ANIMALS IN DRUG & COSMETIC TESTING

Written by ***Simran Chandok* & Laksh Manocha*****

** 4th Year BBA LLB Student, Symbiosis Law School, Pune*

*** 4th Year BBA LLB Student, Symbiosis Law School, Pune*

ABSTRACT

Prior to the 21st century, any drug or cosmetic that came into the market had been subjected to some form of animal testing- the type of animal and the intensity of the test depending upon the product in question- to determine safety levels of the product. With the increased use of chemicals and synthesized materials in products, animal testing became an industry standard since the possibility of the product having a side effect on a human being increased manifold. While science considered animal testing to be the most advanced form of product testing, animal rights were completely neglected. In fact Dr. Gerhard Zbinden, one of the world's leading toxicologists, once described a standard *in vivo* test as little more than "a ritual mass execution of animals.[1]" As per reports from PETA, over 100 million animals (including mice, rats, birds, agricultural animals, etc.) are killed each year in USA alone.[2] Slowly with improvement in science and better, less invasive techniques of product testing having been introduced, industries adopting alternative to animal testing is the need of the hour.

In recent times, India has taken several leaps forward with respect to banning of animal testing on drugs and cosmetics. Now, the Government is encouraging industries to adopt alternative methods of animal testing- the 3R Policy of 'reducing', 'refusing' and 'refining' the pain caused to animals through the testing. In addition to adopting the 3R Policy, India has also made amendments to the Drug and Cosmetics Act, 1940 in 2014 by inserting clauses that not just ban animal testing as a company standard, but also ban the importing of drugs and cosmetics that have been subjected to animal testing in other countries to India. This 2014

[1] The Baltimore Sun. (2010, August 27). Alternatives to Animal Testing Gaining Ground. The Baltimore Sun (MD) Via Acquire Media NewsEdge

[2] The Official PETA Website, http://www.peta.org/issues/animals-used-for-experimentation/animals-used-experimentation-factsheets/animal-experiments-overview/ (Last Accessed on 5th September, 2016 at 22:20)

Amendment has played a major role in propelling India towards becoming a cruelty free country. In fact, India is the first country in South Asia to have banned animal testing in cosmetics and drugs.

This paper will discuss the importance of animal welfare rights and the laws related to promoting such welfare right (e.g. the Prevention of Cruelty Act, 1960, etc.) This paper will also analyse the position of India compared to the other countries in the world with regard to the existing legal framework meant for protection of animal welfare rights. The paper will analyse amendments made to the Dugs and Cosmetics Act, 1940 and the Drugs and Cosmetic Rules in 1945 in recent times and recommend certain changes/modifications to be incorporated for the future in order to successfully curb the menace of animal testing in industries. As common as it may sound, even though animals cannot communicate like humans do, they still have welfare rights that cannot be blatantly disregarded merely for the benefit of humans.

INTRODUCTION

Animals have been used by humans for various reasons over the years. Whether for educational purposes or for testing drugs and cosmetics on animals before introducing them into the market, animals have become indispensable to humans for various reasons. Drug and cosmetic testing on animals has become an industry standard. While animal testing was extremely gruesome and violative of animal rights, it still continued because of the lack of a proper alternative. However, now with the advent of technology, there has been an increase in the want for alternatives to the traditional techniques of animal testing.

The public has started becoming aware of the grotesque treatment rendered to animals by scientists and chemists all over the world. More and more reports of the types of tests conducted by companies and organisations on animals has been released in the news. Non-profit organisations such as PETA and WWF have made excellent headway in leading the anti-animal testing campaign. The pressure to shift to alternative method of testing has never been higher than before.

This paper will deal with the beginnings of animal testing- where it started, why it started, the major traditional animal tests and their alternatives and problems related to animal testing. Then, the paper will deal with laws related to animal testing and experimentation in India, with great detail. Finally, the authors of the paper will give recommendations on how the situation of controlling animal testing should be improved in India.

REASONS FOR RESORTING TO ANIMAL TESTING

Animal Testing is, basically, the process of testing any new drug or cosmetic on animals that have very similar DNA's to human beings and exhibit instincts similar to that of humans under a particular stimulus. Animal testing may also include vivisection- "Operation on a living animal for experimental rather than healing purposes; more broadly, all experimentation on live animals".[3]

[3] Encyclopaedia Britannia, 2007

Generally, animals used in animal testing are chimpanzees that have a DNA 98.4% similar to that of humans and gorillas that have a DNA 97% similar to that of humans.[4] There are several other animals used in animal testing like rats, rabbits, mice, etc.

The whole purpose behind animal testing is to ensure that any drug or cosmetic coming into the market is safe for use by humans. The rationale behind animal testing is that since animals and human beings have very similar anatomies, testing the reaction of a cosmetic or a drug on an animal prior to human use will allow the inventor of the drug or cosmetic to check for any side effects or unwanted effects from the drugs. In the case where a drug has an adverse effect when used on animals during the animal testing phase of its development, then the problem can be solved at that point itself rather than allowing humans to suffer from the similar problems.

