



DRAFT MINUTES

8th December 2015

Committee Room 15, House of Commons

Present: Chris Magee (Understanding Animal Research), Lenny Rolles (RSPCA), Fiona Wright (Ethics & Animals), Tim Morris (Defra), Chris Newman (REPTA), Sarah Wolfensohn (University of Surrey), Lesley Raw (Mrs Raws Paws), Clare Williams (NAWT), Vicki Betton (PDSA), Vanessa Nice-Amoroso (IFAW), Laura Hall (University of Stirling), Hannah Jordan (BVA), Claire Robinson (RSPCA). Catherine Debbie (Dogs Trust), Charlotte Parsons (Dogs Trust), Angie Greenway (ADI) Brett Cochrane (Dr Hadwen Trust), Alpesh Patel (Dr. Hadwen Trust), Caroline Johnson (Woodgreen), Dr Kay Peggs (University of Westminster), Andrew Knight (University of Westminster), Helmut Ehall (LAVA), Ken Applebee (IAT), Elaine Kirkum (IAT), Linda Horan (IAT), Matt Bilton (IAT), Andrew Bolan (ABPI), Bill Lambert (Kennel Club), Melissa Cradock (Kennel Club, Misha Buchkowsky, Ben Myring (RCVS), Mike Webb (Battersea Dogs & Cats Home), Ben Sundall (Battersea Dogs & Cats Home), Julia Carr (Canine Action UK), Emma Garnett, Sue Davey (CARIAD), Gerry Kenna (FRAME), Ian McParland (IPC), Allan Parton (Hounds for Heroes), Lorraine Platt (Blue Fox), Victoria Eisserman (K9 Angels), Anne Wignall, Bob Bayliss (RSPCA), Peter Egan.

Henry Smith MP opened the meeting and gave apologies for the fact he could not stay for the entirety of the meeting as did Rebecca Pow MP owing to a meeting with the Secretary of State for Local Government & Communities regarding their constituencies. Henry stated that there was some concern about Labour representation on APGAW's management aside so he proposed Angela Smith MP to become another co-chair for the Labour Party. Political officers of the group had been informed and no one had raised any concerns.

Rebecca Pow MP – The Dog Conference was a remarkable event, thank you to Marisa for organising it as I think a great deal came out of it to move forward and I am interested in how we will ensure everyone receives information on the day. It shows how strong this group is that the conference was so successful with brilliant speakers and engagement from a wide number of stakeholders. Thanks to everyone who attended.

Marisa Heath – Feedback forms and notes will be collated before Christmas and put on the APGAW website.

Angela Smith MP took over the chair at this point and introduced the speakers.

The Use of Dogs & Cats in Scientific Research

Chris Magee- Understanding Animal Research

The Home Office releases annual statistics on animal use; they look at the number of procedures and the total numbers of animals. Animals are only counted when they are used for the first time. In 2014 3.9 million procedures were carried out with 3434 conducted using dogs and 210 on cats. In terms of trends dog use has come down 4779 in 2013 to 3434 in 2014, a drop of 30%, however it would be misleading to see this as a

downward trend and more reasonable to say dog numbers are broadly stable around 3500-4000 a year. It is common in cats to see numbers around the 200 mark in general. Why are they being used? Cats are overwhelmingly used for veterinary research and lots are used for diet and medicine research, specially formulated cat food to lose weight, vaccines. Cats have a limited utility in human research. Dogs are somewhat unusual in terms of animal research as they are used to test compounds. EU Regulations on new medicines and herbicides require products to be tested on one rodent and one non-rodent. Dogs are often used as the second species here as their reaction to pharmaceuticals are very similar to humans and crucially when you combine toxicity data for two species you significantly increase the probability that a drug will not be dangerous for humans. The data for the efficacy of dogs is spread out throughout the scientific literature and toxicology journals, there are numerous papers that sum it up. What we know is the experiments using one species is around 70% predictive of human responses you can see this from the data set. Around two thirds of dogs are used for repeat dose toxicity testing, it means animals are given a small amount of a drug so it does not cause acute illness, after 28 days minimum its tissues are checked for early signs of pathology which could then lead to disease. We have dose testing for pre-clinical work and acute toxicity testing is done for things like fungicides- there were 122 such procedures in 2014 and in these one male and one female dog will be given a low dosage of the compound, usually a liquid pill and the dosage is slowly increased until the dog appears unwell, is off its food or its blood shows abnormalities and then the dosage is stopped. Dogs are less frequently used for things like heart research, 10 were used for this in 2014. They are being used for muscular dystrophy research as dogs get it in the same way as humans.

