modern digital thermal imaging technology uses an infrared imaging radiometer system to record the temperature of skin at resolutions approaching the nearest 0.05°C for contiguous areas of from one to ten millimeters square. The data obtained in this way is coverted to a digital image for processing by computer.

87. The digital thermal images may be stored electronically on a variety of media and reproduced as required for clinical interpretation.

88. Clinical thermography utilizing modern digital thermal imaging technology compares differences in skin temperature between regions of the body which are relatively thermally symmetrical.

89. Changes in skin temperature may occur as a result of muscular activity, trauma or stimulation of sensory and/or autonomic nerves resulting in vasoconstriction or vasodilatation.

90. Statistically significant thermal asymmetries may indicate neurologic or vascular dysfunction, or inflammatory conditions.

91. Clinical thermography utilizing modern digital thermal imaging technology is a non-invasive, non-manipulative test which does not subject the patient to radiation exposure, injection of radiopaque contrast dyes, or other pharmacologically active chemicals.

92. Thermography enables health care practitioners from a variety of academic and clinical disciplines to obtain information from the skin, in order to evaluate sympathetic nerve function in detail not previously attainable.

93. There are a number of characteristics that make clinical thermography valuable to the health care practitioner.

- clinical thermography utilizing modern digital thermal imaging technology is painless and non-invasive;
- clinical thermography utilizing modern digital thermal imaging technology has no adverse biologic effect;
- clinical thermography utilizing modern digital thermal imaging technology permits objective statistical evaluation of test data;
- clinical thermography utilizing modern digital thermal imaging technology produces a readily accessible permanent record; and
- clinical thermography utilizing modern digital thermal imaging technology is more cost-effective than many other diagnostic procedures.

The Physiological Basis of Thermography

94. That during June, 1990, the American Academy of Physical Medicine & Rehabilitation Subcommittee on Assessment of Diagnostic and Therapeutic Devices and Modalities published a report on *Neuromusculoskeltal Thermography* which concluded

> "Thermography is a safe, non-invasive test which does not involve the use of ionizing radiation. It is a test of physiological function that may aid in the interpretation of the significance of information obtained by other tests. Thermography can be useful in the diagnosis of selected neurological and musculoskeletal conditions. It may facilitate the determination or spinal nerve root, distal peripheral nerve and soft tissue injuries. Thermography is useful in the diagnosis of reflex sympathetic dystrophy syndromes."

Normal Physiology

95. Skin temperature is a reflection of cutaneous blood flow under the control of the autonomic nervous system.

96. The autonomic nervous system has both peripheral and central components.

97. Upon information and belief, a growing body of basic research supports clinical and experimental observations of interactions between, sympathetic nerve fibers and afferent pathways.

98. Core temperature homeostasis is maintained by feedback mechanisms that operate through a temperature regulating center in the hypothalamus.

99. Upon information and belief, heat sensitive neurons begin firing in response to an increase in the temperature of blood flowing through the preoptic nucleus. The resultant inhibition of sympathetic neurons in the posterior hypothalamus reduces the normal vasoconstrictor tone of blood vessels in the extensive subcutaneous venous plexus, causing vasodilatation and concomitant heat loss. Conversely, the flow of venous plexus blood is markedly reduced in response to constriction of sympathetically innervated arteriovenous anastomoses in the subcutaneous plexus.

100. Central control of skin temperature affects both sides of the body uniformly and simultaneously, resulting in symmetry of thermal patterns. Thermal symmetry within documented norms is the expected

norm. Patients, therefore, serve as their own controls.

Abnormal Physiology

101. Various general and autonomic mechanisms have been proposed as the pathophysiologic basis for skin temperature changes in neuromuscular disorders. Among the proposed general mechanisms are localized muscular action, antidromic stimulation of sensory nerves and activation of sinuvertebral nerves.

102. Proposed mechanisms implicating the autonomic system include stimulation of the "spinal parasympathetic" nerve or the sympathetic vasodilatory system, thermal alterations resulting from sympathetic vasoconstriction, and segmental regulation by the somatosympathetic reflex. It is probable that the ultimate pathophysiologic basis for thermographic changes in neuromuscular disorders will include portions of all of these theories.

Clinical Effectiveness of Digital Thermal Imaging

103. Clinical thermography utilizing modern digital thermal imaging technology provides valuable clinical information leading to detection and identification of physiologic abnormalities.

104. As with any other diagnostic procedure, the clinical effectiveness of Thermography is influenced by the quality of the equipment, the technical skill of the equipment operator, the criteria applied for interpretation, and the condition or purpose for which Thermography is performed.

105. The technical quality, sensitivity, specificity, and reliability of digital thermal imaging equipment have improved rapidly during the past decade due to technological advances.

106. As with any other diagnostic procedure, clinical thermography utilizing modern digital thermal imaging technology provides information which the health care practitioner must correlate with clinical signs and symptoms in order to make a diagnosis and enhance patient outcome.

107. Data reported by OHTA show that clinical thermography utilizing modern digital thermal imaging technology is at least as effective as alternative tests in the differential diagnosis of spinal nerve root

compression or soft tissue trauma.

108. Clinical thermography utilizing modern digital thermal imaging technology provides valuable clinical information useful in the management of back pain, neuromusculo-skeletal rehabilitation and other forms of treatment not requiring surgery.

109. Clinical thermography utilizing modern digital thermal imaging technology can provide useful clinical information for monitoring patient progress, post-operative recovery and establishing prognosis without the risks associated with more invasive tests or the high costs associated with new technologies, such as magnetic resonance imaging (MRI) / nuclear magnetic resonance imaging (NMR).

110. Clinical thermography utilizing modern digital thermal imaging technology provides valuable preliminary information prior to calling for more expensive or invasive procedures. In many cases such further procedures can be avoided entirely.

111. Thermography is more sensitive than alternative tests for identifying physiologic conditions which are not associated with anatomical defects, such as the disturbances associated with reflex sympathetic dystrophy (RSD).

112. Recent studies indicate that clinical thermography utilizing modern digital thermal imaging technology may also provide an effective predictor of decubitus ulcers (bed sores).

Clinical Indications for Digital Thermal Imaging

113. Clinical thermography utilizing modern digital thermal imaging technology provides information about cutaneous temperatures and is clinically useful in the detection and characterization of

- nerve root irritation and compression
- peripheral nerve injury, whether as a result of genetic, congenital, or metabolic factors, trauma, infection, exposure to toxic substances, vascular, neoplastic, degenerative/demyelinating conditions, or paroxsysmal causes
- reflex sympathetic dystrophy (RSD)

- occlusive disease of cranial vessels
- cephalgia (headaches)
- neuropathic pain syndromes.