There were several instances where chemical drugs were introduced in the market without the makers knowing the side effects of the use of such drugs and it has adversely affected the public. Some of the most alarming examples where drugs were introduced in the markets without fully knowing the impact of such drugs are as follows:

1. In 1937, a pharmaceutical company created a preparation of sulfanilamide, a drug used to treat streptococcal infections, by using diethylene glycol (DEG) as a solvent. Unknown to the chemist, DEG was poisonous to humans, but he simply added raspberry flavouring and marketed the product as 'Elixir Sulfanilamide.' The preparation led to mass poisoning causing the deaths of hundreds of people. The public outcry caused by this incident and other such instance led to the passing of the 1938 Federal Food, Drug, and Cosmetic Act requiring safety testing of drugs on animals before they could be marketed. The whole purpose of this legislation and safeguard was to ensure that any drug or cosmetic product brought into the market was safe to use by humans with no adverse side effects.[5]
2. Supposed to be a 'wonder drug' for insomnia, coughs, colds, and headaches, thalidomide- a drug- was also found to have an inhibitory effect on morning sickness

[4] Susan Scutti (2013). Animal Testing: A Long, Unpretty history. Available at the link- http://www.medicaldaily.com/animal-testing-long-unpretty-history-247217 (Last Accessed on 31st August, 2016 at 21:47)

[5] Susan Scutti (2013). Animal Testing: A Long, Unpretty history. Available at the link- http://www.medicaldaily.com/animal-testing-long-unpretty-history-247217 (Last Accessed on 31st August, 2016 at 21:47)

and was accordingly, prescribed to thousands of pregnant women in the year 1960. Consequently, more than 10,000 children in 46 countries were born with malformations or missing limbs.[6]

Thus, the importance of animal testing cannot be ignored. For a very long time, there was no alternative to animal testing and therefore it was accepted as a necessary social evil. The justification to animal testing, as selfish as it may seem, was always that better animals suffer than humans.

THE HISTORY OF ANIMAL TESTING

Animal Testing has been rampant since time immemorial. It cannot be restricted to one part of the world and has been practised all over. Greek physician-scientists, Herophilus and Erasistratus, performed experiments on animals and examined sensory nerves, motor nerves, and tendons in order to understand their functional differences. In the 2nd century, Galen of Pergamum, a Greek physician conducted experiments on animals to study the areas of anatomy, physiology, pathology, and pharmacology. Through his experiments he was successful in learning about the complexities of the cardio pulmonary system and speculated the functions of the brain and spinal cord. An Arab physician of the 12th Century, Ibn Zuhr (or Avenzoar) tested surgical procedures on animals before applying them to human patients. In the 16th Century, Andreas Vesalius demonstrated anatomy using systematic vivisections on dogs. In countries like UK, animal testing has been rampant ever since the 17th century through Harvey's Experiments that were used to demonstrate blood circulation. Animal testing has become an important part of every country's drug and cosmetic production. It is a deep-rooted evil that has been encouraged and has evolved over a period of centuries.

[6] Susan Scutti (2013). Animal Testing: A Long, Unpretty history. Available at the link-http://www.medicaldaily.com/animal-testing-long-unpretty-history-247217 (Last Accessed on 31st August, 2016 at 21:47)

ANIMAL TESTING TECHNIQUES & THEIR ALTERNATIVES

1. DRAIZE TEST

In 1944, John H. Draize, a scientist with the US Food and Drugs Administration (FDA) developed the Draize test whereby rabbits were used to assess eye irritation caused by various chemicals. The rabbits are restrained, preventing them from responding naturally to the irritation, and their eyes are evaluated after one hour and then at 24-hour intervals for up to 14 days. Some rabbits were evaluated for as long as three weeks. The level of irritation to the eyes is scored numerically by observing three major tissues of the eye (cornea, conjunctiva, and iris). Rabbits suffered from redness, bleeding, ulcers, and blindness, and were likely killed upon completion of the experiment.

The Draize eye test has been criticized for several reasons. Critics observed that rabbits did not have similar eye structures to humans and their instincts and physiology was quite different as compared to that of humans. The structure of the cornea of the eye of a rabbit differed significantly from that of a human. Rabbits also produced a smaller volume of tears than humans and thus, allowing chemicals and other irritants placed in rabbit eyes to linger longer would cause more irritation. Not only did that make the Draize eye test results unreliable, but it also added to the immense suffering caused by this test.

This test is unhuman, torturous and needed to be changed urgently. While no non-animal alternative has yet been approved as a replacement for the Draize eye test, two alternatives have been created to allow for partial replacement of animal tests in a tiered testing scheme.

2. LD 50 TEST

Acute toxicity testing is used to determine the danger of exposure to a chemical by mouth, skin, or inhalation. For decades, acute toxicity testing meant poisoning large numbers of animals in Lethal Dose 50 (LD 50) tests, which are conducted until at least one half of the test animals die. The LD50 test is conducted infrequently now as it is being replaced by several new, but still lethal, options.

There are 2 alternatives to the LD 50 Test that are being seriously considered as a viable alternative to the LD 50 Test.

- **Fixed Dose Method**- In this method, the scientists will determine a certain level of toxicity to which the animals will be subjected. After that they will make a note of the symptoms exhibited by the animals at different levels of toxicity. However, as soon as the animals have been subjected to the pre-determined level of toxicity, the experiment will stop. The scientist will, then, using their calculations, determine the level of toxicity that will result in death. This is a more humane form of conducting the toxicity test compared to LD 50. The death rate of animals participating in this alternative testing process is a lot lower than in the LD 50 testing method, where minimum 50 % animals participating in the process die.
- **Up and Down Procedure**- It has been recognized as a viable option to the LD 50 test as it requires lesser animals to conduct the tests and get sufficiently accurate results. In fact, in USA, the Food and Drug Administration has approved using the up and down procedure in human trials as well.

