Comments on Resolution 3-2013 Homeopathy, from Connecticut
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> While the AVMA has models, such as their model practice act, the actual practice of veterinary medicine is a legal matter for state veterinary boards. The AVMA model practice act (AVMA2012) and a number of state practice acts include homeopathy specifically, as a reflection of this. The AAVSB comments on its model practice act definition of the practice of veterinary medicine: "The definition in Section 104 [Practice of Veterinary Medicine] is purposely broad in order to provide substantial latitude to the Board in the adoption and implementation of rules." (AAVSB 2009)

This is irrelevant. The resolution has no binding legal force and specifically states that "veterinarians may legally employ any therapy that complies with the applicable laws and regulations governing the practice of veterinary medicine." The fact that some state governments have recognized homeopathy as part of the practice of veterinary medicine has no bearing on whether or not it is an effective therapy. Just as there is political pressure from a passionate minority on the AVMA to reject Resolution 3, so similar pressure has been applied to other organizations to ignore the science showing homeopathy doesn't work.

> AHVMA maintains that one must include an expert in any discussion of a treatment modality, whether it be those taught in the core curriculum of veterinary schools or those taught as electives or special training outside of the core courses. Experts are those who use the modality in practice, and who are invited by practitioners of CAVM to lecture and write about its use. No one person can be an expert in all things, and so the person's expertise should be specific to the subject being discussed. This resolution should be sent to a task force with representatives from both sides of the argument to in order to create a balanced document for delegates to base their decision upon. As a beginning, this document is accompanied by a White Paper supported by the Academy of Veterinary Homeopathy, which presents the rest of the evidence not present in the paper accompanying the Connecticut resolution.

This essentially says that only homeopaths are qualified to evaluate the validity of homeopathy. However, homeopathy is not a recognized medical specialty in veterinary or human medicine, and the expertise homeopaths claim is self-determined. If a committee of believers in homeopathy is formed to evaluate the scientific evidence for homeopathy, the outcome is a forgone conclusion.

Homeopaths have a vested interest in declaring their own practice to be legitimate. The delegates and other veterinarians who may choose to evaluate the scientific literature concerning homeopathy have no "horse in the race," as it were. If homeopathy were effective, conventional veterinarians would simply adopt it and offer it to their patients like any other therapy. This has not happened in the two centuries since the invention of homeopathy because a compelling scientific case for the theories and practices of homeopathy has not been made. It is not necessary that the delegates, or rest of the profession, rely on homeopaths to interpret the scientific evidence concerning homeopathy for us.

> And finally, the White Paper in support of this resolution contains numerous misstatements and so cannot be used reliably to judge the resolution. It only addresses one part of homeopathic practices and by and large ignores others (such as less highly diluted remedies, different methods of diagnosis, etc.) that do not fit the items it is addressing. It ignores hundreds of legitimate research papers. And it relies in part on the 275 page House of Commons Science and Technology Committee (HOC Committee) report on Homeopathy (HOC Committee 2010), which may have been accepted physically by the Chief Scientific Advisor to the British government. However it was NOT accepted by the British government. Part of the reasoning for not accepting the report was:
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> "our continued position on the use of homeopathy within the NHS is that the local NHS and clinicians, rather than Whitehall, are best placed to make decisions on what treatment is appropriate for their patients -including complementary or alternative treatments such as homeopathy -and provide accordingly for those treatments." (Secretary of State for Health 2010)
> This is an essentially political question, and again the resolution does not in any way prohibit veterinarians from choosing to employ homeopathy. It expresses the opinion of the AVMA that the scientific evidence does not support homeopathy to be effective. This is the same conclusion reached by the House of Commons Science and Technology Committee and the science-based medical professions in general. It is up to politicians and courts to decide what implications the scientific consensus has for government health insurance and other matters of public policy, but that again has no bearing on the assessment of the scientific evidence concerning homeopathy.
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> The HOC Committee is a Parliamentary committee consisting of elected officials (laymen), similar to our House and Senate Committees. Like our congressional committees, the attitudes of the members of the committee influence the choice of witnesses called, the evidence accepted, weight given to evidence, and final conclusions. The HOC committee stated "It is not necessary for Scientific evidence to be absolutely