114. A fair preponderance of the substantial and credible scientific evidence establishes that clinical thermography utilizing modern digital thermal imaging technology provides sufficient reliable information about neurologic dysfunction or deficit to accept it as a proven evaluative procedure for the clinical diagnosis or characterization of

- neck or back pain and/or cervical, thoracic, or lumbosacral radiculopathy
- musculoskeletal pain
- neuropathy
- cephalgia (headache)

115. A fair preponderance of the substantial and credible scientific evidence supports the use of clinical thermography utilizing modern digital thermal imaging technology in cases of

- Neurological disorders associated with back or neck pain
- Peripheral sensory and/or autonomic nerve irritation or damage
- Vascular disorders

Thermography in Clinical Practice

Radiculopathy

116. Clinical thermography utilizing modern digital thermal imaging technology has been reported to be useful for the detection of cervical and lumbar nerve root irritation and compression.

117. Clinical thermography utilizing modern digital thermal imaging technology has been reported to be sensitive in recognizing a radiculopathy when that condition is present, and specific in not recognizing the condition when it is absent, as compared with computed tomography (CT), myelography, electromyography (EMG), or surgical exploration.

118. Knowing that radiculopathy is present is helpful in diagnosis and treatment.

119. Clinical thermography utilizing modern digital thermal imaging technology is useful in identifying those cases where it may be necessary to proceed beyond conservative therapy.

120. Clinical thermography utilizing modern digital thermal imaging technology can provide characterizing information in those cases in which it would be helpful to know whether nerve root or a nerve segment is or is not affected and confirmation of the area involved is needed.

121. Thermography is highly sensitive and can differentiate a radicular lesion from a superimposed RSD or myofascial pain syndrome.

Peripheral nerve injuries

122. Clinical thermography utilizing modern digital thermal imaging technology is useful in evaluating the autonomic response associated with peripheral nerve injuries.

123. Clinical thermography utilizing modern digital thermal imaging technology can demonstrate nerve function in acute injuries which are not amenable to immediate evaluation by EMG.

Sympathetically maintained pain syndrome (SMPS)

124. Clinical thermography utilizing modern digital thermal imaging technology can demonstrate an evolving sympathetically maintained pain syndrome by demonstrating persistent vasoconstriction. This permits early diagnosis and treatment long before the condition has progressed to permanently disabling end stage reflex sympathetic dystrophy (RSD).

Reflex sympathetic dystrophy (RSD)

125. Recent medical literature not only supports the use of clinical thermography utilizing modern digital thermal imaging technology thermography in various disease conditions, but attests to its being virtually the only imaging modality that reliably detects the early stages of reflex sympathetic dystrophy (RSD).

126. RSD is a chronic, terribly painful and disabling condition, which is preventable and treatable if diagnosed early. In the later stages of RSD the condition becomes irreversible and deforming.

127. By revealing subtle temperature changes indicative of the initial signs of vasomotor instability that occur in sympathetic dysfunction syndromes, clinical thermography utilizing modern digital thermal imaging technology, can lead to the distinct and clear cut diagnosis required for the successful treatment of the patient with reflex sympathetic dysfunction syndromes.

128. Therapy for reflex sympathetic dysfunction syndromes generally consists of aggressive range of motion exercises, and blockage of sympathetic activity through stellate ganglion block, lumbar sympathetic block or surgical sympathectomy.

129. The affect of sympathetic blocks or sympathectomy can be monitored by clinical thermography utilizing modern digital thermal imaging technology.

130. Clinical thermography utilizing modern digital thermal imaging technology is a useful test in the differential diagnosis of reflex sympathetic dysfunction syndrome. Early diagnosis of this disorder can avoid the need for more complicated therapeutic measures that may be required in patients with chronic injury of this type.

131. Clinical thermography utilizing modern digital thermal imaging technology is now the diagnostic procedure of choice for RSD.

132. Clinical thermography utilizing modern digital thermal imaging technology can identify unsuspected RSD complicating another injury, such as a stress fracture, a surgical "failed back" syndrome, or arthritis.

Headache

133. Clinical thermography utilizing modern digital thermal imaging technology is valuable in the management of headache and can

enhance patient outcome of treatment.

Limb Salvage

134. Clinical thermography utilizing modern digital thermal imaging technology is valuable in the case management of limb insensitivity associated with diabetes and other neuropathic vascular disorders.

Pain

135. Because pain is subjective, its evaluation and management are a frequent source of frustration to the clinician.

136. Clinical thermography utilizing modern digital thermal imaging technology provides quantifiable information about the function of the unmyelinated *C* fibers found in the peripheral sympathetic nerves that are intimately involved in the body's response to painful stimuli.

137. Clinical thermography utilizing modern digital thermal imaging technology compliments nerve conduction studies (NCV), which evaluate only the fastest conducting myelinated fibers, and needle electromyography (EMG), which is limited to evaluation of the motor unit.

138. Clinical thermography utilizing modern digital thermal imaging technology may provide validation of a patient's symptoms when the pain is out of proportion to what have generally been regarded as "objective" findings, and also determine the presence and degree of symptom magnification, if any.

139. Clinical thermography utilizing modern digital thermal imaging technology provides important clues as to the cause of pain or paresthesia (numbness).

140. Clinical thermography utilizing modern digital thermal imaging technology can demonstrate that a pain is maintained by abnormally behaving elements of the sympathetic nervous system in time to prevent permanent disability from reflex sympathetic dystrophy.

141. Clinical thermography utilizing modern digital thermal imaging technology can alert a perceptive clinician to treatable sympathetically maintained pain syndromes complicating arthritis, an injury, or a surgical procedure.

142. Clinical thermography utilizing modern digital thermal imaging technology is important in the management of vertebral subluxation and the neurophysiologic syndromes attendant thereto.

143. Clinical thermography utilizing modern digital thermal imaging technology is an important, cost-effective means of monitoring treatment of myofascial pain syndrome and improving the patient outcome of treatment for these conditions.

144. Notwithstanding unermarkable radiographic and electromyographic studies, a patient with soft tissue injury may still suffer from sufficient pain to preclude satisfactory physical examination. In such cases, clinical thermography utilizing modern digital thermal imaging technology provides useful information not otherwise available to the clinician.

Persistent unexplained pain

145. Clinical thermography utilizing modern digital thermal imaging technology aids in the differential diagnosis of persistent pain, non-invasively, cost-effectively, and without any risk to the patient.

Stress fracture

146. Clinical thermography utilizing modern digital thermal imaging technology identifies the inflammatory reaction secondary to stress fracture promptly and documents its course without the risk of exposure to ionizing radiation.

Rheumatoid arthritis

147. Clinical thermography utilizing modern digital thermal imaging technology is useful and cost-effective in following the course of rheumatoid arthritis and the efficacy of its treatment.