Obviously, the LD 50 tests or even its alternatives are not 100% successes because the anatomy of humans and the animals used for the LD 50 test is different. The instinctual reaction and physiology is also different. While the test result accuracy is not completely accurate, it is still important to conduct such animal tests because they serve as a forewarning if something is wrong with ingesting the drug in a particular way or above a particular quantity.

3. Repeated Dose Toxicity

While Acute Dose Toxicity checks to see the dosage required to be ingested at one time to create a toxic effect, repeated dose toxicity checks to see the dosage required to be ingested at regular intervals over a period of time to prove toxic. Chronic toxicity testing is of 2 types-

- oral, dermal, and inhalation subacute repeated dose studies (28-day)
- sub-chronic repeated dose studies (90-day) in rodents

Some agencies may also require these tests to be completed in a non-rodent species such as dogs or for longer periods of time. Animals are evaluated during the test period and then killed

at the end to look for signs of organ or body system damage. Scaling up the results of repeated dose toxicity tests from small, short-lived animals to humans is difficult; and there is great variation in how chemicals are absorbed and metabolized by different species. Unfortunately, since there is no validated non-animal alternative, this method of animal testing persists even today.

4. Skin Corrosivity/Irritation

Skin corrosion tests assess the potential of a substance to cause irreversible damage to the skin. Skin irritation tests determine the level of damage caused to skin such as itching, swelling, and inflammation. Both tests are typically performed on rabbits. The skin irritation test is often referred to as the Draize skin test and involves placing a chemical on a shaved patch of skin and using another shaved patch as a control.

The problem with conducting skin corrosion tests on animals is that there is a huge difference in the skin structure of humans and animals. The results obtained may often result in incorrect and inaccurate results. Alternatives have been validated to replace skin corrosivity tests is some cases; however, often the alternatives are part of a tiered testing strategy where at least one of the stages will requires at least some animal tests. The alternatives have not been validated for use as a replacement for skin irritation tests and thus, the skin corrosion tests have remained largely unchanged.

5. Skin Sensitization

The skin sensitization test is used to determine if a chemical cause an allergic reaction. Guinea pigs are used for experiments testing drugs and cosmetics for skin sensitization. Substances are applied on the surface or injected onto the shaved skin of guinea pigs.

In the Guinea Pig Maximization Test[7], a chemical adjuvant is injected with the test substance to boost the immune reaction. In the Buehler test[8], no adjuvant is used but the test is less

[7] It is an in vivo form of animal testing where the substance will be ingested or injected into guinea pigs to monitor for skin sensitization. It was introduced by B. Magnusson and Albert Kligman in 1969 and described in their 1970 book *Allergic Contact Dermatitis in the Guinea Pig*

[8] Buehler Test was created by Edward von Buehler in 1960 and further explained in 1980. It is a method of testing allergens for skin sensitization.

sensitive. In both of these skin sensitization tests, multiple doses are applied in order to create an allergic reaction. The guinea pig tests for skin sensitization are highly subjective as the substances are assessed based on the appearance of the skin. In addition, the method of applying these chemicals to the guinea pigs (i.e. injecting them or delivering with an adjuvant) is not consistent with the human use.

Most skin sensitization testing now occurs using an alternative method called the Local Lymph Node Assay (LLNA)[9]. The procedure involves the application of test chemicals on the surface of the ears of mice. This method uses less number of animals than its traditional alternative and the torture that animals are subjected to, is also controlled to quite an extent. LLNA was the first test method to be validated under the Interagency Coordination Committee on Validation of Alternative Methods (ICCVAM) run by the National Toxicology Program spearheaded by the US Department of Health and Human Services by a panel of peer reviewers. Compared to the traditional test, the LLNA can also be completed in a shorter timeframe and provides dose-response information. However, the mice are still killed after their use in these tests. Alternatives involving more refined versions of the LLNA are under consideration to eliminate the need to kill the mice as altogether.

6. Neurotoxicity

Neurotoxicity tests aim to find out if substances cause alterations to the nervous system. Neurotoxicity tests are often used to study the effects of pesticides and primarily involve the use of hens or rats.

In the tests designed for using hens, tests can be conducted in any of the following ways-

- Animals are given a single oral dose of a substance and observed for 21 days
- Animals are given doses of the test substance orally on a daily basis for 28 days.

[9] OECD Guidelines for the Testing of Chemicals guideline No. 429 of 23 July 2010.

The hens are observed during the test for weight changes, behavioural changes, changes in their body temperature, etc. At the end of the tests, the remaining hens are killed and their bodies are evaluated for signs of neurotoxicity.

In the rat neurotoxicity test, the animals are given daily doses of the test substance for-

- 28 days
- 90 days
- One year

The rats are observed for physical and behavioural changes during the test and are killed at the end of the test period and examined for signs of neurotoxicity. There are no regulatory accepted non-animal methods for neurotoxicity testing.

