14th November 2017

Dear David

Thank for your letter of 13th September. We were delighted to hear there was a generally positive response to our petition and would like to respond to the important concerns and criticisms raised by those opposed.

1) **Concern 1**: Botanical medicine does not represent a distinct and identifiable specialty of veterinary medicine.

   We appreciate the specific issues raised and have addressed these throughout the petition. We believe we have made it clear that food, petfood, diet and nutrition belong to the realm of the ACVN. We did not intend to overstep the mark in the first submission but show ways we might work together. In the same way we have attempted to show how we can work together with other Colleges- in a cross disciplinary way. There is overlap, and we agree specialty diplomats are incorporating botanical supplements where scientific evidence supports their use albeit in a relatively limited way or for specific conditions. The ACVBM believes we can provide information and experience to expand treatment options for the reasons these type of supplements are sought.

   In the updated petition we have specifically addressed the major concern 1) above. Veterinary botanical medicine is a distinct discipline that differs in substance, methodology and philosophy from conventional veterinary medicine. We have emphasized the differences in pages 3 to 8 of the petition.

   Importantly we view the field of Veterinary botanical medicine as separate from pharmacology even though there is a phytopharmacological basis. While botanical medicines are therapeutic they are not used in the same way we use drugs- a drug for a particular diagnosis. Botanical medicine is a patient centered approach, rather than a specific herb for a specific condition and patients with the same diagnosis may be treated with different botanical medicines depending on their individual needs as well as their diagnosis. This is discussed in detail in the petition.

   We also recognize that the field of pharmacognosy exists under Pharmacology and respect that distinction. We have defined the role of pharmacognosy in veterinary botanical medicine and emphasized the point that veterinary herbalists do not generally use single active constituents, but rather whole herbs. We utilize the science of pharmacognosy to appreciate the phytopharmacology of whole plants. By the same token, plants that are viewed as toxic in the field of toxicology, may be significant medicines when used at safe doses, an example is *Hypericum perforatum*.

The results of the job task analysis conducted August to October this year are found under Appendix 6 under Job Task Analysis.

2) **Concern 2**. The veterinary interest in botanical medicine cited in the petition is overstated.

The concern highlighted is that the petition included lecture titles, which might indicate advocacy of herbal medicine. We wish to state that the intention was not to highlight advocacy or to demonstrate demand for herbal medicine by those speakers but to highlight interest- and the petition clearly says:

A Sample of Conference titles by Diplomates or academics in the last 5 years that have herbal therapies included in the speakers proceedings.

None the less we have removed all references to the ABVP. And to reiterate we have not suggested there is a demand for botanical CE at AVBP or ACVIM meetings. Simply that proceedings include reference to herbal therapies, indicating interest.

We will state the support from the profession for the petition indicates some interest from veterinarians whether positive or negative.

We have emphasized how the ACVBM will serve a clearly defined need within the veterinary profession on pages 19 to 21. The ACVBM and its Diplomates can serve the profession by acting as a resource for education, information and guidelines for the veterinary profession. We recognize that like Clinical Nutrition and Clinical Pharmacology, Botanical Medicine may be employed by any other practice area, but not to its fullest safety and efficacy potential.

3) **Concern 3**. Veterinary Botanical Medicine is not supported by a basis of scientific knowledge and practice that is acceptable to the profession.

We believe that our Petition appropriately states the current state of play of the science that underpins veterinary botanical medicine. We specifically excluded preclinical studies and phytochemical studies from the petition. The profession has responded to the first petition overall positively and we suggest that the submission of journal article examples; a review of published journal articles in mainstream veterinary journals pertaining to veterinary botanical medicines; as hundreds of abstracts, again in recognized veterinary journals- is a substantial basis for recognizing the potential of veterinary botanical medicine. The volume of publications is comparable with other Colleges forming in their infancy. We expect the volume to increase with support for the College's recognition and one of the reasons we advocate for the formation of this Specialty.

The ACVBM acknowledges the concerns regarding the scientific basis of veterinary botanical medicine. The comment has been made that the published scientific and clinical data supporting the overall safety and benefits of many plant medicines, could be dismissed as questionable- having methodological bias and thus being of inferior quality to trials conducted on conventional drugs. It is important to note that the journal articles and abstracts presented in the petition were derived from mainstream veterinary journals.

At the same time, we agree that published research needs to be critiqued. A quantitative assessment of the reporting of herbal medicine research outlined suggestions for improvements recognizing publication bias and incomplete reporting of outcomes[1]. However to be fair, this is also the case for clinical trials generally. In veterinary medicine for example- a review of 97 clinical trials uncovered a need for more high-quality studies [2]. And more recently a cross sectional study of veterinary randomized controlled trials of pharmaceutical interventions funded by different sources suggested that findings may be affected by the source of the funding and that some RCT's provide a weak evidence base and targeted strategies are needed to improve the quality of veterinary RTCs to ensure there is reliable evidence on which to base clinical decisions[3]. So this is an issue common to both herbal and veterinary research. However to reiterate, the studies provided in the petition are from mainstream veterinary journals.

