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MEMORANDUM

SUBJECT	Multidisciplinary Advisory Committee (MDC) Agenda Item 5.C. Recommendation on Proposed Guidelines for Veterinarian Discussion and Recommendation of Cannabis Within the Veterinarian-Client-Patient Relationship
FROM	Leah Shufelt, RVT, Chair
то	Veterinary Medical Board
DATE	March 28, 2023

Background

In 2018, Assembly Bill (AB) 2215 (Kalra, Chapter 819, Statutes of 2018) was passed by the California State Legislature and signed into law by Governor Brown. The bill allowed veterinarians to "discuss" with clients the use of cannabis on an animal patient for medicinal purposes without the risk of disciplinary action but did not allow veterinarians to prescribe, dispense, or administer the drug. The bill also required, "On or before January 1, 2020, the board shall adopt guidelines for veterinarians to follow when discussing cannabis within the veterinarian-client-patient relationship. These guidelines shall be posted on the board's Internet Web site."

At the Board's October 9-11, 2019 meeting, the Board approved the "Guidelines for Veterinarian Discussion of Cannabis Within the Veterinarian-Client-Patient Relationship" (Guidelines). As required by AB 2215, the Guidelines were posted on the Board's website on November 15, 2019. After the Board posted those Guidelines, industrial hemp stakeholders requested the Guidelines be revised to remove information pertaining to the approval of industrial hemp products by the U.S. Food and Drug Administration. To address the concern, while retaining clarity regarding the safe and lawful use of industrial hemp, the Board approved revisions to the Guidelines at the January 30-31, 2020 Board meeting and subsequently posted the revised Guidelines.

On October 6, 2021, California enacted AB 45 (Aguiar-Curry, Chapter 576, Statutes of 2021), which allows hemp-derived cannabidiol (CBD) to be added to human and animal food, which is contrary to federal law. The federal Agriculture Improvement Act of 2018, also known as the Farm Bill of 2018, removed hemp from being classified as a Schedule I drug under the federal Controlled Substances Act. However, the federal Food, Drug, and Cosmetic Act does not allow food products to contain a substance that is an active ingredient in an approved drug or an active ingredient in a tested potential drug. The United

States Food and Drug Administration (FDA) has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food to which delta-9 tetrahydrocannabinol (THC) or CBD has been added.

During the January 19, 20, 2022 Board meeting, the Board was provided a written request from former MDC Member, Jeff Pollard, DVM, to consider updating the Guidelines to reflect the present use and a recent bill regarding cannabis products. The Board requested the MDC review the request and bring recommendations back to the Board at a future meeting to update the Guidelines to allow veterinarians to recommend and administer hemp-derived products. MDC Chair Richard Sullivan, DVM, and Christina Bradbury, DVM, formed the Subcommittee to complete this task.

At the April 19, 2022 MDC meeting, the Subcommittee presented the item and recommended the Board not update its Guidelines at that time to include hemp or CBD products. The MDC adopted the recommendation, and, at the Board's July 20-21, 2022 meeting, Dr. Sullivan reported the MDC recommendation to take no action at that time.

On September 18, 2022, California Governor Gavin Newsom signed into law Assembly Bill (AB) 1885 (Kalra, Chapter 389, Statutes of 2022). AB 1885 became effective January 1, 2023. Among other things, this bill amended Business and Professions Code (BPC) sections 4883 and 4884 to prohibit the Board from disciplining, or denying, revoking, or suspending the license of, a licensed veterinarian solely for discussing or recommending the use of cannabis on an animal for potential therapeutic effect or health supplementation purposes, absent negligence or incompetence. The bill required the Board to adopt, and post on its website, guidelines for veterinarians to follow when recommending cannabis within the veterinarian-client-patient relationship by January 1, 2024. In addition, the Department of Cannabis Control (DCC) is required to create regulations for animal product standards by July 1, 2025.

To comply with the new guidelines requirement in AB 1885, the Subcommittee began its review of the existing Guidelines and potential revisions necessary to conform to the new legislation. The Subcommittee found that AB 1885 contained a provision that stated: "The department shall promulgate regulations for animal product standards no later than July 1, 2025. Cannabis products shall not be marketed or sold for use on, or consumption by, animals before these regulations for animal standards take effect." (BPC, § 26001, subd. (e)(2).)