7. Pyrogenicity

A pyrogen is a substance (often bacterial) that causes elevation to an animal's body temperature. Pyrogenicity testing seeks to find any possible fever-causing contaminants in items such as vaccines and injectable drugs. The rabbit pyrogen test, in use since the 1940s, requires the injection of the material into the rabbits' blood stream and then monitoring for temperature increases. The rabbits' sensitivity to the test is greatly affected by the strain of the pyrogen, as well as differences in age and gender, which can lead to skewed data. Furthermore, the rabbit pyrogen test simply produces pass/fail results, but drugs injected under the skin or in the muscle in small doses require the formulation of maximum acceptable concentration, which is not obtained by this test. Another pyrogen test has replaced the rabbit test for many, but not all pyrogen testing needs. This test, the Limulus Amebocyte Lysate (LAL) test, uses the amebocytes from the blood of horseshoe crabs in order to demonstrate the immune system to response to pyrogens. Five alternative test methods to the rabbit pyrogen test are currently being evaluated.

PROBLEMS WITH ANIMAL TESTING

While most companies resorting to animal testing will try and portray to the public eye that the animal testing conducted by them is legitimate and sanctioned by laws, this is not always the case. Out of 100 million animals used for animal testing every year, about 95% of such animals are not protected by any animal protection law and are at the mercy of the companies using them for such tests.[10]

Problems related to animal testing are as obvious as they seem. While the motivation to introduce animal testing for drugs and cosmetics is to protect humans from any unknown side effect, the collateral damage is very high. Animal rights are being blatantly disregarded in the process of animal testing. Animals are being subjected to unthinkable pain and suffering. Animals used in various animal tests are mostly killed after the experiments are over. If they aren't killed, they have been subjected to so much torture that they can never lead a normal, healthy life. They will always have some physical or physiological deformity as a result of such animal experiments.

It can definitely not be stated that animal testing is a wasteful activity because its benefits are huge and important. However, with the advent of technology, it is now time for scientists to look for alternative techniques to animal testing. There is no want of funding or brilliant minds. If organisations and governments become serious about eliminating animal testing, then it is a completely doable activity.

With increasing awareness about the importance of protecting animal rights and animal welfare, alternative to animal testing are becoming a serious reality. Several countries including India have taken several steps to control the menace of animal testing. Either by way of legislation or through bans and penalties, several important steps are being taken by countries all over the world to protect animal welfare rights.

[10] Animal Legal Defence Fund. Animal Testing and the Law. Available on the link- http://aldf.org/resources/when-you-witness-animal-cruelty/animal-testing-and-the-law/ (Last Accessed on 31st August, 2016 at 23:12)

CURRENT SCENARIO- ORGANISATIONS WORKING TOWARDS ANIMAL WELFARE PROTECTION AND THEIR ACHIEVEMENTS IN RECENT TIMES

The issue of animal testing has become a big issue these days as a lot of organizations are working hard for spreading awareness about the same and making sure that the government takes steps to ban such activities. Some of those organization are as follows:

a. The European Coalition to End Animal Experiments (ECEAE)

The ECEAE are working hard to help eliminate all animal testing within the European Union. They have been the voice for these helpless animals for nearly 25 years. In that time, they've ended animal testing for cosmetics in the EU and have delivered globally recognized cruelty-free standards for cosmetics, the Humane Cosmetics Standard. The following is the organisations achievement:[11]

1. ECEAE through its long running campaign since 1990, finally made the EU ban cosmetics tested after March, 2013.
2. ECEAE worked hard for passing a legislation which says that 45 days will be given for public scrutiny of certain tests to see if there is existing data or another method that could be used.
3. The ECEAE successfully campaigned for mandatory data sharing so that companies must pool their collective animal-testing data on a particular chemical, ensuring that safety testing should only be carried out once.
4. After a lot of perusal, the development and use of alternatives has been centrally placed in Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[12].

b. People for Ethical Treatment to Animals (PETA)

PETA's page about fighting against regulatory testing on animals is filled with information about animal testing and the resources they are using to fight it. It highlights their accomplishments including donating more than one million dollars to find non-animal testing

[11] Available at http://www.eceae.org/cs/about-us/history-achievements/more-achievements
[12] Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European Union regulation dated 18 December 2006

methods. They received an award from the Institute for In Vitro Sciences. The organization has been successful as follows: [13]

1. PETA fought the Center for Science in the Public Interest's request to the Food and Drug Administration that a natural plant-based sweetener be tested on animals—and won.
2. When the Sierra Club and other groups wanted the EPA to require animal experiments for air fresheners, PETA presented an analysis showing that additional testing was unnecessary—and the EPA agreed.
3. Following the great efforts of PETA the EPA agreed to use non-animal test methods into its Endocrine Disruptor Screening Program, which had the potential to kill tens of millions of animals.

c. The Physicians Committee for Responsible Medicine (PCRM)

The Physicians Committee for Responsible Medicine (PCRM) is a non-profit based out of Washington D.C. that promotes a vegan diet, preventative medicine, and alternatives to animal research. It was founded in 1985 by Neal D. Barnard and has had support from PETA to further their cause. Most recently, doctors involved have offered a $25,000 grant to end the use of live pigs at the University of Mississippi Medical Centre for their physiology course.[14]

India- Existing Laws Governing Animal Experimentation & Recent Amendments

A. Agencies

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) is a statutory committee established under Chapter 4, Section 15(1) of the Prevention of Cruelty to Animals Act, 1960 (PCA Act, 1960). The first ones to enact to rules for experimentation on animals were the Ministry of Agriculture in 1968 and were implemented by a committee setup in pursuance of Section 15(1) of the (PCA Act, 1960). However the committee was later wound up and 13 years later, a recommendation to reinstitute CPCSEA was given by Animal Welfare Board of India[15]. After due consideration of the