uniform in order to establish that a practice is ineffective or unsafe." One might say the same for establishing that a practice is effective or safe.
The citation of the HOC committee was simply to illustrate that bodies with far greater resources than the AVMA House of Delegates have investigated this matter and drawn a clear conclusion about the state of the science. The white paper does not rely on the HOC findings but evaluates the scientific evidence itself and merely uses the HOC hearings to help illustrate points that are rooted in this evidence.

Few of those called as witnesses by the HOC committee were practicing homeopaths: in the Memorandum submitted by David Tredinnick MP, Chairman, Parliamentary Group for Integrated and Complementary Healthcare , he stated:" Only one doctor using homeopathy gave oral evidence, and none are scheduled for Monday. No doctors using homeopathy in a primary care setting have been asked. Dr David Reilly from the Glasgow Homeopathic Hospital is regarded as a leading expert on this subject and should have been called. In addition, the Society of Homeopaths, which was discussed both directly and indirectly as the principal organisation representing non-medical homeopaths, should have had the opportunity to put its views forward. I believe that the Committee should have ensured that all the experts in this field were given the opportunity to give oral evidence."

The HOC did give homeopaths an opportunity to send a representative to present their position, but it did not defer to their expertise because only the homeopathic profession recognizes this as legitimate.

The White Paper accompanying this response from the AHVMA addresses the specific concerns about homeopathic theory and homeopathic research that are raised in the Connecticut White Paper. The following is a critique of the sections of the Connecticut White Paper which contain misleading statements:

Page 1 "There is no consistent body of in vitro or animal model research evidence showing the presence of any biologically active factor in homeopathic remedies or a meaningful biological effect of homeopathic treatment beyond placebo."

(Homeopathic remedies come in 4 groups of dilutions: X, C, L, and M. The X and C dilutions not only have demonstrable factors, some can be tasted. Dilutions made by compounding pharmacies of drugs used for cats and small dogs are in the X range. This includes items such as Humulin U-100 diluted to 10 U/ml, or interferon eyedrops diluted to 30 U/ml. Any veterinarian who uses Interferon as an oral medication and dilutes it as recommended has created a dilution that is the same concentration as a 6X dilution.)

It is disingenuous to suggest that homeopathy is not primarily concerned with the use of ultradilute remedies that do not contain measurable active ingredients. Insulin diluted to 10U/mL is not a homeopathic remedy; it is simply off-label use of a pharmaceutical. And herbal preparations which contain pharmacologically active ingredients are part of herbal medicine, not homeopathy.

According to the Academy of Veternary Hoemopathy, " A homeopathic remedy is a single substance derived from a plant, animal or mineral. This is then subjected to a special procedure called potentization….Dr. Hahnemann discovered that the effect of homeopathic medicines is strengthened dramatically upon successive dilutions and vigorous shaking between each dilution. The final dilution can be very high…These substances are specially prepared so that they have no toxic "side effects"…Homeopathy is a safe form of treatment in that there are no chemicals or drugs in the remedies so there are no side effects." By their own definition, a homeopathic remedy no longer contains any chemicals from the original substance used.

Furthermore, the AVH specifically discourages the use of remedies containing conventional pharmaceuticals or herbal ingredients: "Drugs, herbs and other forms of treatment prevent cure and cause ultimate harm to the patient. Hahnemann states that only the medicine homeopathic to the patient's condition is to be used in treatment…Drugs and methods of treatment which are not homeopathic to the case are to be avoided because of the possibility of interference with the progress of cure."