Unsure of the deadline to update the cannabis guidelines, the Executive Officer, at the Vice Chair's request, contacted Assembly Member Kalra's office to determine how to proceed. During a meeting on January 19, 2023, Assembly Member Kalra's office requested the Board make updates to the Board's current discussion guidelines to make it clear that veterinarians can recommend cannabis to their clients for use on animal patients. Assembly Member Kalra's office also asked the Board to consider revising its Guidelines again, if necessary, when DCC's regulations are effective.

At the MDC's January 24, 2023 meeting, the Subcommittee presented an <u>updated version</u> of the Guidelines to the MDC. After discussion, the MDC decided that more clarity was needed before finalizing the Guidelines. Stakeholders from the Veterinary Cannabis Society

(VCS) asked if they could contribute to the development of the revised Guidelines. The Subcommittee conducted meetings with VCS on February 23, and March 6, 2023, to review and revise the draft Guidelines.

Subcommittee Recommendations

The proposed changes to the Guidelines, attached hereto and discussed in detail below, are a result of the Subcommittee's meetings with Gary Richter, DVM, and Dr. Pollard, representing VCS.

The first decision was to change the first section from "Preamble" to "Introduction," explain why this document was necessary in 2018 and the need to update it 2022, and define and clarify the terms "cannabis," "industrial hemp," and "CBD," so that the Board's licensees better understand how they can "discuss and recommend" these products within a veterinarian-client-patient relationship (VCPR).

In the "Background" section, reference to AB 45 and AB 1885 was added to reflect the passage of those bills since the last revisions to the Guidelines. Since AB 1885 requires DCC to promulgate animal product standards before cannabis products can be marketed or sold for use on, or consumption by, animals, a provision for this has been added. The revisions also make other technical revisions to reflect the amendments to the law in AB 1885.

The "Guidelines" section also has been revised to reflect amendments to BPC section 4884 made by AB 1885. In addition, the last paragraph in that section was moved from the Preamble to this section.

The same additions are made in the next paragraph titled, "Patient Evaluation and Record Keeping." There is also an added legal citation.

The next paragraph, relating to documentation of advice on potential risks of the use of cannabis on animals, has some minor changes. In addition, one bulleted item regarding DCC's promulgation of standards is proposed to be added to reflect the requirement in AB 1885, and three bulleted items are proposed to be removed because they are no longer accurate.

The "Conflicts of Interest" and "Advertising" sections are virtually unchanged except for adding "or recommending."

The "Industrial Hemp" section is changed significantly. Though the FDA has not approved the use of industrial hemp products for treatment in animals, industrial hemp is no longer a Schedule I drug under the federal Controlled Substances Act (CSA). Many drugs and supplements used in veterinary medicine are not approved for use in animals by the FDA. The focus of these Guidelines is on the discussion and recommendation of cannabis, and the Subcommittee felt that industrial hemp is detailed sufficiently for the purposes of the above stated bills and statutory requirements.

VCS voiced concerns regarding including, "Until the California Department of Cannabis Control promulgates animal product standards, cannabis products cannot be marketed or

sold for use on, or consumption by animals" in two sections (Background and Guidelines). They are concerned that this language will be confusing to veterinarians. On one hand, the Guidelines would state it is legal to recommend cannabis, while on the other hand, cannabis and hemp derived CBD products cannot be marketed or sold for use on, or consumption by, animals. The Subcommittee understood their point but felt it is important to educate veterinarians about the current status of the law. The Subcommittee believes it makes sense to include this verbiage in both the Background and Guidelines sections as veterinarians may want to document that they have had a conversation about product labeling with the client in the animal patient's medical record.

The last section is the "Definitions, Abbreviations, Acronyms." All the definitions have been updated and revised for clarification.

During the April MDC meeting, the Subcommittee will request the MDC to review the proposed Guidelines, make any edits that are appropriate, and entertain a motion to recommend to the Board the adoption of the Guidelines for Veterinarian Discussion and Recommendation of Cannabis Within the Veterinarian-Client-Patient Relationship and post them on the Board's website.

Action Requested

If the MDC approves the Subcommittee's request and the Board agrees with the MDC's recommendation, please entertain a motion to adopt the proposed Guidelines for Veterinarian Discussion and Recommendation of Cannabis Within the Veterinarian-Client-Patient Relationship and post them on the Board's website.