Child and spousal abuse

148. Clinical thermography utilizing modern digital thermal imaging technology can provide evidence to support the clinical impression of child or spousal abuse. This is particularly important in dark

skinned individuals who may not show contusions/pettechiae (bruising).

Decubitus ulcers

149. Clinical thermography utilizing modern digital thermal imaging technology is valuable in the early detection of decubitus ulcers.

Other Indications for Clinical Thermography

150. Clinical thermography utilizing modern digital thermal imaging technology has also demonstrated value in assessing a variety of other conditions, among them:

- Temporomandibular-joint (TMJ) disorders
- Deep vein thrombosis (DVT)
- Skin graft viability

The Physics of Thermography

151. The human body is homoiothermic. It must therefore expend energy continuously to replenish the heat it loses to the surrounding environment so that its internal thermal environment can be constantly maintained within a relatively limited range.

152. Most of the heat the human body loses to its surrounding environment is dissipated through the integument or skin.

153. The human body loses thermal energy through four modes: conduction, convection, evaporation, and radiation.

154. The loss of heat by the body through its integument, the skin, is continuous and depends solely upon the temperature gradient between the outer layers of the integument and the ambient environment.

155. Most of the heat loss by radiation from the human body occurs in the infrared range of the electromagnetic spectrum.

The Electromagnetic Spectrum

156. A wave can be defined as any disturbance from an equilibrium condition that travels or propogates in time from one region of space to another. The concept of waves is one of the most important unifying elements of the natural sciences.

157. When either an electric field or a magnetic field changes with respect to time, a field of the other kind is induced in adjacent regions of space. An electromagnetic disturbance consisting of time-varying electric and magnetic fields that can propogate through space and time from one region to another has the properties of a wave. Electromagnetic waves propagate the energy of electric and magnetic fields.

158. The name radiation is given to all electromagnetic waves. Electromagnetic waves have the common property of being propagated (*in vacuo*) with the velocity of light.

159. The electromagnetic spectrum represents a continuum of electromagnetic radiation propagated as waves of varying frequencies, wavelengths and energy levels.

160. The frequency of a wave refers to the number of vibrations that occur during a unit of time. Frequency used to be expressed as cycles per second (cps), but is currently expressed in *Hertz* (Hz) today.

161. The wavelengths of the electromagnetic spectrum are generally expressed in relation to the meter:

One micrometer (10^{-6} m)	is one one-millionth part of a meter, and is also known as a micron (μ).
One nanometer (10^{-9} m)	is one one-billionth part of a meter or approximately 10 angstroms (Å).
One angstrom unit (Å)	is *approximately* one ten-billionth part of a meter (10^{-10} m), because, unlike other measurements of length, the angstrom is not defined from the meter as a primary standard of length, but from the wavelength of a particular spectral line.

162. The speed of propogation of any wave is the product of its wavelength and frequency: $c = \lambda\nu$ in the case of a light wave propogated *in vacuo* The frequency of a wave and its length are inversely related: the higher the frequency, the shorter the wavelength.

163. There exists also a direct relationship between the frequency of the electromagnetic wave and its energy level: the higher the frequency, the higher the energy level.

164. Light is an electromagnetic wave.

165. The portion of the electromagnetic spectrum which can be processed by the human eye, and which we call visible "light," constitutes a very narrow band or window which includes the wavelengths from 0.4 μm, the visible violet, to 0.7 μm, the visible red.

166. Matter when heated emits radiant energy or, more simply, radiation, the quantity and quality of which depend on the temperature of the matter.

167. At ordinary environmental temperatures all material objects are emitting and absorbing thermal radiation.

The Infrared

168. In 1800, when William Herschel made public his discovery of the invisible heat-carrying waves radiated by the sun, references were made in terms of frequencies. Consequently, since these waves had frequencies which were lower than those of the visible red, the term "infrared" was adopted. Today, however, the reference by wavelength is the accepted practice.

169. The infrared portion of the electromagnetic spectrum ranges in wavelength from 0.7 μm (700 nm) to 1 mm (1,000 μm)

170. The photo-sensitive emulsion of infrared sensitive films absorbs radiation in the 0.7 – 1.2 μm range. These wavelengths are sometimes referred to as the photographic infrared.

171. The human integument radiates energy within the detectable infrared spectrum.

172. Not only did William Herschel demonstrate the existence of electromagnetic radiation in the infrared range of the spectrum, but he

also demonstrated that this invisible light, the infrared, behaved very much as does visible light with respect to incidence, absorption, reflection and refraction. The laws and principles of optics are just as applicable to the invisible waves in the infrared range as they are to the light waves that are visible to the human eye.

The Blackbody Radiator

173. Many of the basic concepts and laws describing electromagnetic radiation were derived from works, experimental as well as theoretical, dealing with the isothermal enclosure, a cavity the walls and contents of which are all at a common temperture.

174. A surface which has the property of absorbing completely all radiation falling upon it without any of the radiation being reflected is defined as a "blackbody."

175. Kirchhoff equated radiating power to absorptive power. According to Kirchhoff, the ratio of the radiating power to the absorbing power is the same for all bodies of the same temperature, and therefore a body which absorbs perfectly must radiate perfectly. For that reason, a perfect radiator is often referred to as a perfect blackbody.

176. Blackbody radiation has a universal character because it is independent of the properties of any particular material substance.

177. The energy emitted from any blackbody, called its *emissive power* is related to the energy density in an isothermal enclosure.

178. The *total emissive power* is the total energy radiating from a blackbody at a given temperature (per unit time, per unit surface area).

179. For radiation of a given frequency, the ratio of emissive power to the absorption coefficient is the same for all matter; it depends solely on the frequency of the radiation; its plane of polarization, and the temperature.

180. The *spectral emissive power* is the emissivity of a given body at a specific wavelength.

181. Since the physical bodies encountered in our world are not perfect radiators, at a given temperature the amount of energy they radiate is less than that of a theoretical blackbody. *Emissivity* is the measure of the the amount of energy radiated by a body at a given temperature per

unit time, per unit surface area. The *spectral emissivity* is the emissivity at a specific wavelength.

182. Since the emissivity of any material object is invariably less than the emissive power of a theoretical blackbody at the same temperature and the same wavelength, it can be expressed as a ratio. Emissivity is invariably less than unity since, according to Kirchhoff's law, the Total Absorptive Power equals the amount of radiant energy absorbed less the amount reflected. Initially, emissivity must be expressed as a percentage of the emissive power.

183. Comparing the behavior of photons within a cavity radiator to that of gas molecules within a container, Stefan and Boltzman, independently, reached the conclusion that the total amount of radiation emitted by a blackbody depends solely upon the temperature of the blackbody. They found that both the energy density of the radiation within an isothermal enclosure and the total emissive power of a blackbody are proportional to the fourth power of its absolute temperature (° Kelvin).