Even the AHVMA white paper states, "medicines used in homeopathy are often administered in highly diluted form…their mode of action differs from substances given in pharmacologic doses and having direct agent-dependent actions on the body." The document then goes to great lengths to defend the theory that ultradilute substances can have biologic effects, and all but a few of the papers cited relate to the investigation of ultradilute homeopathic remedies. Ultradilute remedies make up the vast majority of homeopathic treatment, and if these are ineffective (as the evidence clearly shows they are), then homeopathy is no more than a placebo therapy.

> "While some apparently positive studies exist, published almost exclusively in journals dedicated to the promotion of homeopathy and other alternative therapies"
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> I have a 65 page list of references to published homeopathic articles, which includes the following journals in just the first 6 pages:
> Immunology Today
> Exp Biol Med
> Comptes-Rendus de l'Académie des Sciences de Paris

Journal of Allergy and Clinical Immunology
Inflamm.Res.
Micron.
Nature
European Journal of Pharmacology
Biophys
Annals of the New York Academy of Sciences
Immunol Invest.

Page 2:
"some apparently positive trials exist, but these are of low -quality and highly subject to bias. Systematic reviews of the clinical trial literature consistently find no evidence of an effect beyond placebo"

An implication that journals such as Immunology Today, Exp Biol Med, Journal of Allergy and Clinical Immunology, Annals of the New York Academy of Sciences, etc. publish inferior work

The level of evidence within the hierarchy of evidence-based medicine, and the quality of controls for chance, bias, confounding, and other errors, are determined by specific established criteria, including study design, sample size, randomization, blinding, control groups, and many others. The level and quality of a study, and the reliability of the results, is determined by these features, not by the journal in which the report is published. Even highly respected journals can publish results that are clearly false. A paper by Andrew Wakefield suggesting a relationship between vaccination and autism was published in the Lancet in 1998, and it was retracted in 2010 and Dr. Wakefield stripped of his license for the fraudulent and unethical study. The journal Nature published a paper reporting an effect of a homeopathic preparation on basophil degranulation in 1988, and then published a followup title "'High-dilution' experiments a delusion" showing the results to be due to inadequate blinding. Even high-quality journals can, and often do, publish poor quality research.

There is ample evidence for a publication bias in homeopathy journals and other journals devoted to alternative medicine. In 1995, only 1% of studies published in alternative medicine journals reported negative results, and in 2001 95% of such studies reported positive results (Schmidt, K., Pittler, M.H., Ernst, E., (2001a) A profile of journals of complementary and alternative medicine *Swiss Med Weekly* Vol. 131 pp. 588-591; Schmidt, K., Pittler, M.H., Ernst, E., (2001b) Bias in alternative medicine is still rife but is diminishing *British Medical Journal* Vol. 323 no. 7320 p. 1071)

A study published in 2005 (in an alternative medicine journal) found that 69% of homeopathy studies in mainstream journals reported negative results whereas only 30% of studies in alternative journals reported a negative result. (Caulfield, T., and DeBow, S., 2005 A systematic review of how homeopathy is represented in conventional and CAM peer reviewed journals *BMC Complementary and Alternative Medicine* Vol. 5 no. 12)

Of the 16 veterinary studies listed in the CVMA white paper that reported positive results, 11 were published in journals dedicated to homeopathy or alternative medicine. Of the 15 veterinary studies listed in the CVMA white paper that reported negative results, only 2 were published in such alternative journals.

And while some positive studies have been reported in mainstream journals, it is still true that the vast majority are found in dedicated journals with a clear bias. And the systematic reviews cited in the CVMA white paper also demonstrate clearly that the higher level and quality and the better control for bias in a study, the less likely the results are to be positive, consistent with homeopathy being a placebo therapy. Only when low-level and low-quality studies are given equal weight (as in the Swiss homeopathy report) can one manufacture the appearance of strong research support for an effect above placebo.