[13] Available at http://www.peta.org/issues/animals-used-for-experimentation/us-government-animal-testing-programs/animal-testing-depth/
[14] Available at http://www.onegreenplanet.org/animalsandnature/5-awesome-organizations-fighting-to-end-animal-testing/
[15] Available at http://cpcsea.nic.in/Auth/index.aspx

recommendation of AWBI, the committee was set up by the Ministry on 8th February, 1991. The CPCSEA does the following functions[16]:

- Registration of establishments conducting animal experimentation.
- Selection and assignment of nominees for the Institutional Animal Ethics committees of the registered establishments.
- Approval of Animal House Facilities on the basis of reports of inspections conducted by CPCSEA.
- Permission for conducting experiments on animals.
- Recommendation for import of animals for use in experiments.
- Action against establishments in case of established violation of any legal norm stipulation.
- Conduct of training programmes for nominees of CPCSEA.
- Conduct/ Support of Conference/ workshop on animal ethics.

B. Laws

1. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic Rules, 1945

The Drugs and Cosmetics Act, 1940 was enacted to regulate the sale, manufacture, import and distribution of drugs and cosmetics. The drugs and cosmetic act and the drugs and cosmetic rules[17] together govern the manufacture of drugs and everything else. The Drugs and Cosmetics Act, empowers the government to prohibit import of drugs when it finds it to be adulterated or spurious etc[18]. It also can prohibit drugs on the grounds that they are against interest[19]. It also enables the government to prohibit manufacture of the drugs on the same grounds as it prohibits import.[20] Recently exercising the same power, the Government has banned import of cosmetics which are tried and tested on animals, on the grounds that they are against public interest as stated in Sec. 10-A of the Drugs and Cosmetics Act, 1940. To ensure implementation of the same, they have inserted Rule No. 148-C[21] to the existing Drugs and Cosmetics Rules, 1945.

[16] Available at http://cpcsea.nic.in/Content/58_1_Functions.aspx
[17] In exercise of the powers conferred by Sections [6(2), 12, 33 and 33 N] of the Drugs and Cosmetics Act, 1940
[18] Sec. 10 of the Drugs and Cosmetics Act, 1940
[19] Sec. 10(A) of the Drugs and Cosmetics Act, 1940
[20] Sec. 18 of the Drugs and Cosmetics Act, 1940
[21] Prohibition of Testing of Cosmetics on Animals- No person shall use any animal for testing of cosmetics.

The Schedule Y[22] of the Drugs and Cosmetics Rules, 1945 with reference to rules 122A, 122B, 122D, 122DA, 122DAA and 122E of the same lists out the guidelines and the procedure that has to be followed during clinical testing. It also prescribes the detailed methods and the no. and type of animals that are to be used in different tests.

2. The Prevention of Cruelty to Animals Act, 1960

The Prevention of Cruelty to Animals Act, 1960 was enacted on 26 December, 1960 to prevent the infliction of unnecessary pain or suffering on animals and for that purpose amend the law relating to the prevention of cruelty to animals.

This act talks about animal welfare and the rules and regulations that are to be followed while conducting experiments on animals. Sec.14 – Sec. 20 of the Act talks about the same procedure. The act doesn't render the experiments on animals unlawful for the purpose of advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or prolonging life or alleviating suffering or for combating any disease, of any living being.[23] For the purpose of controlling and supervising experiments on animals, the government can, on advice of the Animal Welfare Board, may by, notification in the Official Gazette, constitute a Committee as it may think fit to appoint thereto.[24] It is the duty of the committee to take all such measures to make sure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them[25]. After the amendment of PCA in 1982[26], the committee had powers in the matter of registration of persons or institutions carrying out experiments on animals and other information which shall be forwarded to the Committee by the persons and institutions carrying on the experiments. The committee has its rules designed for securing the following objects[27]:

- That the institution where these experiments are being performed is the responsibility of the person in charge of the institution and where the experiments are being performed outside an institution by individuals, such individuals are qualified in that behalf and they have the completely their responsibility.

[22] Ins. by Drugs and Cosmetics (IInd Amendment) Rules, 2005
[23] Sec.14 of Prevention of Cruelty to Animals Act, 1960.
[24] Sec.15 of Prevention of Cruelty to Animals Act, 1960.
[25] Sec. 17(1) of Prevention of Cruelty to Animals Act, 1960.
[26] Sec. 17(1) (A) Prevention of Cruelty to Animals Act, 1960 (Ins. by Act 26 of 1982, S. 14.)
[27] Sec. 17(2) of Prevention of Cruelty to Animals Act, 1960.

- that experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals feeling pain;
- that animals which, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;
- that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the. like, may equally suffice;
- that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-'pigs, rabbits, frogs and rats;
- that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- that animals intended for the performance of experiments are properly looked after both before and after experiments;
- That suitable records are maintained with respect to experiments performed on animals.

