

1 IN RE: Pennsylvania House of Representatives Judiciary  
2 Committee - Public Hearing Regarding  
3 House Bill 1554

4 Verbatim record of public hearing  
5 held at Allegheny County Courthouse,  
6 Gold Room, Pittsburgh, Pennsylvania,  
7 on Friday, September 23, 1988, at

12:00 Noon

8 Hon. H. William DeWeese - Chairman of House Judiciary Committee

9  
10 MEMBERS OF THE HOUSE JUDICIARY COMMITTEE:

- |                              |                               |
|------------------------------|-------------------------------|
| 11 Hon. Jerry Birmelin       | Hon. Joseph A. Lashinger, Jr. |
| 12 Hon. Kevin Blaum          | Hon. Nicholas Maiale          |
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| Hon. Babette Josephs         | Hon. Christopher R. Wogan     |
| 16 Hon. Gerald A. Kosinski   | Hon. Robert C. Wright         |
| 17 Hon. Allen Kukovich       |                               |

18 ALSO PRESENT:

- |                        |   |
|------------------------|---|
| 19 John J. Connelly    | - Special Counsel to House Judiciary<br>Committee |
| 20 Michael P. Edmiston | - Chief Counsel to House Judiciary<br>Committee   |
| 21 Tony DeLuca         | - Representative, Penn Hills                      |
| Ivan Itkin             | - Representative, Point Breeze                    |

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1 (The public hearing commenced at 12:05 P.M.)

2 CHAIRMAN DeWEESE: Ladies and gentlemen, if you  
3 will take your seats, our hearing will commence.

4 Welcome to the Pennsylvania House Judiciary  
5 Committee meeting of September 23, 1988.

6 I would like to introduce the people here on the  
7 floor and then get right down to our testimony.

8 Mary Beth Marchak, of the Judiciary Committee Staff,  
9 on the far left; Gwen Miller, of our staff, next to the left;  
10 Representative Paul McHale, of Lehigh Valley, on the left,  
11 also, in more ways than one, I might add; John Connelly,  
12 Special Counsel to the Committee; Gerry Kosinski, of Phila-  
13 delphia, the Subcommittee Chairman on Courts, and my right-  
14 hand man on my left-hand side. Then, Mike Edmiston, our  
15 Chief Counsel; and Skip Schaub, of Representative Tom  
16 Murphy's office.

17 I would also like to recognize Tom Flaherty, City  
18 Controller, of the City of Pittsburgh, who is also in the  
19 audience today.

20 My Subcommittee Chairman, Mr. Kosinski, will, as a  
21 co-sponsor of the measure that is our focus today, be in  
22 charge of a substantial amount of the hearing. I will be  
23 in and out of the hearing. So, the Subcommittee Chairman, Mr.  
24 Kosinski, will be at the helm for a great deal of today's  
25 events.

1 I would like to keep the hearing moving. I would  
2 like to ask all of the witnesses to enter from this side, and  
3 to be seated where Representative Tom Murphy is at the present  
4 time, or in one of the chairs next to him, so we can keep a  
5 flow, and the steno and our staff on the left can maintain  
6 their positions.

7 I forgot to introduce myself, didn't I? I am Bill  
8 DeWeese, from Greene County. I represent part of Fayette and  
9 Washington Counties. I am privileged to be the Chairman  
10 of the House Judiciary Committee.

11 Our first witness today will be the Hon. Tom Murphy,  
12 the sponsor of House Bill 1554, and the reason our committee is  
13 in Pittsburgh this afternoon.

14 Without any further ado, welcome, Tom, and we look  
15 forward to your testimony.

16 REPRESENTATIVE MURPHY: My name is Tom Murphy.  
17 Thank you, Bill.

18 (Whereupon, the audience applauds.)

19 CHAIRMAN DeWEESE: Tom, is that for me or for you?

20 REPRESENTATIVE MURPHY: That's for you, Bill. I  
21 would never take that away from you, Bill.

22 I appear here today to testify on a piece of legis-  
23 lation that I have introduced in the Pennsylvania House of  
24 Representatives. This measure, House Bill 1554, addresses  
25 some of the concerns that I and tens of thousands of fellow

1 Pennsylvanians have regarding the humane treatment of  
2 laboratory research animals undergoing experimentation and  
3 testing.

4 First, let me say that I recognize this can be an  
5 emotional and controversial issue. But it is one, as a  
6 society, we must face.

7 If I may go from my text for a moment, and simply  
8 say the foundation of where I come from in this legislation  
9 concerns what we read about for months in the newspapers and  
10 magazines and on television. That is the stewardship of  
11 our environment. We have really, in our society, institutional-  
12 ized the use of animals and the abuse of animals from when we  
13 were in high school and experimented on frogs; to when we  
14 were in college and we used cats to graduate school.

15 We have been teaching people to treat animals and  
16 other living creatures in society very much like we treat  
17 a Pepsi can; that is, to use it and throw it away.

18 I think we have seen the results of that attitude.  
19 So this is but one piece of, I think, trying to raise the  
20 sense of recognition in our society that we are only stewards  
21 to the environment, and that our role is to protect that  
22 environment and not simply to look upon it as disposable;  
23 that we can use it and throw it away.

24 As you all know, my interest in House Bill 1554  
25 is a start to balance the needs of the high tech economy we

1 increasingly have in the United States and the need to provide  
2 a caring and less hurtful world.

3 All of you on this panel know of my interest in  
4 economic development. Part and parcel of that development  
5 is research. I believe in research, and yes, when necessary,  
6 I believe in the concept of utilizing test animals to obtain a  
7 better and safer world.

8 House Bill 1554 does not restrict medical research.  
9 The measure addresses those areas where basic animal pro-  
10 tection in laboratories is either weak or non-existent.  
11 House Bill 1554 deals with duplicate or redundant testing,  
12 cosmetic and commercial product testing, and students' rights,  
13 and employee rights, I might add.

14 It concerns me greatly that cruel and painful tests  
15 are done on living creature subjects for no good reason. In  
16 a few moments, you will see a small video capsule that will  
17 give examples of that. I believe we can do better and have  
18 a progressive scientific society without wholesale and  
19 unnecessary experimentation.

20 The extent of experimentation in our society is  
21 unknown. We have tried to compile numbers for you so you  
22 get an extent of what is going on.

23 We do know a few things. In Pennsylvania, there  
24 are at least eighty laboratories experimenting on animals.  
25 Their voluntary reports indicate that experiments, in 1987,

1 involve the following numbers of subjects:

2 As you can see, it comes close to somewhere  
3 between 75 and 100 thousand animals are used in Pennsylvania  
4 every year.

5 A significant number of those animals have been  
6 reported to suffer pain and distress by the research  
7 institution themselves. Some of the great learning insti-  
8 tutions are involved in experiments that cause pain and  
9 suffering to living subjects. Carnegie-Mellon, Pitt, and  
10 local hospitals all engage in this kind of research.

11 I respect the role these institutions play in our  
12 society, but I do think that we can be creative enough to find  
13 non-painful ways to test inventions.

14 This is a great challenge we have in Pennsylvania,  
15 and throughout the United States, and the world, to continue  
16 our exciting research and resulting technological innovation  
17 to help society progress, at minimal cost in dollars, time  
18 and suffering.

19 Again, let me remind the panel and the audience, that  
20 this measure deals with unnecessary and duplicative research.  
21 It seeks to create checks and balances in our research  
22 industry.

23 Despite the modest intentions of House Bill 1554,  
24 there are those who will oppose any regulation or scrutiny of  
25 animal research. But control of pain and suffering, whether

1 for humans or animals, is inevitable. Let's start to work  
2 together to reach mutual goals.

3 Some will argue that any regulation of animal  
4 research could have adverse effects on certain businesses.  
5 I do not believe that commerce and industry have to rely on  
6 animal killing and suffering to test their products.

7 It is just like arguing that business can't survive  
8 without child labor, or the twelve-hour day. Hundreds of  
9 companies produce products without resorting to animal  
10 testing.

11 We will give you, when you leave today, a packet  
12 of products on the market in our society that are tested  
13 without the use of animals. For example, on this product,  
14 a hair treatment, on the back, it uses as a marketing device,  
15 indication that it is not -- animals are not used in this  
16 testing.

17 I hope you will take these home and use them and  
18 give me a judgment as to whether they are any different or  
19 any better than other products in the market place that have  
20 used animals in testing.

21 The simple fact is that the research industry has  
22 a vested interest in the status quo. Inertia makes all of  
23 us unwilling to change direction. House Bill 1554 helps  
24 make that change.

25 The most controversial element of this bill is its



1 call for a ban on eye-irritancy and lethal-dose testing.  
2 They are two particularly painful tests used for the develop-  
3 ment of products and cosmetics.

4 Despite claims to the contrary, the U. S. Food and  
5 Drug Administration does not require tests which blind or  
6 kill animals. There are a variety of personal care or  
7 cosmetic products which are marketed without animal tests.  
8 It is unacceptable that we inflict pain and suffering to  
9 test lipstick, perfume or hairspray.

10 House Bill 1554 also addresses the inadequacies and  
11 lack of timeliness in Federal inspections of laboratories.  
12 Some labs benefit from infrequent inspection. Some labs  
13 do not have to register at all. Proposed Federal regulations  
14 call for even fewer inspections.

15 Let me add that House Bill 1554 also protects the  
16 rights of the students who, for personal or religious reasons,  
17 refuse to experiment on living creatures. Great Britain did  
18 away with live animal experimentation in medical schools  
19 decades ago. It is not necessary to force students to  
20 inflict pain or suffering.

21 My bill, ladies and gentlemen, is a modest proposal.  
22 It is almost like a sunshine bill for thousands of creatures  
23 who will be subjected to pain. We have compromised to get the  
24 measure in its present form. It's a good start.

25 I urge you to report it to the House floor.

1 I would like to introduce Dan Kinney. He has a  
2 very brief five-minute video, showing two particular examples  
3 of abuse of animals in testing that have been covered in the  
4 last few years in Pennsylvania.

5 Dan.

6 MR. KINNEY: Thank you, Tom.

7 CHAIRMAN DeWEESE: Thank you, Tom.

8 While he is getting the video set up, I would like  
9 the Chair to recognize Terry McVerry, of Allegheny County,  
10 State Representative from Allegheny County, on my right, who  
11 just came in.

12 MR. KINNEY: If the cameraman can kill the house  
13 lights. Can you do that?

14 The film you are about to see contains footage  
15 of two Pennsylvania laboratories. The University of  
16 Pennsylvania Head Injury Lab, it was called one of the best  
17 in the world by The National Institute of Health. Biosart  
18 is a private facility in Philadelphia. This is one of the  
19 world's finest institutions.

20 In this scene, a primate has acid spilled onto him.  
21 Here is an animal obviously not under proper anesthetic while  
22 performing invasive surgery on the skull. These are several  
23 head injuries being performed. These are the researcher's  
24 own words while they are performing it. These precise  
25 surgical instruments are a hammer and a screwdriver.

1           The researchers are joking about opening a dietary  
2 service using this technique. These are complaints by the  
3 researchers of the ventilation system. That is one area that  
4 they are supposed to regulate.

5           Here is a lab worker dropping his instrument onto the  
6 floor, picking it back up, and using it again. It is  
7 definitely not a sterile procedure. Notice that these workers  
8 are smoking. There are flammables nearby and other violations  
9 are being ignored. Notice the cigarette dangling from the  
10 next worker's lips.

11           The next scene you will hear a student complaining  
12 that he has to learn newer surgery in the last three months.  
13 This is a series of head injuries, known as "bangs," by the  
14 individual involved in this research.

15           In this next scene, an unattended monkey was found  
16 dying. They just left part of the animal's ear behind when  
17 they were removing the helmet.

18           While this was occurring, the public statement of the  
19 institution was, "We treat the baboon the way we would treat  
20 human beings."

21           The next scene you will hear some inhumane treatment.  
22 Here we have some workers playing with an injured brain-  
23 damaged animal.

24           The next scenes are from biosurgery. This is a  
25 commercial product testing facility with about one hundred

1 clients in the Philadelphia area. It is narrated by an  
2 individual who has been employed there for a period of time.  
3 It is very brief and briefly describes some of the tests,  
4 toxicity tests being conducted there. You can see how an  
5 individual company tests products is up to them. They do  
6 animal testing to protect themselves. That is from a staff  
7 chemist from the Food and Drug Administration.

8 Dr. Kaufmann, who is an M.D., at the New York  
9 University Medical Center, has stated that as an ophthal-  
10 mologist, he has never used Draize test data, because the  
11 rabbit eye differs from the human eye.

12 CHAIRMAN DeWEESE: How much longer will the film  
13 be going? We were told it was a five-minute film.

14 MR. KINNEY: Sixty seconds.

15 Basically, the next thing is the death chamber. It  
16 is like a miniature off switch for animals. It is just a  
17 gas chamber.