> Also on page 2: the first of several citations from the 2010 report from the House of Commons Science and Technology Committee, which was *not*accepted by the British government

The conclusions were accepted by the Scientific Advisor to the government, but for political Reasons (including pressure from the Royal Family, who are believers in homeopathy, the Official policy of the government has not yet moved into alignment with the position of The scientific and medical communities that the NHS should not offer an ineffective Therapy. However, two of the five homeopathic hospitals funded under the NHS (Liverpool And Tunbridge Wells) have closed in the last year, as well as numerous other facilities Offering homeopathy in the UK. The politics are catching up to the science.

> Page 7, item II G cites the AAVSB's stance that "CE programs that advocate unscientific modalities of diagnosis or therapy are not eligible for RACE approval," implying that they never approve CE on homeopathy. On page 14 item IIA states that "Since 2009, the Registry for Approved Continuing Education (RACE) has denied approval for continuing education offerings involving the teaching of homeopathy." RACE approved the following 3 lectures on homeopathy at the 2009 AHVMA annual conference:
> Pointers to Case Taking andCase Organization
> Some Methods for Handling and Understanding Complex Cases

Dealing with the End Stage and Hospice Patient
All 3 were presented by Larry Bernstein, VMD, who uses homeopathy extensively in his practice, as well as teaching and lecturing regularly on the subject.

In 2011, the AVH sued the American Association of Veterinary State Boards because its RACE committee had begun denying approval for homeopathy CE course which had previously been approved despite not meeting the requirements for RACE approval, which sate:

[approved courses must] build upon or refresh the participant in the standards for practice and the foundational, evidence-based material presented in accredited colleges or schools of veterinary medicine or accredited veterinary technician programs…CE programs that advocate unscientific modalities of diagnosis or therapy are not eligible for RACE approval…All scientific information referred to, reported or used in RACE Program Applications in support or justification of an animal-care recommendation must conform to the medically accepted and scientifically supported standards of experimental design, data collection and analysis.

The AHVMA went so far as to set up an alternative CE approval organization, Registry of Alternative and Integrative Veterinary Medical Education (RAIVE), in order to skirt the mainstream process. This organization is not recognized by any mainstream veterinary group, just as the alternative board certification in homeopathy created by the AVH is not recognized by the AVMA as a legitimate specialty board. These are all examples of the AVH attempted to force homeopathy to be judged by different standards from scientific medicine, standards set by homeopaths. The lawsuit was dismissed by the court in 2012, and RACE does not currently accept homeopathy course as approved CE.

Page 7, item III A: The statement from NCCAM that "Rigorous, well-designed clinical trials for many CAM therapies are often lacking; therefore, the safety and effectiveness of many CAM therapies are uncertain" also applies to the 50% (about 1500) of conventional therapies that are also of unknown effectiveness because of lack of well-designed research. (Clinical Evidence editors, HOC committee 2010) In addition, NCCAM still includes homeopathy in its list of Complementary and Alternative Medicine research that it will fund. (NCCAM)

Simply untrue. While there is rarely perfect evidence for any practice, the evidence base is far stronger for conventional medicine than for homeopathy. (Imrie, R. Ramey, D. The evidence for evidence-based medicine. *Complementary Therapies in Medicine* (2000), 8, 123-126.) A survey of the literature shows that in the following areas of conventional medicine, the majority of practices are based on compelling scientific evidence:

96.7% of anesthetic interventions (32% by RCT, UK)

approximately 77% of dermatologic out-patient therapy (38% by RCT, Denmark)

64.8% of 'major therapeutic interventions' in an internal medicine clinic (57% by RCT, Canada)

95% of surgical interventions in one practice (24% by RCT, UK)

77% of pediatric surgical interventions (11% by RCT, UK)

65% of psychiatric interventions (65% by RCT, UK)

81% of interventions in general practice (25.5% by RCT, UK)

82% of general medical interventions (53% by RCT, UK)

55% of general practice interventions (38% by RCT, Spain)

78% of laparoscopic procedures (50% by RCT, France)

45% of primary hematology-oncology interventions (24% by RCT, USA)

84% of internal medicine interventions (50% by RCT, Sweden)

97% of pediatric surgical interventions (26% by RCT, UK)

70% of primary therapeutic decisions in a clinical hematology practice (22% by RCT, UK)

72.5% of interventions in a community pediatric practice (39.9% by RCT, UK)

Thus, published results show an average of 37.02% of interventions are supported by RCT (median = 38%). They show an average of 76% of interventions are supported by some form of compelling evidence (median = 78%).

