

This data can then be analysed to show the relationship, for example, between the use of a control program in an uncontrolled environment and the prevalence of mastitis.

Provided it is possible to collect enough data, under enough different circumstances it is possible to build a mathematical model from which results can be derived simply by stating the circumstances that prevail.

It is possible to use a new kind of statistics, and for aficionados I refer to Bayesian and neoclassical decision theory which can be used to select between two options in a much more realistic and predictive way than classical statistical analysis.

I have tried to set down the prerequisites for the practice of complex preventive veterinary medicine by bovine practitioners because this is where I think our future lies.

It includes the will on the part of the veterinarians, a suitable financial, technical and

sociological environment on the farms, and a planned package of performance.

I think that all of these prerequisites are, in general, present in our circumstances now. Preventive medicine in the form of herd health programs is already being practised, probably more extensively in this country than in any other.

Where these prerequisites are not already present, agriculture is either vastly underdeveloped or has an uncertain future, anyway.

Where they are present, preventive medicine will bring about major advances, especially if it is linked to a system of self-analysis which keeps it within the bounds of economic reality.

If we can do that, it will be appropriate for us to say at last that:

We have taken everything that science has to offer and turned it to the full advantage of the cattle owner. I can't imagine anything more satisfying than that.

The Bovine Practitioner and the Federal Veterinarian

Francis J. Mulhern, D. V.M., Administrator
Animal and Plant Health Inspection Service
Washington, D.C.

Thank you for inviting me to take part in your annual meeting. We have a few urgent factors that we feel need attention and I appreciate the opportunity of presenting them to you. There are five specific items, as a matter of fact.

1. How good are the biologics that you have available?
2. We better heed withdrawal instructions or we may lose some valuable tools to fight disease.
3. The profession needs to provide leadership in the evaluation of the pros and cons of the significance of chemicals used in our food supply.
4. A re-evaluation of our brucellosis eradication goals.
5. The bovine practitioners' role in emergency animal disease eradication programs.

How Good are the Biologics that You Use?

I have been in Washington since 1952 and during that time I have seen quite an evolution in the

licensing of veterinary biologics. At that time we had our personnel stationed in the establishments monitoring the operation. When we look at today's standards and compare them with them, we must admit that we didn't know too much about the quality of those products.

Many of these products came on the market a lone time before that, so we can say that back then we knew even less than we did in 1952. The product that we knew the most about was hog cholera since we had been producing some type of hog cholera product since 1913. However, I recall vividly that when I attended state veterinary association meetings a lot of conversation was about adverse reactions following vaccination.

It was not until 1930 that the first potency test for rabies vaccine was available. You all are familiar with the steps that followed. Remember at one time we felt that viruses could only be grown in the host animals. But soon we learned they could be grown in chick embryos, then tissue culture

techniques came along, etc. This paved the way for a rapid increase in the number of various types of biologics available.

As late as 1962 we had to rely on our monitoring within the establishment and all judgments had to be made on the basis of information furnished by the licensed manufacturer, or from academic sources, as we had no laboratory support for official evaluation of methods used by the industry.

Let me emphasize one point here. All during this time the veterinary biologics industry was trying to improve the quality of their products. In all honesty, we would have to admit that the caliber of their technical people involved in vaccine production was far better than ours. However, when we got our own laboratory at Ames, Iowa, in 1962, we began surveillance testing, assay development, and inspection coverage from there. We then required the producer to submit samples as well as test results for each batch of each product. During the past eleven years, we have acquired competent personnel and sent our old personnel back to get graduate work. As a result, our technical competence has greatly improved and we feel the quality of our service has likewise.

In 1963 more than 2,000 serials of various products were tested and as high as 10% were found unsatisfactory and the products withheld or withdrawn. As you might expect, there was quite a reaction from the industry. However, after many discussions, conferences, and visits to our laboratory, general accord was reached between their scientific personnel and our own.

For many years we had a Veterinary Biological Licenses Association that evaluated hog cholera serum and vaccine products. Since the Animal Health Institute (AHI) was organized, it has become part of that organization and AHI has set up several subcommittees to work out mutual problems involving many products.

At present, we are emphasizing the importance of host animal efficacy tests. Our staff is requiring proof of efficacy for new products, and host animal data on older products that were licensed without this proof. Our laboratories and the licensed producers are cooperating in experimental work with some of these older products to make sure they are both safe and effective.