18 We will do a few seconds of that and cut this. It  
19 is very easy to see the hoses go in. The substances goes in  
20 until half the animal dies to determine how much inhalation  
21 is required to kill a test group of animals.

22 CHAIRMAN DeWEESE: That's the LD 50 test we read  
23 about?

24 MR. KINNEY: Correct.

25 (Whereupon, the video was terminated.)

1           CHAIRMAN DeWEESE:    The Chair would like to ask  
2 anybody in the hall to try to make their way in.   We will  
3 interrupt for a minute.   There are a few empty seats.  
4 While some people are entering, I would like the Chair to  
5 recognize State Representative Tony DeLuca, on my left, who  
6 just came in.   Tony is from Penn Hills.

7           REPRESENTATIVE DeLUCA:    Thank you.

8           CHAIRMAN DeWEESE:    I have one quick question I  
9 want to ask.   Where did you receive that film?

10          MR. KINNEY:    The biosearch tape was released by a  
11 group called People for the Ethical Treatment for Animals,  
12 in Washington, D. C.

13          CHAIRMAN DeWEESE:    Thanks.   Do we members have  
14 any questions for the gentleman who ran the film?

15          Chief Counsel has one question.

16          MR. EDMISTON:       Your remark when the ventilation  
17 test was being administered as to the USDA's responsibility,  
18 I didn't hear quite all of it.   Can you repeat that for me,  
19 please.

20          MR. KINNEY:    Just briefly, the United States  
21 Department of Agriculture is charged with inspection of  
22 laboratories.   The few areas that they do inspect for are the  
23 areas of proper ventilation.

24          This is the one area which they can cite an  
25 institution for not properly maintaining ventilation.   Even

1 in this one incident where the USDA is responsible for  
2 checking, this is one area that was lacking, particularly  
3 lacking in this one scene.

4 MR. EDMISTON: Thank you.

5 CHAIRMAN DeWEESE: At this time, the Chair would  
6 like to recognize Dr. Martin Stephens. Dr. Stephens has a  
7 Ph. D. and represents the Lab Animal Department of the U. S.  
8 Humane Society.

9 REPRESENTATIVE McHALE: Excuse me. I had one  
10 question.

11 CHAIRMAN DeWEESE: I am sorry. Doctor, if you  
12 will allow Paul McHale, of Lehigh County, for the gentleman  
13 who ran the film.

14 REPRESENTATIVE McHALE: Yes. Sir, if I under-  
15 stood you correctly, the first segment of that film was taped  
16 at the University of Pennsylvania?

17 MR. KINNEY: Right.

18 REPRESENTATIVE McHALE: Since the release of that  
19 film, has there been any change in policy at Penn, or are those  
20 practices still going on?

21 MR. KINNEY: The National Institute of Health with-  
22 drew the funding for this laboratory after they spent approxi-  
23 mately ten million dollars due to the release of the tape and  
24 public pressure that resulted.

25 REPRESENTATIVE McHALE: Has there been any other kind

1 of pledge from the University of Pennsylvania with other  
2 funding sources that these kinds of practices will not  
3 continue?

4 MR. KINNEY: There is no assurance that I know of.

5 REPRESENTATIVE McHALE: Thank you, Mr. Chairman.

6 CHAIRMAN DeWEESE: You are very welcome.

7 The next witness, Dr. Stephens.

8 DR. STEPHENS: Thank you. I am Dr. Martin  
9 Stephens, the Director of the Laboratory Animals Department  
10 of the Humane Society of the United States, which I will  
11 call the HSUS.

12 The HSUS is the nation's largest animal-protection  
13 group, and I am here representing our many constituents  
14 in the Pennsylvania area.

15 I would like to begin by saying that, first of all,  
16 I am thankful for this opportunity to testify. But also to  
17 state that the HSUS has a moderate position on the use of  
18 animals. We believe this is a moderate bill. We are very  
19 much in favor of this bill. The key elements of it are its  
20 provisions for public accountability; namely, the search  
21 warrant provisions, the licensing, the regulations, and the  
22 inspections, and also the provisions for outside members being  
23 on the Animal Care Review Committee. All of which give the  
24 citizens of this state access to what is going on in the lab.

25 The other provisions being the banning on a few

1 particularly cruel tests, and the stipulation that students  
2 shall not be forced to cut up animals against their wishes.

3 I would just like to briefly direct some comments  
4 to each of these provisions.

5 Regarding the search warrants, removing the elimina-  
6 tion for research facilities. I would like to point out  
7 that if that were enacted, that would the Pennsylvania State  
8 Anti-Cruelty Statute in line with that of the majority of  
9 other states in the United States. On the licensing --

10 CHAIRMAN DeWEESE: Can you give us an exact  
11 number?

12 DR. STEPHENS: I believe it is twenty-six.

13 And on the licensing arrangement, if that were  
14 passed, that would put the state in line with sixteen other  
15 states, including a variety of neighboring states of  
16 Pennsylvania. They have some form of licensing of research  
17 facilities. Much of this has already been done.

18 Regarding the provision for outside members, members  
19 of the community on the Institutional Animal Care Committees,  
20 a provision for the state enforcement agencies to serve on  
21 those committees.

22 There is a similar provision in the Animal Welfare  
23 Act, but it is regularly flaunted.

24 I was just at a meeting of Laboratory Animal folks  
25 in Boston, and a member of the audience stood up and boasted



1 that although he represented a coalition of industries that  
2 exploit animals, the mission of the industries was to undercut  
3 the work of animal protectionists. That he was the  
4 community member of no less than four institutions in his  
5 home state. This is the person that those institutions have  
6 put in charge of representing the interests of the animals at  
7 those facilities.

8 So, we need a State law to eliminate that kind of  
9 duplicity.

10 Regarding the prohibited tests, you all saw the  
11 footage. I think there is no doubt about their cruelty.  
12 We should also mention that there is significant doubt about  
13 their scientific relevance, as well.

14 Let me just quote a few remarks by toxicologists  
15 and physicians, not animal protection folks.

16 Quote, "Although the Draize test may appear  
17 quantitative and precise, extrapolating its results from  
18 animals to man is inaccurate and misleading. The LD 50 is  
19 also of little use in poison emergencies."

20 That's a quote by two physicians.

21 Another quote by Dr. Rall, the Director of the  
22 National Toxicology Program, part of the Federal government.

23 "The LD 50 test is an anachronism. I do not think  
24 the LD 50 test provides much useful information about the  
25 health hazards to humans from chemicals."

1 I could go on and on. Studies have been done by  
2 toxicologists, calling to doubt the accuracy of these tests,  
3 the reliability. If you do the same test over, you may  
4 find out that one chemical that you thought was an irritant  
5 is now a non-irritant.

6 So, studies have been done by the scientists,  
7 themselves. I think it is safe to say the LD 50 and Draize  
8 tests are not good tests, and they don't prevent -- they  
9 don't necessarily prevent irritating or poisonous substances  
10 from reaching the market.

11 We are all aware that many of the products we use  
12 in our homes are irritants to the eye, for example. Much of  
13 those were subjected to the Draize test. Yet those chemicals  
14 are in our homes.

15 We know that pesticides are eye-irritants, for  
16 example. The purpose of these tests is not necessarily to  
17 keep dangerous products off the market.

18 I would like to point out that there are alternatives  
19 to many of these tests. The LD 50, there are more humane  
20 alternatives to that test. Unfortunately, they still rely  
21 on animals. But non-animal alternatives are also being  
22 developed.

23 As far as the Draize test goes, we are much further  
24 ahead on the alternatives, and scientists themselves have  
25 been developing these in the last ten years in response to

1 pressure from animal protectionists.

2 The Draize test has been around for forty years,  
3 but only in the last ten or less, have the relevant industries  
4 been working on alternatives. We have got scores of  
5 alternatives. If you read the scientific reports, they are  
6 laced with comments such as, "This test has excellent, an  
7 excellent correlation with the Draize test, time and time again."

8 So, we are saying, "What is stalling this?"  
9 What is keeping these alternatives from being implemented?

10 We shouldn't get bogged down in too much of the  
11 details of the alternatives because the tests, themselves,  
12 the animal tests are so poor. I think Dr. Barnard will be  
13 going into more detail on the alternatives themselves.

14 Let me just say that they fall into roughly three  
15 categories. One is the in vitro, or test tube method, where  
16 isolated cells or corneas or eyeballs, or other tissues from  
17 the human bodies are used instead of the rabbit's eye that  
18 you saw. Very precise, sophisticated tests that bring this  
19 safety testing into the twentieth century.

20 Another form of test is not the in vitro test, but  
21 using animals for organisms that have little or no capacity  
22 for pain or suffering like single-celled animals or a popular  
23 test developed in Pennsylvania using the membranes from a  
24 chicken egg.

25 These are very -- these are vascularized membranes

1 right underneath the shell. They are exposed to chemicals.  
2 The developing embryo feels no pain, but yet those membranes  
3 can show reactions, irritancy reactions in response to  
4 chemicals.

5 There are a variety of sophisticated tests. There  
6 is also a computer modeling which can back up some of these  
7 tests in using data about the structure of chemicals.

8 There is a variety of tests. Pressure from a  
9 Massachussetts ban on these tests, pressure from other state  
10 bills will get the scientific community to do whatever they  
11 feel is necessary to refine these tests, but more importantly,  
12 they will declare that these tests are a sham in regards to  
13 public safety.

14 My last comment concerns the provision for students  
15 not to be forced to cut up animals. We get many requests  
16 from students at The Humane Society for help in helping them  
17 go to their teachers to request permission not to be forced  
18 to conduct those animal experiments, but rather to conduct  
19 alternative experiments.

20 In our opinion, many of these students are granted  
21 their requests, but we don't really hear about them. We hear  
22 about the students that meet with the stone wall and who are  
23 refused by the institution. Those are the ones that make  
24 the newspapers.

25 The Jennifer Graham case, and one in Pennsylvania,

1 that we will hear about. We would like to see a policy put  
2 into place so that students -- the burden is not on the  
3 students to go run the gauntlet to get permission to not  
4 conduct these animal tests.

5 In conclusion, I would like to say that The Humane  
6 Society of the United States obviously supports the intent  
7 of all of these provisions. We recognize that some of the  
8 provisions, the wording of those provisions, may need work.  
9 We would be happy to work with this committee and others  
10 on that re-wording.

11 Thank you.

12 CHAIRMAN DEWEESE: Thank you, Dr. Stephens.

13 Do members of the committee have questions for the  
14 doctor?

15 Paul McHale, Lehigh County.

16 REPRESENTATIVE McHALE: Doctor, I support  
17 House Bill 1554. I was appalled by the tape that we saw  
18 earlier. In that context, in speaking for your organization,  
19 under what circumstance is animal testing ethically and  
20 legally justifiable?

21 DR. STEPHENS: That's a tough question to answer.  
22 I would say that at a minimum, the test would have to really  
23 protect human health.

24 Number one, really be a meaningful test.

25 Number two, there would be no possible alternative

1 to the test, and the products that are being tested should  
2 be of significance to human health, not be another brand of  
3 eye shadow or lipstick, or even another what is called  
4 "Me-too" drug, a drug where we got plenty of drugs of that  
5 type already on the market, but some company wants to break  
6 into that market share.

7 So, I think those are some of the basic elements.  
8 I would also add a fourth. I think there are some tests that  
9 regardless of their relevance, are just beyond the pale of  
10 acceptability. There is too much pain, suffering, and  
11 death.

12 As a civilized society, we got to say that we will  
13 do what we can to do without this test.

14 REPRESENTATIVE McHALE: In your view, however,  
15 this is a moderate piece of legislation which does not get  
16 into the gray area, is that correct?

17 DR. STEPHENS: In my view, that's absolutely  
18 correct. What perhaps is rousing some opposition, and there  
19 are several provisions to the bill. So, industries that are  
20 affected by the various positions, are going to band together  
21 to oppose it. I think if you look at the individual  
22 provisions, they are moderate.

23 REPRESENTATIVE McHALE: Doctor, I agree with your  
24 position. Thank you, Mr. Chairman.

25 CHAIRMAN DeWEESE: You are very welcome, Paul.

1 Any other questions?

2 Thank you very much, sir.

3 The next witness will be Annette Charuk. Am I  
4 pronouncing that correctly?

5 MS. CHARUK: Yes.

6 CHAIRMAN DeWEESE: Regional Director of the  
7 Pharmaceutical Manufacturers Association. As Annette makes  
8 her way to the witness area, the Chair would like to recognize  
9 a colleague and one of our leaders in Harrisburg, Dr.  
10 Ivan Itkin, from Point Breeze.

11 Doctor, welcome to our hearing. Thank you for  
12 being here.

13 MS. CHARUK: Good morning. Thank you, Mr.  
14 Chairman and members of the committee.

15 My name is Annette Charuk. I am here representing  
16 the Pharmaceutical Manufacturers Association. I am also  
17 a practicing registered pharmacist in the Washington, D. C.,  
18 area.