It is not possible to make generalisations about the wrongness and rightness of each experiment, it needs to be done on a case-by-case basis. Each experiment goes through two tiers of ethical review to determine if that particular experiment is worthwhile with the Animal and Ethical Review Board with vets, license holders, laypersons, statisticians and then the Home Office will have a look at costs and benefits but also alternatives. When we talk about 'suffering' there are many different definitions of the word. We now have retrospective assessment of suffering of animals and 73% of dogs experiments were in the mild category which is blood withdrawal at its minimum. 0.3 % was severe and 20% moderate, which implies there will be recovery. On welfare I defer to the RSPCA and CFI. I personally think a ban on using dogs and cats in the UK would not save a single animal as the experiments are done to satisfy European legislation and you would still get the experiment done in Europe, simply offshore even to China or India. It is done to satisfy a regulation. There would be a slight rise in the number of primates and a great deal of work taken offshore would be out of our stricter welfare controls. What needs to happen is a significant increase in alternative funding by the national centre of the 3Rs which is funded by BIS but has just had its budget cut. That needs to be ring-fenced and indeed doubled.

Dr Penny Hawkins – RSPCA

The RSPCA is extremely concerned about the use of dogs and cats in research and testing, and wants to see these species - and all other animals - replaced with humane alternatives, as rapidly as possible.

Our concerns are shared by the public too. In the most recent Mori poll, when asked which types of animals it was acceptable to use in research to benefit humans, the public placed dogs and cats at the bottom of the list, on a par with great apes. With respect to research into animal health, only primate use was deemed less acceptable than the use of dogs and cats. Aside from the suffering caused by scientific procedures - which can be severe - laboratory housing, husbandry and care is also a welfare issue. As the Home Office advice note on 'Use, keeping alive and reuse' points out, even 'good' laboratory conditions of housing and husbandry will compromise the animal's well-being to some degree.

Thankfully, the numbers of dogs and cats used every year in the UK are falling. For example, beagle use has fallen in the UK, partly pioneered by the RSPCA with our 'Dog Project' in association with FRAME and the pharmaceutical industry. Good progress is still being made, with initiatives involving animal protection groups, 3Rs organisations and industry. Nobody would deny that the downward trend in numbers is a change for the

better, but this still represents a very large number of sentient, individual animals, who are no different from the companion animals who share our homes and lives. There is a moral imperative to replace these animals, but it should not just involve a change to other species that can suffer just as much. For example, another option sometimes proposed for some regulatory tests using dogs is the mini-pig, but in the RSPCA's view this raises exactly the same serious ethical and animal welfare issues as using dogs.

Most dogs are used to attempt to develop drugs for humans and a significant number are used to develop and test veterinary vaccines, worming and flea treatments, and other drugs, for companion dogs. 82 % of the 184 cats who were used in 2014 were used for the purpose of 'animal diseases and disorders'. The use of laboratory dogs and cats to develop and test treatments for the same species when kept as companions is a very serious ethical dilemma for the RSPCA as well as companion animal guardians. We have worked to raise awareness of this issue and promote faster development of alternatives, and reductions in suffering, in veterinary vaccine development and testing. Beagles are often used as a 'second species' (in addition to rats or mice) in safety tests within human drug development, and for safety testing substances such as agricultural chemicals - both of which are currently required by law. The RSPCA is aware of and engaged in the serious debate about the validity and usefulness of many regulatory tests that currently use dogs, as clearly set out recently by Jarrod Bailey and others. We are also aware that the large amount of regulatory data that has been generated using beagles is a disincentive to change to alternative testing paradigms, yet the change will have to be initiated at some point - so why not now? The RSPCA believes that all groups who perform regulatory testing should critically review their data and should have to make the scientific case for the dog as the best predictive model of human safety - if this can indeed be made - rather than simply perpetuating the status quo. In general, far more attention, effort and resources are needed to develop and validate non-animal methods which must then be accepted and their use enforced by regulatory bodies.