We do not believe we have over stated the science. We started by saying there are there are over 143000 published journal articles on plant extracts of which there are over 7000 Systematic Reviews or reviews. Further, over the last 15 years there has been an increasing publication of research on plant extracts in animals, with more than 10000 studies published from 2010 to 2014 alone. This demonstrates the emerging and substantial research being undertaken on plants in medicine. Animal models are an important source of information on toxicology, safety and phytochemistry. Veterinary Botanical Medicine draws on such resources to inform rational phytotherapy. However we discussed in some detail specific examples of research in various species and cited over 70 veterinary and allied journals that have published studies on botanical medicines in the petition.

We believe there is a strong and rational basis for veterinary botanical medicine as a distinct and scientifically based discipline. It is true that preclinical research doesn't always translate into a treatment benefit once evaluated in people or animals. But there are substantial studies now in people using double blinded RCT studies -over 3500 such studies. We agree there are too few in veterinary medicine comparatively, but just because that research isn't available, does not mean there isn't a rational basis nor scientific research that can be drawn upon for clinical decision making -supporting evidence based medicine.

Exam test question examples have been provided under Appendix VI Outline of Proposed Examination. These would need to be validated and would not be included in the examination because of public availability in the exam.

4) **Concern 4.** The lack of regulation and scientific evidence will negatively impact public safety and not result in improved veterinary medical services to the public.

The legitimate concerns of correspondents to the petition highlight the very reason why there should be an ACVBM. Until there is appropriate regulation, practitioners are much better placed to

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[1] Naumann K[1]. A Quantitative Assessment of the Reporting Quality of Herbal Medicine Research: The Road to Improvement. J Altern Complement Med. 2017 Sep 15.

[2] Brown DC[1]. Control of selection bias in parallel-group controlled clinical trials in dogs and cats: 97 trials (2000-2005). J Am Vet Med Assoc. 2006 Sep 15;229(6):990-3.

[3] Wareham KJ[1], Hyde RM[1], Grindlay D[2], Brennan ML[1], Dean RS[3].Sample size and number of outcome measures of veterinary randomised controlled trials of pharmaceutical interventions funded by different sources, a cross-sectional study. BMC Vet Res. 2017 Oct 4;13(1):295.

evaluate the safety of a product than the general public. There are ways and means of establishing quality and reliability of botanical medicines. We emphasize the importance of the veterinary profession supporting animal health with botanical medicine rather than the general public seeking advice and products via the internet or non-veterinarians.

Were veterinarians in a position of having absolutely no knowledge of herbal medicine, the absence of a veterinary botanical medicine college that could provide safe answers to the public might be excusable; but now that veterinarians have discovered botanical medicines that safeguard animal well-being while responsibly filling a demonstrated public need, we strongly suggest the veterinary profession has an obligation to provide such a college, where the needs of the public and their animals can be prioritized.

Safety of patients is paramount. There is a comment on the interaction of herbs with anesthetics and analgesics- we know there are interactions with all drugs. This is exactly the area that the ACVBM can advise upon, having knowledge and experience in utilizing botanical medicines with drugs means risks can be mitigated and potential side effects from drugs alleviated.

While the AMA does not recognize a similar specialty, this should not be a reason to suggest that the ACVBM has less rigor and less care than human medicine. We are in a unique situation as veterinarians being trained across species and having the ability to evaluate and critique information and applicability to medicine. Conventional veterinary medicine frequently requires us to consider the use drugs off label and where no research has been conducted. A cautious approach has been taken by the ACVBM, and there is a cumulative several hundred years of experience in the group to be able to guide safe use. Most practitioners of botanical medicine use consistent, quality products where issues around safety have been evaluated. It is the pet or stock owner that goes unguided to the internet and even the veterinarians who sends a client to the health food store to buy a herb that puts the patient at potential risk.

The ACVBM can help guide policy and regulation and advise on appropriate use of botanical medicines based on product quality, efficacy and safety. Currently members of the ACVBM have been involved in product development, research and regulation, and with the College accepted by the Profession, this will give more strength to the profession's involvement in ensuring animal safety from an informed perspective.

Finally under this concern, there is a comment that there doesn’t appear to be a core charter of diplomates with the expertise to guide this group. We have purposefully excluded having Charter Diplomates. However we have 8 Diplomates on our organizing committee that will work with the rest of the committee towards the development of new evidence based knowledge. One Diplomate is already involved in a multicenter clinical trial of a botanical formula through specialty practices.

A number of the organizing committee will present their credentials and undertake the first examination proposed for 2018, should the College be approved. This will help us to determine the pass rate for the examination and to build our Diplomate base as has been done with other RVOs establishing themselves in the first instance.

5) **Concern 5**. The training , education and experience requirements are not sufficiently robust to ensure mastery of an evidence based and scientifically sound body of knowledge that is the basis of a specialty.

   The Residency Program in this resubmission has been developed over the past year with support of the Diplomates on our organizing committee- and has preempted some of the comments received. We believe our current program addresses the concerns outlined in your letter.