19 The Pharmaceutical Manufacturers Association is a  
20 non-profit trade association representing some one hundred  
21 companies that research and develop nearly all new drugs  
22 manufactured in this country. Five of these companies are  
23 headquartered here in Pennsylvania, and several others have  
24 major facilities in the Commonwealth.

25 We appreciate this opportunity to offer our comments

1 and concerns about House Bill 1554, which would among  
2 other things, prohibit the use of the Draize and LD 50 tests in  
3 Pennsylvania. I will limit my comments to these issues.

4 We are sensitive and appreciate the concerns that  
5 have been expressed about the Draize test. The procedure,  
6 however, is essential to the pharmaceutical industry as a  
7 screen to provide safeguards from unexpected human risk due  
8 to the administration of compounds to the eye or inadvertent  
9 contact with the eye.

10 It is important to note that both Federal regulations  
11 and the Helsinki agreements on the protection of human  
12 subjects require that animal tests be conducted before a drug  
13 substance is introduced into humans. Currently, the only  
14 valid test of eye irritancy is the Draize test.

15 Developing safe and effective new drug products  
16 requires the use of animals for experimental purposes to  
17 insure that thorough and adequate research is conducted before  
18 a potential new product is ever tested in human subjects.

19 Member firms of the PMA support efforts to develop  
20 new methodologies that may replace or reduce the number of live  
21 animals used in research. However, the numerous in vitro  
22 tests that have been proposed as alternatives to the Draize  
23 test suffer from the lack of a sufficient data base and/or a  
24 lack of a mechanistic correlation with ocular irritancy or  
25 toxicity.



1           None of these tests, therefore, can replace the  
2 Draize test at this time. We are hopeful, after further  
3 validation, that these alternative tests will be able to be  
4 used for in-house screening programs to reduce the number of  
5 Draize tests performed.

6           On September 14, 1988, just about a week ago, a  
7 joint government-industry workshop on "Progress Towards  
8 Alternatives to the Draize Test" was sponsored by the Consumer  
9 Product Safety Commission, the Environmental Protection  
10 Agency, and the Food and Drug Administration, and three trade  
11 associations, in Washington, D. C.

12           This workshop was intended to develop guidance for  
13 validation of non-animal alternatives to the Draize test. At  
14 the conclusion of this workshop, the three Federal agencies,  
15 CPSC, EPA and FDA reaffirmed --

16           CHAIRMAN DeWEESE: CPSC?

17           MS. CHARUK: Consumer Product Safety Commission.  
18 Sorry. -- reaffirmed that further validation is needed before  
19 these alternative tests can replace the Draize test.

20           Many of our firms have already reduced the number of  
21 Draize tests performed by using a skin irritation test as the  
22 primary screen. If a positive response is observed, using  
23 a skin irritation test, the Draize test is not performed.

24           Despite this reduction, the scientific consensus  
25 is that no reasonable alternatives to the Draize test currently

1 exist to assure that a drug won't harm the human eye, even  
2 though other tests may indicate no harm to the skin.

3 Because of the known existence of certain compounds  
4 whose toxicity is observed only through administration  
5 directly in the eye, any law preventing a person from per-  
6 forming the Draize test could result in exposing the public  
7 to risks from unexpected toxicity.

8 Acute toxicology studies in animals are also essential  
9 to drug development. Often such experiments seek to establish  
10 precisely the median lethal dose, LD 50, in rodents.

11 As scientific needs rarely require the exact value,  
12 practices and regulations should be changed to provide the  
13 option of obtaining adequate information on the acute toxicity  
14 of a drug with fewer animals than the precise LD 50 test  
15 demands.

16 The PMA Pharmaceutical Manufacturers Association,  
17 Board of Directors, on October 12, 1982, adopted a policy  
18 encouraging the use of alternative tests to the LD 50, when  
19 a precise value is not required, and this test has been  
20 largely eliminated in drug product safety testing. A copy  
21 of that position is attached to my testimony.

22 Also, as a practicing pharmacist, I would like to  
23 say when I dispense, whether it be a prescription drug for the  
24 eye or also any item that a customer, patient may come with  
25 advice to me from a shelf, they ask me very often about advice

1 as to interactions or other problems they may have, I feel  
2 that this safety, these products have been safely tested,  
3 and I feel confident when I give my advice.

4 I think that this committee should not put  
5 pharmacists and physicians in a position that they may have to  
6 second-guess.

7 For the above reasons, we respectfully request that  
8 you reject House Bill 1554.

9 We appreciate your consideration on this very complex  
10 issue, and would be pleased to provide you with any  
11 additional information or respond to any questions regarding  
12 this testimony.

13 CHAIRMAN DeWEESE: Thank you very much.

14 Are there questions?

15 Before we get to the questions, the Chair would  
16 like to recognize the attendance of Mike Dawida, State  
17 Representative from the South Side, and Senator-to-be.

18 I think it indicates the magnitude of our concern  
19 just by the fact that we have eight State Representatives.  
20 The average hearing we conduct might not always get eight  
21 State Reps. I am grateful for the good attendance we have  
22 today. That is my own editorial comment.

23 Do we have some questions for the lady?

24 Paul McHale.

25 REPRESENTATIVE McHALE: You indicated in your

1 testimony that your trade association represents one hundred  
2 companies, approximately.

3 MS. CHARUK: Approximately.

4 REPRESENTATIVE McHALE: Are these exclusively  
5 pharmaceutical companies producing drugs, medications?

6 MS. CHARUK: We represent pharmaceutical  
7 manufacturers.

8 REPRESENTATIVE McHALE: So we are not talking about  
9 cosmetic firms?

10 MS. CHARUK: They may have subsidiaries for  
11 cosmetic firms.

12 (Whereupon, the audience applauds.)

13 REPRESENTATIVE McHALE: Could you indicate  
14 approximately how many of the one hundred companies do have  
15 subsidiaries that are essentially cosmetic firms?

16 MS. CHARUK: I am not aware of that. I can get  
17 that answer for you.

18 REPRESENTATIVE McHALE: I would appreciate that  
19 if you would, please. You indicated in the second paragraph  
20 of your testimony that the Draize test is the only, quote,  
21 valid test, unquote, of eye irritancy. Whose definition of  
22 validity are you referring to?

23 MS. CHARUK: The Federal agencies. The Food and  
24 Drug Administration primarily, who do the testing where our  
25 drug products have to be approved by the FDA.

1           REPRESENTATIVE McHALE:     You are indicating under  
2 current Federal law the Draize test, by law, is the only test  
3 they will accept?

4           MS. CHARUK:     Under their requirements, there is  
5 no other accepted alternative.     In fact, the conference which  
6 I referred to on September 14, the FDA was a part of that.     In  
7 the conclusion of that, which I believe somebody else  
8 following me will be addressing some of those results,  
9 indicated that at this time, there is no other validated test.

10          REPRESENTATIVE McHALE:     Does the FDA insist on  
11 Draize testing?

12          MS. CHARUK:     I am not sure as to the specifics of  
13 their requirements.     They required that there will be eye  
14 irritancy testing done.

15          REPRESENTATIVE McHALE:     Lastly, on the second page  
16 of your testimony, you indicate that many firms have already  
17 reduced the number of Draize tests.     Why not all?

18                 You indicate that many of your member organizations  
19 have reduced Draize testing, beginning initially with a skin  
20 irritancy test.

21          MS. CHARUK:     Right.     That is one of the ways to  
22 reduce it.

23          REPRESENTATIVE McHALE:     My question is, since many  
24 of your firms have done this, why have not all of them done  
25 this?

1 MS. CHARUK: Because if they don't get the results  
2 out of the skin irritancy, they have to go on and perform the  
3 Draize test in that case.

4 REPRESENTATIVE McHALE: Ma'am, you are apparently  
5 not understanding my question. You indicate, I think,  
6 pointing to the humaneness of the testing, that many of your  
7 firms now begin with a skin irritancy test, and then, if there  
8 is a positive result, or then, in the wake of that result,  
9 move on possibly to the Draize testing. Why --

10 MS. CHARUK: That's my understanding.

11 REPRESENTATIVE McHALE: My question is, and I  
12 don't mean to belabor this, why do not all of your member  
13 organizations begin with the skin irritancy test?

14 MS. CHARUK: I am not sure if they do or don't.  
15 I would have to find that out. I am not the scientist.  
16 They may all do that. I am not certain.

17 REPRESENTATIVE McHALE: I would appreciate finding  
18 out why it is that only some of your member organizations  
19 begin with the skin irritancy test.

20 Thank you, Mr. Chairman.

21 CHAIRMAN DeWEESE: Any other questions for the lady?  
22 Tony DeLuca, from Penn Hills.

23 REPRESENTATIVE DeLUCA: Thank you, Mr. Chairman.

24 As I understand the previous testimony, sixteen  
25 other states have this type of legislation. Well, that is

1 what was stated. Can you tell me, if we have sixteen other  
2 states that have this type of legislation, doesn't your  
3 organization operate in them sixteen states?

4 MS. CHARUK: Pharmaceutical -- Well, the major  
5 states --

6 REPRESENTATIVE DeLUCA: Do you have any companies  
7 that operate in the sixteen states?

8 MS. CHARUK: It depends which states they are.  
9 New Jersey, they are.

10 REPRESENTATIVE DeLUCA: I presume you must have  
11 some, right?

12 MS. CHARUK: Yeah.

13 REPRESENTATIVE DeLUCA: How are they developing the  
14 new products in that area?

15 MS. CHARUK: Testing is not done in every state.  
16 Some research facilities may not be in that state, in other  
17 words.

18 REPRESENTATIVE DeLUCA: In other words, you put your  
19 research facility in states that permit?

20 MS. CHARUK: Right.

21 REPRESENTATIVE DeLUCA: Why should Pennsylvania  
22 permit that?

23 (Whereupon, the audience applauds.)

24 MS. CHARUK: This may also be an economic point  
25 for Pennsylvania. As I indicated, there are five companies

1 that have headquarters here. If this Committee, and if this  
2 law were to pass, this research and many of the jobs would  
3 be lost because we would have to take them elsewhere.

4 REPRESENTATIVE DeLUCA: You always hear that  
5 about losing jobs, no matter what the issue is, since I have  
6 been in the State House.

7 CHAIRMAN DeWEESE: Tony, with the sirens on, can  
8 everybody hear?

9 REPRESENTATIVE DeLUCA: I heard that issue pertaining  
10 to a lot of things. We always talk about losing jobs. That  
11 seems to be everybody cop-out, losing jobs. That really  
12 doesn't affect me too much.

13 Just one more question. Did you see that film that  
14 was shown here?

15 MS. CHARUK: Yes.

16 REPRESENTATIVE DeLUCA: What is your comment to  
17 that type of situation?

18 MS. CHARUK: It is not very pleasing to see things  
19 like that. I can't say that happens at every facility.  
20 That is one facility.

21 REPRESENTATIVE DeLUCA: It is happening in one.  
22 If it is happening, if it is not happening in every facility,  
23 what should we do to prevent this from happening in every  
24 facility?

25 MS. CHARUK: There are inspections that are conducted



1 at all research facilities, I presume. I am not familiar with  
2 the research or with the inspections that take place. But  
3 perhaps tighten up on that to make sure that people aren't  
4 making jokes of such tests that are done.

5 REPRESENTATIVE DeLUCA: Thank you, Mr. Chairman.

6 CHAIRMAN DeWEESE: The ooh's and aah's are  
7 understandable. Please try your best to restrain yourselves  
8 so the steno can get the essence of the testimony.

9 Are there other questions from other members to this  
10 witness?

11 I have one. Before I ask that one, I would like  
12 to introduce State Representative David Mayernik, from Ross  
13 Township. David is the secretary of the Judiciary Committee.  
14 We are pleased to welcome David to this afternoon's hearing.

15 The only question I have is, on page one of your  
16 testimony, the fourth paragraph, member firms of the PMA  
17 support efforts to develop test methodologies that may replace  
18 or reduce the number of live animals used in research.  
19 Do you folks put your money where your mouth is? How much  
20 money are you folks spending to develop tests that would  
21 disallow what we just saw?

22 MS. CHARUK: I can get that answer for you easily.  
23 It is very expensive for us to use animals. Why would we want  
24 to use these animals if cheaper alternatives could be used?  
25 It is an economic issue.

1           CHAIRMAN DeWEESE: Tom Murphy talked about computer  
2 models that were being developed. As we race pell-mell toward  
3 the twenty-first century, there seems to be unlimitable  
4 horizons for our computer technology. One would think that  
5 these kinds of efforts on behalf of animal rights would be  
6 appropriate and desirable.

7           MS. CHARUK: Absolutely.

8           CHAIRMAN DeWEESE: One would hope we could move  
9 in that direction.

10          Thank you very much for your involvement.

11          REPRESENTATIVE McHALE: Mr. Chairman, if I may  
12 just very briefly before she leaves.

13          CHAIRMAN DeWEESE: Annette, could you remain  
14 localized for thirty seconds.

15          REPRESENTATIVE McHALE: You made reference to the  
16 cost of testing. You indicated why would your member organi-  
17 zations use animals if there were less expensive alternative  
18 tests available.