The Committee can at any time as may deem to be reasonable may inspect any institution where experiments on animals are carried out so as to make sure that the regulations are complied with[28] and if it finds out that the conditions are not complied with, the committee on giving a chance to be heard, prohibit the person or institution from carrying on any such experiments either for a specified period or indefinitely, or may allow the person or institution to carry on such experiments subject to such special conditions as the Committee may think fit to impose[29]. If a person or institution contravenes the order passed by the committee, then he shall be penalized and has to: he shall be punishable with fine which may extend to two hundred rupees, and, when the contravention or breach of condition has taken place in any institution the person

[28] Sec.18 of Prevention of Cruelty to Animals Act, 1960.
[29] Sec.19 of Prevention of Cruelty to Animals Act, 1960.

in-charge of the institution shall be deemed to be guilty of the offence and shall be punishable accordingly.[30]

3. **Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998**

The Breeding of and Experiments on Animal (Control and Supervision) Rules, 1998 were established under Sec. 17(1) of the Prevention of Cruelty to Animals Act, 1960. The rules describe very comprehensively all the procedures right from registration to experimentation and de-registration. Para 9, talks about how the experiments are to be carried out and how the animals should be treated during and after the experiments, in what cases can the animal be killed. It also states that experiments cannot be done for illustrative purposes and as a public demonstration. The rules also state that if an animal is in pain during the experiment then what is to be done with them. Experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment[31] and experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthesia to prevent the animal feeling pain and it shall remain so throughout the experiment.

The rules are a comprehensive guideline as to how the entire process of experimentation is done and what all has to be taken care of. The rules were amended in 2006 and three sub paragraphs to sub paragraph b, c and f of Para 9 were added namely bb, cc and ff respectively which talked about animals who provide 95% accurate results should be preferred and how the animals have to rehabilitated and the responsibilities of supervisor in doing the same and lastly, the parameters that have to be kept in mind while the application of euthanasia.[32]

It can be understood from the above that there is definite improvement in the situation in India through the creation of such laws. However, there is a problem of insufficient penalties and lack of enthusiasm of implementation that needs to be tackled with before the laws will have some real sizeable effect. With people hugely interested in the problem of animal testing and

[30] Sec.20 of Prevention of Cruelty to Animals Act, 1960.
[31] Para 9 of Breeding of and Experiments on Animal (Control and Supervision) Rules, 1998
[32] Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006.

the resulting violation of animal rights, there is now real hope that there will be an improvement of the situation and these well-rounded legislations will prove more effective than merely being pieces of paper.

4. **Other Acts**

Recently, the Medical Council of India amended its regulations and now the. The guidelines for the Establishment of Medical College Regulations, 1999, and the Minimum Standard Requirements for 50/100/150/200/250 MBBS Admissions Annually Regulations, 1999 states that no animals shall be used in teaching at universities. The Pharmacy Council of India (PCI) has amended the Education Regulations, 1991, and the Pharm D Regulations, 2008, to read, "Wherever animal experimentations are prescribed in the curriculum, the required knowledge and skill should be imparted by using computer assisted modules"

Comparison of Laws in Different Countries for Animal Protection

As can be seen the first law introduced in India for animal protection from experimentation was only in 1940. This was actually quite late compared to other countries like UK.

In United Kingdom, the first act meant for regulating animal experimentation was introduced by the Parliament in 1876[33]. It was called the Cruelty to Animals Act and was meant to control the menace that animal experimentation has become. The Cruelty to Animals Act, 1876 became a cornerstone legislation for such acts introduced by other countries. It became a guiding light along the lines of which several countries drafted their own animal experimentation control legislation.

Subsequently, UK has introduced the Animals (Scientific Procedures) Act 1986 and the Guidance on the operation of the Animals (Scientific Procedures) Act 1986 were introduced to better control the problem of rampant animal testing. Several amendments have been introduced to these acts, and there is some headway being made by UK in controlling this problem effectively.

[33] History of Animal Research, available on the link- Available at http://www.understandinganimalresearch.org.uk/resources/animal-research-essay-resources/history-of-animal-research/ (Last Accessed on 5th September, 2016 at 21:26)

In United States of America, Animal Welfare Act, 1966 was the first federal law introduced in the country to regulate animal experimentation.[34] The law defined the standard of care animals to be taken at research facilities. However, the extent of animals covered under the Act, 1966 was extremely restricted. It excluded almost 95% of the animals tested upon (such as rats, mice, birds, fish, and reptiles) and provided only minimal protection for the rest. Labs are not required to report non-AWA protected animals, thus, effectively giving organisations a free hand to misuse and treat animals however they deem fit.

In USA, the Public Health Services (PHS) oversees the Food and Drug Administration (FDA) and the Centres for Disease Control and Prevention (CDC). The CDC conducts infectious disease research on nonhuman primates, rabbits, mice, and other animals. The FDA exploit animals in pharmaceutical research. Since the PHS requires only written assurance of compliance through the Office of Laboratory Welfare (OLAW), there is not much useful action that is being taken by the PHS in controlling illegal and unregistered animal experimentation because OLAW takes little action, has no mandated follow-up, or on-site inspection against those research facilities found lacking of following proper regulation.

With a department of only 120 inspectors, the United States Department of Agriculture (USDA) oversees more than 12,000 facilities involved with research, exhibition, breeding, or dealing of animals. Federally-owned facilities, like the Department of Defence, are not inspected by the USDA. Those research facilities will come under the purview of the Animal and Plant Health Inspection Service (APHIS) under the Animal Welfare Act, 1966. Penalties for non-compliance are often virtually inconsequential in comparison to massive research revenues- a similarity to the Indian Legal situation.

