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AMERICAN VETERINARY MEDICAL ASSOCIATION
WASHINGTON D.C. OFFICE
1101 VERMONT AVENUE N.W., SUITE 710 • WASHINGTON, D.C. 20005-3521
PHONE 202-789-0007 • 800-321-1473 • FAX 202-842-4360

January 13, 1993

The Honorable Bob Dole
141 Hart Senate Office Building
U.S. Senate
Washington, DC 20510-1601

Dear Senator Dole:

On behalf of veterinarians, pet and livestock owners, the agricultural community and other people concerned about the humane treatment of animals, we would like to thank you for your support as a cosponsor of S 2667 in the 102nd Congress. S 2667 would have legalized the veterinarian's ability to use his or her professional judgement in treating animal patients, by permitting the use of approved drugs in an extra-label manner.

As you are aware, veterinarians are currently prohibited from using any product not labeled for the specific species, dosage and medical condition that they are treating. Often, a veterinarian may be aware of an FDA-approved product that has been shown to be effective in that species, but has not been approved for that use by FDA. This legislation would give that veterinarian the latitude to use that product legally. FDA has recognized the conflict between modern veterinary practice and the law, and has stated that it will not ordinarily prosecute veterinarians who use drugs in this way, provided that certain conditions are met.

Sens. Howell Heflin, Larry Pressler and Richard Shelby have told us that they intend to introduce a bill to codify FDA's existing policy (identical to S 2667) on January 21, 1993. It is our understanding that they have already written to you to request your support. We hope that you will agree to be among the initial cosponsors. If you wish to cosponsor this bill, please contact Chuck Penry in Sen. Heflin's office at 4-4124.

Thank you very much for your consideration and past support. If we may answer questions or provide additional information on this or any other issue, please do not hesitate to call. We look forward to working with you in the 103rd Congress.

Sincerely,

Marcia D. Brody
Governmental Relations Division

Malcolm A. Kram, DVM
Governmental Relations Division

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ISSUE BRIEF

THE NEED TO AMEND THE FEDERAL FOOD, DRUG AND COSMETIC ACT

I solemnly swear to use my scientific knowledge and skills for the benefit of society through the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge.
--Excerpt from the Veterinarian's Oath

Today, practicing veterinarians must often choose between fulfilling the Veterinarian's Oath by providing animal patients with the most effective therapies available or ignoring scientific knowledge by restricting treatment choices to those products that are permitted under federal law. In order to modernize the law and make it compatible with current scientific knowledge, veterinarians and animal owners, joined by agricultural and animal welfare groups, are supporting legislation to restore the veterinarian's ability to provide their patients with the best treatment possible.

During the 102nd Congress, 158 members of the House of Representatives cosponsored HR 5297 which was introduced by Rep. Charles Stenholm (D-TX) and 49 members of the Senate cosponsored S 2667, introduced by Sens. Howell Heflin (D-AL), Richard Shelby (D-AL) and Larry Pressler (R-SD). Sens. Heflin, Shelby and Pressler, as well as Rep. Stenholm and many key original cosponsors plan to reintroduce identical versions of these bills early in the 103rd Congress.

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Background Information

According to Section 512 of the federal Food, Drug and Cosmetic Act (FD&C) Act (21 USC 360b), an animal drug may be used only for the species and usage(s) specified on its label. Unfortunately, an insufficient number of effective drugs are labeled for the conditions and species that veterinarians routinely encounter in practice. Therefore, strict interpretation of the FD&C Act makes it impossible to practice veterinary medicine in a modern and scientific manner. This compromises the veterinarian's ability to provide for the health and welfare of all animals.

Many times -- for conditions ranging from ulcers to cardiac arrest to mastitis -- the most effective drug is not labeled for the animal being treated or for the necessary dosage. Many drugs that are labeled for a specific use and species may also be safe and effective in treating other conditions and species. For example, Ketamine, an anesthetic that is labeled for use in cats and primates, can be used effectively in dogs, pigs and horses -- and frequently is, although technically prohibited by law.

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The Food and Drug Administration (FDA) has recognized the dilemma created by the FD&C Act and has adopted a policy of not ordinarily penalizing veterinarians who prescribe or use FDA-approved drugs in a discretionary or "extra-label" manner, provided that the veterinarian has judged that the health of the animals to be treated is "immediately threatened and suffering or death would result from failure to treat the affected animals."

In recent years, FDA's policy of discretionary enforcement has come under increased scrutiny. Some critics have demanded that the FD&C Act be enforced as written and that FDA prosecute veterinarians for extra-label drug use. The proposal gives FDA the authority to provide clear-cut regulatory direction for drugs used in animals, including specific and appropriate penalties for violation. The legislation would not increase or alter overall patterns of drug usage by veterinarians.