19          My question to you is, would your organization  
20 support alternative, more humane tests if they were more  
21 expensive?

22          MS. CHARUK: I would imagine so if they were  
23 acceptable by the FDA.

24          REPRESENTATIVE McHALE: Even if they cost more?

25          MS. CHARUK: Sure.

1 REPRESENTATIVE McHALE: Thank you.

2 CHAIRMAN DeWEESE: For the record, Annette,  
3 would you please submit the answers to the two or three  
4 questions you are going to research to the secretary, Mr.  
5 Mayernik, or to our staff within the next month or so?

6 MR. CHARUK: Okay.

7 CHAIRMAN DeWEESE: Thank you very much for your  
8 involvement. I would like at this time to turn the gavel,  
9 as figurative as it might be, over to my cohort from  
10 Philadelphia, the Honorable Gerald Kosinski. I think the  
11 next witness has an Eastern European background. I think  
12 it is appropriate that this be the juncture that Gerry takes  
13 charge.

14 I will probably be back after awhile. But now the  
15 gentleman from Philadelphia will be chairing the hearing.

16 Mr. Kosinski.

17 REPRESENTATIVE KOSINSKI: Thank you, Mr. Chairman.

18 Before we get to the next witness, if anybody from  
19 around the door area would like to move over to this side,  
20 because I think they are going to need that door area for  
21 access and egress.

22 Next to testify is Dr. Gloria Binkowski.

23 DR. BINKOWSKI: Hello. My name is Gloria  
24 Binkowski. I have a Master's Degree in Microbiology and  
25 Biochemistry, and I am a veterinarian who works in a small

1 animal practice at this time.

2 Bill 1554 is legislation which will benefit both  
3 people and animals. I wish to speak about the part of the  
4 legislation concerning students and the use of animals in the  
5 classroom and laboratory.

6 Why do some students wish to have alternatives to  
7 classroom and laboratory exercises in which healthy animals are  
8 killed or are forced to endure pain?

9 The students and I believe that there are many,  
10 especially at the level of grammar school and high school,  
11 perceive this to be a form of violence, and rightly so.  
12 They are not questioning authority just for the sake of  
13 questioning authority. They are not, by and large,  
14 vegetarians or animal rights activists. They are not trying  
15 to avoid work. They are for the most part apolitical, and  
16 they simply have a deep-seated belief to not participate in  
17 violence. A student's right to alternatives does not intrude  
18 upon teachers' rights because no teacher should be able to  
19 force a student to act contrary to his or her ethical beliefs.

20 The present system of biological/medical education,  
21 however, selects for a population of students who view animals  
22 as disposable tools, and it discourages compassionate and  
23 qualified students who do not regard non-human animals solely  
24 as research or learning tools from entering careers in biology  
25 or medicine.

1 All too often, the killing/maiming of animals is  
2 effectively a rite of initiation into the study of biological  
3 science/medicine, and those students who find the sort of  
4 activities in which they must engage to be distasteful or  
5 reprehensible are often informed by their teachers that they  
6 are not suited for the study of medicine or biology and that  
7 they should consider pursuing other careers. I know, because  
8 this happened to me.

9 The biomedical research establishment relies so  
10 heavily on invasive procedures on animals because the  
11 educational system deliberately trains students to depend upon  
12 this type of experimentation. In today's society, a  
13 common criticism of the medical profession is that it lacks  
14 compassion. It is ironic, therefore, that the educational  
15 process deliberately excludes people with this quality.

16 Alternatives which do not require invasive  
17 procedures to be performed upon animals do exist. They  
18 can, in fact, be superior with regard to educational value  
19 and they can be less expensive. The types of procedures which  
20 are performed in the United States, in classroom and laboratory,  
21 are outlawed in other countries such as Great Britain, yet  
22 Great Britain produces fine scientists.

23 There are several British-trained veterinarians on the  
24 faculty of the veterinarian school at the University of  
25 Pennsylvania. Why, then, do students have so many problems,

1 and they do, in obtaining alternatives? Why is legislation  
2 necessary to allow students to abide by their consciences?  
3 Legislation is necessary because of the intractability of some  
4 administrators and educators in the biological sciences when  
5 they are approached by students who wish alternatives. The  
6 basis of this intractability includes lack of imagination,  
7 laziness, guilt, and defense of vested interests. In other  
8 words, money and the livelihood based upon using animals.

9 As an aside, I think the response of scientists  
10 in the biomedical research community at large request to use  
11 non-animal alternatives is quite similar to that of  
12 administrators and educators. Sometimes the reaction of  
13 educators and administrators to requests for alternatives  
14 can be quite extreme, and students can find the entire forces  
15 of an institution marshalled against them as was the case for  
16 me and another veterinary student at the University of  
17 Pennsylvania.

18 Let me give you a synopsis of my experiences at the  
19 veterinary school. I was concerned about the use of animals  
20 in the veterinary school curriculum previous to my acceptance  
21 into the school. Yet, the school catalog would lead a  
22 reasonable person to believe that the school was a place of  
23 tolerance.

24 In the 1984-1985 catalog, the year that I was  
25 accepted to the school, the following statement relating to

1 the treatment of animals in our society was included in

2 "The Mission:"

3 "We take" and this is a quote. "We take cognizance  
4 of the fact that in our complex school, as in our complex  
5 larger society, we must satisfy legitimate and essential needs  
6 which may at times be incompatible with one another, either on  
7 philosophic or operative grounds. We must find our way,  
8 meeting the demands for research, teaching and patient care,  
9 by means of information sharing, thoughtfulness, tolerance  
10 and a long-range collegial view."

11 Also, when I went to a pre-admission interview at  
12 the school in the spring before my matriculation, talking with  
13 the upperclassmen was part of the interview process. When I  
14 asked them about the uses of animals in laboratories and  
15 requests for alternatives, all of the students said that they  
16 knew most of the faculty to be reasonable. I soon discovered  
17 that the lofty language in the school catalog was lip service  
18 and that the students' assessment of the faculty was generally  
19 inaccurate.

20 In hindsight, I can see that the students' assessment  
21 was inaccurate because they really had no experience in asking  
22 the faculty for alternatives to such laboratories as pharma-  
23 cology. An overwhelming majority of students do not ask for  
24 alternatives either for fear of their careers being affected  
25 in a negative manner if they are perceived to have questioned

1 authority, or because the current educational system in the  
2 biological sciences has been so very efficient in selecting  
3 for students who find it acceptable to perform invasive,  
4 painful procedures on healthy animals.

5 In my sophomore year of veterinary school, a  
6 required course was pharmacology lecture and laboratory. The  
7 laboratory included among other exercises, the killing of  
8 guinea pigs in order to remove their hearts on which the effects  
9 of various drugs were observed and the poisoning of mice with  
10 organophosphate in order to observe the effects.

11 These laboratories are exercises, not experiments,  
12 because the aim was to use the animals to demonstrate well-  
13 established scientific principles, not to perform original  
14 scientific experiments to prove or disprove hypotheses. The  
15 veterinary school at the University of Pennsylvania was one  
16 of the few remaining veterinary schools in the United States  
17 in which such laboratories were conducted.

18 There were 107 students in the class; one of the  
19 students conducted a survey of the class attitudes towards the  
20 laboratories. Several of the students thought that the  
21 exercises in the laboratories inflicted so much pain and  
22 suffering on the animals that they thought the laboratories  
23 were unjustifiable and ought not to be conducted for this  
24 reason.

25 A larger percentage of the class preferred not to



1 label the laboratories unjustifiable, but these students would  
2 have preferred alternatives. There were, of course, many  
3 students who thought the laboratories were a justifiable use  
4 of animals or who were neutral about the laboratories.

5 Two classmates and I went to speak to the instructor  
6 about the possibility of obtaining alternatives to the  
7 laboratory, such as doing extra reading assignments and writing  
8 a paper. We wanted to make it clear that we were not trying  
9 to avoid work. We never got a straight answer. Instead, we  
10 got a runaround. The instructor, who was in charge of  
11 teaching the course, and head of the Pharmacology Department,  
12 told us that he did not have the authority to offer alternatives.  
13 He said that only the Dean of the school had this authority.

14 The Dean of the school told us, however, that he  
15 did not have the authority to offer alternatives because that  
16 power belonged solely to the faculty. Failure to attend  
17 laboratories would result in a failure in the course since  
18 attendance at the laboratories is mandatory. The Dean also said  
19 that people with our concerns did not belong in veterinary  
20 school, and furthermore, he wished that there were some way  
21 of identifying people like us during the application process  
22 in order that they would not be accepted into the school.

23 Students were left with a choice of attending the  
24 laboratories or being failed in the course. Continued  
25 refusal to participate in the laboratory eventually would

1 result in expulsion from the school. The students became  
2 aware of the reaction of the faculty and administration, and  
3 by the time of the first pharmacology laboratory, the number  
4 of students who still refused to participate had dwindled to  
5 two people; another classmate and me.

6 And for the first time in recent history of the  
7 course, attendance was taken at the laboratories in order to  
8 identify people who did not attend and to intimidate the  
9 students.

10 The grade in pharmacology was to be determined by  
11 performance in written examinations evaluating the students'  
12 knowledge of the material presented in the lectures and  
13 laboratories. My classmate and I did well on the exams.  
14 In fact, we each received an "A" in the course. To our  
15 surprise, the veterinary school had backed down on their  
16 threats to fail us. Very likely the school backed down because  
17 they would look foolish, since, as I stated earlier, other  
18 veterinarian schools had abandoned this archaic teaching of  
19 method, if you can call this teaching.

20 The University of Pennsylvania was also just  
21 recovering from the scandal of the head injury laboratory and  
22 probably did not want any further negative publicity. You  
23 always hear scientists say, "Oh, yes, if there were alternatives  
24 to using animals, we would love to use them."

25 Here is a case where no doubt there were alternatives,

1 but the school was threatening to fail us if we did kill the  
2 animals. So much for sincerity about wanting to use  
3 alternatives. So much for collegiality and tolerance.

4 The following year, this same classmate and I  
5 requested alternatives to a mandatory course in surgical  
6 exercises in which surgical procedures were to be performed on  
7 healthy animals which were allowed to recover from one surgery  
8 and were then operated upon once again and then killed. We  
9 never questioned the need to do the surgical exercises, but  
10 we did not want to perform the surgical procedures on healthy  
11 animals which would then be killed.

12 The alternatives which we suggested included an  
13 apprenticeship-type learning program in which we would work  
14 with clinicians, first observing and gradually taking on more  
15 responsibility until we were capable of performing the entire  
16 surgical procedure. Another alternative we suggested was  
17 to perform the required procedures on anesthetized terminally  
18 ill animals and to euthanize the animals immediately afterwards.

19 We began approaching the faculty of the course with  
20 our requests for alternatives approximately six months before  
21 the course was to begin. Our request for alternatives  
22 initially was turned down by the faculty without explanation  
23 and our subsequent appeal processes within the school were  
24 blocked and/or manipulated by the administration to ensure that  
25 the response from the school to our request would be negative.

1           In fact, an administrator at the very highest level  
2 within the veterinary school confided to a distinguished  
3 professor that, of course, alternatives to the surgery course  
4 which would be agreeable to us were possible, but we were not  
5 going to get them.

6           The behavior of the administration at the veterinary  
7 school is documented and described in the lawsuit which we  
8 filed in April, 1987, naming the University of Pennsylvania  
9 and Dean Robert Marshak as defendants, after we received  
10 grades of "F" for not participating in the surgery course and  
11 after refusing to accept a bogus alternative in which we would  
12 kill four healthy dogs instead of two healthy dogs.

13           Failure in the course would prevent my classmate  
14 and me from matriculating into our senior year, and it would  
15 ultimately result in our expulsion from the school.

16           Our lawsuit was settled out of court in May, 1987,  
17 over one year after we had initiated a request for alternatives  
18 when the veterinary school agreed to allow us to perform the  
19 surgical procedures on two privately owned terminally ill  
20 animals which were euthanized immediately after the surgery  
21 without being allowed to regain consciousness. It took  
22 public scrutiny and the supervision of a Federal judge for the  
23 veterinary school to begin to behave in a forthright manner.

24           After performing the surgical exercises, on  
25 terminally ill animals, we then went on to begin our senior

1 year. In May, 1988, we graduated and we both currently are  
2 working as veterinarians in small animal practice.

3 The cost of standing by our beliefs was high. Our  
4 legal fees were thousands of dollars. However, the legal  
5 expenses of the school which may in some way have been passed  
6 on to the State, were probably much greater. We had one of  
7 our lawyers donate his services to us.

8 Huge amounts of time were consumed in dealing with  
9 the faculty, the appeal processes and the lawsuit. We also  
10 paid an emotional price. For example, the certainty of  
11 expulsion if we lost our appeals and lawsuit and the hostility  
12 of students and faculty directed toward us during our year-long  
13 wrangle with the veterinary school was stressful.