184. The power (energy per unit time), H (the Heat current) radiated from a blackbody of area A at absolute temperature T is given by what has come to be known as the *Stefan-Boltzmann Law,* $H = A\sigma T^4$

185. The power associated with a radiating blackbody is not uniformly distributed over all wavelengths (λs), but can always be described by a power distribution function $F(\lambda)$. This power distribution function has the property that the area under the curve when $F(\lambda)$ is plotted against the wavelength (λ) – the $\int F(\lambda)$ – is the total power per unit area.

186. The intensity of radiation varies with its frequency for different temperatures. $i_\nu = F(\nu, T)$ The higher the temperature the greater the intensity at any given frequency. When temperature is increased, the radiation of maximum intensity is displaced progressively toward the higher frequencies. The frequency of maximum intensity is directly proportional to the absolute temperature (° Kelvin). This relationship is known as the *Wein displacement law.*

Quanta and Photons

187. The Electromagnetic Wave theory, formulated by James Clerk Maxwell during the middle of the Nineteenth Century, explained the phenomena of light, the visible as well as the invisible, in terms of continuous energy waves propagated in a hypothetical medium, the *aether*. However, experimental data gathered toward the latter part of the Nineteenth Century could not be accounted for or explained in terms of such a theory. Consequently in 1900, Max Planck advanced a new theory, the Quantum Theory, according to which electromagnetic energy was not emitted as a continuous wave. Rather, such energy was radiated as discrete particles or packets of energy called "quanta" (the singular is quantum).

188. As a consequence, Planck was finally able to derive the precise form of the blackbody power-distribution function, $F(\lambda)$,

$$F(\lambda) = \left\{ \frac{2\pi hc^2}{\lambda^5} \frac{1}{e^{\frac{hc}{\lambda kT}} - 1} \right\}$$

where h is Planck's constant, c is the speed of light, k is Boltzmann's constant, T is the absolute temperature (°K), and λ is the wavelength. This work resolved the apparent inconsistencies between the Wein Distribution Law and the Stefan-Boltzmann law that had appeared irreconcilable under the classical electromagnetic theory of Maxwell.

189. In 1905, Albert Einstein published his work on these discrete quanta of light which he called "photons". Einstein also explained the phenomenon of the "photoelectric effect" whereby the electric equilibrium of an absorbent material is altered by the photons incident upon it.

190. As predicted by Planck and Einstein, visible light, as well as all electromagnetic radiation, including infrared radiation, exhibits simultaneously the properties of a propagated wave and properties of discrete particles, photons. This apparent contradiction, inherent to electromagnetic radiation, but acceptable under the theory of *quantum mechanics* has even become a part of the philosophy of modern science as the "wave/particle duality" of nature.

Infrared Radiation from the Human Body

191. In 1928, L. B. Aldrich published a monograph on the infrared radiation from the human body. Utilizing a radiometric device developed at the Smithsonian Institute in Washington, D. C. and named *Melikeron* after the Greek for honeycomb, Aldrich measured the infrared radiation emitted from the human body and computed the temperature of the skin from the radiation emitted in accordance with the Stefan-Boltzman law. He compared these temperature values with those obtained from thermo-electric elements applied directly to the skin and concluded that the radiation from the human skin approximates that of a blackbody, or perfect radiator, with emissivity that approaches unity.

192. Aldrich determined that the human skin radiates in the infrared "almost wholly between the wavelengths of 4μ and 50μ with a maximum at 10μ."

193. Aldrich also noted that the temperatures computed on the basis of radiometric measurements were significantly higher than the temperatures recorded directly from the skin by thermo-electric devices attached to it, and concluded that since the skin is a porous structure, the *Melikeron* was probably recording radiation emitted from layers of the human integuement below the surface which are apparently warmer.

194. Among the other results and conclusions reached by Aldrich were:

- That increasing ambient air motion rapidly decreases the percentage of body heat lost by radiation and increases that which is lost through convection.
- That total body radiation similarly decreases with air motion.
- That increase in room temperature produces a progressive lowering of radiation loss.
- That normal fluctuations in the ambient humidity produce only negligible effect upon the spectral emissivity of the skin.

195. In 1934, James D. Hardy made public his definitive work on the emissivity of the human skin in the infrared. The four parts of his paper were published *seriatim* in volume 13 of the *Journal of Clinical Investigation*. Hardy constructed a radiation detection device which he called a "radiometer" to measure thermal radiation from human skin. It

was a device of greater sensitivity and accuracy and with a faster reaction time than the themocouples and thermopiles that had been used before. It was accurate to ± 0.1 °C. The Centigrade degree and the absolute degree Kelvin represent the same change in temperature. The Kelvin Scale, however, begins at absolute zero (−273°C).

196. Hardy repeated the studies of Aldrich in comparing the results obtained through radiometry with those obtained by the direct application of thermocouple (electric) thermometers to the skin. Skin temperature measurements based on radiometry were found to be accurate and precise within a margin of ± 0.1 °C.

197. Hardy concluded that the emissivity of the human skin is not affected by its color, that the amount of reflection in the infrared is "about the same for black skin as it is for white skin," and, that the presence of water vapor and carbon dioxide next to the skin did not "appreciably affect the radiation from the surface."

198. The experiments conducted by Hardy in collaboration with Carl Muschenheim, led to the conclusion that most of the infrared radiation incident upon the human skin is absorbed at the very outer layers of the integument and that at the peak of the spectral emissivity of the human skin, the *stratum corneum* absorbs most and therefore emits most of the infrared photons detected. "The energy distribution curve of the radiation of the normal human skin has been found to correspond with that which would be expected of physical blackbody of the same temperature. The low reflecting and transmitting power of the skin for radiation in the region of the spectrum in which the skin radiates is further evidence in support of this conclusion.

199. The visible color of the skin exerts no influence on its absorbing power in the infra-red. The absorption and emission of infrared radiation occurs in the outer layers of the skin.

200. In a later paper in 1939, Hardy measured the effective emissivity of the human skin in two ways, by reflection and by infrared radiometry relying upon the Stefan-Boltzman law.

201. In examining the absorptive-emissive properties of the human skin, Hardy and Muschenheim noted that scattering and the angle of incidence did not materially affect its absorptive-emissive spectral powers. Save for some focal warming of skinfolds secondary to re-

radiation, the contour of the body surface did not significantly alter its emissivity.

Early Thermal Measuring Instrumentation

202. In 1821, Thomas Johann Seebeck discovered the thermoelectric effect sometimes called the thermocouple effect. In an electric circuit incorporating two dissimilar metals, such as copper and silver, heating or cooling one of the metals or the point of coupling these metals would alter the electric flow in the circuit in proportion to the temperature changes effected.

