

**The
American
Legion**



For God and Country

★ WASHINGTON OFFICE ★ 1608 "K" STREET, N.W. ★ WASHINGTON, D.C. 20006-2847 ★
(202) 861-2700 ★

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2-2-91/16

March 26, 1991

Honorable Edward J. Derwinski (271A)
Secretary of Veterans Affairs
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, D. C. 20420

Deliver by Hand

Dear Mr. Secretary:

This is in response to the Federal Register notice of February 25, 1991, wherein the Department of Veterans Affairs announced its proposed rules concerning adjudication regulations to establish service-connection for soft tissue sarcomas based on exposure to herbicides containing dioxin.

The American Legion is concerned that the list of soft tissue sarcomas contained in the proposed rules is incomplete and overlooks soft tissue tumors and tumor like lesions that our nation's veterans develop as a result of exposure to Agent Orange while serving in South Vietnam or elsewhere in the military service.

The proposed rules to modify current VA guidelines for the evaluation of claims relating to health effects of dioxin are inadequate at this time. The rules proposed by the VA are inadequate because they fail to provide the methodology for selecting the soft tissue sarcomas (the list is shown in the definitions of soft tissue sarcomas). The list is limited in scope when compared to the current available scientific literature.

The view here is that dioxins and herbicides made together or separately lead to cancers in humans and animals. We do not know of all of the types of cancers which may be related in humans to dioxin and phenoxyherbicide exposure. The policy decisions which must be made while this uncertainty exists should favor the potentially damaged veteran and his or her family so long as doubt as to causality exists.

Honorable Edward J. Derwinski

March 26, 1991

In light of the limited list of soft tissue sarcomas shown in the proposed rules, it is recommended that a special panel be established for the specific purpose of determining which soft tissue tumors should be included in the VA regulations. Veterans who file claims for soft tissue sarcomas that are not included in these proposed rules should not be disqualified because his or her particular tumor was inadvertently left out of the regulations.

In addition, provisions should be made in the VA regulations for veterans who file claims for STSs that are not published in the final regulations to provide appellate reviews by appropriate scientific experts.

Dr. Franz Enzinger and Dr. Sharon W. Weiss, experts in the field of soft tissue tumors, have compiled a histological classification of soft tissue tumors. This list is contained in a manuscript titled Soft Tissue Tumors, Second Edition, published by C. V. Moby Co., 1988. Dr. Enzinger provided The American Legion with the list of soft tissue tumors, which should be reviewed by a special panel for inclusion in VA regulations.

Sincerely yours,



RICHARD S. CHRISTIAN, Deputy Director
for Research and Technology Assessment
Veterans Affairs and Rehabilitation

cc: Anthony Principi

Attachment

Histological classification of soft tissue tumors

I. Tumors and tumorlike lesions of fibrous tissue

A. Benign

1. Fibroma
2. Nodular fasciitis (including intravascular and cranial types)
3. Proliferative fasciitis
4. Proliferative myositis
5. Fibroma of tendon sheath
6. Elastofibroma
7. Nuchal fibroma
8. Nasopharyngeal fibroma
9. Keloid

B. Fibrous tumors of infancy and childhood

1. Fibrous hamartoma of infancy
2. Myofibromatosis (solitary, multicentric)
3. Fibromatosis colli
4. Infantile digital fibromatosis
5. Infantile fibromatosis (desmoid type)
6. Giant cell fibroblastoma
7. Gingival fibromatosis
8. Calcifying aponeurotic fibroma
9. Hyalin fibromatosis

C. Fibromatoses

1. Superficial fibromatoses
 - a. Palmar and plantar fibromatosis
 - b. Penile (Peyronie's) fibromatosis
 - c. Knuckle pads
2. Deep fibromatoses
 - a. Abdominal fibromatosis
 - b. Extraabdominal fibromatosis
 - c. Intraabdominal fibromatosis
 - d. Mesenteric fibromatosis (Gardner's syndrome)
 - e. Postradiation fibromatosis
 - f. Cicatricial fibromatosis

D. Malignant

1. Adult fibrosarcoma
2. Congenital and infantile fibrosarcoma
3. Inflammatory fibrosarcoma
4. Postradiation fibrosarcoma
5. Cicatricial fibrosarcoma

