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## **Responsible Drug Use: Has the Regulatory Cloud Been Lifted?**

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Since the title of this presentation was generated, the phrase responsible drug use has taken on a different meaning and has been and will be used in a different context. The issue(s) surrounding antibiotic use and microbial susceptibility patterns will drive future considerations of responsible drug use. Yet, the ultimate goal of the veterinary professional, particularly in food animal practice, should be the responsible use of available therapeutic tools. It is important that principles of responsible drug use apply to therapies administered by a licensed veterinarian and by food animal producers operating under the direction of a veterinarian. Federal law dictates that prescription or Rx drugs “be used by or on the direction of a licensed veterinarian”. Prescription drugs must be sold by a veterinarian or on the order of a veterinarian who maintains a valid veterinarian-client-patient-relationship (VCPR) and must bear a label containing specific proscribed information. For extralabel use of either an over-the counter (OTC) or Rx drug, a valid VCPR is necessary and the regulations promulgated to enact the Animal Medicinal Drug use Clarification Act of 1994 (AMDUCA) must be followed.

The manner in which Rx drugs are marketed to food animal producers has been a contentious issue for several decades in various parts of the United States. Currently this issue is providing fodder for considerable and often heated discussion in the State of Minnesota. In determining who will provide prescription drugs to food animal producers, three major concerns have to be addressed. These are the legality of such sales, the inherent need to prevent violative residues from occurring in food animal products, and the economic considerations pertaining to the sale of the prescription animal health products. The first two of these are extremely important to the food animal industry and the veterinary profession as they deal with issues regulated by the government and which impact the image and standing of both the industry and the profession in the eyes of the consuming public. The economic issues are locally very important due to the impact on practices and practitioners. Trends in the way that practices function have been ongoing for many years and predictions for the future of food animal practice suggest that these types of changes will continue and will generally be positive.

### **AMDUCA: Is It Much Ado About Nothing?**

Prior to the passage of AMDUCA, extralabel use of drugs by veterinarians was illegal based upon the Food, Drug and Cosmetic Act. The Center for Veterinary Medicine had adopted a Compliance and Policy Guide (CPG 7125.06) which created a discretionary policy allowing ELDU to prevent animal pain and suffering. The CVM also recognized that the number of available label claims was limiting to the practice of veterinary medicine, thereby providing another valid justification for ELDU. This CPG was valuable to the practice of veterinary medicine but lacked the stability and predictability

of actual law. Legalizing or codifying the CVM's discretionary policy and lifting the cloud of illegality for the practitioner was the primary driving force behind the AMDUCA legislation.

The regulations enacting the AMDUCA have nothing to do with who markets animal health products to food animal producers. The major issue dealt with by AMDUCA is the extralabel use of drugs. The regulations implementing AMDUCA provide legal standing to the definition of a valid VCPR. This definition had been originally developed by the AVMA and is accepted as a primary criteria for the administration, prescribing and dispensing of veterinary prescription drugs.

Animal health products which are used on label, regardless of source of the product, are not regulated by AMDUCA. Labeling requirements and guidelines for prescription drugs have been established by many state pharmacy boards for prescription products. These regulations may vary by state but the first item of information invariably is the name, address, and telephone number of the prescribing veterinarian. Veterinary prescription orders issued by veterinarians authorize drug distributors to deliver veterinary prescription drugs to a specific client, or authorize pharmacists to dispense such drugs to a specific client. Any prescription or prescription order must include adequate directions from which an appropriate label may be generated by the product source. The AMDUCA regulations used existent prescription labeling requirements as a basis for labeling requirements for drugs prescribed and dispensed in an extralabel fashion. The AMDUCA is clear about what information needs to appear on the label for a product which will be used in an extralabel manner. Regardless of source, private practitioner or drug distributor, any prescription drugs which are on a food animal production unit must be properly labeled.

### **The VCPR: Bringing Contrast to Grey Areas**

In issues related to the distribution of animal health products, the presence or absence of a valid VCPR becomes pivotal for determining what is proper and what is not. There will always be grey areas in these regulated concerns because regulations and guidelines cannot be written to explicitly cover every circumstance. Many sources have suggested that the VCPR definition be amended to make certain areas more specific, for instance specify the number or frequency of visits that constitute a VCPR. Because of the inherent differences among the various species groups, the guidelines were purposely written in a general broad strokes fashion.

