



10th February 2018

Dear Dr. David Banasiak

Thank you for the opportunity to respond to the questions of the Development of New Specialities committee of the American Board of Veterinary Specialties. We will respond to each question (shown in italics) - in the order presented to us and look forward to the review in March.

1. Resident training.

a. Given the diverse approaches to herbal medicine currently being practiced by veterinarians (for example, Chinese Traditional Herbal Medicine, Western Traditional Herbal Medicine, and variations of Western contemporary herbal medicine), will ACVBM integrate these different approaches into training programs? If so, how? And how will certification by the ACVBM reflect those different approaches as it was not clear from the results of the Job Task Analysis. For example, is it the intent that individuals will master and be certified in all approaches to herbal medicine, or does the ACVBM intend to have certifications specific to each approach to herbal medicine?

ACVBM believes all Diplomates should have a common knowledge base grounded in biomedical aspects of botanical medicine based on science and published research. Candidates are examined in Part 1 is Section I on a General botanical medicine section (all candidates are required to take this section) which covers pharmacognosy, principles, phytochemistry and pharmacology as well as issues around manufacture, quality and safety. This will be mapped to the job tasks such as Providing treatment: Know species specific pharmacology; Know pharmacological actions of herbs (pharmacognosy) - vs pharmaceutical drugs; Know herbal energetics; Know herb use based on research; Know how to integrate herbal medicine with conventional medicine. The exam questions will incorporate the actions and constituents of herbs common to the various traditions, as well as those that are readily available and known to the public such as *Zingiber officinalis*, *Allium sativa*, *Cinnamon sp.*, *Zizyphus spinosa*, *Crataegus sp.*, *Salvia miltiorrhiza*, *Aloe vera*, *Ginkgo biloba*, *Mentha piperita*, *Astragalus membraneous*, *Panax ginseng*, *Foeniculum vulgare*, *Rehmannia glutinosa*. This part of the exam will also cover herbs such as kava, medical cannabis, neem and other herbs which all Diplomates should be able to answer questions on, even if they don't prescribe them. A complete list of herbs about which candidates are expected to be knowledgeable will be provided. There are sub-committee members with expertise for Western botanical medicine and for Chinese botanical medicine. The two committees contribute equally to the general portion.

The second section of the examination is focused on a specific botanical medicine category. We have adopted this approach based on the ACVSMR and ACVN model. The college will use a core exam (Part 1) that tests knowledge across herbs common to all botanical medicine categories (Western or Chinese) then in Part 2, instead of focusing on species we will focus on a choice of system, Chinese or Western. This Part 2 then covers: Section II History and Philosophy pertaining to chosen botanical medicine category; Contemporary herbal medicine issues (residues, conservation, safety); Herb Drug Interactions; Botanical medicine mechanisms of action; Herbal Therapeutics across all systems; Materia medica (the plant properties and use) knowledge; Section III Veterinary botanical medicine for equine, production and small animals covering current research and case based application across species and conditions and Section IV Botanical identification of 20 medicinal plants for that category or system of botanical medicine.

The proportion of exam questions in each section will be distributed based on the job description and a detailed outline of Topics that will be examined will be provided to Candidates.

Therefore we expect the Diplomate to be a Master of at least one category. Candidates will be expected to choose their category of interest to undertake intense training utilising the principles and practices of the chosen system however the job tasks are essentially the same when using botanical medicine in veterinary practice. How those herbs are chosen and prescribed does vary and this is examined in Part 2 of the exam. However, candidates should also be a generalist on veterinary botanical medicine as examined in the General botanical medicine section: they must be familiar with popular herbs utilised by the public and known to veterinarians more broadly. The ACVBM residency Clinical Training requirement consists of a minimum of 60 weeks immersion in botanical medicine practice, which is supervised by the Primary Advisor or a co-advisor.

We would not require that a Diplomate who passes the test specify that their certification was in a specific type of herbal medicine, but they certainly can do so if they primarily use one type.

b. As noted in the petition, multiple training sites offer certification in herbal (including veterinary) medicine. Some are (or are becoming) accredited. The ABVS is seeking clarification as to how persons that successfully complete these programs might seek certification in the ACVBM.

We wish to clarify that the “certification” courses currently available are continuing education courses for veterinarians that provide a basic to advanced level of education in botanical medicine and in no way reflect the training undertaken in a residency program where we expect candidates to become specialists. Those “certification” courses would NOT be used to create “Diplomates”.

