

Plenary Session

Dr. Glen Hoffsis, *Presiding*

The Veterinary Practitioner, Our Essential Ally

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Thank you, Dr. Hoffsis, officers, members, and guests. Just over two months ago, I met some of you at the North American Symposium on Bovine Respiratory Diseases in Amarillo. Here I am, today, back among bovine practitioners.

At the risk of some repetition, and with some new thoughts as well, I will share some mutual concerns and discuss some issues that affect your profession and the field of animal health.

Just about 100 years ago, in May of 1884, Congress established the Bureau of Animal Industry, the first bureau in the U.S. Department of Agriculture. The first assignment of the bureau was to eradicate contagious bovine pleuropneumonia. At that time, that highly destructive bovine disease was spreading among our domestic herds and threatened to destroy our Nation's fledgling export trade in livestock.

Today the Bureau of Animal Industry no longer exists by that name, but it is my privilege to administer successor

agencies that carry on the regulatory work begun under the BAI. I find it significant that this country's animal health programs began with a special concern for bovine disease. That small cadre of veterinarians succeeded in eradicating contagious bovine pleuropneumonia in just eight years.

Their next campaign was considerably more difficult. BAI undertook eradication of Texas fever, which today we know as bovine piroplasmiasis, or tick fever. It was not an easy job--no shortcuts. First there was basic research into the previously unknown nature of vector-borne diseases. Then there were quarantines that involved all the cattle in one-fourth of the country. Cattle had to be dipped and dipped, again and again. It took more than 40 years to eradicate tick fever.

But they did the job, and many others along the way. Since establishment of the BAI, the veterinary arm of USDA has eradicated twelve major diseases of livestock and poultry.

It should be noted here that BAI did not achieve this record alone. From the very start, the first chief, Dr. D. E. Salmon, developed the concept of cooperative state-federal agreements. State and federal veterinarians became partners in coordinated programs against major diseases and parasites. That concept is as important today, in our current programs, as it was in the 19th century.

Cooperation did not stop there. Industry became involved through the founding of the U.S. Livestock Sanitary Association, now known as the U.S. Animal Health Association. For 87 years, this association has provided a forum where the federal government, the states, and the livestock industry can discuss common goals and objectives. Today, as then, we work toward agreement on animal health programs.

When all of this began, little was known about most animal diseases. Research had to proceed hand-in-hand with eradication procedures. Together with the scientific knowledge gained through research, other ingredients were added -- the solid experience gained doing the job, a common-sense approach, and cooperation. Over the years the agency and the veterinary profession grew in stature.

It was virtually inevitable that the government and the practicing veterinarian would become partners as well. In 1921, the government began accrediting graduate veterinarians to do official work for USDA. This arose out of necessity; there were not enough government veterinarians to do the testing for the new program against bovine tuberculosis.

Today, accredited practicing veterinarians are basic to our cooperative animal health program. They are an essential part of our efforts. When the accredited veterinarian fulfills his official responsibilities, no longer is he a private individual. He is a representative of the government. He is making animal health programs work.

Interstate and international livestock movements depend on examinations, testing and certification performed by practicing veterinarians. Tracebacks and epidemiology depend on the identification and documentation that often is part of your work. Our surveillance against major diseases--especially potentially disastrous foreign diseases--depends in large measure on your observation and reporting.

I would be less than honest if I did not acknowledge a few problems. From time to time, an animal disease program is hindered when livestock are shipped under conditions that are not quite right. We have suffered some serious setbacks in the export market because some shipments were not processed as they should have been.

The Animal and Plant Health Inspection Service, which administers USDA accreditation and veterinarians, needs the best the profession can provide. Otherwise, even the best of programs will fail. The agency and the department insist on compliance with the professional standards that undergird these programs.

APHIS is giving special attention to this potential for excellence by forming a task force to review the performance of accredited veterinarians and the methods by which they maintain their performance. It will be composed of representatives from APHIS Veterinary Services, state animal health agencies, veterinary practitioner groups (such as yours), and the industry.

We have laid the groundwork carefully. Within the past year, APHIS and the states organized field study teams, which examined the function and work of accredited veterinarians. They reviewed the relationship between the veterinarian and governmental agencies.

And just last month, on October 25th, we conducted a workshop on veterinary accreditation instruction. This was developed in cooperation with the Association of Teachers of Veterinary Public Health and Preventive Medicine.

Within the next year, veterinary accreditation will be the focus of much discussion. I assure you that the views of this Association will be a valuable ingredient in any recommendations or action.

