SECTION I

CLINICAL TRIALS--THE ISSUES

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POTENTIAL ROLE OF THE VETERINARY MEDICAL TEACHING HOSPITALS IN THE EVALUATION OF NEW DRUGS

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During a program concerned with problems of drug evaluation in animal patients,[1] D. G. Low stated the following:

> "A real need exists for establishing drug evaluation centers to bring personnel, case material, facilities, and equipment together for the specific purpose of evaluating drugs. Such a center should be associated with a university veterinary teaching hospital, even though this may require building some additional space to house the drug evaluation unit. The advantage to the drug industry and FDA are immediately apparent. Of added benefit would be the excellent graduate training program in clinical investigation this facility could provide. There should be several similar units established in different geographic areas of the United States. Such a program would go far in providing the training opportunities in clinical pharmacology so badly needed today, while at the same time providing the most reliable drug evaluation anywhere by a group totally dedicated to and trained for the task at hand. Fewer treated cases would be needed in most instances because many pitfalls associated with non-adherence to protocol, poor recording, poor reporting, inadequate records, and unreliable laboratory results would be eliminated."

> "The presence of drug evaluation centers would not preclude utilizing existing drug evaluation arrangements where they are adequate, but it provides for a method of meeting the more demanding testing protocols. Support for the center should be shared by the university involved, the drug industry, and FDA. The cooperative effort could do much to improve evaluation of the potent chemicals available for therapy today."

This was an excellent suggestion which has never been implemented, and the need is as real today as it was ten years ago. The feasibility of establishing such centers in the United States should be studied by a committee composed of Fellows of the A.A.V.P.T. representing industry, the CVM, and academia.

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The veterinary medical teaching hospitals (VMTH) and institutions, such as Animal Medical Center in New York City and Angell Memorial Hospital in Boston, represent a national resource for veterinary clinical investigation of therapeutic agents. Presently, this environment which brings together sick animals, trained veterinary specialists, and excellent physical facilities is virtually unused as a setting for the evaluation of safety and efficacy of new drugs. This is unfortunate because the utilization of presently existing expertise and facilities for the conduct of such evaluation could have a number of salutory effects. It would provide impetus for the training of veterinary specialists in the science and art of evaluating drugs in animal patients, for the exploration and development of better methodology for non-destructive testing of new drugs, and for the critical and objective appraisal of the role of drug therapy in clinical management of various diseases of animals.

The number of animal patients seen annually at the VMTHs exceeds 0.5 million (Table 1). To this number can be added the thousands of small animal accessions of AMC and Angell Memorial Hospital. Most all of these institutions have active research programs, together with excellent support facilities--such as clinical pathology, histopathology, radiology, and nuclear medicine--and in a few cases laboratories for therapeutic drug monitoring, clinical microbiology, and clinical immunology. With proper leadership and financial support, these already existing capabilities could be brought to bear on the important problems surrounding the clinical investigation of drugs. The best example of the efficacy of this type of approach is the development of the field of veterinary anesthesiology over the past twenty years. Today this is a well-recognized specialty which carries out, in cooperation with industry, the clinical evaluation of new anesthetic and analgesic products. It is apparent that the clinical investigations conducted by anesthesiologists have produced a degree of sophistication in the practice of anesthesia and methodologies for clinical investigation of anesthetics that could not have been imagined twenty years ago. Much of the success of this effort may be attributed to the application of a scientific approach to the practical problems arising within the milieu of the VMTH.

For the potential value of the VMTHs in the drug evaluation process to be realized, there are several obstacles that first must be overcome. There must be a general understanding among the clinical staff regarding utilization of patients in investigations. Frequently, this is a thorny issue which, if not resolved, can obviate the fulfillment of a study protocol. Although drug evaluation studies should be coordinated by the clinical pharmacology unit of the hospital, the clinical staff must feel that they are active participants and that there exists some personal advantage in their participation (publications, research support, etc.). The clinical investigations should be structured in such a way that they present an intellectual challenge rather than simply being regarded as "busy work." The universities involved in such studies need to examine their policies concerning charges for indirect costs. This appears to be

Table 1. Number of Accessions of Veterinary Medical Teaching Hospitals in United States -- 1982

School	Caseload		
	L.A.	S.A.	Ambulatory
Auburn	5,074	10,150	21,645
California	10,930	20,112	Given in L.A.
Colorado	3,355	16,362	--
Cornell	2,945	14,051	--
Florida	1,942	10,860	942
Georgia	ND	ND	ND
Illinois	2,630	12,000	20,613
Iowa	5,390	9,592	--
Kansas	7,370	15,601	26,454
Louisiana	1,812	7,351	11,244
Michigan	2,378	14,734	2,822
Minnesota	1,742	8,606	--
Mississippi	14,416	1,707	--
Missouri	ND	ND	ND
N. Carolina	ND	ND	ND
Ohio	3,941	19,687	--
Oklahoma	3,305	7,547	12,978
Oregon	ND	ND	ND
Pennsylvania	8,373	18,900	00
Purdue	3,240	6,234	35,048
Tennessee	ND	ND	ND
Texas	37,209	10,817	--
Tufts	ND	ND	ND
Tuskegee	1,143	4,379	503
Virginia	ND	ND	ND
Washington	2,160	6,664	87,719
Wisconsin	ND	ND	ND
TOTALS	119,360	215,355	219,968

ND -- No data were available.
Source: Council on Education, A.V.M.A.

a major disincentive for industry to utilize academic settings for the conduct of drug evaluations.

In summary, the veterinary medical teaching hospitals in the United States could serve as potentially excellent centers for the evaluation of new animal drugs. The feasibility of their serving such a role should be studied by a committee appointed within the American Academy of Veterinary Pharmacology and Therapeutics.

REFERENCES

1. Low DG: Evaluation of therapy in small animals. In Davis LE, Faulkner LC (eds): Pharmacology in the Animal Health Sector. Colorado State University Press, Fort Collins, 1976, pp 329-332.