   Specifically the residency requirements, activities and supervision are detailed in Appendix 4. including rotations and a minimum of 3 years training. There are no non-veterinarians involved. We have no intention of churning out Diplomates as suggested by one correspondent. We appreciate the rigor and the responsibility we have to have as a College.

   We have provided evidence that facilities and programs are available for advanced training that will lead to certification should the ACVBM be approved. Those letters of support are found under Appendix III.

   We have removed any references to training/ examination beyond botanical medicine which was inadvertent in the first submission.

   An index has been provided to the Petition and to the Appendixes.

   We look forward to your consideration. We appreciate it is a huge volume to consider.

Regards,

Dr. Cynthia Lankenau
Secretary, American College Veterinary Botanical Medicine

1) The lack of regulation and scientific evidence will negatively impact public safety and not result in improved veterinary medical services to the public.

   Another serious concern is that a large number of botanicals can be purchased by import from countries without stringent quality control measures to prevent contamination or ensure adequate levels of the botanic itself with the product. Until these products are regulated by the Food and Drug Administration with consistency and regularity, we are concerned about the overall safety of these products without further scientific review and regulatory oversight.

   A concern that we believe must be addressed in the application for specialty status by the ACVBM is that the strength and purity of herbal compounds are not rigorously certified, raising the potential for dosing errors, contamination with deleterious substances and errors in formulation. The use of herbal agents may delay more evidence-based medical care to patients sometimes adversely affecting case outcomes.

   The potential interaction of botanicals with recognized anesthetic and analgesic drugs and the lack of knowledge as to their mechanism of actions and side effects, when administered to veterinary patients, poses a medical risk to the patients as well as liability risks to the professionals who care for them.

   As a veterinary nutritionist, I am aware of the interest from the general public for herbal medicine but the evidence for most of these practices is not yet strong enough to warrant a specialty college. In addition to lack of evidence for efficacy, there are major concerns with quality control, potential adverse effects, and risks for interactions with medications. These adverse effects and interactions are not uncommon in my patients which are often taking numerous medications and have serious underlying diseases. Even in healthy animals, the risks of these compounds and the lack of quality control (both for having the ingredients they are supposed to have and for not having contaminants) are important to consider. Given the lack of evidence and the substantial risks, the American Medical Association does not recognize a similar specialty. I would hate for veterinary medicine to be subjected to less rigor and care than human medicine.

   It is unclear how recognition of the ACVBM as a veterinary specialty by the ABVS enhances patient care since minimal research is being performed by this organization's membership.

   There is no evidence that there currently is a core group of charter diplomates with the scientific and clinical expertise to guide this specialty group towards the development of new evidence-based knowledge.

Based on the sampling of public comments above, explain how ACVBM will provide improved veterinary medical services to the public.

2) The training, education, and experience requirements are not sufficiently robust to ensure mastery of an evidence-based and scientifically sound body of knowledge that is the basis of a specialty.

   The proposed track to certification by the ACVBM does not require the acquisition of such a body of knowledge, requiring only to keep a case log for 3 years while working under the supervision of an individual similarly trained through an experiential, rather than didactic pathway.

   The residency requirements do not seem as stringent as current resident programs. The duration of 2 years seems meager, most programs are 3 years. I also did not see any requirements for rotations in other specialties, for example surgery residents and emergency critical care residents have requirements to spend time in anesthesia, radiology, and medicine.

   One avenue towards certification would involve completion of a residency under the "direction of an ACVBM board mentor of a PhD in a field related to botanical medicine." We are not aware of other veterinary medical specialties that provide a provision for postgraduate residency training to occur under the guidance of an individual without formal clinical training. We were also troubled by the publication requirement for both tracks that state "one (1) peer reviewed/refereed without indicating whether this could be met by developing a review paper. Such an approach would clearly be inconsistent with other veterinary specialty boards.

   I am also not happy that these residents do not need on site supervision from a diplomate it can be long distance, I know of no other specialty that allows that, direct time with a diplomate is required for a significant period of time for on clinic supervision and for things such as resident rounds and journal club. Is this college saying those requirements are superfluous? And also to have supervision by a non-veterinarian but PhD? This strikes me as a quick way to churn out residents and seems somewhat disrespectful of all those who have labored long and hard for diplomate status with the idea it meant you had achieved a worthy goal.

Based on the sampling of public comments above, explain how ACVBM will ensure that all training or experience requirements and all prerequisites for examination serve the purpose of assessing the competency of the candidate and that established routes through education, training, and experience will qualify candidates for examination. Also provide evidence that facilities and programs are available for advanced training of veterinarians that will lead to certification in the specialty.

The CDNS also notes that a portion of the original petition refers to practices that would seem to exceed that of both the title of the organization, and the training/examination proposed – ie, more than 'botanicals' but also including administration of animal- or microbe-based substances. Please clarify.

Additional concern: the ACVBM is asked to include a table of contents to its petition, in order to

facilitate searching and reading of the document.