Attachment

1. Proposed Guidelines for Veterinarian Discussion and Recommendation of Cannabis Within the Veterinarian-Client-Patient Relationship

State of California Department of Consumer Affairs Veterinary Medical Board's

Guidelines for Veterinarian Discussion <u>and</u> <u>Recommendation</u> of Cannabis Within the Veterinarian-Client-Patient Relationship

Effective January 1, 2020Revised [Board Adoption Date]

PREAMBLEINTRODUCTION

The Veterinary Medical Board (VMB) provides these Guidelines for Veterinarian Discussion and Recommendation of Cannabis Within the Veterinarian-Client-Patient Relationship (VCPR) as required by Business and Professions Code (BPC) section 4884, subdivisions (c) and (d).

Since the Board originally published the Guidelines for Veterinarian Discussion of Cannabis Within the Veterinarian-Client-Patient Relationship in 2019, the veterinary profession has expressed confusion regarding the terms CBD, cannabis, and hemp in relation to veterinary medical care. As a cursory matter, the Board provides the following definitions of these terms.

Cannabis means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. Cannabis does not include industrial hemp or the weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product. (Cal. Health & Saf. Code, § 11018.)

Industrial hemp or hemp means an agricultural product, whether growing or not, that is limited to types of the plant *Cannabis sativa* L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plan, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol (THC) concentration of no more than 0.3 percent on a dry weight basis. (Cal. Health & Saf. Code, § 11018.5, subd. (a).)

CBD, an abbreviation for cannabidiol, is a non-psychoactive, naturally occurring compound present in both hemp and cannabis.

Pursuant to Business and Professions Code (BPC) section 4884, subdivision (b), a California licensed veterinarian will not be disciplined by the Veterinary Medical Board (VMB) solely for discussing the use of cannabis in an animal for medicinal purposes. As required by statute, the Board has developed these guidelines for veterinarians to follow when discussing cannabis within the veterinarian-client-patient relationship (VCPR).¹

BACKGROUND

On September 27, 2018, California Governor Edmund G. Brown, Jr. signed into law AB 2215 (Kalra, Chapter 819, Statutes of 2018). AB 2215 became effective January 1, 2019. This bill amendeds section 4883 of, and addeds section 4884 to, the BPC, relating to veterinarians.

On October 6, 2021, California Governor Gavin Newsom signed AB 45 (Aguiar-Curry, Chapter 576, Statues of 2021). AB 45 went into effect immediately upon signing. Among other things, AB 45 authorized the sale of hemp-derived products in California retail outlets.

On September 18, 2022, California Governor Gavin Newsom signed into law AB 1885 (Kalra, Chapter 389, Statutes of 2022). AB 1885 became effective January 1, 2023. Among other things, this bill amended BPC sections 4883 and 4884.

The bill prohibits Following enactment of these bills, the VMB is prohibited from disciplining, or denying, revoking, or suspending the license of, a licensed veterinarian solely for discussing or recommending the use of cannabis on an animal for potential therapeutic effect or health supplementation, medicinal purposes, absent negligence or incompetence. The bill also prohibits a veterinarian from dispensing or administering cannabis or cannabis products. The bill does not pertain to industrial hemp. Until the California Department of Cannabis Control promulgates animal product standards, cannabis products cannot be marketed or sold for use on, or consumption by, animals.

Under both the federal Controlled Substances Act (CSA)¹ and the California Uniform Controlled Substances Act (CUCSA)², cannabis is listed as a Schedule I drug, characterized as having a high potential for abuse, havehaving no currently accepted medical use in treatment in the United States, and lacking accepted safety for use under medical supervision. A veterinarian is prohibited from prescribing, administering, or dispensing a Schedule I drug.

<u>GUIDELINES</u>

The VMB has adopted the following guidelines for the discussion with veterinary clients and recommendation for the use of cannabis on an animal for potential therapeutic effect or health supplementation purposesfor animal use within the VCPR.

Veterinarian-Client-Patient Relationship: The VCPR is fundamental to the provision of acceptable veterinary medical care. <u>Pursuant to BPC section 4884, subdivisions (c) and (d), veterinarians should follow these guidelines when discussing or recommending cannabis within the VCPR. As such, tThe veterinarian should document that an appropriate VCPR <u>has been is established prior to any discussions or recommendation</u> of cannabis with the animal owner client.³</u>

A California licensed veterinarian will not be disciplined by the VMB solely for discussing or recommending the use of cannabis on an animal for potential therapeutic effect or health supplementation purposes.⁴

Patient Evaluation and Record Keeping: <u>The</u>A documented physical examination and collection of relevant clinical history is required. This history should include both subjective and objective data and must be obtained prior to discussion <u>or recommendation</u> of cannabis for potential therapeutic effect or health supplementation purposesa <u>medical purpose</u>. Medical

records must meet the accepted minimum satisfy all of the requirements for record keeping as defined by the Veterinary Medicine Practice Act and supporting regulations.⁵