According to Dr. Gerald B. Guest, director of FDA's Center for Veterinary Medicine, "abolishing the policy would not likely change the extent of extra-label use in animals but would tend to drive these uses underground." Moreover, if veterinarians cannot use medically appropriate drugs to treat sick animals, livestock producers may be inadvertently encouraged to ship untreated, diseased animals to market rather than to watch the animals suffer, die or infect the remainder of their herds. For these reasons, scientifically sound extra-label drug use by veterinarians helps to safeguard the food supply.

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S. 2667

October 7, 1992

COSPONSORS

ALABAMA
Heflin (D)
Shelby (D)

ARKANSAS
Pryor (D)

ARIZONA
McCain (R)
DeConcini (D)

CALIFORNIA
Seymour (R)

CONNECTICUT
Dodd (D)
Lieberman (D)

DELAWARE
Roth (R)

FLORIDA
Graham (D)
Mack (R)

GEORGIA
Fowler (D)
Nunn (D)

IDAHO
Craig (R)

INDIANA
Coats (R)

IOWA
Grassley (R)
Harkin (D)

KANSAS
Dole (R)
Kassebaum (R)

KENTUCKY
McConnell (R)
Ford (D)

LOUISIANA
Johnston (D)

MAINE
Cohen (R)
Mitchell (D)

MICHIGAN
Levin (D)

MISSOURI
Bond (R)

MISSISSIPPI
Cochran (R)

MONTANA
Burns (R)

NEBRASKA
Kerrey (D)
Exon (D)

NEVADA
Reid (D)
Bryan (D)

N. CAROLINA
Sanford (D)

OHIO
Glenn (D)

OKLAHOMA
Boren (D)
Nickles (R)

OREGON
Packwood (R)

PENNSYLVANIA
Wofford (D)
Specter (R)

RHODE ISLAND
Chafee (R)

S. CAROLINA
Hollings (D)

S. DAKOTA
Daschle (D)
Pressler (R)

TENNESSEE
Sasser (D)

UTAH
Hatch (R)

VERMONT
Jeffords (R)

VIRGINIA
Warner (R)

WASHINGTON
Adams (D)
Gorton (R)

WYOMING
Wallop (R)

TOTAL COSPONSORS OF THE 102ND CONGRESS 50

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102D CONGRESS
2D SESSION

S. 2667

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use.

IN THE SENATE OF THE UNITED STATES

MAY 6 (legislative day, MARCH 26), 1992

Mr. HEFLIN (for himself, Mr. ADAMS, Mr. BOREN, Mr. CRAIG, Mr. DASCHLE, Mr. DODD, Mr. EXON, Mr. FOWLER, Mr. GORTON, Mr. GRASSLEY, Mr. JOHNSTON, Mr. MCCONNELL, Mr. PRESSLER, Mr. PRYOR, and Mr. SHELBY) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) the Federal Food, Drug, and Cosmetic Act currently permits the use of an animal drug, or a drug intended for human use, that is approved by

the Food and Drug Administration, only in accordance with the specific labeling approved for the drug;

(2) there are not such approved animal drugs available to relieve pain and suffering, or to treat every specific disease or condition found, in each species of animal;

(3) it is sometimes necessary for veterinarians to use such an approved animal drug or approved drug intended for human use in a manner that is not in accordance with the label of the drug if—

(A) the health of an animal is immediately threatened; and

(B) suffering or death would result from failure to provide effective treatment; and

(4) veterinarians possess the professional training and medical judgment to administer drugs in a clinically-appropriate manner that benefits animals and safeguards the public health.

(b) PURPOSES.—The purposes of this Act are—

(1) to permit veterinarians to use such an approved animal drug, or approved drug intended for human use, for therapeutic purposes in animals in a manner that is not specified on the label of the drug, if a valid veterinarian-client-patient relationship exists; and

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(2) to permit the Secretary of Health and Human Services to establish conditions for such use as may be necessary to protect the public health.

SEC. 2. ALTERNATE USES.

Section 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)) is amended by adding at the end the following new paragraphs:

"(4) If an approval of an application filed under subsection (b) is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of section 501(a)(5), and shall be exempt from the regulations of section 502(f), with respect to a different use or intended use of the drug, if such use or intended use—

"(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship; and

"(B) is in compliance with regulations promulgated by the Secretary that establish such conditions for such use or intended use as may be necessary to protect the public health.

"(5) If an approval of an application filed under section 505 is in effect with respect to a particular use or intended use of a drug intended for human use, the drug shall not be deemed unsafe for the purposes of section

501(a)(5), and shall be exempt from the requirements of section 502(f), with respect to a use or intended use of the drug in non-food producing animals, if such use or intended use complies with the requirements specified in subparagraph (A) or (B) of paragraph (4).".

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