II. Fibrohistiocytic tumors

A. Benign

1. Fibrous histiocytoma
 - a. Cutaneous (dermatofibroma)
 - b. Deep
2. Atypical fibroxanthoma
3. Juvenile xanthogranuloma
4. Reticulohistiocytoma
5. Xanthoma

B. Intermediate

1. Dermatofibrosarcoma protuberans
2. Bednar tumor

C. Malignant

1. Malignant fibrous histiocytoma
 - a. Storiform-pleomorphic
 - b. Myxoid (myxofibrosarcoma)
 - c. Giant cell (malignant giant cell tumor of soft parts)
 - d. Inflammatory (malignant xanthogranuloma, xanthosarcoma)
 - e. Angiomatoid

III. Tumors and tumorlike lesions of adipose tissue

A. Benign

1. Lipoma (cutaneous, deep and multiple)
2. Angiolipoma
3. Spindle cell and pleomorphic lipoma
4. Lipoblastoma and lipoblastomatosis
5. Angiomyolipoma
6. Myelolipoma
7. Intramuscular and intermuscular lipoma
8. Lipoma of tendon sheath
9. Lumbosacral lipoma
10. Interneural and perineural fibrolipoma
11. Diffuse lipomatosis
12. Cervical symmetrical lipomatosis (Madelung's disease)
13. Pelvic lipomatosis
14. Hibernoma

B. Malignant

1. Liposarcoma, predominantly
 - a. Well-differentiated
 - (1) Lipoma-like
 - (2) Sclerosing
 - (3) Inflammatory
 - b. Myxoid
 - c. Round cell (poorly differentiated myxoid)
 - d. Pleomorphic
 - e. Dedifferentiated

IV. Tumors of muscle tissue

A. Smooth muscle

1. Benign

- a. Leiomyoma (cutaneous and deep)
- b. Angiomyoma (vascular leiomyoma)
- c. Epithelioid leiomyoma (benign leiomyoblastoma)
- d. Intravenous leiomyomatosis
- e. Leiomyomatosis peritonealis disseminata

2. Malignant

- a. Leiomyosarcoma
- b. Epithelioid leiomyosarcoma (malignant leiomyoblastoma)

B. Striated muscle

Histological classification of soft tissue tumors—cont'd.

1. Benign
 - a. Adult rhabdomyoma
 - b. Genital rhabdomyoma
 - c. Fetal rhabdomyoma
 2. Malignant
 - a. Rhabdomyosarcoma, predominantly
 - (1) Embryonal (including botryoid)
 - (2) Alveolar
 - (3) Pleomorphic
 - (4) Mixed
 - b. "Ectomesenchymoma"
(rhabdomyosarcoma with ganglion cell differentiation)
- V. Tumors and tumorlike lesions of blood vessels
- A. Benign
 1. Hemangioma
 - a. Capillary (including juvenile)
 - b. Cavernous
 - c. Arteriovenous
 - d. Venous
 - e. Epithelioid (angiolymphoid hyperplasia, Kimura's disease)
 - f. Granulation tissue type (pyogenic granuloma)
 2. Deep hemangioma (intramuscular, synovial, perineural)
 3. Hemangiomatosis
 4. Glomus tumor
 5. Hemangiopericytoma
 6. Papillary endothelial hyperplasia (intravascular vegetant hemangioendothelioma of Masson)
 - B. Intermediate
 1. Hemangioendothelioma
 - a. Epithelioid
 - b. Spindle cell
 - c. Malignant endovascular papillary angioendothelioma
 - C. Malignant
 1. Angiosarcoma
 2. Kaposi's sarcoma
 3. Malignant glomus tumor
 4. Malignant hemangiopericytoma
- VI. Tumors of lymph vessels
- A. Benign
 1. Lymphangioma
 - a. Cavernous
 - b. Cystic (cystic hygroma)
 2. Lymphangiomatosis
 3. Lymphangiomyoma and lymphangiomyomatosis
 - B. Malignant
 1. Angiosarcoma
- VII. Tumors and tumorlike lesions of synovial tissue
- A. Benign
 1. Giant cell tumor of tendon sheath
 - a. Localized (nodular tenosynovitis)
 - b. Diffuse (florid synovitis)
 - B. Malignant
 1. Synovial sarcoma (malignant synovioma), predominantly
 - a. Biphasic (fibrous and epithelial)
 - b. Monophasic (fibrous or epithelial)
 2. Malignant giant cell tumor of tendon sheath
- VIII. Tumors of mesothelial tissue
- A. Benign
 1. Localized fibrous mesothelioma (subserosal fibroma)
 2. Multicystic peritoneal mesothelioma
 3. Mesothelioma of the genital tract (adenomatoid tumor)
 - B. Malignant
 1. Diffuse and localized mesothelioma, predominantly
 - a. Epithelial
 - b. Fibrous
 - c. Biphasic
- IX. Tumors and tumorlike lesions of peripheral nerves
- A. Benign
 1. Traumatic neuroma
 2. Morton's neuroma
 3. Neuromuscular hamartoma
 4. Nerve sheath ganglion
 5. Neuroilemonna (benign schwannoma)
 6. Neurofibroma, solitary
 - a. Localized
 - b. Diffuse
 - c. Pacinian
 - d. Pigmented
 7. Granular cell tumor
 8. Neurofibromatosis (von Recklinghausen's disease)
 - a. Localized
 - b. Plexiform
 - c. Diffuse
 9. Pigmented neuroectodermal tumor of infancy (retinal anlage tumor)
 10. Ectopic meningioma
 11. Nasal glioma
 12. Neurothekeoma