If I have spent some time discussing the practicing veterinarian, it is because he (or she) wears two hats--one, as private practitioner; the other as a government official. The veterinarian helps to make research pay off, advising

producers on scientific advances and implementing them in his practice. He or she is a key partner in the fight against TB, brucellosis, and other diseases. Vaccination, testing, health certification are primary aspects of these programs.

The veterinarian is the key person in assuring the health of exported cattle.

He or she can help producers avoid residue problems in their livestock. We are working with you and with producers to assure this through the Residue Avoidance Program. Through cooperative agreements with industry, we identify problems when they arise, and work with the industry and producers so that appropriate, joint actions may be taken.

The veterinarian is in the front line of our surveillance against foreign and domestic animal diseases. Through our own monitoring and epidemiology, we make every effort to watch for the introduction or spread of diseases, but it is often the practicing veterinarian who is the first to spot an outbreak. And the practicing veterinarian is the authority on the local scene for the use and administration of drugs and biologics.

I mention this last aspect of your work, recognizing your concern for an issue that has been in the forefront of your discussions.

I appreciate your concern over proposed FDA rules for extra label uses of veterinary drugs. This is not my bailiwick, so it is not appropriate for me to make editorial comments. However, I want you to know my awareness of the problems that are raised in terms of the veterinary-client relationship and of professional competence to recommend treatment.

Of course, those concerns have to be balanced against legal questions raised by the law itself. I sincerely hope this problem can be resolved in a way that will satisfy the needs of the law, the interests of animal health, and the standards for the practice of veterinary medicine. In USDA we are responsible for the licensing of veterinary biologics. I don't foresee problems affecting your right to exercise professional judgement in the use of these licensed products. I don't believe we have had residue problems from the use of veterinary biologics when they have been used or administered by veterinarians.

With respect to biologics, we are making every effort to be responsive to industry needs -- without sacrificing the safety, purity, potency and effectiveness that are the criteria for USDA-licensed products.

Along these lines, we have recognized the valid need for emergency and limited use products. Through new procedures, we are licensing these with enough restrictions to protect the producer and the public. But we are also leaving enough freedom to permit their development and use in a timely way. This approach recognizes the economic problems of qualifying a product that may be used only for a limited time or within a limited area.

There is one major long-range problem that concern us, and it should concern veterinary practitioners as well. I am speaking about unregulated biologics, supposedly produced solely for intrastate use.

How top veterinarians are helping clients artificially inseminate their heifers more efficiently, without the usual time requirements.

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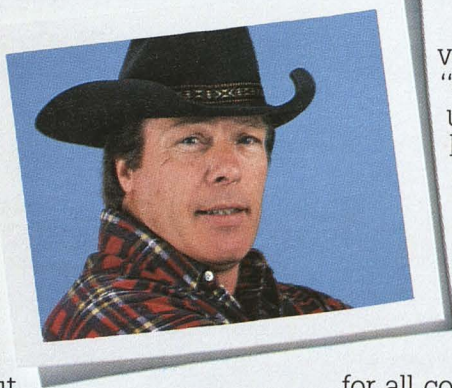
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They're finding that "synchronized" breeding can reduce time and labor requirements.

SYNCRO-MATE-B is not a prostaglandin. It is a unique combination of two hormones: Norgestomet, a potent progestin, and Estradiol Valerate, the salt of the naturally occurring Estradiol. Together, these hormones produce precisely synchronized estrus.

SYNCRO-MATE-B works any time during a heifer's heat cycle. It is not necessary for the animal to have a functional corpus luteum at the time of treatment. Yet fertility of this induced estrus is comparable to that of the heifer's own natural cycle.

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Dairymen can group their heifers to reduce time and labor and facilitate the entry of replacement heifers into the milking string.

SYNCRO-MATE-B, together with a well-managed A.I. breeding program, can increase the production efficiency of just about any operation. But that's just one reason why so many veterinarians are interested.

They're getting more animals pregnant, fewer calving problems.

SYNCRO-MATE-B makes possible a breeding program that is both practical and safe. Not only are producers getting more animals pregnant in a shorter period of time, but they are having fewer problems, too.

It's all a factor of time management. By scheduling breeding earlier in the breeding season, calving can be moved up by two weeks or more.

As a result, cattlemen can plan ahead and have you standing by to put a quick stop to any calving difficulties. You can spend more time with problem calvers, and greatly improve your clients' calf mortality records.