We also wish to note:
the Banerji protocol (using homeopathic remedies) Best Case Series on cancer was accepted by NCCAM and NCI at NIH. It was presented to the Cancer Advisory Panel for Complementary and Alternative Medicines. NCI is devising “Practice Outcomes Monitoring and Evaluation Systems Study for Bronchogenic Carcinoma” at their clinic, with a goal of designing a protocol for treatment of these cases at institutions in the US. (Banerji 2007) The NIH has asked for animal studies before final approval, and currently a board-certified veterinary oncologist is working with the proponents of the Protocol to develop a design for the study.

After 200 years, the best homeopathy can show is a “best case series?” It is well-established that case reports and case series are useful for generating hypotheses, not proving or disproving them. The CVMA white paper cites numerous systematic reviews of clinical trials, a much higher level of evidence, which shows homeopathy does not work.

In conventional science, radical ideas are proven or disproven, and accepted or rejected accordingly, much more quickly. The notion that *Helicobacter* caused GI ulcers was radical when proposed in 1982 and had won a Nobel prize by 2005. This was because compelling evidence at all levels, including high-quality clinical trials, was developed. Homeopathy has failed to do this but proponents refuse to accept this and continue to argue for more research. How long is it reasonable to continue investigating despite persistent failure when the notion is theoretically impossible and incompatible with established science to begin with? As the House of Commons Committee concluded, “There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious. Competition for research funding is fierce and we cannot see how further research on the efficacy of homeopathy is justified in the face of competing priorities.”

> Page 8:
> Thefourth paragraph describing “sympathetic magic” has nothing whatsoever to do with the way that homeopathic remedies are selected.

Sympathetic magic is a term from cultural anthropology. The theory of sympathetic magic was first developed by Sir James George Frazer in *The Golden Bough*. He further subcategorised sympathetic magic into two varieties: that relying on similarity, and that relying on contact or 'contagion' (emphasis added):

> “If we analyze the principles of thought on which magic is based, they will probably be found to resolve themselves into two: first, that **like produces like**, or that an effect resembles its cause; and, second, that things which have once been in contact with each other continue to act on each other at a distance after the physical contact has been severed. The former principle may be called the **Law of Similarity**, the latter the Law of Contact or Contagion. From the first of these principles, namely the Law of Similarity, the magician infers that he can produce any effect he desires merely by imitating it: from the second he infers that whatever he does to a material object will affect equally the person with whom the object was once in contact, whether it formed part of his body or not.”

Homeopathy is a classic example of this variety of pre-scientific superstition.

> The paragraph describing what one is able to buy in a homeopathic preparation also has nothing to do with the homeopathic idea of “like cures like.”

These examples illustrate the fact that homeopathic remedies are produced from starting materials that have no plausible connection to any disease etiology. The basis for such choices is pre-scientific superstition, including the notion that anything which causes symptoms of illness in a healthy person can be used to combat those same symptoms, regardless of their cause, in a patient.

> Vaccines and some conventional medications, such as nitroglycerin for angina, stimulants for attention-deficit hyperactivity disorder, and digoxin for congestive heart failure match the "like cures like" principle.

Again, untrue. Vaccination doesn't work because of the "like cures like" principle. Vaccine antigens stimulate a specific immune response to a particular antigen from a pathogen by a mechanism that has been intensively investigated and characterized in detail. There are many different kinds of vaccines (whole cell, protein-based, DNA-based, killed and modified live, etc) which are developed and which function to treat or prevent specific diseases according to the pathogenesis of those diseases.