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Amplified

Histological classification of soft tissue tumors—cont'd.

- B. Malignant**
1. Malignant schwannoma, including malignant schwannoma with rhabdomyoblastic differentiation (malignant Triton tumor), glandular malignant schwannoma, and epithelioid malignant schwannoma
 2. Peripheral tumors of primitive neuroectodermal tissues (Neuroepithelioma)
 3. Malignant pigmented neuroectodermal tumor of infancy (retinal anlage tumor)
 4. Malignant granular cell tumor
- X. Tumors of autonomic ganglia**
- A. Benign**
1. Ganglioneuroma
 2. Melanocytic schwannoma
- B. Malignant**
1. Neuroblastoma
 2. Ganglioneuroblastoma
 3. Malignant melanocytic schwannoma
- XI. Tumors of paraganglionic structures**
- A. Benign**
1. Paraganglioma (solitary, multiple, familial)
- B. Malignant**
1. Malignant paraganglioma
- XII. Tumors and tumorlike lesions of cartilage and bone-forming tissues**
- A. Benign**
1. Panniculitis ossificans
 2. Myositis ossificans
 3. Fibrodysplasia (myositis) ossificans progressiva
4. Extraskeletal chondroma or osteochondroma
 5. Extraskeletal osteoma
- B. Malignant**
1. Extraskeletal chondrosarcoma
 - a. Well-differentiated
 - b. Myxoid (chordoid sarcoma)
 - c. Mesenchymal
 2. Extraskeletal osteosarcoma
- XIII. Tumors and tumorlike lesions of pluripotential mesenchyme**
- A. Benign**
1. Mesenchymoma
- B. Malignant**
1. Malignant mesenchymoma
- XIV. Tumors and tumorlike lesions of disputed or uncertain histogenesis**
- A. Benign**
1. Congenital granular cell tumor
 2. Tumoral calcinosis
 3. Myxoma (cutaneous and intramuscular)
 4. Aggressive angiomyxoma
 5. Amyloid tumor
 6. Parachordoma
- B. Malignant**
1. Alveolar soft part sarcoma
 2. Epithelioid sarcoma
 3. Clear cell sarcoma of tendons and aponeuroses (malignant melanoma, soft parts)
 4. Extraskeletal Ewing's sarcoma
- XV. Unclassified soft tissue tumors and tumorlike lesions**

necrosis. As shown in Table 1-3, soft tissue tumors can be divided into those that are usually glycogen positive and a few with variable staining as defined by light microscopy. As a result of this property, the PAS stain is useful in narrowing down certain diagnostic alternatives and is helpful in several situations, including evaluation of the following: (1) pleomorphic tumors in which the differential diagnosis includes carcinoma, melanoma, pleomorphic leiomyosarcoma, and malignant fibrous histiocytoma; (2) round cell tumors such as neuroblastoma, rhabdomyosarcoma, and extraskeletal Ewing's sarcoma; and (3) spindle cell neoplasms in which the diagnosis is either a neural or smooth muscle lesion. In the first situation, the presence of glycogen in the lesions will usually exclude a malignant

fibrous histiocytoma but would necessitate addition for mucin, melanin, and especially immunostain for keratin or S-100 protein. In the second situation usually excludes the diagnosis of neuroblastoma. In the last situation, glycogen would make a smooth muscle tumor more likely than a neural tumor.