So while people within science and industry often tell us that they do not want to use dogs, the RSPCA is not convinced that sufficient efforts are made to challenge requirements for dog use, or to reduce numbers and suffering. With respect to both dog and cat use, the RSPCA wants to see:

- more investment from the pharmaceutical industry, Government agencies and the chemicals industry into developing and validating humane, completely non-animal alternatives to dog and cat use, with urgent focus on human and veterinary medical research and safety testing;
- this Government commit to making further progress with the previous Government's delivery plan to reduce the use of animals in scientific research;
- more public acknowledgement and serious consideration, by regulators, researchers and industry, of the growing concerns about the scientific validity of dog use in human medical research;
- more efforts made to reduce suffering and improve the welfare of laboratory dogs while their use continues, including housing that enables a full range of natural behaviours such as larger pens, access to outdoor runs and more frequent exercise periods; and
- more effort made to rehome animals, to give them the chance of a new, good quality life as companions.

Dr Nick Palmer – Cruelty Free International

Our starting point is to end all animal experiments but on the specific issue of dogs and cats, we are keen to avoid a dichotomy such as seen in Korea at the moment where people are increasingly keeping them as pets whilst also consuming them as meat. Korea are looking at defining two legislative categories; one for pets and one for food and there is a danger to that kind of approach. Toxicity seen in dogs means it is likely to also be present in humans, however this is variable and with no clear pattern in terms of types of toxic effects or types of drugs so it is not consistent nor reliable. The absence of toxicity in dogs provides essentially no insight into the likelihood of toxicity in humans. As the absence of toxicity in animals is the critical factor for the progression of a new drug into clinical trials, this has important implications for drug development. Up to half of the drugs that pass human clinical trials are later withdrawn or relabeled because of adverse effects not predicted by animal tests.

A typical experiment is tested the second time on dogs yet 63% of adverse affects in humans have not shown an affect on animals. The cost in practical terms is a delay in developing new medicines and a risk that the medicine could not be safe for humans. Is this actually profitable for industry and is it a bureaucratic hurdle which delays the introduction of new medicine for no additional value. The current position is this is a function of EU legislation requiring the double testing. To some extent we are discussing should the Government raise this issue at EU level –whether it is still useful to have this second species testing and the second question is it useful and appropriate that dogs are still used? The use of dogs is inappropriate as it is so difficult to keep them humanely in laboratories. Additionally, how do we measure the benefits against these risks. Some of the well known experiments on cats are known as the kittens’ eyes being sewn shut in order to see how the ocular alternative would develop but that does not seem to have led to any practical benefit to human research. The difficulty we encounter is that whilst it is good to increase knowledge and it is hard to argue against it, the benefits are not often clear. There are 20 inspectors who look at applications for experiments are very overworked and it is challenging for them to make the decisions on the benefits. So it is up to us to decide as a society whether we want to accept this not being challenged and reviewed. Cruelty Free International would like to propose that we bring our new research which looks at 200 experiments and that we establish a round table approach with industry, the researchers and universities and the Home Office in an attempt to see whether there is a way forward. At the moment the position is deadlocked and we need to move forward. The people carrying out the experiment tell us they are doing it because the law requires it so there are some real potential benefits in having a constructive discussion on how we can make progression.