We expect the pool of currently “certified” veterinarians to provide a source of residents wanting to undertake the Diplomate training. As such we would recognise they may come into the program with a level of expertise and experience.

One of the requirements for the residency training consists of 24 weeks of independent study on topics related to botanical medicine or independent immersion in botanical medicine

practice. Residents can choose an existing “certified” herbal training program under the supervision of the Primary Advisor. A “certification” of herbal medicine will be considered as Independent study. 40 CE hours of the existing certified herbal training program will be calculated as one week of ACVBM independent study.

Those that may have already undertaken “Certification” in their chosen category of botanical medicine may wish to undertake continuing education in another botanical medicine field in order to broaden their knowledge of General botanical medicine. Or they may choose to undertake other education in a related field such as in-depth pharmacognosy or botany with negotiation and the agreement of their supervisor.

c. Multiple Colleges of Veterinary Medicine have expressed, through letters of support, a willingness to support veterinary herbal medicine residency programs at their institution. However, given the increasing competition for increasingly limited funds, the actual implementation of these programs is questionable. Can the petitioners address this concern? Further, can the petitioners document that sufficient diplomates will exist at academic training sites such that residents can be supported?

There are two questions to be answered here.

First, funding. The residency program at the College of Veterinary Medicine (CVM) will primarily be self-funded by the income from clinical cases. The caseload is important. As long as there are enough cases in a CVM Veterinary Medical Teaching Hospital (VMTH), a primary advisor will generate enough revenue to fund a residency.

We may also seek support from some companies and funds for sponsoring programs until we can show that the service is of financial benefit to schools. The possibility of dual residency programs has also been raised eliminating the need for expansive funding from colleges. Private integrative practices are already generating revenue from veterinarians with this expertise. Finally specialties might not generate significant revenue for schools but yet still be funded because they are unique or add value to the overall services. As an example the Integrative Medicine Service at the University of Florida has been self-funding the Sports Medicine Residency programs. Since there are strong demands from the public for botanical medical care, ACVBM believes that the residency program will be self-funded as well.

The second question is concerning the availability of Diplomates such that residents can be supported. This is a concern for this college because there will be fewer initial Diplomats in academic positions than in other colleges. We have already identified founding members in academic positions that are willing to start a training program right away. We also have letters of support from Diplomates who also have herbal training who are willing to support residents in private practice and at Colleges. Our founding members have the opportunity to undertake the exam provided they meet the criteria for Diplomate status we have set. We would also consider an initial applicant path for a few years that allows veterinarians that weren't founders but otherwise qualified to sit the exam to do so without a residency. We anticipate that this would expand numbers quickly; however we still only anticipate a handful of residency programs similar to the ACVSMR and Nutrition programs. With a larger number of Diplomates we would expect that this may influence the interest in residency programs moving through the Veterinary Colleges that at least offer Integrative services and certainly the private Specialty practices that already offer these services.

d. Is there a mechanism to bridge those (non-CVM affiliated) programs already offering certification with the criteria for residency training such that the opportunities for residency training might be increased?

Thank you for raising this question. We had initially focused on younger veterinarians wishing to undertake training from the beginning. However there is a large body of veterinarians who have already undertaken herbal training. The rigorousness of assessment for these programs and the supervision and development of practice time is not the same as the Diplomate program. Assessment is usually by way of examination and cases; however there is no specific monitoring or logging of practical experience or direct supervision in most courses. Therefore it is expected that graduates of these continuing education programs graduate with the basic skills and knowledge. This would be recognised as contributing to the Independent study requirement. We have yet to ascertain the currency of such courses, whether we would need to consider that those courses would have to be undertaken within a set time frame to be considered current and therefore eligible to contribute to the Independent Study requirement, or leave it to the Primary Supervisor to judge based on the course, outcomes, and currency. However we would certainly promote the availability of the Diplomate program to veterinarians in those courses as a potential pipeline of candidates.

e. Graduate training is listed as required for residency training. Can you verify that a sufficient number of graduate courses will be offered at various residency training sites to meet this requirement? Also, can you clarify what role continuing education (as required in the annual evaluation form) is to play in residency training?

Graduate training is not required for the ACVBM residency training. However, for the Formal Study, residents must undertake graduate-level continuing education training in Botanical Medicine. In other words, as long as these courses are related such as pharmacognosy, plant pharmacology, medical botany, plant toxicology and are at graduate level (not undergraduate courses), they will be appropriate for this requirement. It is not a requirement that the course be undertaken at their own site; the primary supervisor will assist the candidate with selection of courses which might also be delivered online, in which case the choice of courses increases.