IMMUNOHISTOCHEMISTRY

Immunohistochemical preparations, more than stains, have profoundly changed the approach to diagnosis of soft tissue tumors. In fact, the utilization of immunohistochemical markers has permitted an accurate diagnosis unheard of only a few years ago. Because of the importance and complexity, the application of

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NATIONAL VETERANS LEGAL SERVICES PROJECT

2001 S STREET NW
SUITE 610
WASHINGTON DC 20009-1125
TEL (202) 265-8305
FAX (202) 328-0063

HAND-DELIVERED
March 27, 1991

Secretary Of Veterans Affairs (271A)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Derwinski:

These comments are directed at the proposed rules relating to soft-tissue sarcomas (STS) published in the Federal Register on February 25, 1991, 56 Fed. Reg. 7632-34. They are submitted on behalf of Vietnam Veterans of America, a nonprofit, Congressionally chartered veterans service organization, and the National Veterans Legal Services Project, a nonprofit public interest law firm that represents numerous Vietnam veterans who were exposed to herbicides containing dioxin during their military service.

The VA proposes that the rule should have an effective date of September 25, 1985. We believe an earlier effective date is necessary and appropriate. When the VA promulgated rules regarding claims for service connection for non-Hodgkins lymphoma (NHL) by veterans who served in Vietnam during the Vietnam Era, it assigned those rules an effective date of August 5, 1964. See 55 Fed. Reg. 43123-24 (Oct. 26, 1990). The reasons for this early effective date were set forth in the "supplementary information" section of the cited Federal Register publication.

For these same reasons, August 5, 1964 should be the effective date for the proposed STS rules, rather than September 25, 1985.¹ There is no valid reason for treating Vietnam veterans who develop NHL any differently from Vietnam veterans who develop STS.

The VA cannot validly justify the difference in treatment on the fact that the Nehmer decision, to which the STS proposed rules refer, may not require an effective date earlier than September 25, 1985. The VA did not purport to establish a 1964 effective date

¹ This would enable veterans to recover retroactive payments of service-connected disability compensation for claims filed as far back as 1964, which is the case for veterans who suffer from NHL.

for NHL on the ground that this date was legally required. Rather, the agency cited discretionary factors to justify its decision. These same factors justify a 1964 effective date for STS.

Separate from the issue of the appropriate effective date is the issue of providing adequate notice to the public of whatever effective date is ultimately chosen. We urge the VA to include within the terms of the regulation itself whatever effective date is ultimately chosen. This will enable the public to gain knowledge of the effective date by reference to future editions of the Code of Federal Regulations. If the VA simply announces the effective date in the portion of the Federal Register publication of the final rules that precedes the text of the final rules, claimants and other members of the public will not have adequate notice.

Another comment we have relates to the Agent Orange Act of 1991, Public Law 102-4. According to VA Circular 21-91-5 (March 5, 1991), the Act establishes a presumption of service connection for veterans with service in Vietnam during the Vietnam era who subsequently develop STS to a degree of 10% or more. Yet, the proposed rules on STS, which were published after the effective date of the Act, do not even refer to the Act.

We urge the VA to amend the proposed rules to implement this legislation and include an explanation how the rules are both consistent with the Act and the requirements of Nehmer. For example, included among the issues the rules should address are:

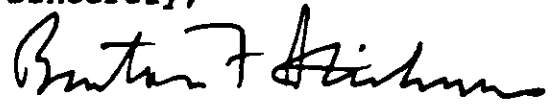
1. to what extent, if any, do the rules implementing Nehmer accord a presumption of service connection to types of STS that are not accorded service connected status by the Act; and
2. to what extent, if any, does the Act accord a presumption of service connection to types of STS that are not accorded service connected status by the rules implementing Nehmer.