203. In 1829, Leopoldo Nobili (1784–1835) created a more effective device by using several thermocouples together to create a thermopile. His friend and coworker, Macedonio Melloni (1798–1854) further advanced, developed and perfected the thermopile. Using small rods of bismuth-antimony, Melloni painted the pile with lampblack and demonstrated that the galvanometer incorporated into the circuit could register the electric flow generated by the electromagnetic radiation absorbed by the thermopile.

204. To quantify the absorbed infrared radiation, Melloni utilized two thermopiles: one blackened thermopile exposed to radiation and an identical circuit covered and protected from radiation. The latter was connected to a voltaic battery, and the deflection of the galvanometer effected by absorbed radiation could be matched by the galvanometer connected to the battery. Melloni called his instrument "*thermomultiplicateur.*"

205. Melloni's principle served as the basis of an endless line of radiometric devices well into our own time. Both Aldrich's *Melikeron* and Hardy's Radiometer were constructed on the principle of Melloni's *thermomultiplicateur.* Electric compensation from a voltaic battery provided for the quantification of the radiation absorbed by the thermopile.

206. The early radiometric devices, the *Melikeron* and the Radiometer, held close to the skin could record from only a relatively small area: 10 or 20 cm^2. Within the area under study the radiometric device recorded the total radiation, producing, in effect, results that represent averaging of the emissions per unit surface-area.

207. Military needs and the accompanying secrecy put a halt to the development of the thermographic imaging in civilian use until after the end of the World War II.

208. According to Barnes, the first black-and-white thermal image produced was that of a Liberty Ship, accomplished in France in 1946. It took 90 minutes to complete.

Digital Thermal Imaging

209. Since infrared photons behave as do the photons of visible light, in general, the principles and laws of geometrical and physical optics apply. Consequently, systems of optical devices were developed to collect and filter infrared spectral emissions and focus them upon a detector capable of responding to photons within the infrared range. The electrical signal generated from the detector can be processed and displayed. Thermal imaging systems are now commercially available in the United States, Europe and Japan which produce real-time thermal images.

210. In the thermocouples and thermopiles used in the past, one coupling point was maintained at a constant temperature, usually at room temperature, to provide the reference point needed to convert the radiometric results to temperature values in accordance with the Stefan-Boltzman formula.

211. The quality of a thermal imaging system depends upon many elements: quality of the photon detectors, the speed of photoelectric response and capacity to reach instant equilibrium, and the response of the optical system associated with the photon detectors.

212. Modern digital thermal imaging systems include a device for the collection of infrared radiation with its associated detector of infrared radiant energy– the infrared imaging radiometer system, and an image processing and analysis system.

213. Modern infrared imaging radiometer imagers collect radiant thermal energy, focus the energy on a detecting element, and then convert the detected energy into some form of electronically processable output signal.

214. In order to obtain good signal to noise ratios, modern infrared imaging radiometer system detectors must be cooled to cryogenci temperatures.

215. The performance of infrared imaging radiometer systems can be characterized in terms of certain fundamental parameters, among them: thermal sensitivity or thermal resolution; spatial resolution; frame rate or scanning rate, and field of view.

216. The Noise Equivalent Temperature Difference (NETD) describes the Thermal Sensitivity of infrared imaging radiometer systems. NETD is a measure of the thermal resolving power of the infrared imaging radiometer system. Modern digital thermal imaging systems suitable for clinical thermography will demonstrate an NETD of 0.1°C.

217. Spatial Resolution refers to ability of the optical elements of the infrared imaging radiometer system to distinguish between the thermal radiation of one area from that of another nearby area. Spatial resolution is often described in terms of the Instantaneous Field Of View (IFOV) of the infrared imaging radiometer system detector expressed in angular measure.

218. Frame Rate is the frequency with which an electronically scanned thermographic image is updated by a new one. Commercial television in the United States maintains a frame rate of 30 Hz. The TV camera scans its field of view 30 times each second and the TV receiver displays a new image frame 30 times each second.

219. The MRTD, an acronym for Minimum Resolvable Temperature Differences, is a measure of the thermal resolution of an infrared imaging radiometer system as a function of a number of factors, among them the thermal sensitivity, spatial resolution, and scan rate of the system.

220. The limit of thermal image resolution is the optical resolution of the infrared imaging radiometer, not the display resolution of the video monitor.

221. Modern digital thermal imaging systems use internal black body radiation sources whose calibration can be traced to the National Bureau of Standards. Modern digital thermal imaging systems can be calibrated dynamically from the low temperature limit of the dynamic range to the high temperature limit for the study being conducted. If this process of dynamic calibration is conducted continuously during the examination of a patient, the temperatures of the black body standard and the temperatures recorded from the patient become part of the patient's

data record, establishing that the instrument had been properly calibrated at the time of the examination.

222. Field Of View (FOV) defines in angular measure the extent of the area scanned by the infrared imaging radiometer system.

223. Modern digital thermal imaging systems use analog to digital (A/D) converters to map the analog temperature data from the infrared imaging radiometer system to digital information for image processing and storage. The accuracy of this conversion determines the dynamic range of the system as well as its absolute accuracy.

224. The dynamic range of a digital thermal imaging system is determined by the minimum temperature difference detectable, the system gain factor, and the resolution of the A/D converter.

225. The image processing and analysis systems associated with the infrared imaging radiometer systems appropriate for clinical thermography generally possess at least the following capabilities.

- date and time as measured to the second will be continuously updated and automatically displayed in every image frame, together with some means of positive patient identification.
- temperature range and temperature level of any given instrument setting will be continuously updated and automatically displayed in every frame.
- images will be digitally processed and capable of reproduction in a variety of display formats.
- to facilitate contralateral comparisons, at least two areas of any shape or size must be definable on the image; and at least two discrete points in selectable locations on the image must be definable and identified by both their absolute temperatures and the temperature difference separating them.
- area thermal contents must be simultaneously definable in real time in terms of their minimum, average and maximum temperatures, as well as the minimum, average and maximum temperature differences between definable areas.
- area thermal information should be recorded in a format permitting statistical analysis.

226. Modern digital thermal imaging systems produce a high resolution image. The displayed image thermal information is extremely accurate, stable and repeatable.

Plaintiffs' Claims Against Office of Health Technology Assessment

227. The Office of Health Technology Assessment (OHTA) failed to apply established analytical criteria in its evaluation of clinical thermography utilizing modern digital thermal imaging technology.

Incomplete Review of the Open Published Literature

228. The Office of Health Technology Assessment (OHTA) failed to review all the relevant studies and reports concerning the use of clinical thermography which can be found in the scientific, technical and medical literature.