Charlie Chambers – Institute for Animal Technology

It has been a privilege for me to work with dogs and cats over 40 years. I worked for a large pharmaceutical company in 1972. Conditions have got much better over that time but the people who have looked after the animals have been the same and have worked all through the ranks. My institute has ensured high welfare for dogs and cats. It is difficult for those who do not know what it is to be an animal technician to understand how we can work with animals and put them down at the end of the experiment. There are over 2000 of us and you have to have proper animal people to do the job well. The animal technicians have to look after the animals and we have to keep cat and dog research in the UK as letting it drift out to European countries would be a real mistake for welfare. We have come so far in the UK and the EU guidelines were all about the 3Rs. We need experts who understand how to look after the animals to ensure their welfare.

Questions

Christine Wynne (Run Free Alliance) – Chris, you mentioned Beagles have muscular dystrophy but actually they do not. They have genetically modified version taking version genes from Bichon Frise and Cavalier King Charles Spaniels so they do not have it naturally.

Chris Magee – The dogs bred for the experiments were bred from dystrophic dogs.

Christine Wynne (Run Free Alliance) – You mentioned “mild” suffering and I think this is a misleading statistic. There are a great number of dogs under this as “mild” only refers to the very first procedure that the dogs undergo which is normally an anesthetic and they then go on to have a second procedure and the majority 2589 are then euthanized. You have given the impression that the dogs are not suffering but in fact they are. This new format of data collection gives a false impression and the listeners should be aware of that

Chris Magee – If they have had an anesthetic that would reduce suffering.

Dr. Andrew Knight – There is a rate of false positives in these tests for compounds so I think for a balanced perspective we need to know about this.

Brett Cochrane (Dr Hadwen Trust) – I am interested in the ethical review process, with respect to refinement and reduction and the large element of replacement approaches which are being overlooked. It is not being evaluated thoroughly enough and it is difficult for Animal Welfare and Ethical Review Bodies (AWERBs) to progress replacement within establishments. Replacement technology is being developed swiftly so it should be happening faster with less animals being used.

Chris Magee- I speak a lot about the rise in alternatives as we have seen a remarkable rise in alternatives being used alongside animal models. Nobody is using animals for the sake of it, it is to satisfy regulations. If we can move away from it great. At the moment there is a particular problem with false positives coming from alternatives and that is going to present the same problem, although it does not have the same ethical issues. How can we get regulatory authorities to accept alternatives where they are as good as where we need to get to.

Penny Hawkins – The Animal Welfare and Ethical Review Body (AWERB) is a local committee which has to be in place at every establishment that uses, breeds or supplies lab animals. In the view of the RSPCA the AWERB is a very strong force for good if it is effectively empowered and if it knows how to challenge animal use. Replacement is the ultimate goal but it is important to reduce suffering and improve welfare for the animals being used. We are working with the IAT, Laboratory Animal Science Association and Laboratory Animal Veterinary Association to try to ensure AWERBS are empowered to dealing with all their tasks.

Charlie Chamber - There is always an animal technician on AWERB and we see it as being a very significant body. The refinement element is essential.

Dr Nick Palmer – The availability of money is significant. If scientists want to get a grant ultimately they have an easier chance with a well established animal model than they do with a non-animal model. The funding bodies have an inherently conservative element in them that they tend to favour continued research using animals. There is not a very effective lobby for stopping the inappropriate use of animals, the scientists want research grants, the funding bodies want results and they feel familiar techniques will get this. The Committee AWERBS are not necessarily specialized enough to challenge the judgment of the researcher and the inspector who improves the license does not have the time or expertise. One way forward is publication of anonymous versions of the license and the results. The REACH programme by the EU to test chemical procedures has a process whereby if a proposal comes to it, it is published before it is carried out so there is a short period where it can be challenged and it have saved lots of animals. The process in Britain is secretive and so it is not possible. The Freedom of Information Act should apply to animal experiment licences with deletion of names and addresses. We could then have an informed discussion. We should see the results so we can avoid duplication.