This is drastically different from a magical principle of "like cures like" that is applied to every medical condition regardless of the etiology or pathogenesis. The superficial similarity of vaccines using small (but measurable and highly specific) doses of an antigen and homeopathy using small (and usually non-existent) doses of a starting material is not a true correspondence between the theories behind the two interventions, nor does it demonstrate that homeopathy works. Even so-called "nosodes" homeopathic "vaccines" made from material gathered from a sick individual and diluted and shaken until nothing remains then used to treat or prevent that illness in a real patient, have been proven not to work (e.g. Larson L., Wynn S., and Schultz R.D. A Canine Parvovirus Nosode Study. *Proceedings of the Second Annual Midwest Holistic Veterinary Conference* 1996.)

> Page 14, Item II B states "The AVMA requires specialty boards to demonstrate "a substantial body of scientific
> knowledge, " and does not recognize the Academy of Veterinary homeopathy certification process due to the failure to meet this requirement." The Academy never applied forspecialtyboard certificationand so has never been judged by AVMA or the ABVS for any body of scientific knowledge. (This was verified by both the Academy of Veterinary Homeopathy and by the American Board of Veterinary Specialties in November 2012.)

The AVH has not applied because they know they cannot meet the standard. Human homeopathy is also not recognized as a medical specialty. Unless homeopaths can meet these standards and

obtain this status, they have no legitimate claim to any specialized expertise that must be acknowledged or deferred to.

> Page 15, item IIA quotes items about the British Medical Association dating from an anti-homeopathy campaign in that countryduring the year of 2010. The statements attributed to the British Medical Association are not found on their website. Instead their websitesuppliesinformation about the Society of Homeopaths, the Faculty of Homeopathy, and the regulation of homeopathic medicines, as well as the Complementary and Natural Healthcare Council which informally regulates homeopathy as well as other modalities.In addition, a recent article in the Sept 14 isue of the British Medical Journal was favorable, stating "Modern medicine has real capacity to do harm but often minimal good; homeopathy has minimal capacity to do harm but real capacity to do good. Homeopathy is an easy target; we would be better to focus on the failings of conventional medicine. Homeopathy is bad science but good medicine." (Spence, 2012)

A small number of individual physicians, like individual veterinarians, may support homeopathy, but it is not accepted as legitimate medicine by the BMA or mainstream medicine. At a BMA conference in 2010 voted overwhelmingly in favour of banning homeopathic remedies being funded by the NHS and withdrawing backing for the UK's four homeopathic hospitals. They added that NHS doctors should not be given homeopathy training and remedies should be taken off shelves "labelled medicines" and put on shelves "labelled placebos".(http://www.nursingtimes.net/whats-new-in-nursing/primary-care/bma-votes-against-homeopathy-funding/5016611.article, http://www.telegraph.co.uk/health/healthnews/7861240/Chemists-should-be-forced-to-label-homeopathic-remedies-as-placebos-say-doctors.html)

> One general comment about foreign organizations(cited starting on page 15):
> The EU recognizes homeopathy. Germany, France, and India incorporate homeopathy as part of their health systems. The British government has pointed out to the HOC Committee that if they were to enact their recommendations, it would breach their treaty with the EU.(Secretary of State for Health, 2010)

Numerous veterinary and human medical groups have acknowledged that homeopathy is not a legitimate therapy. Political pressure to refrain from such a declaration is stronger in some places than others, but this has nothing to do with the state of the scientific evidence or the truth of the matter.

As examples:
In the UK, in December 2011, the Veterinary Medicines Directorate (VMD) in the Department for the Environment Food and Rural Affairs (Defra) – which governs the use of medicines in

animals – made clear that homeopathic treatments could only be classed as medicines, and thus prescribed by vets, if they were able to demonstrate efficacy. In the past year the British Medical Association has adopted an extremely robust approach on the issue, rejecting the use of homeopathy by the British National Health Service and calling for homeopathic products to be stored away from medicines in pharmacies and chemist shops on shelves marked "placebos".