229. A complete review of the literature regarding Thermography would include all recent references. More recent studies deserve more weight than older studies due to improvements in digital thermal imaging technology and interpretive criteria.

230. OHTA did not collect or review a complete list of references or studies currently available regarding the clinical effectiveness of Thermography. The Report omitted at least 40 currently available relevant references.

231. OHTA's reviewing strategy was deficient in a number of areas including failure to discuss possible explanations for variations among study results, failure to evaluate the reliability of alternative tests, or any serious consideration of the relative cost effectiveness of comparable tests.

Incomplete Analysis of the Open Published Literature

232. The Office of Health Technology Assessment (OHTA) failed to adequately analyze the data contained in those few studies and reports concerning the use of clinical thermography which it did consider in its report, *Thermography for Indications Other Than Breast Lesions*.

233. The methodology used by OHTA to review the medical, scientific, and technical literature regarding Thermography was seriously flawed.

234. While it is possible to systematically review, analyze and synthesize the studies which OHTA reported relying upon, none of the many accepted formal reviewing techniques were employed by OHTA.

235. OHTA did not attempt to synthesize the results of the studies it claimed to have relied upon, but instead, simply summarized a number of articles regarding a variety of clinical applications of Thermography without any critical evaluation of the methods reported or the results claimed.

236. While OHTA cited 123 references in its bibliography, it did not adequately discuss most of the studies which it summarized in its report.

237. OHTA did not properly aggregate or even summarize results across studies.

238. OHTA drew conclusions from selected studies which it did not otherwise describe or summarize.

239. OHTA relied on studies that failed to apply established analytical criteria in their interpretation of clinical Thermography.

240. Certain principles are generally accepted by the scientific community in the review and evaluation of published literature, among them

- a reviewing strategy should include precise questions,
- disagreements in study findings should be analyzed and resolved or explained, if possible,
- quantitative and qualitative information should be synthesized and subjected to content analysis, and
- conceptual clarity should not be sacrificed for statistical precision.

The Method OHTA Chose to Evaluate Thermography was Flawed

241. OHTA's methodology was flawed because it gave undue weight to factors that are unrelated to the clinical effectiveness of Thermography.

242. In many cases, OHTA relied upon outdated reports, or failed to properly consider differences in interpretive criteria.

243. OHTA drew conclusions which were not supported by, or even consistent with, the studies which it purportedly relied upon.

244. OHTA cited studies that did not support its conclusion.

245. OHTA relied on studies which failed to apply established analytical criteria for their evaluation of Thermography.

Differences Among Thermal Imaging Equipment

246. The technical quality, sensitivity and reliability of thermal imaging equipment has improved rapidly over the past decade due to technological advances.

247. In its review of studies, OHTA did not report or discuss differences in the accuracy and reliability of Thermography equipment.

248. OHTA failed to ackowledge, much less account for, the dramatic improvement in sensitivity and reliability of digitial telethemography instruments during the past decade.

249. In its review of studies, OHTA only sporadically reported the type of Thermography equipment employed for testing, and failed to consider or even acknowledge that some types of Thermography equipment produce more accurate and reliable results than others.

Interpretation of Thermograms

250. The topographical pictorial representations of skin temperature differences produced by clinical thermography utilizing modern digital thermal imaging technology provide the clinician with a rich database but require skill and experience to interpret.

251. Inter-observer reliability is high when experienced readers interpret the results of clinical thermography utilizing modern digital thermal imaging technology.

252. In some cases, OHTA reported, but did not discuss, much less evaluate the effects of, differences in the skill, training or experience of readers employed for Thermogram interpretation. However, such differences in reader ability may substantially affect the interpretation of Thermography results.

253. There is no question that clinical thermography must be performed by appropriately qualified technicians using recently designed and manufactured infrared telethermography equipment and that Thermograms should be interpreted by appropriately qualified readers.

254. Properly trained clinicians who comply with established standards obtain high levels of sensitivity and specificity with their thermographic diagnoses.

Criteria for Interpretation

255. OHTA reported differences in interpretive criteria in some cases but did not discuss the effect of these differences on study results.

256. The criteria used for interpretation of Thermograms are primarily related to asymmetry of skin temperature between anatomically identical body parts.

257. Consistency of criteria used to perform and interpret Thermography is necessary when comparing results across studies.

258. Some studies considered by OHTA did not report interpretative criteria or the authors employed criteria which differed substantially from criteria generally accepted as appropriate by those experienced in the practice of clinical thermography.

OHTA Failed to Consider the Reliability of Its Reference Tests

259. According to the coverage criteria proposed by the Health Care Financing Administration (HCFA), the evaluation of Thermography as a diagnostic procedure must assess the clinical value of Thermography relative to the accuracy of alternative tests.

260. Non-invasive test procedures to which clinical thermography utilizing modern digital thermal imaging technology may be appropriately compared include clinical examination (patient history and physical examination) and MRI (magnetic resonance imaging).

261. Invasive procedures include computerized axial tomography (CT/CAT Scan), myelography, electromyography (EMG), diskography, and surgery.

262. None of these tests offers a truly reliable standard against which to evaluate the accuracy or reliability of clinical thermography utilizing modern digital thermal imaging technology. Rather, each test offers only an imperfect reference point with which the results of Thermography may be correlated.

263. Studies reported by OHTA showed that reference tests relied on to evaluate the effectiveness of Thermography were themselves inaccurate.

264. Sensitivity and specificity are the measures which are commonly used to evaluate the results of clinical tests and therapies. *Sensitivity* is defined as the percentage of correctly identified cases from among those sought to be identified by the clinical test or improved by the therapy under study – the *true positives*. *Specificity* is defined as the percentage of correctly identified normals or cases sought to be ignored by the clinical test or remain unaffected by the therapy under study – the *true negatives*. Sensitivity indicates how accurate the test is among truly affected subjects and specificity indicates how accurate the test is among unaffected or normal subjects (controls).

265. Incorrectly identified cases are referred to as *false positive* – those cases which were incorrectly identified as included among those sought to be identified by the clinical test; or *false negatives* – those incorrectly identified as normals or otherwise ommitted from the cases sought to be identified.

266. OHTA compared Thermography with certain reference tests but incorrectly assumed that these reference tests offered an accurate standard against which to evaluate Thermography.

267. Reference tests relied upon by OHTA for comparison with Thermography included myelogram, computerized axial tomography (CT/CAT) scan, electromyography (EMG), magnetic resonance imaging (MRI/NMR), clinical examination (history and physical), and surgery.

268. For some indications, such as low back pain, alternative tests are not entirely reliable.

269. While several studies summarized by OHTA reported that each of the reference tests produced inaccurate results in the form of both false positive and false negative results, OHTA simply summarized studies which compared Thermography with results of a variety of invasive and non-invasive tests.