Gerry Kenna (Frame) – One aspect which has not come up is the reality of safety testing of dogs undertaken primarily for industrial purposes to support safety assessment for pharmaceuticals as well as pesticides etc. That is undertaken as it is believed it has scientific value under regulations but I just wanted to say I would prefer the pressure to be on how we can bring forward scientifically valued, non-animal human based alternatives and how can that work be implemented in our lifetimes. The country which has moved forward most is the U.S who has funded scientific research and has had pressure from the FDA and Environmental Protection Agency which have demanded new methods are brought forward.

Peter Egan – I am patron of Dr Hadwen Trust and For Life on Earth who have led EDM 373 which calls for a discussion on the benefits on animal testing for human health by independent scientists. If there was a debate, we move forward so we would get a non-influenced argument which is not supported by those who need the money or does who just care. Patients Campaigning for Cures is made up of critically ill people who recognise medicines tested on animals can kills people and can fail people. Even identical twins can suffer from different diseases and need different approaches to treat the same disease. We need an honest debate that is separated from the agendas some may have so we can fully understand whether there is a need to use animals.

Chris Magee - "Patients For Cures is the sister organisation of For Life On Earth and both constitute just a handful of people who are the acolytes of pseudoscientist Ray Greek. Greek's ideas, which are presented as a book rather than peer reviewed papers, have been debated, examined and found to be severely flawed on a number of occasions with particular criticism levelled at his factual inaccuracies, unrepresentative or self-referencing references and tiny sample sizes. On the For Life On Earth website, for instance, the homepage features a lecture with Dr Greek and at around the 12-minute mark you can see he's used a sample size of 6, featured in an anecdote in an out-of-print book of essays from 1990, as the reference to support a key point. To mythbust that sort of trickery, I needed to get a second hand copy of the book of essays from a shop in Maryland in the US, which would be impossible in the midst of a debate. Dr Greek does get one thing right - he is critical of Jarrod Bailey's statistical approach in the paper cited by Nick (Palmer). Essentially, Ray Greek uses the correct formulae and a tiny sample size, Bailey uses a good sample size but the wrong formula for the question normally being asked, but if you run Jarrod's data through Ray's statistical model you get the 90% and above concordance rates between human and animal toxicity that I referenced in my opening remarks. Michael Mansfield did indeed endorse the FLOE debate, but if you look, it's cleverly worded to exclude some 80% of animal research, such as using mouse hormones to treat breast cancer. Presumably if Mr. Mansfield feels this is a fair system he'd be happy to fight his next case in court with 80% of his most compelling evidence missing."

Dr Penny Hawkins – I cannot leave with saying this: I always wonder what makes one set of animals special, just because we have a 'special relationship' with them. We need to spare a thought for the millions of other animals used in research and testing, especially rodents and zebra fish who can suffer just as much as cats and dogs. I understand the purpose of focusing on species of particular interest, trying to make something happen and coming up with a model we can then apply in wider circumstances, but testing is not just about cats and dogs. I feel we have had a good discussion tonight and should continue pushing for alternatives.

Angela Smith MP – If you can allow me to take the suggestion of a roundtable away, I will do so as I need to speak to colleagues. We will discuss it within APGAW and continue to look at the issue of alternatives.

The B&K Beagle Breeding Facility Planning Permission Update

Christine Wynne- Run Free Alliance

The B&K Universal Group, based north of Hull, was run formally by cleaning product manufacturer Reckitt Benckiser before the then junior laboratory technician Gerald C Batin took over the running of the business in 1972. The company was run by the Bantin family who bought some of the import vans from Shamrock Monkey farm when they closed down and ran a similar primate deal with their broker in Singapore. In October 2009 the company was sold to the USA Beagle breeders Marshal BioResources. This company also owns the Greenhill Beagle Breeding facility in Italy.

In April 2012 a demonstration was carried out at the Italy premises to object against planned expansion to include the construction of five large breeding sheds to allow the holding of 5,000 beagles.