In addition, insofar as there may be different effective dates for awards for STS depending on the type of STS the claimant has, the regulation should be amended to describe specifically how these different effective dates are to be determined. With regard to this last issue, we note that the Stipulation and Order in Nehmer sets forth certain requirements regarding the effective date that must be accorded to awards of service connection under regulations implementing Nehmer. These requirements should appear in the rules

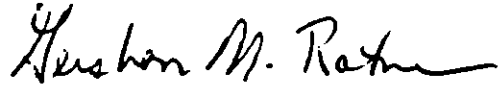
governing STS so that claimants and the public are informed of the substantive rules under which the agency is operating.

We appreciate the opportunity to comment on these important rules.

Sincerely,



Barton F. Stichman



Gershon M. Ratner

4. In redesignated § 3.551(b)(1) remove the phrase "... and service pension based on entitlement prior to July 1, 1960."

5. In § 3.551(c)(1) after the word "furnished" and before the word "domestic" add the words "hospital, nursing home or" remove the dollar amount "\$60" and add, in its place, the dollar amount "\$50".

6. In § 3.551 remove paragraphs (c) (2), and (4), (6) and (7) and redesignate paragraphs (c)(3) and (c)(5) as (c)(2) and (c)(3), respectively.

7. In redesignated § 3.551 (2) and (c)(3) remove the dollar amount "\$60" wherever it appears, and add, in its place the dollar amount "\$50".

8. In redesignated § 3.551(h)(2) remove the paragraph designations "(c)(2)", "(c)(3)", and "(c)(1)" wherever they appear, and add, in their place, the paragraph designations "(d)", "(e)", and "(h)(1)", respectively.

9. In redesignated § 3.551(h)(3) after the word "monthly" and before the word "payable" add the phrase "or \$90, if reduction is under paragraph (e)(1)."

§ 3.454 (Amended)

10. In redesignated § 3.454(b)(1) and (c) remove the dollar amount "\$60", wherever it appears and add in its place, the dollar amount "\$50".

11. In § 3.454 (b) and (d) remove "§ 3.551(c)" and add, in its place, "§ 3.551(d) or (e)".

12. In § 3.454(d) after the word "monthly" add the words "if reduction is under § 3.551(d) or (e), or \$90 monthly if reduction is under § 3.551(e)(1)."

13. In § 3.454 add paragraph (b)(3) to read as follows:

§ 3.454 Veterans disability pension.

(b) * * * (3) When the amount of approved pension payable to a married veteran under 38 U.S.C. 521(b) is reduced to \$90 monthly under § 3.551(e)(1) an apportionment may be made to such veteran's spouse upon an affirmative showing of hardship. The amount of the apportionment generally will be the difference between \$90 and the rate payable if pension was being paid under 38 U.S.C. 521(c) including the additional amount payable under 38 U.S.C. 521(e) if the veteran is so entitled.

Authority: 38 U.S.C. 3203(a)

38 CFR Parts 3 and 4

RIN 2900-AE09

Claims Based on Exposure to Herbicides Containing Dioxin (Soft-Tissue Sarcomas)

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulations.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations to establish service connection for soft-tissue sarcomas based on exposure to herbicides containing dioxin. VA is also proposing to amend the Schedule for Rating Disabilities to add specific diagnostic codes for soft-tissue sarcoma as well as evaluation criteria. These changes are necessary to implement our determination that it is at least as likely as not that there is a significant statistical association between exposure to herbicides containing dioxin and soft-tissue sarcoma. The intended effect will be to establish a rule for making determinations regarding service connection for soft-tissue sarcomas for all veterans who were exposed to herbicides containing dioxin during service.

DATES: Comments must be received on or before March 27, 1991. Comments will be available for public inspection until April 8, 1991. The change to part 3 is proposed to be effective September 25, 1985. The changes to part 4 are proposed to be effective the date of publication of the final regulations.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding these changes to the Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments will be available for public inspection only in the Veterans Services Unit, room 132, at the above address and only between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays) until April 8, 1991.

FOR FURTHER INFORMATION CONTACT: Joel Drembus, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration (202) 233-3005.

SUPPLEMENTARY INFORMATION: Under 38 CFR 1.17(c), when VA determines that a significant statistical association exists between exposure to a herbicide containing dioxin and any disease, 38 CFR 3.311a shall be amended to provide guidelines for the establishment of service connection for the disease(s). These determinations are to be made

after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards (Advisory Committee) based on its evaluation of scientific or medical studies. In making these determinations, VA must apply the reasonable doubt doctrine found in 38 CFR 1.17(d)(1).