Another area we are emphasizing is product purity—one aspect of product safety. Although cell culture of viruses has led to vastly improved virus vaccines, the process is not without its dangers. Both primary cells and cell lines may carry passenger viruses and so may the serums, trypsin,

and other ingredients of cell culture media. Only extensive testing can demonstrate freedom from hitchhiking agents. We have published a standard for testing cell lines and another for primary cells that soon will be adopted as a standard.

We have quite a problem with contamination of bovine virus vaccine with the virus of bovine virus diarrhea. A large percentage of fetal bovine kidneys used for virus growth carry this virus. Even when virus-free cell lines are used, the fetal or calf serum may be contaminated.

Fortunately, every serial of vaccine is tested by the producer for BVD and a heavy load of confirmatory testing is being carried out by our biologics laboratories. So the problem is serious to the producer and regulatory groups, but has been prevented from becoming a problem in the field.

We in a regulatory agency realize that some of our actions may cause delays in availability of new products, but we must apply our newer knowledge as it becomes available and what was good yesterday is not necessarily good enough for today.

We believe that you, the users of these biologics, and the cattle owner who pays for their application, must have confidence in the quality of the product being administered.

We Better Heed Withdrawal Warnings

We talk about changes that occur as new knowledge becomes available. Today we have a system we call objective monitoring of meat and poultry products. We are expected to test these products to see if there are any illegal residues present. Once we find residues then we go into a selective phase which means concentrating on the source to see if the residue problem can be eliminated. We are expected to look into areas where we are more likely to find residues if we have such leads. You may recall this is why we lost DES.

Not that I'm bragging about it, but a lot of our problems are that warnings have been ignored. I realize that lay people use these antibiotics and drugs, but you must use your influence to caution them.

We are just as concerned that we may lose the use of some of our better antibiotics. To date most of our testing reveals the levels are under tolerance accepted in downer cows or cows obviously with mastitis. Last year's survey showed one-fourth of the animals in these classes were over the tolerance levels. A similar survey of veal calves showed that one-tenth of this class was over the tolerance.

The wide practice of treating dry cows with high levels of antibiotics to eliminate or prevent udder infection is a potential source of high residues in

tissues of animals sold too soon after treatment. Unless label instructions on intramammary dry treatment products specify earlier release, cows should be held at least 30 days following treatment. Cows given intramuscular penicillin and dehydrostreptomycin should be held for 60 days.

The days of slugging them with an antibiotic and then getting them to market can be a costly recommendation. Also, the source of such animals is so easily traced today that whoever practices such techniques very often is identified.

Significance of Chemicals Used in Food Supply

Speaking of residues in our food supply, we are in somewhat of a crisis. Most of you are aware of the Delaney Clause that says that if a particular chemical is capable of causing cancer that no amount of it can exist in our food supply. When this came about, what most of us learned in college that dose/response relationship was necessary before a chemical could be judged a carcinogen has been discussed. Since then, we don't allow any chemical that is a potential carcinogen to be in our food supply.

Today's society does not know what to believe as they listen to extremists on both sides state their position. Like most issues, the true answer may be between the extremes.

Last week I attended a seminar at the Teachers of Meat Hygiene annual meeting in which both sides were expounded upon. It was very enlightening and I feel that the profession, and particularly this group, should use its influence to communicate the need to be objective on these issues.

President Handler of the National Academy of Sciences has chided the scientists that they have let the non-scientists take away the leadership they should have on these issues. I think we as a profession can make a real contribution by being fully informed on where we are and where we may be going on these issues.

A Re-evaluation of Brucellosis Eradication Program

Prior to the outbreak of VEE, the brucellosis eradication program was on track. Since then we have had an upsurge in hog cholera, an emergency in Newcastle disease, and an increase in the prevalence of fever ticks and cattle scabies. Thus, funds and people were diverted from the brucellosis program. This resulted in modification being taken that caused serious adverse effects to the eradication goals.

Our findings are that exposed animals are being moved back and forth and several clear areas have been reinfected as a result. We are not getting back

to infected herds frequently enough. In other words, we are not doing what we know needs to be done to reach the goal. We are calling a meeting of the industry to get the program back on track. This will be tightening the program nationwide. Emphasis will be placed on getting areas completely free and keeping them free. Vaccine will be used as long as it is needed.

The highest incidence of the disease remains in the Southeast. Also, the movement of exposed animals is the most prevalent there. Getting this program back on the track won't be easy and we will need your help.