14 Students need your support of Bill 1554 because they  
15 should not be forced to battle for the right not to harm non-  
16 human animals in their education. Many students for one  
17 reason or another may not be able to be as persistent as my  
18 classmate and I in requesting alternatives.

19 For example, we were fortunate to have the strong  
20 support of a professor at the law school, a few professors  
21 at the veterinary school, and the community. Young students,  
22 grammar school students and high school students, may have to  
23 deal with the additional problems of unsupportive parents and  
24 other authority figures. They may not have the resources which  
25 we had available to us.

1                    Alternatives to invasive and harmful procedures  
2 performed on animals in the classroom and laboratory do exist,  
3 and these alternatives must be made freely available to students  
4 by law in order that compassionate students not be penalized  
5 or excluded from the study or, or careers, in biological and  
6 medical science, or worse still, have their spirits broken  
7 when they are forced to perform or participate in purportedly  
8 educational activities which they believe are cruel to animals  
9 and morally reprehensible.

10                    Thank you.

11                    (Whereupon, the audience applauds.)

12                    REPRESENTATIVE KOSINSKI:    Thank you, Dr. Binkowski.

13                    Do we have any questions?

14                    REPRESENTATIVE McHALE:        Thank you, Mr. Chairman.

15                    Doctor, let me first of all say that I greatly  
16 admire your courage.    When you initially suggested to the  
17 veterinary school that an alternative be permitted pursuant  
18 to which you would perform the surgery on anesthetized  
19 terminally ill animals, I gather from your later testimony  
20 that that was, in fact, the basis for the settlement of your  
21 lawsuit.

22                    DR. BINKOWSKI:    Yes.

23                    REPRESENTATIVE McHALE:        When you initially proposed  
24 that, what was the response from the veterinary school?

25                    DR. BINKOWSKI:    We got a variety of responses,

1 different responses from different people, conflicting  
2 responses. There was a lot of intrigue. But they said it  
3 could not be done. It was against the law was one of the  
4 major complaints.

5 REPRESENTATIVE McHALE: Did they actually say it  
6 was against the law?

7 DR. BINKOWSKI: Yes. University regulations would  
8 not allow it.

9 REPRESENTATIVE McHALE: I see. But ultimately,  
10 that was the basis for settling your lawsuit?

11 DR. BINKOWSKI: That's right.

12 REPRESENTATIVE McHALE: Thank you, Mr. Chairman.

13 REPRESENTATIVE KOSINSKI: Representative Dawida.

14 REPRESENTATIVE DAWIDA: Dr. Binkowski, I had an  
15 experience twenty-some years ago in high school that I  
16 remember vividly and unpleasantly where I was forced to open  
17 up an animal. Would this law, and I have been thinking  
18 almost solely about the commercial side and haven't thought  
19 about the high school. What would this law do with regard  
20 to high school and college students? I am not talking  
21 about the veterinary school which I think you described ably.  
22 I haven't given thought. Would you lay out a scenario of  
23 what a student like myself could do if this law were passed.

24 DR. BINKOWSKI: Well, yes, if a teacher was  
25 offering in the course, a laboratory course, where animals

1 were going to be used in the laboratory, the teacher must  
2 make available to the students an alternative, not using  
3 that animal. That could be a computer model. That could  
4 be a paper. It is unlimited what that alternative could be.

5 The teacher must offer an alternative, either spell  
6 it out or tell the student to think of something that would  
7 give him the same information as what he would get from using  
8 the animal.

9 REPRESENTATIVE DAWIDA: It is your opinion that  
10 such models would be readily available at the high school  
11 level?

12 DR. BINKOWSKI: Yes.

13 REPRESENTATIVE DAWIDA: Sorry I didn't hear this  
14 twenty-five years ago. It would have helped.

15 Thank you.

16 REPRESENTATIVE KOSINSKI: No, it wouldn't. You  
17 wouldn't have become a legislator, Mike. You would have  
18 become a doctor.

19 Further questions? Representative Itkin.

20 REPRESENTATIVE ITKIN: I assume from your title  
21 that you are licensed to practice in Pennsylvania now?

22 DR. BINKOWSKI: Yes.

23 REPRESENTATIVE ITKIN: You do perform surgery?

24 DR. BINKOWSKI: I am a new veterinarian. I am  
25 beginning to perform those things. I am qualified to perform



1 surgery. In doing an alternative, we got as much surgical  
2 experience, if not more, than the rest of the students in the  
3 class.

4 REPRESENTATIVE ITKIN: You would feel comfortable  
5 as a practicing veterinarian to perform surgery --

6 DR. BINKOWSKI: Yes.

7 REPRESENTATIVE ITKIN: -- in view of the experience  
8 you had?

9 DR. BINKOWSKI: As I said, we got the same experience  
10 and more than the other students in our class.

11 REPRESENTATIVE ITKIN: The potential opportunity  
12 to use terminal animals for this type of a learning experience,  
13 is it appropriate for the substantial number of students?

14 DR. BINKOWSKI: At this point, for the number of  
15 students who are asking for alternatives in veterinary school,  
16 it probably is appropriate. But that is only one of the  
17 alternatives. The other alternative is an apprenticeship-type  
18 program where you would work with clinicians and gradually  
19 get more responsibility in doing surgery. For that, one  
20 could use cadavers to practice on first, the way the medical  
21 surgeons do. Gain some skill there and go on to work with  
22 the live animal.

23 REPRESENTATIVE ITKIN: So, basically, you are  
24 saying to become a veterinarian, obviously, you must do some  
25 invasive techniques in order to practice your profession.

1 However, the training of such person does not need to use  
2 invasive techniques on so many animals to complete those  
3 experience requirements?

4 Dr. Binkowski: You don't have to use invasive  
5 techniques on healthy animals, and you don't have -- you  
6 necessarily don't have to perform unnecessary surgery on  
7 healthy animals.

8 REPRESENTATIVE ITKIN: Limit the amount of surgery?

9 DR. BINKOWSKI: No, it is not really limiting the  
10 amount of surgery. We did the same amount of surgery as  
11 the other students. It was a different way of learning  
12 surgery.

13 REPRESENTATIVE ITKIN: I guess I am confused now.  
14 When you say you were learning how to do surgery, one way was  
15 to perform it.

16 You say you limited the performance?

17 DR. BINKOWSKI: No. As I said, we got the same  
18 amount of surgical experience, if not more, than the other  
19 students. The difference was in the animals that we used.  
20 The other students were using healthy animals which were  
21 brought from laboratories. Do a surgery on them, let them  
22 survive one time, and then do another surgery on the animal  
23 and kill the animal.

24 What we did was, we used client-owned animals that  
25 were terminally ill. One had mammary cancer, which had already

1 metastasized to the lung. We anesthetized that animal.  
2 We did all the surgeries on that animal. We did two surgeries  
3 each. The other students did one surgery on their dog.  
4 Then we euthanized the animal right on the table.

5 REPRESENTATIVE ITKIN: There is a pool of  
6 euthanized or animals that are apparently to be euthanized  
7 out there in the general domain, isn't that true?

8 DR. BINKOWSKI: I am sorry.

9 REPRESENTATIVE ITKIN: I am saying that there is a  
10 population of animals that are ill, that are going to die,  
11 that could be used for this purpose?

12 DR. BINKOWSKI: There is a pool there. There  
13 is a small pool, yes.

14 REPRESENTATIVE ITKIN: Thank you.

15 REPRESENTATIVE KOSINSKI: Further questions, staff?

16 Dr. Binkowski, thank you very much.

17 We do have some open seats if the people who have  
18 been standing so patiently for awhile would want to fill them  
19 in. You are welcome to.

20 Next to testify would be Dr. Neal Barnard, Chairman  
21 of the Physicians Committee for Responsible Medicine.  
22 That would Dr. Barnard, as in Christian.

23 DR. BARNARD: Thank you. It is a pleasure to  
24 be able to address this important piece of legislation,  
25 House Bill 1554, because it provides some very basic and

1 very simple but very essential measures.

2 First of all, let me address the issue of animals  
3 in education. It is essential to provide for the needs of  
4 students who decline to use animals in their education. As  
5 time marches on, our ethical sense changes. There are many  
6 students who refuse to use animals for religious reasons.  
7 It is unthinkable that we do not provide for those.

8 Law does not exist to provide for those. I think it  
9 is long overdue that it does something.

10 In addition, there is a group of people who for  
11 ethical reasons do not wish to use animals. Let me mention  
12 in my own education, that I am a physician. I am currently  
13 Chairman of the Physicians Committee for Responsible Medicine,  
14 which is a nationwide group of doctors headquartered in  
15 Washington, D. C.

16 Many of our doctors never trained on animals at all.

17 In my own case, I was at the George Washington  
18 University studying medicine, and I spent the entire first  
19 semester dissecting a human cadaver. At the end of that time,  
20 we moved into physiology instruction. I was supposed to  
21 take a live dog and give the dog drugs, and before the afternoon  
22 was over, the dog was going to be dead.

23 I had been a rather good student up to that time,  
24 and I said I can learn physiology without killing this dog.  
25 I am not going to kill my first patient. They thought, well,

1 he is a little soft-hearted. There were other students who  
2 made the same decision.

3 Back in those days, we didn't care much about animal  
4 rights, and there was not much controversy. I completed the  
5 four years of medical school without ever touching an animal,  
6 and they put me on the faculty where I am now.

7 (Whereupon, the audience applauds.)

8 DR. BARNARD: I am not trying to say that this is  
9 their position or that I am speaking for them. What I am  
10 saying is that you can be a doctor and well-respected and a  
11 good practitioner without ever touching an animal. If a  
12 doctor can do that, then don't you think a college student  
13 or high school student, can't they meet the requirements of  
14 their biology class or comparative anatomy class without  
15 having to experiment on animals.

16 Unfortunately, today, I think some things are in  
17 some ways worse. There was a student recently who called me  
18 up. Her name is Mary Domenico. She was at a school that  
19 shall remain nameless. She was a very good student and a  
20 mother of two, and did not want to rock the boat.

21 She was given the same requirement. "You got to  
22 cut up an animal. The dog is going to be dead before the  
23 afternoon is over."

24 She said, "Look. I want an alternative activity."

25 They said, "Your alternative, young lady, is to

1 take a leave of absence. When you are ready to come back  
2 and be a doctor, then do so."

3 She left medical school. She said, "I don't want  
4 to have any part of that."

5 I think that is a tragedy because we lose our best  
6 students when we don't understand that there are broader  
7 implications that must be respected.

8 Let me also bring to your attention the current  
9 Journal of Medical Education, which is the leading journal of  
10 medical education. You will find in there an editorial and  
11 survey. The survey states that many medical schools no  
12 longer include animals, period, in their required curriculum.  
13 You can graduate from Hahnemann, for example, and many other  
14 medical schools without ever being offered animals.

15 Only 47 percent of medical schools still use  
16 animals to teach physiology. Fifty-three percent don't.  
17 Only 19 percent of schools still use animals for practice  
18 surgery. Eighty-percent do not.

19 What do they use? You can use a computer model.  
20 You can use high tech videotapes. But you need not. We  
21 rely on lectures, we rely on reading, and basic instruments  
22 that have been used for years.

23 Most importantly, we get our students into the  
24 hospital so they can learn through years of supervised  
25 instruction. No dogs, no other animal is going to take the

1 place of learning at the hands of a skilled practitioner.

2 I might mention that an editorial in the same  
3 journal stated that there is no data showing that education  
4 on animals is better. Clearly, there is a strong trend away  
5 from use of animals in medical education, and I hope other  
6 levels of education would follow suit.

7 Let me move on from this to talk a little bit about  
8 regulations on animal research. What happened at the  
9 University of Pennsylvania, obviously, was very lamentable  
10 from a lot of ways, the least of which was that it gave  
11 research a black eye. It gave those of us who are concerned  
12 about human health a black eye, I think. It should have been  
13 settled quietly and quickly within the State of Pennsylvania.

14 When one reviews those records, it is clear there  
15 is a lot of local concern, even within the University, the  
16 animal care community. Unbeknownst to me, at the time, the  
17 animal care community shot them down once, but they began  
18 again.

19 The local Humane Community was very concerned that  
20 these baboons were being head injured cruelly, repeatedly.  
21 They could not get in. They were denied access.

22 It took Margaret Heckler, the then Secretary of  
23 Humane Health and Services, to step in and slap their wrists  
24 and close them down. It was very damaging to the University.  
25 All of their animal facilities were suspended. That doesn't

1 work. That doesn't look good.

2 This should have been handled quietly. If  
3 Pennsylvania law had the provisions that it needs, it could  
4 have been done without the devastating effects that that  
5 scandal had. I am sorry to say that Federal law simply can't  
6 do the job.

7 The Animal Welfare Act specifically omits any animal  
8 involved in an experiment. Animals are covered with basic  
9 provisions before an experiment begins and after the experi-  
10 ment ends. During the experiment, there is no Federal law  
11 protection whatsoever.