2. Quality of products upon which ACVBM will be based.

a. As a result of DSHEA (1994), human herbal products are minimally regulated (GRAS criteria). Animal “dietary supplements” do not fall under DSHEA but are minimally regulated. How will confidence in these products be addressed in the implementation of patient care provided by ACVBM diplomates? What role does ACVBM envision it will have in addressing the lack of regulation and thus quality of products used and/or promoted by its diplomates?

One of the advantages of having a program to educate veterinarians in herbal medicine is to provide them with the knowledge of the regulatory frameworks for the companies they want to work with and a set of questions to ask to qualify the quality of their products.

A well-constructed education program can help veterinarians develop their own Vendor Qualification Questionnaire which should contain questions such as:

- Under which regulatory category is your product labeled for distribution?
- Is your company compliant with all applicable regulations?

- Is your company registered with the FDA? If not, why not?
- Do you/does your manufacturer have a Quality Control System? How do you handle:
 - o Testing Raw Material Identity
 - o Heavy Metals
 - o Micro Activity
 - o Pesticides Policy
- Has your company been inspected by the FDA? When?
- Are you a member of any Trade Associations?
- How long have you been in business?
- Is your company recording Adverse Events that occur with Animals?

With respect to Dietary Supplements, which under the US regulatory system is a term that applies only to Dietary Supplements for humans, it is important to note that they are not just regulated by Dietary Supplement Health and Education Act of 1994. There are also regulatory requirements for Facility Registration under the Bioterrorism Act of 2002. And the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding requirements for adverse event reporting and record keeping for dietary supplements and non-prescription drugs marketed without an approved application. It is the combination of these 3 Acts and their attendant regulations that give the FDA the ability to identify companies who they regulate, through inspection to correct any regulatory issues and identify any problem products in the industry. This is relevant for veterinarians sourcing high quality herbs from human herb suppliers.

The regulations developed for compliance with the Dietary Supplement Health and Education Act of 1994 are not minimal. There are certain requirements for products in the market prior to 1994. These regulations are quite strict and center on the confirmation of raw material identity, elimination of any adulterants or contaminants and consistency in manufacturing. A documented Quality Control System with specifications and master manufacturing procedures, personnel training, equipment and facility cleanliness, recording of customer complaints and adverse events are required. Regulations for label claims that must be filed with the FDA within 30 days of making such claims, limit the scope of what can be said about the product to how it affects the structure and function of a body. Such claims require research backup to be kept on file. Any product introduced for sale in the market after 1994 must submit a New Dietary Ingredient Application for approval by the FDA which must include the documented history of use or other evidence of safety. In addition, there are several trade associations that add Trade Recommendations, which must be complied with to maintain a membership.

Products labeled for animal use are under a completely different regulatory framework. They are either regulated as drugs by the FDA or as Foods which must comply with federal and state laws, guidance for such compliance can be found in documents provided by AAFCO (the Association of American Feed Control Officials.) The National Animal Supplements Council (NASC) trade organization provides its members with an audited, self-regulatory framework that includes a Documented Quality Control System, definition of claims to mirror those allowed with human dietary supplements, adverse event reporting and recommends animal drug registration with the FDA.

Currently all imported products or ingredients being sold in quantity to veterinarians are subject to intense FDA scrutiny – much more than is applied to products manufactured in the USA from USA ingredients. Products are screened for contaminants, and labels reviewed for misleading claims and disallowed ingredients, on an ongoing basis. Companies manufacturing within the US have the option to join the NASC. Membership which entails an audit process, and which requires demonstration of compliance with Good Manufacturing Processes (GMP) practices (similar to the pharmaceutical industry). An example is the use of mass spectrophotometry and thin layer chromatography to demonstrate appropriate levels of active ingredients as one part of the process. Reputable companies often fully disclose details of their own quality assurance programs on their websites, and are thus easily identified as useful resources by college members.

It should be noted that many pet food companies that veterinarians rely upon receive no more regulation from the FDA than what is detailed above. Additionally efficacy of therapy is not determined by the FDA, but is determined post-market based on treatment outcomes. When a product or approach is consistently rewarding for similar cases, this is directly suggestive of product consistency across batches, and by extension suggests a high level of quality control for that manufacturer. Naturally it is these more reliable products and methods that will form the core of any education imparted to college members, however as a College we do not advocate any specific brands or products in order to remain impartial.