In April 2011 B & K applied to East Riding of Yorkshire Council for planning permission to erect 4 new buildings at the Hull premises to increase the number of Beagles being bred for sale and supply to research facilities in the UK. The new buildings would house 3,000 Beagles per annum. In June 2011 the planning authority issued a Refusal Notice whereby the applicant issued an Appeal. This Appeal was "recovered" by the then Secretary of State, the Rt Hon Eric Pickles MP. The Planning Inspector visited the site in Hull in November 2011 and recommended refusal and Eric Pickles agreed with this conclusion.

In July 2012, the State Forestry Police seized the Italian facility with the alleged crime being animal cruelty. The police found 100 dog carcasses in a freezer and many puppies have been euthanized simply because they were surplus. 2639 Beagles were liberated and in September 2012 the site was legally closed.

In April 2013 B & K approached UK Trade and Industry (UKTI) and it is reported that they wanted advice on whether they could avoid scrutiny by local elected councilors by having the issues decided by unelected officials. B & K wrote "I believe that delegated powers can be used...without referring the application to a full planning committee". UKTI advised that elected councilors would be likely to want to make the decision but they added "we could explore such scenarios at any pre-application meeting" although they noted the danger of giving the impression "that we are trying to interfere." B & K stated they had arranged a private meeting with council officials and requested UKTI attend. They also requested a meeting in advance to which UKIT agreed.

In July 2013 the Italian Government banned to breeding of dogs, cats and some other species for animal experimentation, although animal experimentation itself was not banned.

On 1st August B & K stated that the pre-application had been made "we should remain under the radar until September" and the application moved forward in secret until it was revealed shortly before the committee was due to consider it. The applications were refused.

At that point, the industry lobbyists, Association of the British Pharmaceutical Industry (ABPI) entered the arena by inviting the Department for Business, Information & Skills with Marshall Bio-resources to a meeting. An immediate reply from this Department stated that they were disappointed in the local council's decision and were discussing how they could "support Marshalls in developing and progressing your next steps." They offered to discuss "what we are currently doing to manage the risk for animal rights activity."

On 3rd December Marshalls came back to the Department with a new idea "in some regions of the world agriculture is designated as a nationally important activity and it protected from local interference as long as it occurs in an agricultural zone. Is it possible to designate lab animal production in a similar way?" The Department of BIS replied on 4th December "we every much agree with the general tone of what you are suggesting:" and "we are again checking that we have not overlooked any potential option for the Government to support this planning process." On 5th December B &K asked UKTI to help them find a planning advisor and UKTI obliged by putting forward a name.

On 13th April DLA Piper, on behalf of the applicant, put forward an Appeal of the planning applications which was then "recovered" by the then Secretary of State, the Rt Hon Eric Pickles MP. It was decided the decision would be made after the General Election.

Following the General Election, the new Secretary of State, Greg Clark MP, issued his decision to allow the two Appeals going against the refusal recommendation from the Planning Inspector and the democratic decision made by the local planning authority.

B & K has repeatedly stated they are seeking to breed Beagles in the UK to reduce the stress and improve welfare by eliminating the need for global transportation. Approximately 1800 dogs were bred for use in animal experimentation in the UK in 2014 together with the 2000 that B & K anticipate they will breed with their new facility. Charles River has recently been granted a licence in Eire to breed up to another 2000 beagles. Under 3000 dogs were used for 4107 procedures in 2014 so where are the surplus dogs going?

Dr Nick Palmer – The status is that the original application was rejected on the basis of the noise by Officer recommendation. The Home Office gave the company a statement that it was acceptable for an exception be made for the dogs to be kept inside despite EU legislation. On the basis of that statement, Greg Clark overruled the local council and allowed the application, Cruelty Free International has challenged the Home Office decision and if we are successful at getting judicial review of that it will change the basis on which Greg Clark made his decision. We hope this will revise his decision,

Angela Smith MP – I suspect no harm will be done to the case by profile on this so anything anyone can do in this room would be good. Animal Welfare is of paramount important but there is a fundamental point here about the democratic process as well and as an ex-councillor I feel strongly about that. The shenanigans that have gone here to overturn a decision by local politicians and a planning officer recommendation is dreadful. Please do all you can to raise the profile.

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