In a public meeting on May 16-17, 1990, the Advisory Committee met in Washington, DC. At that meeting, the committee considered more than 80 scientific and medical documents relating to the connection, if any, between exposure to a herbicide containing dioxin and soft-tissue sarcoma. The committee found that the relative weights of valid positive and valid negative studies (as defined in 38 CFR 1.17(d)(2)-(4)) permitted the conclusion that it is at least as likely as not that there is a significant statistical association between exposure to a herbicide containing dioxin and soft-tissue sarcoma.

In making our determination, we recognized conflicting results among scientific and medical studies. Some studies in Scandinavia reported an association of soft-tissue sarcomas with exposure to herbicides. Other studies there, as well as in the United States and New Zealand, found no such association. Valid Vietnam experience studies were both positive and negative. While the negative studies were of some significance, we have determined that the relative weights of the valid positive and valid negative studies permit the conclusion that it is at least as likely as not that there is a significant statistical association between exposure to herbicides containing dioxin and soft-tissue sarcoma.

Accordingly, we propose to amend 38 CFR 3.311a to provide standards for the establishment of service connection for soft-tissue sarcomas based on exposure to herbicides containing dioxin. In addition, to insure equitable treatment of veterans who may have been exposed to herbicides containing dioxin during service other than in Vietnam during the Vietnam Era, e.g., in activities related to testing, storage or shipping of herbicides, we propose to remove the restriction limiting the regulation to herbicides. ~~we propose to remove the restriction limiting the regulation to~~ } duplicated words veterans who served in Vietnam during the Vietnam Era. Exposure to herbicides containing dioxin during service other than in Vietnam during the Vietnam Era would have to be established by appropriate evidence.

There is disagreement even among pathologists as to what tumors the term "soft-tissue sarcoma" encompasses.

With the assistance of the Chief Medical Director and the Advisory Committee, we compiled a list of those tumors which we will consider to be soft-tissue sarcomas and included it in the proposed regulation. For compensation purposes, such tumors must be malignant and arise from tissue of mesenchymal origin, including muscle, fat, blood or lymph vessels, or connective tissue (but not cartilage or bone). Tumors of infancy or childhood, and those having a strong, known causal association with a specific etiology (such as HIV infection or asbestos exposure) have been excluded because it is unlikely that there is a reasonable probability of a significant statistical association between such tumors and exposure to a herbicide containing dioxin.

Soft-tissue sarcomas are currently rated by analogy because there are no specific diagnostic codes in the rating schedule. We, therefore, also propose to amend 38 CFR part 4 to add specific diagnostic codes for soft-tissue sarcoma as well as evaluation criteria. In addition, we propose to amend diagnostic code 5327 to exclude soft-tissue sarcoma and to revise the point at which evaluations will be based on residual disability from 1 year to 6 months following cessation of treatment. The revision is made because medical advances have reduced the recovery time needed following surgery, chemotherapy, etc.

In *Nehmer v. United States Veterans Administration*, 712 F. Supp. 1404 (N.D. Cal. 1989), the court invalidated VA's requirement of proof of a causal relationship in determining service connection for diseases associated with dioxin exposure. Accordingly, § 3.311a(d) is currently of no force and effect. The Secretary will be making determinations for other diseases, including porphyria cutanea tarda, pursuant to the court's remand order after receiving the advice of the Advisory Committee. We propose to remove and reserve § 3.311a(d) until such determinations are made.

Further, because the *Nehmer* decision invalidated VA's original service connection determinations in 38 CFR 3.311a *ab initio*, and because those determinations were the original regulatory response to the mandate in section 5(a)(1) of Public Law 98-542, we propose to make the amendment to § 3.311a(c) effective retroactively to September 25, 1985, the original effective date of the section. We believe that, in light of the remedial nature of these regulations, and because they serve as a substitute for void regulations issued

under an impermissibly demanding standard in 1985, this effective date is appropriate.

The Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The reason for this certification is that these amendments would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

In accordance with Executive Order 12291, Federal Regulation, the Secretary has determined that these regulatory amendments are non-major for the following reasons:

(1) They will not have an annual effect on the economy of \$100 million or more.