The ACVBM and its Diplomates will play a role in encouraging veterinarians using herbs to ask the important questions, to report adverse events and to work with companies to improve quality where it matters to safety in particular and also work with industry such as NASC to improve regulation. Having a College and Diplomates will raise the profile of botanical medicine, and improve safety by giving the public and veterinarians a source for referral and advice other than Dr Google and the thousands of websites selling uncontrolled herbs.

b. The practice of veterinary herbal medicine is vitally interfaced with nutrition (diet), clinical pharmacology (acute versus chronic therapy, for example), toxicology and acupuncture (particularly traditional Chinese herbal Medicine). Can the ACVBM address how the training of their residents and the activities of their diplomates might interface with these colleges? This might also impact the requirement of 30 hours of continuing education/year in herbal medicine. What opportunities will ACVBM diplomates have to facilitate this collaboration?

Note that at this time we are not familiar with the College of acupuncture although we are aware there was a petition to form a College. Traditional Chinese herbal medicine would fall under our new American College of Veterinary Botanical Medicine.

The ACVBM looks forward to the opportunity to be recognised as a source of expertise in botanical medicine which we strongly believe has the potential to substantially improve animal health. With the challenges we face in both human and animal medicine it is in fact imperative we collaborate in particular with clinical pharmacology where many of our current drugs face limited use and we need new solutions for treating diseases like antibiotic-resistant infections. We also need to enhance general veterinary knowledge about herbs, considering the growth in popularity and ease at which animal owners can obtain and use them. This is critical for animal health and welfare as self-directed treatment by owners becomes a bigger trend. We already have one Diplomat boarded in nutrition who has expertise in botanical

medicine. We expect this to be a potential area of interest to collaborate on functional benefits of botanicals in pet foods. Most veterinarians are familiar with plant toxicology and view many common weeds as potentially poisonous. Diplomates in botanical medicine can collaborate with toxicologists and together provide distinctions in the way the plants can be both poisons and medicines depending on dose in order to assist in the education of veterinarians. A classic example is *Hypericum perforatum*, which we learn at veterinary College to be a photosensitizing plant, with the potential to cause serious adverse effects in livestock. As a botanical medicine it is best known for the treatment of mild depression in people however research supports its benefits in treating neuralgias, nerve injuries, spinal cord injury and pain.

Residents under the guidance of their Supervisor can elect to spend time with Diplomates in the fields of Nutrition, Toxicology and Clinical Pharmacology. Our current proposed Residency Program, already submitted has placed Clinical Pharmacology and Nutrition at the top of the list. It states:

B. Specialty Rotations Training

This requirement consists of **16 weeks** of immersion in specialty veterinary practice, as negotiated with Primary Advisor in 4 or more specialties (2 or more weeks per specialty) including but not limited to the following areas:.

- Clinical Pharmacology
- Nutrition
- Internal Medicine in general (equine, canine, or feline)
- Internal Medicine in oncology
- Internal Medicine in cardiology
- Internal Medicine in neurology
- Veterinary Exotics
- Veterinary rehabilitation
- Veterinary Behavior
- Theriogenology
- Veterinary Dermatology

ACVBM Diplomates can help facilitate the interface of botanical medicine with the various Colleges through raising the profile of the College, participation in meetings and conferences, encouraging residents to attend the same, and becoming an active part of the community of Diplomates from all fields. We expect there are opportunities we haven't even recognized yet, however it will also be vital for the existing Colleges to be open to what we have to offer. We are very excited to be able to contribute to our profession.

3. Other

Several other less important issues:

a. The petition refers to case reports and a medical log. Can you clarify if both are required? Does the "medical log" need further description?

Both are required. The medical log is basically an appointment book providing evidence of appointments seen and time spent with each. It is used to verify total hours spent seeing herbal cases. A case report is a complete write-up of an individual case, in a manner suitable for publication.

b. The petition indicates that certificates will not be time stamped, but AVBS policies and procedures do require time stamping of certificates (maximum of 10 years).

Certificates will be time stamped in order to ensure that Diplomates are keeping up with current advances in their field of expertise. The time will be 8 years.

On behalf of the ACVBM we welcome any further questions prior to our meeting in March.

Yours sincerely

Dr Cynthia Lankenau
Secretary ACVBM.