12 Beyond that, when the Animal Welfare Act was passed  
13 in 1966, it was sent to the Department of Agriculture to  
14 enforce. The Secretary of Agriculture never wanted to be  
15 involved with this, and he defined animal in a very limited  
16 way, so that only those labs that had what he considered  
17 animals would have to be covered. So, a monkey is an animal  
18 for the purpose of the Animal Welfare Act, but a bird is not.  
19 A bird is not an animal. A guinea pig is an animal, but a  
20 rat is not an animal. A mouse is not an animal. Farm animals  
21 are not animals according to the law.

22 So what does that mean? It means that if you have  
23 a facility operating in Pennsylvanis, with birds and rats and  
24 mice and farm animals, they are not animals. They don't  
25 need to register with the USDA. They do not need to be



1 inspected. Federal law offers no protections. As bad as  
2 that is, the General Accounting Office, a couple years ago,  
3 said, "Well, what is the situation in labs? What is the  
4 inspection like?"

5 They talked to the Department -- the part of the  
6 USDA that inspects laboratories, and assures enforcement.  
7 It is called the Animal and Plant Health Inspection Service.  
8 They said, "What do you need to enforce this law?"

9 They said, "We need inspections of every covered  
10 lab four times a year."

11 The GAO took twelve months of records. They found  
12 that over half the labs in California and half the labs in  
13 New York were never inspected at all in the entire twelve  
14 months of records they examined. Even so, among those  
15 inspected, 114 sites had major deficiencies.

16 What does that mean? People will say, well, lab  
17 animals are cared for well. They are scientists. They  
18 are careful. What they can't tell is any piece of data that  
19 shows that the people they empower to care for the animals  
20 in doing their jobs because the data just shows they are not.

21 I am not suggesting that the laws have to be terribly  
22 much more strict at this time than they need be. There is a  
23 good case to be made. What I am saying is that this law  
24 provides basic provisions when something grievous happens in  
25 the lab that local people are empowered to do something about.

1           Let me move on to a discussion on the Draize  
2 test. There is something that I want to highlight more than  
3 anything else, that I think is the key point when you are  
4 talking about the Draize test. Some people call the Draize  
5 test a safety test. A Draize test is not a safety test.  
6 It was invented by John H. Draize, in 1944 and is not a safety  
7 test.

8           It is a litigation hedge.

9           When people call this a safety test, it is not. It  
10 is not used for that purpose. When you hear a discussion,  
11 are there good alternatives or bad alternatives, and so forth,  
12 let me suggest that you set that aside because the Draize  
13 is not used as a determinant test as to whether or not products  
14 will get on the market.

15           Let me give you an example of that. I have here  
16 a handout that the Clairol Company, a large manufacturer,  
17 made available to its beauticians and others that use its  
18 products. If the Draize test were a safety test, what that  
19 would mean is that Clairol used the Draize test and took those  
20 things that were dangerous and set them aside, and those that  
21 were safe, they let their beauticians use.

22           If you review their products, almost every one is  
23 classified as an eye-irritant. They are on the market anyway.  
24 Did they do the Draize test? Sure. Do they appear to be  
25 irritants? Often. Is it used as a safety test? Never.

1           The Draize test is used as a litigation hedge so  
2 that if I believe I have got something in my eye, maybe it  
3 wasn't your product or whatever, but I think I was damaged.  
4 I sue the company. The company wants to adhere to whatever  
5 the other company is doing and has some data to suggest the  
6 product may be more or less safe.

7           They will try very hard to get animal data that  
8 shows that their products are safe, regardless of the effect  
9 they have on people. They will try and pay firms to run  
10 and re-run these tests over and over again until they get  
11 test results that seem to indicate that the products are  
12 relatively safe.

13           Let's look at these. It caused eye irritancy  
14 and caution is written in bold letters. I might mention,  
15 it did not appear to be an irritant in rabbits. If you look  
16 at a semi-permanent hair color, again, caution, in capital  
17 letters, "Eye Irritant." Were they Draize tested? Sure.  
18 Are they on the market? Absolutely. Does the Draize test  
19 protect consumers? It does not.

20           Peroxide, again, caution in capital letters, eye  
21 irritant, may cause severe and possible permanent eye injury.  
22 When you hear testimony, saying what are the alternatives to  
23 the Draize test, the question is, are you calling the Draize  
24 test a safety test. Why didn't it stop these things from  
25 being on the market? They are clearly dangerous.

1           These are not isolated examples.

2           If you look at their bleach product. Again,  
3 caution, eye irritant. May cause severe irritation and  
4 possible permanent eye damage.

5           It says, "Flush with plenty of water immediately,  
6 remove contact lenses, get medical attention immediately,"  
7 in capital letters.

8           What protection is offered by the Draize test?

9           Shampoos. Again, eye irritant. Obviously,  
10 everyone knows this. It is common knowledge if you take  
11 something off the shelf and it gets in your eye, it will be  
12 an irritant. The Draize test does you no good.

13           Aerosol hairsprays, also from Clairol. Potential  
14 eye irritant. I could go on and on.

15           The Draize test is a good test for pharmaceutical  
16 companies. It is not good for safety, but it is good if you  
17 want to show that something looks safe, whether it is or not.  
18 The Draize test suffers from what we call false negatives.  
19 Things look safe, and they are not.

20           The results are negative, and when humans use it,  
21 they can be damaged. In 1948, the Draize test was four years  
22 old. In that year, researchers found a concentrated solution  
23 of physiniphosphate caused only a very slight and transient  
24 reaction in a rabbit eye. They made it concentrated. They  
25 used the standard Draize. They got a very slight reaction.

1 It was then used in humans, where even a very diluted solution,  
2 one to fifty thousand, causes severe response. Salina Sulfito  
3 caused no reaction in the Draize test, but in humans, it  
4 caused irritation and inflammation. Several detergents have  
5 passed the Draize test. In humans, they are very, very  
6 irritating.

7 Ozone had levels of two to thirty-seven parts per  
8 million and are not injurious to rabbits, but in humans they  
9 are very irritating. Why are there so many differences  
10 between the rabbit results and the human results?

11 Part of it is that rabbits are rabbits. They have  
12 large eyes. The Ph of their tears is about 8.2, which is  
13 ten times different from that of people. The Ph of human  
14 tears is 7.1. Every one degree of change in the Ph means  
15 a ten-fold difference in the acidity of the tears.

16 The corneal thickness is very different on rabbits.  
17 They are not used because they are good models for people.  
18 They are used because they have very large eyes. It is  
19 very easy to pull out the lower lid of the rabbit, put something  
20 in, push it against the eye and hold it in stock for two  
21 days. It is very easy. You can hold them still and put  
22 whatever you want in their eyes. That is absolutely routine.  
23 Is it a safety test? It is not.

24 Scientists from Carnegie-Mellon were concerned  
25 about the Draize test. They took a look at it and published

1 a report. They said that not only is the Draize test a  
2 bad test, if you want to predict human response, it is also  
3 a hard test to run consistently. A lab over here will get  
4 one result, and a lab over there will get very different  
5 results. Even within a lab, different workers will get  
6 different results.

7 Let me just quote from the Carnegie-Mellon  
8 researchers.

9 "Certain laboratories consistently recorded unusually  
10 severe scores for the materials tested. Other laboratories  
11 reported consistently non-irritating scores. Certain  
12 materials were rated as the most irritating tested by some  
13 laboratories, and contrary-wise, as the least irritating by  
14 others. Thus, the tests which have been used to decide the  
15 degree of eye irritancy produced quite variable results  
16 among the various laboratories as well as within the  
17 laboratories."

18 They went on to suggest, and I quote, "It is  
19 suggested that the rabbit eye procedure should not be  
20 recommended as standard procedure in any new regulation."

21 You will hear maybe three arguments that I commonly  
22 hear regarding the Draize test. People that want to continue  
23 to use it and have access to it as a litigation hedge.

24 They will say, well, the Draize isn't so good, we  
25 will give you that, but alternatives aren't so good, either.

1 The alternatives take advantage of the chicken egg embryo where  
2 you use the membrane right under the shell of a chicken. Put  
3 a little hole very carefully in the shell. There is a little  
4 membrane there that has blood vessels and epithelial tissue,  
5 and you can test directly on them.

6 CHAIRMAN DeWEESE: What is epithelial tissue?

7 DR. BARNARD: The epithelial cells are the type of  
8 cells that cover the skin, the outer surfaces of the body.  
9 This was developed by Dr. Joseph Leighton, M.D., and his  
10 other colleagues at the Medical College of Pennsylvania, and  
11 other institutions in Philadelphia.

12 The nice thing about it is, it is simple. It is  
13 cheap. You can run a thousand eggs and get very standardized  
14 results, as opposed to running six or twelve rabbits in the  
15 Draize test.

16 Again, let me suggest that the alternatives are not  
17 the issue. The Draize test is simply not used as a safety  
18 test and doesn't keep dangerous things off the market. People  
19 will also tell you that the FDA requires it or it is the only  
20 test the FDA uses.

21 Let me ask you to keep in mind that that is patently  
22 untrue. Some of the biggest manufacturers, such as Paul  
23 Mitchell, I see here Nexxus. Ask your family, have you ever  
24 seen Nexxus hair products at the hair salon. Call them up  
25 and ask them when is the last time you used the Draize test.

1 They don't use it. Paul Mitchell doesn't use it.

2 As I was coming here today, I saw a big billboard  
3 for Elizabeth Taylor's Passion Perfume. Was it Draize  
4 tested like other perfumes? No. Why not? Because they  
5 know it is not a safety test. They know it doesn't protect  
6 consumers.

7 What they do is two things, and every manufacturer  
8 has to do these two things. You formulate your product  
9 using what we know about chemistry. This is 1988. We know  
10 about ingredients. We know what is iffy, and we know what  
11 is safe.

12 These companies put things in their products that  
13 they know are safe. Now, you can test, but if you want to  
14 test, the way you do test, is you use a very dilute solution,  
15 and you test them on paid human volunteers. It sounds  
16 crazy. This is what all the companies are doing.

17 They know the rabbit eye test using a handful of  
18 rabbits is no indicator. Volunteers, medical students and  
19 others, will go in and for a small payment, they will put a  
20 little bit of the shampoo, or whatever, on their arms and wash  
21 it off. More concentrated solutions will be used. Dilute,  
22 very, very dilute solutions may later, if the safety results  
23 on the skin allow it, may allow eye application provided you  
24 know -- provided there is reason to believe that that formu-  
25 lation is safe.



1           The rabbit eye tests have not and are not being used  
2 as safety tests.     The FDA will say, well, we don't render  
3 an opinion as to the quality of the alternative tests.  
4 That's right.     The FDA does not regulate those things.

5           Any manufacturer can submit their data as to the  
6 safety of components.     That's why Paul Mitchell and Nexxus  
7 make huge amounts of money and employ huge numbers of people  
8 without using the Draize test.

9           Let me just briefly mention the LD 50.     It is  
10 ludicrous to defend this test.     I will only spend a few  
11 moments criticizing it.     The LD 50 stands for Lethal Dose 50  
12 Test.     It is an archaic test that no doctor takes seriously.

13           In the Lethal Dose 50 Percent test, rats, mice, other  
14 animals, typically those not covered by Federal protection,  
15 have tubes put in their stomachs, down their throats into  
16 their stomachs and force fed compounds until half of them are  
17 dead.

18           Now, this is the most humane test when you use a  
19 very toxic substance, because these animals tahnkfully die  
20 rapidly.     When it is not a very toxic substance, the LD 50  
21 doesn't end until half the animals die.

22           If you are doing an LD 50 of shampoo, you are not  
23 going to kill your rats very quickly.     So you put a greater  
24 and greater amount, more and more concentrated amounts.     The  
25 animals don't have to die from the shampoo.     They can die from

1 bloating. They can die from hemorrhage. They can have  
2 damage to their internal organs. But when you reach the  
3 LD 50 and half die, then the test ends and not before.

4 The LD 50 is very crude and varies tremendously  
5 between species. It is of no use. Banning it is long overdue.

6 For all these reasons, this bill is a modest proposal.  
7 It is a very good proposal. It is very basic. It will  
8 protect animals. More importantly it protects, or just as  
9 importantly, it protects students, it protect consumers,  
10 and it protects those concerned about the credibility of  
11 medicine.

12 Thank you. I urge your support of House Bill 1554.

13 (Whereupon, the audience applauds.)

14 REPRESENTATIVE KOSINSKI: Thank you very much,  
15 Doctor. I wish I had you as an expert witness. As a young  
16 attorney, the first case I ever handled was with an elderly  
17 woman who burned her eyes with a shampooing compounds, and we  
18 had to settle because the court did rely on the Draize eye  
19 test and a few others. It has opened my eyes considerably  
20 to the abuses of the test.