They're proving that artificial insemination of heifers is both practical and profitable.

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For both, SYNCRO-MATE-B has become a profitable breeding management tool. And as a veterinarian, you can share in their success.

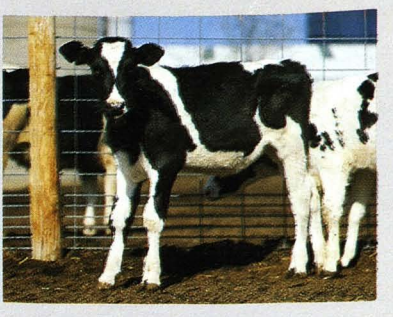
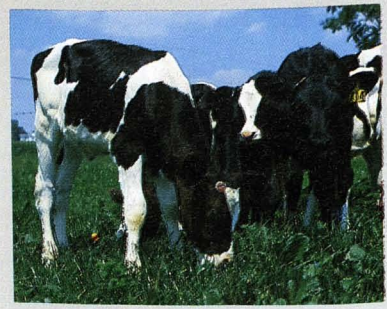
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The licensing of veterinary biologics began under the Virus-Serum-Toxin Act, which was enacted in 1913. A great deal has happened since then. Products and methods of production have changed. Scientific knowledge has expanded vastly. Also, there are some gray areas and ambiguities between the authority of FDA for drugs and USDA's authority over biologics.

And the law has been challenged in the courts. From the beginning USDA's authority did not cover products for intrastate use. And more recently that authority has been further restricted in certain key cases.

USDA's limited authority leaves some 200 producers without effective regulation, since their unlicensed products presumably are intended only for intrastate distribution.

We might hope that state regulations would cover this gap, but that is not the case. Of the 19 states that have laws on veterinary biologics, most only cover distribution; they do not require monitoring for the safety or effectiveness of these products. Only 11 states require manufacturer registration. Only two report any testing of their approved products. And not surprisingly, the bulk of these unlicensed biologics are produced in the states with the least regulation.

Presumably these products are only for intrastate distribution. But somehow they find their way into interstate or foreign commerce.

There is ample reason for concern over the gaps in veterinary biologics regulation. Several years ago, USDA sampled and tested 36 lots of unlicensed animal biologics from 14 producers. Tests for sterility, safety and potency showed that 56 percent failed to make the grade. The failure rate for licensed products, which are closely monitored, ranged from 4 to 5 percent when tested in the same laboratory.

When any serials of the 500 licensed biological products fail to meet USDA standards, they are destroyed. In 1982, out of 22 billion doses of biological products produced in licensed establishments, 782 million doses were destroyed -- about three-tenths of one percent. Licensed producers pay the costs of quality control and testing. And they bear the cost of doses destroyed.

It is fair to presume that if the unlicensed producer is not required to test, he will not test. And the unlicensed producer will move all his doses onto the market. A failure rate of 54 percent is hardly surprising.

The unlicensed producer is at a distinct economic advantage, and competes in the same marketplace as the licensed producer.

To remedy these deficiencies, we are anticipating new legislation.

We look forward to introduction of a completely new veterinary biological act. We intend to cover the gaps. We believe all producers should be on equal footing, competing equally in the production of safe, pure, potent and effective products. We want all products to meet the same high standards that have made the USDA-license a valued ingredient on every product label.

I want to assure you of our commitment to preserving, in any new legislation, the client-practitioner relationship and your right to responsible judgement in the practice of your profession.

While I am on the subject of legislation, it is appropriate to mention some important amendments to the Food, Drug and Cosmetics Act, and other food safety and inspection laws. Current bills before Congress--H.R. 4121 and S. 1938--would redefine what is considered "safe" in federally inspected products. This legislation would attempt to balance risks against benefits and the use of additives, and take into account "negligible" risks, rather than being bound by the zero risk requirements of existing laws. I believe adoption of these proposals would offer a rational and practical approach to food inspection without sacrificing safety.

When I spoke at the Symposium on Bovine Respiratory Diseases, I discussed a number of promising research projects. These included respiratory diseases and stress in livestock shipments, plus a wide range of projects under the Agricultural Research Service and through grants administered by the Cooperative State Research Service. The results of this research should assure better health of livestock whenever they are moved or placed in stress producing situations.

In other research, an additional \$500,000 has been added this fiscal year to research improved vaccines for brucellosis. This work will address the ever-expanding technology for vaccines, and help in the fight against this insidious disease.