Documentation of discussions <u>and recommendations</u> should include the indication<u>s</u> and safety <u>considerations for</u> of the use of cannabis. The discussions <u>and recommendations</u> should be evaluated in accordance with accepted standards of practice <u>for the use of cannabis on an animal</u> as they evolve over time. This documentation may include advice about potential risks of the <u>medical</u> use of cannabis <u>on animals</u>, including, but not limited to, the following:

contamination, potentially harmful co-ingredients, e.g., xylitol, chocolate, butter).
No federal or state agency oversees standardization of animal cannabis product concentrations.
Until the California Department of Cannabis Control promulgates animal product standards, cannabis products cannot be marketed or sold for use on, or consumption by, animals.
Research to date is lacking conclusions regarding dose, toxicity, and efficacy.
The side effects and signs of overdose <u>or of THC</u> toxicity (e.g., ataxia, depression, vomiting, urinary incontinence, bradycardia, hyperthermia, tremors, anorexia, adipsia, hypothermia, seizure, stupor, tachycardia, weakness).
<u>The importance of s</u> Safeguarding of cannabis products from <u>exposure</u> to other pets and human <u>s</u> <u>exposure</u> s.
The uUse in service animals that may place human handler safety in jeopardy.
The pPossible interactions with other treatments and prescribed medications.
Reminder to the client that cannabis is not being recommended or prescribed by the veterinarian.
The importance of periodic re-evaluation of the <u>animal</u> patient in accordance with good veterinary practice.

Conflicts of Interest: A veterinarian, registered veterinary technician (RVT), or veterinary assistant controlled substance permit (VACSP) holder may be disciplined for the offer, delivery, receipt, or acceptance of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration as compensation or inducement for referring patients, clients, or customers to a cannabis licensee.⁶ In addition, the Board is authorized to discipline a veterinarian who accepts, solicits, or offers any form of remuneration from or to a cannabis licensee.⁷ if the veterinarian or his or her immediate family have a financial interest with the cannabis licensee.⁸ "Financial interest" includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service.⁹ Further, discussing medicinal or recommending cannabis for use with a client_while the veterinarian is employed by, or has an agreement with, a cannabis licensee is prohibited.¹⁰

Thus, a veterinarian should not have a professional office located at a dispensary or cultivation center or receive financial compensation from or hold a financial interest in a cannabis licensee. Nor should the veterinarian be a director, officer, member, principal, employee, or a retailer of a

cannabis product. A cannabis licensee may not directly or indirectly employ a veterinarian to discuss cannabis with clients. A veterinarian may not be directly or indirectly employed by a cannabis licensee for the purpose of discussing cannabis with clients.

Advertising: The Board is authorized to discipline a veterinarian, RVT, or VACSP holder if he or shethey distributes any form of advertising for cannabis in California.¹¹

Industrial Hemp: Under federal and state law, ¹² industrial hemp is not a controlled substance regulated under the Uniform Controlled Substance Acts and is not regulated under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA). ¹³ Rather, industrial hemp is regulated by the federal Department of Agriculture and the California Department of Food and Agriculture. ¹⁴ <u>Further, any industrial hemp product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or intended to affect the structure or any function of the body of an animal is a drug. ¹⁵ The federal Food and Drug Administration has not approved the use of industrial hemp products for treatment in animals.</u>

Thus, if a veterinarian administers, <u>prescribes</u>, <u>dispenses</u>, furnishes, recommends, or discusses the use of industrial hemp in an animal patient, the veterinarian would not be subject to the statutory provisions regarding cannabis but would be subject to the provisions of the Veterinary Medicine Practice Act applicable to diagnosing, prescribing, or administering a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals.¹⁶

Industrial hemp is not tested or regulated in the same manner as cannabis, so the veterinarian should use caution when administering, dispensing, furnishing, recommending, or discussing industrial hemp and ensure the product to be used is industrial hemp and not cannabis. Further, any industrial hemp product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or intended to affect the structure or any function of the body of an animal is a drug. There are no FDA approved drugs containing industrial hemp for use in animals. A veterinarian who manufactures, markets, or sells drugs not approved by the FDA is in violation of federal law. 18

Definitions, Abbreviations, Acronyms

California Uniform Controlled Substances Act (CUCSA) – regulates the manufacture, importation, possession, use, and distribution of certain substances. (Cal. Health & Saf. Code, § 11000 et seq.)