270. The reference tests used to evaluate Thermography have not been demonstrated to be any more accurate or reliable than Thermography for correctly identifying affected and unaffected patients in the case of spinal nerve root compression.

271. When Thermography is compared to other diagnostic techniques without a reliable and consistently accurate reference standard, the accuracy of Thermography will be under-estimated to the extent that the reference test yields less than perfect results.

272. OHTA did not adequately account for the unreliability inherent in tests it used as reference tests or standards against which to compare the effectiveness or reliability of Thermography. This serious methodological error caused OHTA to under-estimate the effectiveness of modern digital thermal imaging techniques as they are now utilized in the practice of clinical Thermography.

273. OHTA did not take into account the physiologic basis of Thermography as opposed to the anatomic basis of certain reference tests. Thermography has greater sensitivity to certain abnormalities, such as impaired function of the autonomic nervous system, than do reference tests, such as CT scan, myelography or MRI, which detect only anatomic abnormalities. Where a thermographic study seems to disagree with a radiologic study, each must be evaluated within the context of its diagnostic purpose: thermography is a physiologic study reporting autonomic nervous system function while radiology is an anatomic study demonstrating form and structure.

OHTA Failed to Consider Risks Associated With Its Reference Tests

274. According to NIH and others, clinical thermography utilizing modern digital thermal imaging technology is entirely safe because it is non-invasive. NIH stated, "there is no disagreement as to its [Thermography's] safety."

275. The Office of Health Technology Assessment (OHTA) did not make any significant, good faith effort to weigh the significance of risks from other tests in comparison with the safety of clinical thermography utilizing modern digital thermal imaging technology.

276. OHTA failed to adequately account for the risks associated with alternatives to clinical Thermography, and failed to give adequate weight and consideration to the safety of the digital thermal imaging techniques which now form the basis for clinical thermography.

277. OHTA alluded only briefly to risks associated with certain invasive procedures but made no efforts to evaluate those risks against the safety and lack of risk associated with clinical thermography utilizing modern digital thermal imaging technology.

278. OHTA did not consider that CT/CAT scans and myelography are often performed after injection of radiopaque contrast dye and carry associated risks of paralysis, anaphylaxis, or complications due to allergic dye reactions.

279. OHTA made no real effort to balance the risks associated with invasive tests against the marginal benefit of their sensitivity, if any, compared with that of Thermography. All such comparisons favor clinical thermography utilizing modern digital thermal imaging technology due to its convenience and complete safety.

OHTA Failed to Consider the Cost-Effectiveness of Thermography

280. The rule proposed by the Health Care Financing Administration (HCFA) in 54 *Fed. Reg.* 4308 (1989) includes cost-effectiveness as an additional criterion for Medicare coverage of medically reasonable and necessary services.

281. To establish the cost effectiveness of a particular technology, HCFA has proposed to follow what it claims to be standard analytic techniques:

1. Identify alternative technologies for comparison;
2. Identify and quantify likely patient outcomes;
3. Identify and quantify expected costs to Medicare and other payers; and

4. Consider non-quantifiable (qualitative) factors as modifiers of the analysis.

282. HCFA has proposed to use a flexible definition of cost effectiveness that recognizes at least four circumstances under which it would consider a technology cost effective:

1. a technology is very expensive but provides significant medical benefits not otherwise available,
2. the technology is less costly and at least as effective as an alternative Medicare covered technology,
3. a technology is less effective and less costly than an existing alternative, but is a viable alternative for some patients, or
4. a technology is more effective and more costly than a Medicare covered technology, but improved health outcomes justify additional HCFA expenditures. (54 *Fed. Reg.* 4317)

283. It is incumbent upon the Health Care Financing Administration (HCFA) to select the approach which produces the greatest net benefit to patients and the national Economy when evaluating health care technology such as clinical thermography utilizing modern digital thermal imaging technology.

284. The Office of Health Technology Assessment (OHTA) and/or HCFA should be required to conduct a full and complete cost-benefit/cost-effectiveness analysis evaluating the impact on HCFA, other third party payers and patients of changes in government and insurance carrier policies concerning clinical thermography utilizing modern digital thermal imaging technology.

285. OHTA indicated that Thermography is effective as a preliminary or screening test upon a variety of clinical presentations, however, OHTA did not undertake a cost-effectiveness/cost-benefit analysis of clinical thermography utilizing modern digital thermal imaging technology as either a screening test or a substitute for other more costly invasive tests subjecting the patient to greater risk and the health care benefit system to greater long term costs.

286. OHTA failed to properly consider the relative costs of alternative tests and the economic damage to patients as well as the personal injury they may suffer as a result of changes in Medicare and other

insurance coverage for clinical thermography utilizing modern digital thermal imaging technology.

287. OHTA failed to account for either current or potential savings that are available to third party payers from the use of clinical thermography utilizing modern digital thermal imaging technology in the diagnosis and management of many disabling conditions.

288. If clinical thermography utilizing modern digital thermal imaging technology rather than CT scan is used as the initial test in cases of chronic low back pain, Medicare could save at least $5.2 million.

289. If clinical thermography utilizing modern digital thermal imaging technology rather than MRI is used as the initial test in cases of low back pain, Medicare could save at least $40 million.

290. Potential savings to all payers based on patient charges could exceed $139 million per year if clinical thermography utilizing modern digital thermal imaging technology rather than MRI is the initial test.

The Cost-Effectiveness of Digital Thermal Imaging

291. Clinical thermography utilizing modern digital thermal imaging technology is safer and less expensive than some alternative tests which are covered by Medicare.

292. Clinical thermography utilizing modern digital thermal imaging technology identifies patients who do not require further testing that may be more expensive and pose greater risk to the patient.

293. Clinical thermography utilizing modern digital thermal imaging technology is more cost effective than alternative tests for spinal nerve root compression and Deep Venous Thrombosis (DVT) based on Medicare allowable charges.

294. As a preliminary test for patients with back pain, clinical thermography utilizing modern digital thermal imaging technology currently provides estimated savings to HCFA of approximately $260,000 per year based on Medicare allowable charges, and could provide savings to HCFA of as much as $5.2 million per year through appropriate use of Thermography rather than CT scans.

295. Clinical thermography utilizing modern digital thermal imaging technology is a cost effective preliminary test for patients with particular symptoms, such as back pain and suspected DVT. Further testing is not necessary following a negative Thermogram for either of these indications. Thus, Thermography avoids further testing with more expensive or invasive procedures.

Damages to the Class

296. The taxpayers of the United States and all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology will lose a significant opportunity to realize potential savings for the Medicare program and Medicare beneficiaries if the Health Care Financing Administration of the United States Department of Health & Human Services limits or withdraws coverage for clinical thermography utilizing modern digital thermal imaging technology as a result of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast.