In addition, funds have been shifted to develop better testing for bluetongue. The lack of a quick, economical and reliable test continues to limit us as we try to overcome foreign rejection of U.S. exports because of this disease.

We are strengthening the cooperation between the research and the regulatory arms of the department. We have just realigned the functions at Plum Island, N.Y., where our foreign animal disease research and diagnostic work is done. As of October 1, the diagnostic aspects of that facility will be under the direction of APHIS's National Veterinary Services Laboratories, while research on foreign animal diseases will remain with the Agricultural Research Service.

Another step that should help the practicing veterinarian is the establishment of the new Leptospirosis Reference Center at Ames, Iowa. Again, this represents the cooperative approach between research and diagnosis. The Agricultural Research Service will continue to research the disease at the National Animal Disease Laboratory, while APHIS will provide serotyping, diagnosis and referencing through the National Veterinary Services Laboratories.

I would add that this also represents some cooperation between you and the livestock industry. The Leptospirosis Reference Center is largely the result of requests brought to the department by the National Cattlemen's Association and the American Veterinary Medical Association.

The department is trying to help veterinarians and animal health officials in other ways. Currently we are building up

the Brucellosis Information System, a highly computerized operation, based in Fort Collins, Colo., which tracks the location, movement and health status of livestock in participating states. In those states where it is in effect, it has vastly improved tracebacks and identification of herds of origin. It has reduced paperwork and improved efficiency. And this is helping us to eradicate brucellosis.

One of our most promising efforts is the National Animal Disease Surveillance System, or "NADS," a monitoring of all diseases and health conditions on a statistically reliable sampling of the country's farms and ranches. For too long, animal health agencies have had to react after disease problems reach critical levels. And for too long, they have lacked solid information on a host of conditions that might some day demand urgent action.

Overall coordination and administration will be under the Animal and Plant Health Inspection Service. However, NADS will involve close cooperation and support of state agencies, the Economic Research Service, the Extension Service and others.

The need for comprehensive information is not our problem alone. The practicing veterinarian knows very well what actions on the producer's part will result in better herd health. But he is not well equipped to tell that producer exactly what the economic consequences are. How much is a particular disease costing the industry? Where is it prevalent? Is it increasing in incidence, in virulence?

Some examples come to mind. In the sixties and the seventies, hog cholera was a major concern of the department. Steadily and aggressively we fought this highly destructive disease, and finally, by 1978, we eradicated it. Only then did we discover that another disease, pseudorabies, was killing baby pigs in large numbers and causing reproduction problems. Perhaps a comprehensive survey might have alerted us.

Recently, I am sorry to say, Wisconsin lost its bovine TB-free status. The problem lay in several dairy herds among which livestock movements had occurred. The disease built up in incidence--without officials becoming aware for some time. I wonder, could a survey have helped us in spotting this earlier?

Establishment of the Leptospirosis Reference Center indicates our need in that area. What do you need to know, what should we know, about Johnes disease?

Both we in government, and the veterinary practitioner, need to know more about the total animal health picture. NADS is designed to provide just that.

We have started to develop NADS with pilot projects in Ohio and Tennessee. Twenty five veterinarians in each state, including some from the state universities, will be monitoring the total health picture on sample farms and livestock producing units. For two to three years they will develop and build up the methodology for assessing health conditions. Meanwhile we are preparing to go forward with other pilot projects in California, Montana, and Iowa.

I can think of few better investments in the future of animal health. In other agricultural areas, such as crop research and fertilizers, research has produced immense benefits. But to date, this is the first comprehensive look at the overall economic and physical picture of diseases as they affect our livestock and poultry.

The nation has an immense investment in its cattle industry. Beef is the staple meat protein of this country. Milk and other dairy products are basic to our diet. Yet nationwide, out of \$4.6 billion spent annually for veterinary services, 82 percent was on dogs, cats, other pets and horses. Bovine practice received 15.2 percent, or \$704,000,000-- not an insignificant figure.

But, if we have a large stake in the health of our nation's cattle, we certainly have a large stake in the veterinary treatment of those herds. I sincerely hope that animal health responsibilities of the government and the professional needs of the practicing veterinarian will move forward together.

We cannot succeed without a strong corps of veterinary practitioners. And 100 years ago a small cadre of government veterinarians started the work that continues today in support of the livestock industry. On the whole, I believe we have worked well together over the years. Great things are happening, and I look forward to working with you as we build on these solid foundations.