Cannabis – Cannabis means aAll parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include either of the following:

- (a) Industrial hemp, as defined in Section 11018.5.
- (b) The weight of any other ingredient combined with cannabis to prepare topical or oral administrations, food, drink, or other product. (Cal. Health & Saf. Code, § 11018.)

CBD – abbreviation for <u>Ccannabidiol</u>, which is one <u>out of 60of many</u> naturally occurring compounds present in cannabis. It is the second most prevalent cannabinoid in both hemp and marijuana and is non-psychoactive. CBD oil is mostly extracted from hemp and not marijuana. When extracted from hemp, this type of extract has less than 0.3 <u>percent</u>% of THC.

CSA – The federal Controlled Substances Act (21 USCA § 801 et seq.).

Dronabinol, Marinol, Nabilone – Synthetic cannabinoids.

Epidiolex – CBD product approved in June 2018 by the U.S. Food and Drug Administration (FDA) for controlling seizures in people with difficult-to-treat childhood-onset epilepsy.

Industrial Hemp or hemp — (a) Industrial hemp means a cropAn agricultural product, whether growing or not, that is limited to types of the plant <u>Ceannabis sativa</u> L. <u>and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plan, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis. (Cal. Health & Saf. Code, § 11018.5, subd. (a).) having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom.</u>

(b) Industrial hemp shall not beis not subject to the provisions of the CUCSAthis division or of Division 10 (commencing with Section 26000) of the Business and Professions CodeMAUCRSA, but instead shall beis regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agriculture Code, inclusive. (Cal. Health & Saf. Code, § 11018.5, subd. (b).)

Marijuana – <u>Under California law, marijuana means "cannabis." (Health & Saf. Code, § 11032.) Under federal law, (A)</u> Subject to subparagraph (B), the term "marijuana" means all

parts of the plant <u>Ceannabis sativa</u> L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

- (B) The term "marijuana" does not include:
 - (i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946 [7 USCS § 1639o]; or
 - (ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. ([21 USCS § 802])

Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) – establishes a comprehensive system to control and regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both of the following:

- (1) Medicinal cannabis and medicinal cannabis products for patients with valid physician's recommendations.
- (2) Adult-use cannabis and adult-use cannabis products for adults 21 years of age and over and cannabis products intended for use on, or consumption by, animals.

 MAUCRSA also defines the power and duties of the state agencies responsible for controlling and regulating the commercial medicinal and adult-use cannabis industry.

 (BPC §, 26000 et seq., subd. (b).)

Oils – Cannabis oil, whether CBD, THC, or both, is extracted from the flowers, leaves, and stalk mainly using different solvents. Hemp oil is made only from pressed seeds.

Terpenes – aromatic metabolites found in the oils of all plants (i.e., flavor or fragrance). Terpenes work together to modulate cannabinoids resulting in the so-called "entourage effect." Terpenes have their own medical effects, for example, interacting with neurotransmitters.

THC – delta-9 tetrahydrocannabinol, the primary psychoactive ingredient in marijuana, is one of at least 113 cannabinoids identified in cannabis.

Veterinarian-Client-Patient Relationship (VCPR) – a fundamental provision to acceptable veterinary medical care. A VCPR shall be established by the following:

- (1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,
- (2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and

- 3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance. (CCR, tit. 16, § 2032.1.)
- ¹21 USCA § 801 et seq.
- ² Cal. Health & Saf. Code, § 11000 et seq.
- ³ California Code of Regulations (CCR), title 16, section 2032.1, Veterinarian-Client-Patient Relationship.
- ⁴ BPC, § 4884, subd. (c).
- ⁵ CCR, tit. 16, § 2032.3, Record Keeping; Records; Contents; Transfer.
- ⁶ BPC, § 650 et seq.
- ⁷ BPC, § 26001
- ⁸ BPC, § 4883, subd. (p).
- ⁹ BPC, § 650.01.
- ¹⁰ BPC, § 4883, subd. (q).
- ¹¹ BPC, § 4883, subd. (r).
- ¹² 21 USCA § 802(16); and Cal. Health & Saf. Code, § 11018.5.
- 13 BPC, § 26000 et seq.
- ¹⁴ 7 USCA § 1639o; Cal. Food & Agr. Code, § 81000.
- 15 21 USCA § 321(g); BPC, § 4025.
- ¹⁶ BPC, § 4826, subds. (b), (c).
- ¹⁷ 21 USCA § 321(g); BPC, § 4025.
- * 21 USCA § 360b.