Your Role in Our Emergency Animal Disease Programs

How would you like to be in my position and be aware that if we get a disease like foot-and-mouth disease that your organization will have to handle it? Then, you know that your inspectors are actually taking tons of meat from passengers' baggage that could be a source of introducing outbreaks—you know that you are not stopping all of it. Smuggling is always a problem.

You know that livestock people travel all over the world and could very easily bring the disease back with them. Since we have not had the disease since 1929, people have become complacent.

You know that if the disease enters and is identified in an isolated area it will be a miracle. You also know how vulnerable we are to marketing practices that can spread diseases nationwide almost overnight.

You also know that when these diseases enter, the agent can be attenuated thus atypical lesions are observed and can be overlooked as a domestic disease. You know that there aren't enough state and federal veterinarians to adequately find any outbreak in its early stages, so it is evident that if a disease like this does appear, a bovine practitioner may be the first to see it. There is nothing I know that can bring a person into the spotlight more than when a disease like this is first reported. Everybody wants to know how it was spotted, how soon was it diagnosed, and how did it get in.

You can't imagine how many people interviewed the veterinarian who saw the first case that occurred in Canada. It also became a political issue and it seemed to me as an observer that initially they were more interested in putting the finger on a fall guy than getting rid of the disease. This was also true when it occurred in Mexico, and it will happen here. **Therefore, let me stress a philosophy. Any symptoms that even closely resemble FMD or rinderpest should be checked out—it's just not**

worth overlooking. Contact your state or federal veterinarian and get him in on it.

Have you ever stopped to think what happens when a foreign disease like FMD is introduced? Its contagiousness is so great that the most practical solution is to freeze all movements of susceptible animals and man. Naturally this can't be done fully, but the extent to which it can must be put into effect until you know where you are. It can have a direct effect on your practice routine.

We have learned a great deal handling three emergencies in the last three years. We have an emergency organization that takes over the direction once the Secretary makes his declaration.

We have one plan to eradicate FMD with a slaughter program if its feasible. If the disease is widespread, we will have a backup program that includes vaccination. The conditions could warrant the need to vaccinate 10 to 40 million animals a month. We need to determine what role you would play. I would suggest that your regulatory committee should work closely with our emergency unit so that an effective plan can be established.

When these foreign diseases are introduced, it is essential that our profession be unified in its support of what is being done to combat them. This is more apt to occur when there is adequate planning and when the majority of us are fully informed.

It should be obvious to all why I was pleased to accept this opportunity to put some of the problems I see before your organization. I believe if there is one group in this country that can do something effective about all these problems that yours can.

In summary, we have a highly reputable biologics industry that is trying to produce safe and effective products. We, as a regulatory group, require very high standards to be met. In order to assure that we have data to substantiate that the products are safe and effective, some old products will undoubtedly not be available. Newer products may be slower in coming.

Withdrawal periods following use of antibiotics must be adhered to or we will find their use restricted.

We have a responsibility to communicate to the layman both sides of the issue relative to chemicals in our food supply. We are not going to be poisoned or wiped out because they are being used but, on the other hand, we need to be aware of the realistic harm that can occur from some of their uses.

Look for a tightening up of regulatory and

program requirements in the brucellosis eradication program.

Finally, you have a real stake in any emergency program to diagnose and eliminate foreign animal diseases should they appear. Your practices are going to be affected if a disease is introduced. Your organization should get involved in the planning that is underway to combat these diseases should they appear. The time to do it is now when we don't have a crisis. We need you and you need us if we are going to effectively protect the meat and poultry supply of this country from the ravages of animal disease.

**THE RITCHEY
EAR TAG***



★NOW
IN OUR
8TH YEAR

FOR CATTLE, SHEEP, SWINE, GOATS
One piece flexible ear tag with a functional design so clean it eliminates the major reasons ear tags come out.

- Made of finest materials available.
- Write on numbers, brands, codes, etc., with paint applicator.
- Paint (not ink) developed and formulated by our company. Tested for five years. Guaranteed for life of tag.
- Installing tool — one piece stainless steel about the size of pocket knife.
- Unbelievable stay ability.

WRITE FOR FREE SAMPLE:
RITCHEY MANUFACTURING CO.
Dept. N ● Route 3 ● Box 58
BRIGHTON, COLORADO 80601
Phone: (303) 659-0681