(2) They will not cause a major increase in costs or prices.

(3) They will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects

38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

38 CFR Part 4

Handicapped, Pensions, Veterans. Catalog of Federal Domestic Assistance program numbers are 64.101, 64.109, and 64.110.

Approved: January 11, 1991.

Edward J. Derwinski,

Secretary of Veterans Affairs.

PART 3—(AMENDED)

38 CFR part 3, Adjudication, is proposed to be amended as follows:

1. In § 3.311a, paragraph (d) is removed and reserved, and paragraph (c), and the authority at the end of the section are revised to read as follows:

§ 3.311a Claims based on exposure to herbicides containing dioxin.

(c) Service connection based on exposure to herbicides containing dioxin. Except as provided in paragraph (e) of this section, exposure to herbicides containing dioxin together with the development of the following

diseases within the periods specified is sufficient to establish service connection for resulting disability:

(1) Chloracne manifested not later than three months from the date of exposure.

(2) A soft-tissue sarcoma manifested at any time after service.

Note: The term "soft-tissue sarcoma" includes the following:

Adult fibrosarcoma.
Dermatofibrosarcoma protuberans.
Malignant fibrous histiocytoma.
Liposarcoma.
Leiomyosarcoma.
Epithelioid leiomyosarcoma (malignant leiomyoblastoma).
Rhabdomyosarcoma.
Ectomesenchymoma.
Angiosarcoma (hemangiosarcoma and lymphangiosarcoma).
Proliferating (systemic) angioendotheliomatosis.
Malignant glomus tumor.
Malignant hemangiopericytoma.
Synovial sarcoma (malignant synovioma).
Malignant giant cell tumor of tendon sheath.
Malignant schwannoma, including malignant schwannoma with rhabdomyoblastic differentiation (malignant Triton tumor), glandular and epithelioid malignant schwannomas.
Malignant mesenchymoma.
Malignant granular cell tumor.
Alveolar soft part sarcoma.
Epithelioid sarcoma.
Clear cell sarcoma of tendons and aponeuroses.

(See paragraph (g) of this section with regard to service connection on other grounds and § 3.307(c) in cases where chloracne is initially misdiagnosed.)

(Authority: Pub. L. 98-542; 38 U.S.C. 210(c).)

PART 4—(AMENDED)

38 CFR part 4, Schedule for Rating Disabilities, is proposed to be amended as follows:

1. In § 4.73, diagnostic code 5327 is revised and diagnostic code 5329 is added following diagnostic code 5328 to read as follows:

§ 4.73 Schedule of ratings—muscle injuries.

	Rating
5327 Muscle, new growth of, malignant (excluding soft-tissue sarcoma).....	100
Note: The 100 percent rating will be continued for 6 months following the cessation of surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. At this point, if there has been no local recurrence or metastases, the rating will be made on residuals.	
5329 Soft-tissue sarcoma (of muscle, fat, or fibrous connective tissue).....	100

Rating

Note: The 100 percent rating will be continued for 6 months following the cessation of surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. At this point, if there has been no local recurrence or metastases, the rating will be made on residuals.

2. In § 4.104, diagnostic code 7123 is added following diagnostic code 7122 to read as follows:

§ 4.104 Schedule of ratings-cardiovascular system.

Rating

7123 Soft-tissue sarcoma (of vascular origin) 100

Note: The 100 percent rating will be continued for 6 months following the cessation of surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. At this point, if there has been no local recurrence or metastases, the rating will be made on residuals.

3. In § 4.124a, diagnostic code 8540 is added following diagnostic code 8730 and an authority citation is added at the end of the section to read as follows:

§ 4.124a Schedule of ratings-neurological conditions and convulsive disorders.

Rating

8540 Soft-tissue sarcoma (of neurogenic origin) 100

Note: The 100 percent rating will be continued for 6 months following the cessation of surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. At this point, if there has been no local recurrence or metastases, the rating will be made on residuals.

(Authority: 38 U.S.C. 355).

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FEDERAL MARITIME COMMISSION

46 CFR Parts 580 and 581

[Docket No. 89-20]

Definition of Shipper and Availability of Mixed Commodity Rates

AGENCY: Federal Maritime Commission.