Other regulatory bodies charged with protecting animals, such as the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) and mandatory Institutional Animal Care and Use Committees (IACUC), are self-chosen, self-policing bodies with little or no punitive power.

While several steps have been taken by the United States of America to control the problem by introducing the various laws and committees, there is still a long way to go for USA to reach a completely intolerant system. Research work towards development of alternative methods of animal testing is extremely promising.

[34] The Official Animal Welfare Institute, USA Website available on the following link- https://awionline.org/content/animal-welfare-act (Last Accessed on 5th September, 2016 at 21:28)

From the above, we can see that all countries are edging towards the 3R Policy of Reduction, Refinement and Replacement. While several steps have already been taken by them, there is still some way to go. However, with the intent in place, all the countries will eventually successfully become zero tolerance zones for inhuman animal testing.

RECOMMENDATIONS

The authors have come up with recommendations to be implemented to improve the prevalent situation with respect to animal experimentation and animal testing. These recommendations are-

1. Fines for not complying with the guidelines should be increased. In the various acts that are there for protection of animal rights the fine that is imposed is hardly anything. For example, Sec. 11 (o) of The Prevention of Cruelty to Animals Act, 1960 states:

"(o) promotes or takes part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting: he shall be punishable (in the case of a first offence, with fine which shall not be less than ten rupees but which may extend to fifty rupees and in the case of a second or subsequent offence committed within three years of the previous offence, with fine which shall not be less than twenty-five rupees but which may extend, to one hundred rupees or with imprisonment for a term which may extend, to three months, or with both"

In this particular section, the amount of fine is just ten rupees for a crime like killing of an animal for entertainment. The condition is the same throughout the act. In the Drugs and Cosmetic Act, 1940 also, under Sec. 13(b):

"(b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which extend to five thousand rupees or both"

The fine extends for a maximum of five hundred rupees. Thus, with such less amount of fine there is no deterrence and thus there is a failure in implementation of law. Hence, the increase

in the amount of fine, will not only increase deterrence but will also make sure that the law is being implemented properly.

2. Under Chapter 2 of the Prevention to Cruelty to Animals, 1960, there is a provision for the creation of an Animal Welfare Board of India. This Board was constituted in 1962 and has been an actively functioning body ever since. The Board has taken several steps to reduce animal suffering and violation of animal rights due to various human activities including animal experimentation. In 2011, the Animal Welfare Act Draft was also created by the Animal Welfare Board of India to improve the situation of animal right violation. Since the Animal Welfare Board of India has been quite successful in its attempts to improve the plight of animals, the authors suggest the creation of a structure under the headship of the Animal Welfare Board of India.

Rather than continuing with the unsuccessful State Welfare Board System, the Animal Welfare Board of India can constitute District level Animal Welfare Associations. These Associations will be statutory bodies with perpetual succession. They will be constituted by the AWBI. The members will constitute 2-3 representatives from each NGO doing notable work for the protection of animal rights caused by illegal experimentation or any other illicit activity. About 5-6 notable NGO's can be represented in the Association. Apart from these representatives, the membership of the Association will include a representative from the common public willing to donate their time to the cause of animal right protection. These members will all work pro bono. They will have to keep minimum one meeting every month. There will be a designated post box number for the Association wherein any anonymous complaints can be filed by any member of society. This box will be opened during every meeting and the problems will be discussed. If the solution for a particular situation is within the scope of authority of the Association then, they can implement the solution and make a detailed report for the same. In those cases where the solution is out of the scope of authority of the Association, they need to make a report and forward it, along with all other details, to the AWBI Multi- District Representative.

A group of about 10 District Level Animal Welfare Associations will report to the AWBI Multi-District Representative. This representative will be appointed by the AWBI and will