21 Again, thank you for your testimony.

22 DR. BARNARD: Thank you.

23 REPRESENTATIVE KOSINSKI: Stay around, please.

24 There are always questions.

25 Representative McHale.

1           REPRESENTATIVE McHALE:    Doctor, during your  
2 testimony, you touched on a point that I raised earlier in  
3 the day.  There was a representative here from the  
4 Pharmaceutical Manufacturers Association who testified in  
5 reference to Federal law, and I quote, "Currently, the only  
6 valid tests of eye irritancy is the Draize test," end of  
7 quote.

8           I understand from your testimony that that former  
9 testimony was inaccurate at best.

10          DR. BARNARD:    Yes.  Well, with all due respect,  
11 I do disagree with the pharmacist who testified earlier, along  
12 several lines.

13          First of all, the Draize test which was proposed in  
14 World War II and is still practiced today, was never validated.  
15 You can't say it is the only validated test.  It is not  
16 valid.  It was never validated.  It is patently invalid.

17          Valid means a good model of what shall come after.  
18 A validated test means that a rabbit eye would function  
19 similar to the human eye.  There are so many examples where  
20 that is not the case.  It is not validated.  That's why it  
21 is not a good safety test.

22          There are a number of other systems that are available.  
23 But if you are waiting for someone on high to say yes, these  
24 are all now validated, validation is not -- there is no gold  
25 seal of validation.

1            Things can come into common use as the Draize, and  
2 other things are available to be used. One of the best is  
3 Clonetics Epi-Paks where they will sell you skin cells,  
4 cultured skin cells, and you can test directly on them. The  
5 correlations are very, very good with that test. There are  
6 several others.

7            Here again, I don't want to try to detract from the  
8 point, because we can get mired very much in whether the  
9 alternatives are better than the Draize, worse than the  
10 Draize. It is totally aside from the point, because that  
11 makes the assumption that somehow the Draize is protecting  
12 people.

13            As the litigation you mentioned, and others are  
14 aware of, the Draize test isn't used as a safety test. It  
15 is a terrible test if you are going to use it as that. There  
16 are other ways to do that.

17            REPRESENTATIVE McHALE: I have a second related  
18 question. Again, during earlier testimony, when I asked the  
19 Representative from the Pharmaceutical Manufacturers Associa-  
20 tion the more specific question, and I quote, "Does the FDA  
21 require Draize testing?" She was unable today to give me  
22 a response to that question.

23            Can you answer that question?

24            DR. BARNARD: Yes. The FDA does not require the  
25 Draize test. The FDA does not require any specific testing.

1 What they will say is that we need your safety data from a  
2 company. If I am Nexxus, and I find the Draize test useless  
3 or abhorrent, I submit to them the basis for which I made my  
4 safety determination. That's all that has been acceptable to  
5 the FDA, provided it is reasonable. You don't need to use the  
6 Draize test. That's why so many big companies don't use it.

7 REPRESENTATIVE McHALE: Doctor, immediately prior to  
8 your testimony, as a matter of fact, just seconds before you  
9 began to testify, I was handed a copy of written testimony  
10 which has been submitted on the letterhead of the University  
11 of Pittsburgh, Central Animal Facility, Office of the Director  
12 of Laboratory Animal Resources. The letter is signed by  
13 Daniel J. Simons, Ph. D., Chairman of the University Animal  
14 Care and Use Committee, and Paul H. Bramson, Doctor of  
15 Veterinary Medicine, University Veterinarian.

16 The conclusion of that letter reads, and I will  
17 quote, "We contend that House Bill 1554, as currently written,  
18 is at best unnecessary or in need of substantive modification."

19 My initial question goes to the Chief Counsel of our  
20 committee. Were these gentlemen given an opportunity to  
21 actually appear in front of our committee?

22 REPRESENTATIVE KOSINSKI: They are going to testify  
23 next.

24 REPRESENTATIVE McHALE: Let me raise a point that  
25 is contained in their written testimony. They indicate, and

1 I quote from the first page of their letter, "We contend that  
2 unnecessary costs to the taxpayer would be incurred by the  
3 establishment of a State regulatory agency whose function  
4 would be essentially to duplicate that of an already existing  
5 Federal agency, Animal and Plant Health Inspection Service,  
6 APHIS."

7 Now, I cross-reference to the second page of your  
8 testimony where you make reference to the GAO study on that  
9 very issue. You indicate in your testimony, "The General  
10 Accounting Office examined APHIS inspection records for an  
11 entire calendar year and found serious oversights, including  
12 the failure to inspect half the animal research facilities  
13 in New York and California, the states with the greatest  
14 number of animal laboratories."

15 In light of your testimony, would you comment upon  
16 the assertion that we received by letter from the University  
17 of Pittsburgh. Does APHIS work?

18 DR. BARNARD: APHIS is not working, and that is  
19 for a couple of reasons. The main reason is that APHIS  
20 has no interest in fulfilling its regulatory obligation and  
21 as such, has never requested moneys that are sufficient to  
22 its tasks. APHIS, in all of its history, has never done an  
23 adequate job of enforcing the Animal Welfare Act.

24 In fact, in most of the years of the 1980's, has  
25 requested zero dollars to the lab inspections. What they are

1 saying is, if we are not given money to do so, we don't have  
2 to bother with that task.

3 They have a lot of other things on their minds,  
4 inspecting fruits that come across borders, and inspecting  
5 farm animal operations, and so forth. They want to have  
6 nothing to do with laboratories.

7 As I mentioned, they are very poorly organized.  
8 Let me expand on that. That APHIS jurisdiction does not  
9 extend to most of the laboratories in Pennsylvania. As I  
10 mentioned earlier, it only extends to those facilities  
11 using animals as defined in the regulations enforcing the  
12 Animal Welfare Act.

13 Let's say that I have a test facility and I only  
14 use rodents, which are commonly used, but yet feel pain and  
15 are subject to neglect and abuse. APHIS isn't going to go  
16 in. You don't even have to register with the USDA. So,  
17 there are huge gaps in what APHIS could do even if it works  
18 well. But it works very poorly.

19 REPRESENTATIVE McHALE: Your conclusion, then, at  
20 least based in part on the General Accounting Office study,  
21 which showed that half the animal research facilities in New  
22 York and California were not even inspected. That the reliance  
23 and the faith and indicated by Drs. Bramson and Simons that  
24 APHIS would be misplaced.

25 DR. BARNARD: Well, I think when they look into it,

1 they may see things a bit differently.

2 REPRESENTATIVE McHALE: Thank you, Doctor.  
3 Thank you, Mr. Chairman.

4 REPRESENTATIVE KOSINSKI: Further?  
5 Representative McVerry.

6 REPRESENTATIVE McVERRY: Dr. Barnard, thank you  
7 very kindly for coming here today. I am very impressed with  
8 your testimony. I think I am getting a better understanding  
9 of the issues from you and other people that are willing to  
10 share your expertise. This is a rather elementary question.

11 Would you describe for me and tell me what the Draize  
12 test is. How does it work, how do you do it? What is it?

13 DR. BARNARD: It works essentially the same today  
14 as when it was invented by John Draize, who worked for the  
15 FDA. I might mention that he began this, I don't think, with  
16 pernicious motivations. There were cases where things on the  
17 market caused blindness early in the century. There clearly  
18 was a need to have some way of ascertaining safety of a  
19 compound.

20 No one said, "We don't need to ensure that things are  
21 safe." On the basis of this, he took rabbits and put them in  
22 a stock. In fact, I can give you a picture of the apparatus  
23 pictured in his original set-up, which is much used today.

24 Rabbits are held so that they cannot scratch their  
25 eyes or in any other way get the compound out. The technician



1 takes the lower lid of the rabbit, pulls it forward, and  
2 puts a drop of the substance into the eye. This can be any  
3 household product, cosmetic, whatever it is. There is no  
4 limit to what it could be.

5 The eye is then pushed closed, and the animal is  
6 left then for 24, 48, 72 hours, as prescribed in the protocol.  
7 A battery of animals is used. You just don't use one.

8 The other eye is used as a control. So, at the end  
9 of that time, you look at the damage done to the eye and  
10 compare it with the other side. It can range from no effect  
11 at all to -- The eye can have almost literally rotted out.  
12 It can have been encroached. That is, the eye becomes dead.  
13 It can become infected, pus can form. You can see in pictures  
14 of the Draize test as performed in one of the Pennsylvania  
15 facilities, and, obviously, it is one of the tests that is  
16 very upsetting to those who perform it.

17 Does that answer your question?

18 REPRESENTATIVE McVERRY: Yes. It is your point of  
19 view that, in reality, this test is not used to keep products  
20 from getting to the market, but rather to hedge bets as to  
21 how much potential damage it may have if on the market, and/or,  
22 and correct me if I am wrong here, the development of an  
23 antidote in the event that it does create a malady?

24 DR. BARNARD: No. I think that is not quite  
25 correct. The rabbits are not given antidotes. There is no

1 treatment of the rabbit. The only treatment of the rabbits  
2 if they have not had much damage, they will go into another  
3 test. If they are damaged, they will be killed. There is  
4 no treatment predicated on this.

5 The ophthalmologists and emergency physicians who  
6 are members of the Physicians Committee all concur that the  
7 Draize test gives them on clinically relevant information.

8 But it is not -- when I call it a litigation hedge,  
9 I am not suggesting that the companies use this to judge  
10 whether or not they will be sued, or how likely it is to  
11 damage eyes. Something can be damaging, as you saw, in the  
12 Benetton product that was damaging to the eye. But their  
13 marketing teams were all set to go, and they went forward  
14 marketing this compound. They are not interested in  
15 engaging in the likelihood of the suit, as far as I can tell.

16 What they are interested in doing is having a body  
17 of data showing that they adhere to the industry standard for  
18 testing. Just myself, as a physician, or any other physician,  
19 if someone says a physician did not perform their work properly,  
20 they don't have to say that it was a state of the art, or the  
21 world's best job, or valid, or accurate. Only that they  
22 adhered to the prevailing practices. The prevailing practice  
23 has been the Draize test since World War II.

24 REPRESENTATIVE McVERRY: There is no standard --  
25 Correct me, is there a standard established by the Draize test

1 that says if you are at this level, you better not use it,  
2 and if you are at this level, you are safe to use it. Do  
3 you know what I mean?

4 In other words, the testing takes place. You get a  
5 body of knowledge, but is there a result from that that  
6 determines you should or shouldn't use the product?

7 DR. BARNARD: No. There isn't any danger zone  
8 with the Draize test exactly. The subjects are given  
9 numerical scores. One would think, obviously, that on the  
10 basis of a numerical score, you would decide whether or not  
11 to market the product.

12 But what is routinely the case is that even in the  
13 case of eye damage, products may be marketed anyway. And  
14 in cases where there is no eye damage, the companies are bound  
15 by practice or by good sense, I should think, to indicate  
16 labels suggesting you keep it out of your eye.

17 So, it is really not relevant.

18 REPRESENTATIVE McVERRY: One other thing I wanted to  
19 ask you about.

20 DR. BARNARD: Let me maybe sum up and say that I  
21 am sure you will hear others say that the Draize test is the  
22 best thing since sliced bread and protects children and so  
23 forth, and that it is a safety test. It is not.

24 REPRESENTATIVE McVERRY: Your message came through  
25 loud and clear on that.

1 DR. BARNARD: Sorry for overemphasizing that  
2 point.

3 (Whereupon, the audience applauds.)

4 REPRESENTATIVE KOSINSKI: Further questions?

5 I want to remind the committee members that we are  
6 approximately forty minutes behind schedule and we do have a  
7 number of people who need to catch flights out. Please limit  
8 our comments to things that haven't been covered before, and  
9 for the future speakers, we are going to try to strictly  
10 enforce that twenty minutes.

11 REPRESENTATIVE McVERRY: You made a point, and I  
12 think it is well-taken, that the definition of an animal in  
13 Federal regulations has been -- is inadequate or inappropriate  
14 or inappropriately applied. Do you believe the definition  
15 contained in 1554 is sufficiently broad to cover these species  
16 that are birds and mice, for instance, that aren't covered  
17 in the Federal definition?

18 DR. BARNARD: Let me defer comment on that, if I  
19 could. As I initially read the bill, yes, it seems so. But  
20 I don't want to preclude the possibility that it may need to  
21 be broadened.

22 REPRESENTATIVE McVERRY: One last question. Is the  
23 use of live animals in high school and colleges wide-spread?  
24 You indicated it was on the decline. Is it, nevertheless,  
25 wide-spread?

1 DR. BARNARD: In colleges, it is quite wide-spread.  
2 In high schools, less so. The uses cover a very wide range.  
3 They can range from comparative biology classes to psychology  
4 classes where students are given animals to study their  
5 behavior, and so forth.

6 Again, this bill doesn't prohibit any of that. It  
7 allows students to object to not participate.

8 REPRESENTATIVE McVERRY: Thank you very much.

9 REPRESENTATIVE KOSINSKI: Thank you very much,  
10 Doctor.

11 Next up is Dr. Paul Bramson, Director of Central  
12 Animal Facilities, University of Pittsburgh, and Dr. Sheldon  
13 Adler, Associate Dean and Professor of Medicine, University  
14 of Pittsburgh, School of Medicine.