ACTION: Discontinuance of proceeding.

SUMMARY: The Federal Maritime Commission ("Commission" or "FMC") is discontinuing this rulemaking proceeding, which would have amended the definition of "shipper" and required that mixed commodity rates be made

available only to shippers and shippers' associations, as defined. The Proposed Rule would also have imposed certain requirements on those shippers, particularly non-vessel-operating common carriers ("NVOCCs"), which utilized mixed commodity rates. The Proposed Rule has proved, on the basis of the record before the Commission, to be irreparably flawed in its attempt to define who is and is not a shipper. Moreover, one of the objectives of the Proposed Rule—to preclude untariffed NVOCC operations and to ensure that persons acting as shippers pursuant to the Shipping Act of 1984 ("1984 Act") qualify to do so—is similar to that of recent legislation, i.e., the Non-Vessel-Operating Common Carrier Amendments of 1990.

FOR FURTHER INFORMATION CONTACT: Joseph C. Polking, Secretary, Federal Maritime Commission, 1100 L Street, NW., Washington, DC 20573, (202) 523-5725.

SUPPLEMENTARY INFORMATION: The Commission initiated this proceeding by publishing in the Federal Register (54 FR 40891) a proposed rule ("Proposed Rule") to amend its tariff and service contract rules in 46 CFR parts 580 and 581. The stated objective of the proposal was

To limit the scope of those that can act as "shippers" vis-a-vis the ocean common carrier, preclude untariffed NVOCC operations and otherwise ensure that the statutory scheme contemplated by the Shipping Act of 1984 is preserved.

The Proposed Rule was intended to accomplish this objective first by amending the definition of shipper to mean "the person who is legally responsible to pay the ocean common carrier for the transportation." Under the Proposed Rule, the term would include the owner of the cargo, a consignor, a consignee, or a tariffed NVOCC, but not a shipper's agent, an ocean freight forwarder, a broker, or an untariffed NVOCC. The revised definition was essentially a device to effectuate certain substantive restrictions; the Proposed Rule would require that mixed commodity rates be made available only to a "shipper" as newly defined, or a shippers' association as presently defined in the Commission's rules. It would also impose various requirements on shippers seeking mixed commodity rates: they would have to indicate their claimed status as a shipper on the bill of lading, state their NVOCC tariff number, if applicable, and provide other specified information.

Over fifty comments on the Proposed Rule were received. Only a few

submissions, primarily from vessel operating common carriers and conferences thereof, expressed support or partial support for the proposal. Most of these emphasized their concurrence with the objective of the Proposed Rule rather than the rule itself, and nearly all offered suggested amendments to the proposal.

The majority of the comments urged either abandonment or major modifications to the Proposed Rule. Many shippers and/or NVOCCs took the position that the narrowed definition is unnecessary, and will cause serious problems and major uncertainties about presently accepted relationships. The remainder of the submissions raised a multitude of difficulties with the proposed shipper definition and the concomitant proposed restriction on access to mixed commodity rates.

The "legally responsible to pay" standard of the Proposed Rule drew most of the commenters' criticism. Many contended that this standard was itself ambiguous and noted that a carrier may not have the means of determining whether a particular entity is the one legally responsible to pay transportation charges. It was also argued that often more than one party may be responsible to pay, and that an entity's interest in a shipment, such as ownership, rather than responsibility to pay is the more appropriate criterion for defining a shipper.

Many commenters challenged the proposed categorical exclusion of certain entities from the definition, arguing that this too fundamentally alters the legislative definition. They variously argued that forwarders, brokers, agents, and shippers' associations (to the extent they act as "agents" for shippers) would be barred from shipper designation, improperly so under certain circumstances. Shippers' associations contended that they should be expressly included in the proposed shipper definition, apparently interpreting the Proposed Rule's failure to do so as an attempt to restrict shippers' associations' rights under the 1984 Act. Some parties objected to the Commission's linking NVOCC tariff filing requirements to a shipper definition, stating that these requirements should be enforced as part of a regimen not affecting entities other than the NVOCCs themselves.

The basic criticism of the "mixed commodity rates" part of the Proposed Rule was that it is just as common for NVOCCs to ship single commodity loads as mixed loads. The proposed provision requiring a shipper to provide a carrier with certain information as proof of its