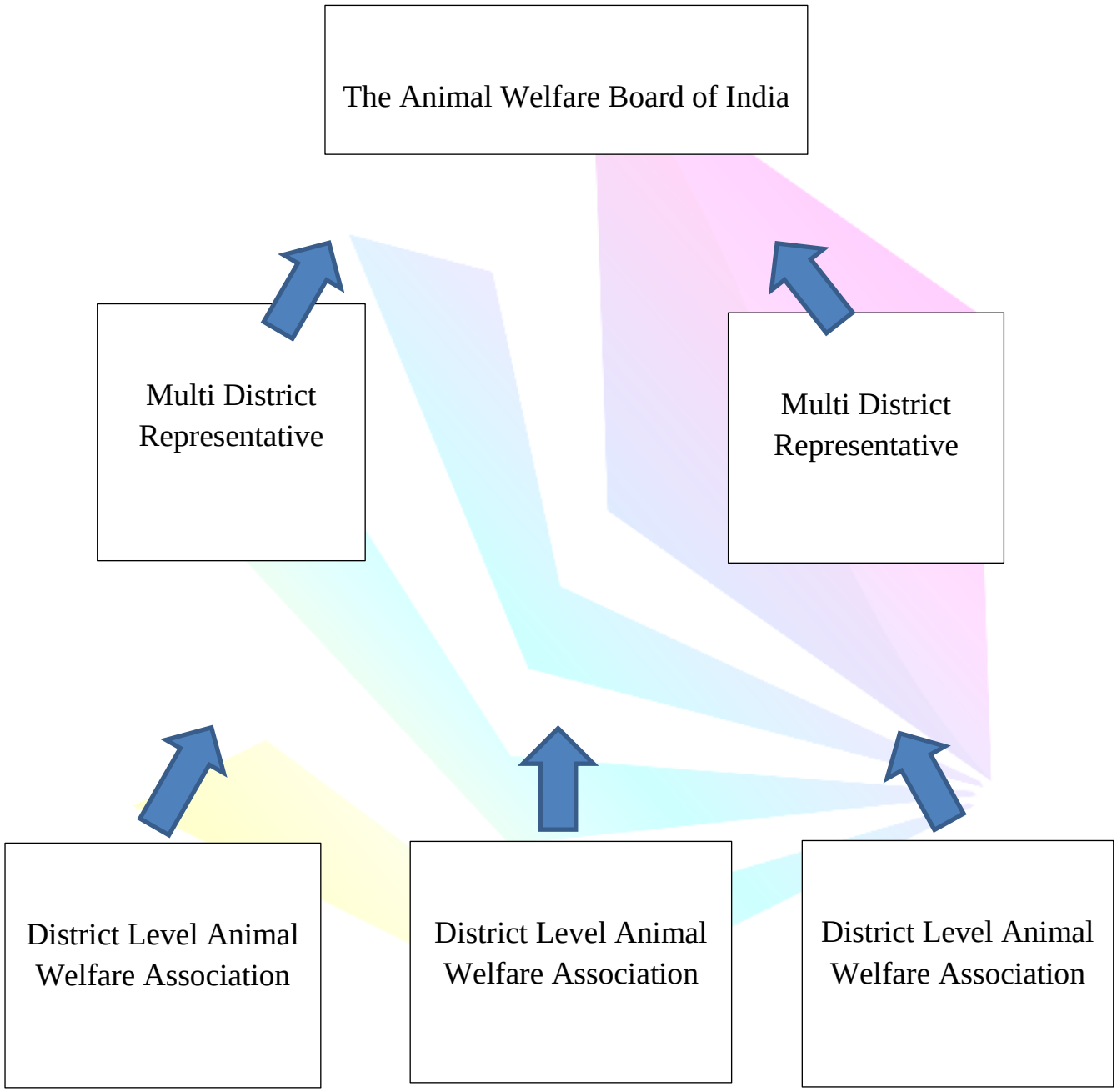
draw a salary from the fund allotted to the AWBI. The process of selection and qualification will be as per the discretion of the AWBI. This representative has the following responsibilities-

1. Inspect monthly reports submitted by the District Level Associations for those problems solved by them to ensure that they have not acted ultra vires and the solution given is plausible and effective. In case, the representative finds that the Association has acted ultra vires, then he will undo the decision of the Association and forward the matter to the AWBI, who will then make a decision.
2. To forward those complaints that the Association does not have the authority to solve to the AWBI.
3. To form a link between the AWBI and the Associations for communications of any problems or for any other reason.

The AWBI will be in constant contact with these representatives. They will look into those matters where the Association may have acted ultra vires or where they have insufficient authority to take a decision. The decision will be given after getting all the relevant information from the representatives. The representatives will then be responsible for communicating the decision to the Association, who in turn, will convey the decision to the relevant parties at hand.

Hence the involvement of State Governments becomes unnecessary and the entire structure can be run by the AWBI. The AWBI must accordingly be given a bigger budget and approval to increase its man force as much as needed to be able to run this 3-tier system. Hopefully, this system will prove more efficient than the defunct and un-operational State Welfare Boards of India.

A Diagrammatic Representation of the System of Animal Welfare & Protection of Animal Rights against Experimentation and Other Illegal Activities proposed by the authors:



CONCLUSION

From the above paper, we can see that there has been a real change in wave with respect to importance given to animal welfare rights and the protection of animals against inhuman acts by governments and organisations. People have finally realised that animal rights cannot be written off as collateral damage. This wave of realisation was needed and is well-received. Non-profit organisations like PETA and WWF have had several major successes recently with respect to controlling illegal animal experimentation.

The plight of animals in experimentation is deplorable. They are subjected to torture without any justification, except, for the benefit of humans. When there was no other option, the rationale that 'animals better than humans' would have still floated. However, now, with availability of so much technology, the idea of resorting to the traditional techniques of animal testing is perverse.

Several Indian cosmetic companies like Forest Essentials have completely done away with animal testing. Since all ingredients used in the creation of their products are organic, there is no need for animal testing because there will be no side effect from the use of natural products like kesar, amla, tulsi, etc. With the recent amendment to the Drugs & Cosmetic Rules, 1945, banning the import of cosmetic products undergoing animal testing, India has taken a very big leap towards the dream of becoming a zero-tolerant country. With India being a huge market for several cosmetic companies like MAC, Shishedo, etc. these companies are now forced to look for alternatives to the traditional techniques of animal testing if they want to continue import to India.

While India may not have been the first country to create a legislation for animal protection against experimentation, unlike UK, it has still managed to create a very well rounded legislative mechanism. With acts like the Prevention to Cruelty to Animals, 1960 and the Drugs and Cosmetic Act, 1940- India has managed to move several step forward in its fight for animal protection and against the traditional, grotesque techniques of animal testing for drugs and cosmetics.