In Sweden, veterinarians are prohibited from prescribing homeopathic remedies.

In November 2005 the Federation of Veterinarians in Europe (FVE) issued a strategy document including the statement that the veterinary profession is rooted in science and evidence-based veterinary medicine. In the explanatory discussion of this strategy document it was explicitly stated that the FVE rejects non-evidence based medicines such as homeopathy.

Earlier in 2005 the European Board of Veterinary Specialisation (EBVS) made a clear statement with regard to alternative modes of treatment: The EBVS only recognises scientific, evidence-based veterinary medicine complying with animal welfare legislation. Specialists or colleges practising or supporting implausible treatments with no proof of effectiveness run the risk of withdrawal of their specialist status. No credit points can be granted for education or training in these so-called supplementary, complementary and alternative modes of treatment.

In October 2006, the general assembly of the Royal Netherlands Veterinary Association agreed to discontinue the official status of the group of veterinarians working with homeopathy.

> page 16: Item IIIC “the FDA ... has made no attempts to regulate their use or require any evidence of safety and efficacy”
> ignores the fact that the proper preparation of homeopathic remedies is recognized by the FDA and is part of their Pharmacopoeia.
> You can read FDA regulations regarding homeopathic remedies here:
> http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm
> (accessed 10/29/2012)

Homeopathy was grandfathered into the 1938 law establishing the FDA because it was proposed by a Senator who was also a homeopath. What this means is that homeopathic remedies do not have to prove safety and efficacy through scientific testing as conventional medicines do. This exception to the usual standards of scientific evidence is a historical and political one, but it is not an endorsement of homeopathy by the FDA. As the National Center for Complementary and Alternative Medicine states, “FDA does not evaluate the remedies for safety or effectiveness.” The FDA’s own web site state, “FDA is not aware of scientific evidence to support homeopathy as effective.”(http://labels.fda.gov/)

As for veterinary homeopathy, the FDA has stated that the grandfathering of homeopathic remedies for human use into drug laws do not apply to veterinary medicine. In a 2006 statement regarding regulation of milk pasteurization, for example, the agency stated, "Homeopathy is an alternative therapeutic modality developed in the late 1700's by a German physician for use in humans. Homeopathic medicine is considered an unconventional form of veterinary practice. FDA can find no justification for regulating veterinary homeopathic drugs any differently from other drugs subject to the FFD&CA. **There are currently no FDA approved homeopathic drugs for veterinary use.**" The FDAs CVM has chosen not to enforce this law, as yet another political concession to homeopaths, but this by no means constitutes FDA approval of homeopathic remedies as effective the way a drug approval does. (www.**homeopathic**pharmacy.org/pdf/articles/**vet_drugs**.pdf*)*
The FDA CVM identifies all drugs intended for animal use which have not passed the new drug approval process as unapproved animals drugs, and this is true for homeopathic remedies as well (http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268128.htm). Use of such drugs are tolerated, but veterinary use of homeopathy is not approved or endorsed by the FDA.

Page 16, Item III D:

European regulations (the regulations in question are from DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use.)

Despite what is implied, those regulations were established for "***clinical trials***, to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications." (Emphasis is the author's.) In other words, instead of labeling them "for hepatitis" the ***label***would have no indications. They also have to be in a form "which do(es) not present a risk for the patient."

"The smallest dose *that results in the obligation to submit a doctor's prescription"***does not mean inactive**. Advil is active, as is prescription-level amounts of ibuprofen, but Advil does not need a doctor's prescription.

In addition "acknowledged to have no recognized therapeutic use" is for those remedies eligible for the simplified procedure. The rest of the regulations say "The usual rules governing the authorization to market
medicinal products should be applied to homeopathic medicinal products placed on the market ***with therapeutic indications***."Despite the implications, the rest of the regulations make it clear that these regulations recognize that there are homeopathic remedies with therapeutic use.