297. Such action would tend to increase the frequency of more expensive test procedures, such as CT scan and MRI, as well as subjecting all those so unfortunate as to be denied access to clinical thermography utilizing modern digital thermal imaging technology as a result of the actions of the Office of Health Technology Assessment, United States Public Health Service and the Health Care Financing Administration, United States Department of Health & Human Services to unnecessary additional risks associated with other tests.

298. In addition, any reduction in third party coverage for clinical thermography utilizing modern digital thermal imaging technology at this time will cause substitution of more costly procedures such as MRI and CT scans, further driving up the cost of medical care in the United States without producing any concomitant increase in the quality of life and health for the People.

299. If the Health Care Financing Administration of the United States Department of Health & Human Services limits or withdraws coverage for clinical thermography utilizing modern digital thermal imaging

technology as a result of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology are at risk of permanent injury, physical pain, and mental anguish.

300. If the Health Care Financing Administration of the United States Department of Health & Human Services limits or withdraws coverage for clinical thermography utilizing modern digital thermal imaging technology as a result of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology face a reasonable probability of incurring substantially increased expenses for medical care and treatment.

301. If the Health Care Financing Administration of the United States Department of Health & Human Services limits or withdraws coverage for clinical thermography utilizing modern digital thermal imaging technology as a result of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology face a reasonable probability of substantial lost earnings, reduced income, economic loss, and damage.

302. If the Health Care Financing Administration of the United States Department of Health & Human Services limits or withdraws coverage for clinical thermography utilizing modern digital thermal imaging technology as a result of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast, all those individuals who are injured, disabled,

ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology will be permanently injured and generally damaged.

Equitable Considerations

303. Unless the equitable relief sought herein is granted, all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology will suffer serious, permanent, and irreparable damage.

304. Because the Defendants Office of Health Technology Assessment and Health Care Financing Administration have expressed their intent to withdraw the coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast and, as a result of this proposed action, federal and state agencies, as well as third party payers have declined to pay for clinical thermography utilizing modern digital thermal imaging technology, all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology are at risk of being deprived of appropriate medical care and treatment without due process of law.

305. There exists a real dispute between all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology and the federal agency defendants involving the rights of the plaintiffs and the prerogatives of the executive agencies.

306. There is no adequate remedy at law available to all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology.

Prayer for Relief

Wherefore, the Plaintiff, Texas Chiropractic Association, on behalf of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology, prays this Court for an Order

Certifying this action as a class action for the purpose of adjudicating and determining the common issues of law and fact arising out of the Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast;

Designating and Appointing the Plaintiff, Texas Chiropractic Association, as the next friend or guardian *ad litem* and representative of the Class of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology and who reside in the State of Texas;

Declaring clinical thermography utilizing modern digital thermal imaging technology to be a safe and effective technique for the diagnosis or characterization of

- nerve root irritation and compression
- peripheral nerve injury, whether as a result of genetic, congenital, or metabolic factors, trauma, infection, exposure to toxic substances, vascular, neoplastic, degenerative/demyelinating conditions, or paroxsysmal causes
- reflex sympathetic dystrophy (RSD)
- occlusive disease of cranial vessels
- cephalgic sysndromes (headaches)
- temporomandibular joint (TMJ) dysfunction
- neuropathy and neuropathic pain syndromes
- musculoskeletal pain

and for monitoring the treatment of such conditions.

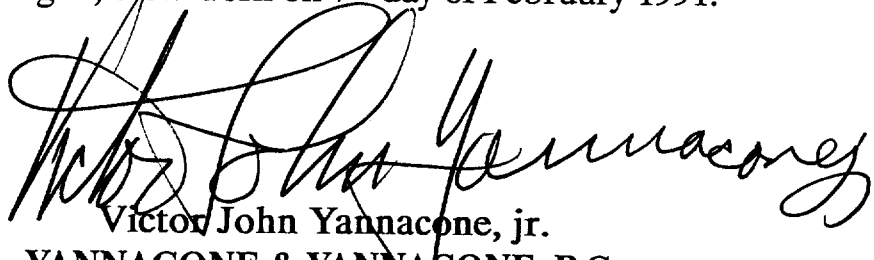
Declaring the Office of Health Technology Assessment, United States Public Health Service Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas

other than the breast to be unsupported by a fair preponderance of the substantial and credible evidence and a legally insufficient and inadequate basis for the promulgation of any national policy affecting clinical thermography utilizing modern digital thermal imaging technology.

Restraining, enjoining, and prohibiting the Health Care Financing Administration, United States Department of Health & Human Services from promulgating, adopting, or executing any rule, regulation, or policy denying reimbursement, under Medicare or any other federal programs, for clinical thermography utilizing modern digital thermal imaging technology, where such rule, regulation, or policy, is based upon the Office of Health Technology Assessment, United States Public Health Service Assessment on *Thermography for Indications Other than Breast Lesions* which recommended that HCFA discontinue coverage of thermography for the diagnosis of conditions in anatomic areas other than the breast.

All together with such other and further relief as to this Court shall seem just and proper under the circumstances including all the costs and disbursements of this action incurred on behalf of the plaintiffs, and the reasonable attorneys fees associated with prosecution of this action by and on behalf of the entire class of all those individuals who are injured, disabled, ill, or suffering from disease, and whose diagnosis, care, and treatment can be enhanced through the use of clinical thermography utilizing modern digital thermal imaging technology.

DATED at Patchogue, New York on 7th day of February 1991.



Victor John Yannacone, jr.
YANNACONE & YANNACONE, P.C.
Attorneys for the Plaintiffs
Office & Post Office Address
39 Baker Street
Post Office Drawer 109
Patchogue, New York 11772+0109
(*Area Code* 516) 475-0231

VERIFICATION

STATE OF NEW YORK
COUNTY OF SUFFOLK *ss:*

Victor John Yannacone, jr., being duly sworn, does depose and say that by resolution of the Texas Chiropractic Association at a meeting held on 9 February 1991 in Austin, Texas, I have been designated attorney for the Texas Chiropractic Association, the representative Plaintiff in the within action; that by resolution of the Texas Chiropractic Association at a meeting held on 9 February 1991 in in Austin, Texas, the Texas Chiropractic Association agreed to commence this action; that as attorney for the Texas Chiropractic Association I have read the foregoing complaint and I believe the allegations of this complaint to be true.

Victor John Yannacone

Sworn to before me, this
12 th day of February 1991

Muriel A Aldrich

MURIEL A. ALDRICH
Notary Public, State of New York
No. 4624573
Qualified in Suffolk County
Commission Expires July 31, 1992