Since the VCPR may be the pivotal point in the very contentious issue of how animal health products arrive on the farm, a detailed evaluation of specific points in the accepted definition may clarify the issue of legality. The first point states that "the veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions". This passage has several implications which are pertinent, such as insuring that adequate communication has occurred between the producer and the

veterinarian to allow decisions to be made about therapeutic needs and the affirmation that recommendations will be followed. Both of these issues become increasingly important in the food safety arena.

The second point in a VCPR revolves around the knowledge or background that the prescribing veterinarian has of the animals, producer and production management practices on a farm. As the section goes on to further define this “knowledge” with several phrases such as “has recently seen” and “medically appropriate and timely visits” which can vary for each practice situation. This same latitude may be viewed by some as providing an opportunity for animal health products to arrive on the farm without adequate and appropriate safeguards. The potential definitions for “has recently seen” are numerous. A dairy practitioner may be on a farm weekly to treat sick animals, twice monthly to perform reproductive examinations, or quarterly to provide nutritional overview and advice. Which of these relationships provides the “best” VCPR. Perhaps all of them, perhaps none of them. The validity of the VCPR hinges on the quality of interaction and communication not the frequency of visits to an operation. The situation is amplified in cow/calf consultation practices due to the episodic nature of routine work. Swine and poultry practitioners may visit operations very infrequently but maintain constant communication with trained technicians on operations that provide detailed and up to date information. These practitioners are “personally acquainted with the keeping and care of the animal(s)”, another excerpt from the VCPR definition that varies from one type of practice to another.

The final and key consideration for evaluating the validity of a VCPR is the availability of the veterinarian for follow-up. In the definition, an option for the provision of emergency care allows distant consultants the opportunity to be involved with the choice and use of animal health products. For multiple person practices, the AVMA has adopted a “practice availability” stance, however the recognized definition does not currently include this verbiage. “Availability for follow-up” is also open to interpretation, but does allow another perspective for evaluating the degree of validity of the VCPR.

The VCPR is a unique concept which has tremendous relevance to responsible use of animal health products on food animal operations. Each situation is different and this makes for “grey areas” which defy discrete categorization. However, the terms used in the definition of the VCPR provide a tangible basis for evaluating the relationship between the source of the animal health products and the end user. The bottom line of the issue hinges on whether there is adequate information transfer and client education to insure proper use, appropriate animal care, and the maintenance of a safe food supply.

### **Who will be Selling Veterinary Drugs in the Future?**

Trends which have their origins in the 1970’s have shaped the way in which animal health care products have been sold, distributed, and used on food animal operations. Factors which impact veterinary medicine and the sale of veterinary prescription products include the size of operation, the development of consultation practice, the economics of

food animal production, and the economics of veterinary practice. Some of these factors have driven the trends and some have been forced to adjust to the changes. These changes can be tracked over time, geographic portions of the country, and different facets of food animal production. As the trend enters new geographic locations so does the concern about the impact on local food animal practice.

The most critical question to be asked is who **IS** going to be selling veterinary prescription drugs in the future? Does this actually equate to “who is going to be making money selling veterinary drugs in the future”? Societal business trends and pressures will usually favor the economy of scale and all food animal producers struggle to enhance profitability, either through increased production or reduced expenses. If business related pressures are going to force a shift from a practice oriented sale of prescription drugs to the large volume purchaser, it may be best to concentrate on the really important question. Who will provide input or have control over the use of animal health products in the future?

The food animal practitioner of today and tomorrow will have to work to ensure optimal animal health and productivity. Of equal importance is the concern of food safety issues. Lastly, the food animal practitioner needs to be able to provide enough valuable services to the food animal producer that food animal practice remains a financially successful endeavor. To be able to satisfy these objectives will require a different practice approach than in the past. To be in control of the animal health products on future food animal operations will require a valid VCPR, the use of prescribed items, in depth knowledge of animal health and management on an operation, and the manner in which animal health products are used on an operation.

### **Summary Comments**

This is a difficult and contentious issue. It is incumbent upon the food animal practitioner to do what is best for his client and the consumer without sacrificing the practice of food animal medicine. The validity of the VCPR is crucial to the issue as is the willingness to provide prescriptions where necessary. Refusing to provide a prescription for a client abdicates the practitioner’s role in the purchase and use of animal health operations. In order to stay in touch with the selection and use of animal health products on an operation, the practitioner needs to be involved in the acquisition of product and this may include providing a prescription to a distributor. In many aspects of business, current trends favor large volume, low overhead entities and this probably cannot be successfully countered or reversed. The best way to adjust to this trend is to remain involved in the changing facets of the producers operation. In the future, the successful food animal practitioner will not be the source of animal health products but will be positioned to remain the premiere health care provider available.