Nonsense. The language of these regulations is intended to allow homeopathic remedies to be marketed despite having no proof of efficacy for specific clinical indications. The caveat is that they cannot claim such an indication on the label. This is one more political accommodation for homeopaths that exempts homeopathy from the standards of evidence to which conventional medicine is held, and the AVMA should not continue to tacitly approve of such a double standard by refraining from stating the obvious: that homeopathy has failed the standards of proof expected of legitimate scientific medical therapies.

> "3. The label indicates the absence of any recognized therapeutic use" is describing the ***label***, not the remedy.

Labels are regulated in both Europe and the U.S. as a way of ensuring that false claims are not made regarding safety and efficacy. If a product cannot be labeled as having a specific effect, that is because it has not been scientifically shown to have that effect. That's the whole purpose of a drug label.

> Page 17, III E
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> "NHMRC's position is that it is unethical for health practitioners to treat patients using homeopathy,"
> The current Homeopathic Working Committee, working until June 30 2013, is creating an information paper and position statement on homeopathy. The draft is not published on their website and the 2010 paper cannot be considered an official representation of their opinion.(NHMRC 2012)

While not yet official policy, it indicates that before the application of outside political pressure, groups like the Homeopathic Working Committee of the NHMRC and the House of Commons Science and Technology Committee consistently come to the conclusion, when evaluating the evidence, that homeopathy is ineffective. Whether these conclusions are then adopted as official policy depends, as in the case of Resolution 3, on political factors as well as scientific evidence.

> Page 17, item IV A discussing "The dangers of homeopathy" states "There have been some reports of detectable heavy metal contamination of homeopathic remedies."
> There is a single citation which reports contamination of products from Croatia. Products used in the US are of American and British origin.This was cited by the flawed HOC Committee report.

That was simply one example. There is ample evidence of the harm from the use of homeopathy, both direct and indirect.

For example, Posadzki P, Alotaibi A, Ernst E. Adverse effects of homeopathy: a systematic review of published case reports and case series. Int J Clin Pract. 2012 Dec;66(12):1178-88 states:

"In total, 38 primary reports met our inclusion criteria. Of those, 30 pertained to direct AEs of homeopathic remedies; and eight were related to AEs caused by the substitution of conventional medicine with homeopathy. The total number of patients who experienced AEs of homeopathy amounted to 1159. Overall, AEs ranged from mild-to-severe and included four fatalities. The most common AEs were allergic reactions and intoxications. Rhus toxidendron was the most frequently implicated homeopathic remedy. Conclusion: Homeopathy has the potential to harm patients and consumers in both direct and indirect ways. Clinicians should be aware of its risks and advise their patients accordingly."

Similarly, Freckelton I. Death by **homeopathy**: issues for civil, criminal and coronial law and for health service policy. J Law Med. 2012 Mar;19(3):454-78 states:

"In India, England, New South Wales and Western Australia civil, criminal and coronial decisions have reached deeply troubling conclusions about homoeopaths and the risk that they pose for counter-therapeutic outcomes, including the causing of deaths. The legal decisions, in conjunction with the recent analyses of homoeopathy's claims, are such as to raise confronting health care and legal issues relating to matters as diverse as consumer protection and criminal liability. They suggest that the profession is not suitable for formal registration and regulation lest such a status lend to it a legitimacy that it does not warrant."

> Page 18 states "not all homeopathic medicines are administered at a high dilution." This istrue for a wide variety of homeopathic medicines. This negates the general representation of the Connecticut white paper that homeopathic remedies have no effect because of their ultra-high dilutions.

Yet the vast majority are, and the remainder have been exempted from demonstrating safety and efficacy by scientific investigation by the label "homeopathic." If they are truly effective, there should be clinical trial evidence to show this, and there is not.