15 CHAIRMAN DeWEESE: Dr. Bramson, Dr. Adler, welcome.

16 DR. BRAMSON: Members of the Committee, my name is  
17 Paul Bramson. I am a veterinarian, University Veterinarian  
18 at the University of Pittsburgh.

19 I am Chairman of our Animal Care and Use Committee.  
20 I drafted this letter. If I could, I would like to read  
21 from it.

22 We would like to provide written testimony relative  
23 to House Bill 1554. As citizens of the Commonwealth of  
24 Pennsylvania, and as members of the biomedical research  
25 community, we find several aspects of the bill objectionable

1 or in need of clarification.

2 Most aspects of the bill relating licensure,  
3 development of regulations, and the requirement for  
4 Institutional Animal Care Committees are redundant as they are  
5 already required by Federal laws. These include the Animal  
6 Welfare Act, the Health Research Extension Act of 1985, the  
7 Good Laboratory Practices Act of 1978, FFRA, and TSCA.

8 These acts already require any organization  
9 submitting research data obtained from non-clinical studies  
10 utilizing animal models to be licensed by the United States  
11 Department of Agriculture and to comply with the Animal  
12 Welfare Act.

13 We contend that unnecessary costs to the taxpayer  
14 would be incurred by the establishment of a State regulatory  
15 agency whose function would be essentially to duplicate that  
16 of an already existing Federal agency; namely, APHIS.

17 As specified in the proposed bill, the mandate of this  
18 newly created State agency would require the establishment of  
19 written regulations so broad as to cover the full spectrum of  
20 handling, treatment, and care of research animals. The  
21 formulation of such sweeping regulations would require extensive  
22 time commitments on the part of the proposed review committee,  
23 and these costs would be borne by the taxpayers.

24 The requirement for an Institutional Animal Care and  
25 Use Committee duplicates requirements of two existing Federal

1 laws. Moreover, the membership of the proposed state  
2 committees differs from that already required by the Federal  
3 laws.

4 In the worst case, this would require the establishment  
5 of a second committee, and each institution would have two  
6 such committees in order to comply with differing sets of  
7 regulations. At the least, the proposed law would require  
8 expansion of the existing committees to include additional  
9 members from outside the institution.

10 These individuals would have to be available to  
11 perform weekly reviews of research protocols and to attend  
12 frequent committee meetings. Depending on the expertise of  
13 these individuals in modern research methodologies, the  
14 functioning of the committees could be severely impaired.  
15 This would most affect the large research institutions  
16 whose committees review numerous protocols on a frequent basis.

17 The section of the proposed law dealing with issuance  
18 of search warrants for alleged violations requires clarifica-  
19 tion. It is not clear what criteria would be used to support  
20 an allegation of non-compliance and whether and how these criteria  
21 would be applied to institutions engaged in biomedical  
22 research.

23 The impoundment of laboratory records and/or the  
24 seizure of research animals on the basis of alleged violations  
25 that are subsequently found to be erroneous would seriously

1 disrupt a productive research program.

2 On the basis of the above considerations, we contend  
3 that House Bill 1554 as currently written is at best  
4 unnecessary or in need of substantive modification.

5 CHAIRMAN DeWEESE: Thank you, Dr. Bramson.

6 Are there additional comments or observations from  
7 the gentleman to your left?

8 DR. ADLER: No. I think the medical school  
9 in this case supports fully the position outlined by Dr.  
10 Bramson and Dr. Simons in the document. The concern we have  
11 is not to do so much with when people break the law, but the  
12 fact that the law itself should be enforceable in a proper  
13 fashion and followed by people.

14 We think the regulations now, in effect, the Federal  
15 regulations do spell that out, and that we are concerned  
16 that we shouldn't impair the efficacy of the research now  
17 going forward, which indeed has decreased the numbers of  
18 animals being used because of the advances, but, unfortunately,  
19 cannot totally substitute for the use of certain other types  
20 of investigations or complimentary functions. Not ones that  
21 are at odds with one another.

22 CHAIRMAN DeWEESE: Mr. Kosinski, from Philadelphia,  
23 has a series of questions.

24 REPRESENTATIVE KOSINSKI: Doctor, I am somewhat  
25 upset by your last statement because it is obvious that you



1 think you are above the law.

2 DR. ADLER: I did say I misspoke. On the contrary --

3 REPRESENTATIVE KOSINSKI: You do think you are above  
4 the law, Doctor. Let me finish my statement, please.

5 Very simply, I am subject just like any other citizen  
6 of the United States and the Commonwealth of Pennsylvania, to  
7 have a valid search warrant issued for my premises if there is  
8 probable cause of any violations going on there. As a  
9 responsible citizen of this Commonwealth, and of this nation,  
10 I agree to that. I do not want to be exempted from such.

11 If I am guilty of violating the law, so be it. I am  
12 subject to penalty. There is somewhat of an arrogance by the  
13 University of Pittsburgh, and as I see later, the University  
14 of Pennsylvania, and other facilities that readily accept our  
15 money, our State funds are non-preferred appropriations, not to  
16 be subject to similar proceedings as everybody else is.  
17 Now, do you know a search warrant is issued?

18 DR. ADLER: Not precisely. I don't understand what  
19 you are saying that is in this document that says it is against  
20 the law.

21 REPRESENTATIVE KOSINSKI: You are above the law  
22 because you want to be exempt from a search warrant.

23 DR. ADLER: I don't hear that in any of the comments.

24 REPRESENTATIVE KOSKINSKI: I certainly do.

25 CHAIRMAN DeWEESE: Just to momentarily arbitrate,

1 I believe that my young colleague here is upset about the fact  
2 that you folks don't think you should have people issuing search  
3 warrants and coming in and looking at the activities that we  
4 witnessed earlier on the screen.

5 Again, I am naive to a colossal degree on the  
6 subject matter. That's why I am here, just to learn.

7 I would tend to agree that if there are certain  
8 things going on that are legal or, well, illegal, that people  
9 should be able to come in and take a look. I think that is  
10 where we have a disagreement. What do you think?

11 CHAIRMAN DeWEESE: I certainly am not a partisan with  
12 Mr. Murphy on his legislation. I come here as a neutral  
13 observer on this whole matter. I want to find out what you  
14 gentlemen think about the search warrant. I would ask that  
15 there would not be these moments of acclamation. I don't think  
16 they are necessary. We all know whose side everybody is on.  
17 You can answer this and then I will give the mike back to Jerry.

18 REPRESENTATIVE KOSINSKI: Can I clarify my comments.  
19 Do either of you gentlemen know what is needed to issue a  
20 search warrant?

21 DR. ADLER: No.

22 DR. BRAMSON: We are not lawyers.

23 REPRESENTATIVE KOSINSKI: Then why did you write it  
24 down in your testimony if you don't know what we are talking  
25 about or what protections there are for people like you within

1 the search warrant procedure? To get a search warrant, for  
2 example, I have problems getting search warrants for known  
3 drug dealers in my district because there must be probable  
4 cause submitted to an independent Magistrate or Judge. The  
5 judge then decides upon the law.

6 It is a very tough procedure to get a search warrant.  
7 And for people to come in here and to tell the public that we  
8 want to be exempted from search warrants or we do not want a  
9 search warrant procedure to me is reprehensible. It also  
10 bothers me that you would come here talking about search warrants  
11 not knowing what they are.

12 CHAIRMAN DeWEESE: I don't think -- Mr. Kosinski, I  
13 don't think that is essentially relevant to the dialogue. But  
14 nevertheless, you can expand on further questions.

15 REPRESENTATIVE KOSINSKI: No more questions?

16 DR. ADLER: Again, I think that the search warrant  
17 issue was not the issue that was brought by this group. I  
18 think that within the bill, the proposed bill, and I can read  
19 it, and I am again not a lawyer --

20 CHAIRMAN DeWEESE: Neither is the Chairman.

21 DR. ADLER: Search warrants where a violation of  
22 this section is alleged. I don't know what that means.

23 REPRESENTATIVE KOSINSKI: Then why comment on it?

24 DR. ADLER: Because I am concerned when I don't  
25 know what something means.

1           REPRESENTATIVE KOSINSKI: Ask. What bothers me is  
2 when people come to testify in front of us and parrot the party  
3 line and they don't know what they are parroting. It insults  
4 my intelligence as a legislator and as an attorney. I am  
5 more than happy to tell people if they don't know.

6           If you will notice, that's why we are here today.  
7 The Chairman, on a few occasions, and myself, have asked when  
8 we didn't know some medical terms, what they were.

9           DR. ADLER: I guess I reject the party line. What  
10 is the party line?

11          REPRESENTATIVE KOSINSKI: Apparently the people who  
12 want to protect illegal activities going on in animal labs.

13          DR. ADLER: I reject that. We are not asking to  
14 protect the illegal. That is an ad hominem remark.

15          REPRESENTATIVE KOSINSKI: It is a difference of  
16 opinion.

17          CHAIRMAN DeWEESE: I would agree with the position  
18 that it's an ad hominem remark. But who cares whether I agree  
19 or don't agree. I want to keep order in the proverbial court.  
20 I think it is essential that we have a substantive debate. I  
21 think we have. At the same time, I don't reject some high-  
22 spirited exchange. I think it is obviously part of our program  
23 here, part of our essential democracy. I hope no one is  
24 offended by the high-spirited exchange.

25          Mr. Dawida is another high-spirited person.

1           REPRESENTATIVE DAWIDA: First of all, do you agree  
2 that at least the aspect of the bill that would give people  
3 an opportunity to use alternative types of service such as  
4 the doctor in medical school, such as me when I was in high  
5 school, that they found very repugnant, is a good aspect of  
6 the bill? Do you have any problems with that element of  
7 this legislation?

8           DR. BRAMSON: No, I don't.

9           REPRESENTATIVE DAWIDA: Your concern is basically --

10          DR. ADLER: Let me say the medical school -- The  
11 animal issue is not an issue in the medical school.

12          REPRESENTATIVE DAWIDA: The real issue as far as  
13 you are concerned is the aspect of what your work at the lab  
14 is in regards to long-term benefits to the society that  
15 you feel your lab is able to produce?

16          DR. BRAMSON: What we are saying is essentially  
17 now we are being policed by a number of different Federal  
18 agencies and State agencies. What we are doing is adding  
19 another agency to the list of policing groups.

20          REPRESENTATIVE DAWIDA: So at least part of the  
21 bill is okay. You are zeroing in on the one aspect?

22          DR. BRAMSON: That is correct.

23          REPRESENTATIVE DAWIDA: That is going to be a  
24 matter of fact for us to determine. Thank you, Mr. Chairman.

25          CHAIRMAN DeWEESE: Yes, sir. Dr. Ivan Itkin, from

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1 Point Breeze.

2 REPRESENTATIVE ITKIN: Does the University utilize  
3 the Draize test?

4 DR. BRAMSON: No, we do not.

5 REPRESENTATIVE ITKIN: Do you utilize the LD 50  
6 test?

7 DR. BRAMSON: No, we do not.

8 REPRESENTATIVE ITKIN: Do you have any comments  
9 in view of the prior speakers in view of the tests who  
10 alleges the tests themselves are not very useful?

11 DR. BRAMSON: In all honesty, I don't have  
12 experience with the tests. They are not generally used in  
13 academia. Therefore, I can't comment on it.

14 REPRESENTATIVE ITKIN: Thank you.

15 CHAIRMAN DeWEESE: Yes, sir. Paul McHale.

16 REPRESENTATIVE McHALE: Thank you, Mr. Chairman.

17 Doctor, you indicated you think this area of the law is  
18 already adequately policed. In light of what I witnessed  
19 earlier on the video screen, it is my view that we could use  
20 a few more policemen. Now, the Animal and Plant House  
21 Inspection Service is the Federal agency, as I understand  
22 it, part of the Department of Agriculture, which has the  
23 responsibility for lab inspections; is that correct?

24 DR. BRAMSON: That is correct.

25 REPRESENTATIVE McHALE: In your testimony, you

7 1 indicated some considerable degree of faith in APHIS. You  
2 indicate, and I will paraphrase your testimony, that in your  
3 view, the creation of the State agency would be an unnecessary  
4 duplication of an already existing effective Federal agency;  
5 is that correct?

6 DR. BRAMSON: That is correct.

7 REPRESENTATIVE McHALE: Now, you were present  
8 here in the hearing room during the testimony of Dr. Barnard;  
9 is that correct?

10 DR. BRAMSON: Yes, I was.

11 REPRESENTATIVE McHALE: He testified in detail  
12 with regard to a General Accounting Office Study which  
13 indicated that records were examined for an entire calendar  
14 year, and that serious oversights were found and effective-  
15 ness of the APHIS regulatory process. Specifically, that  
16 that investigation revealed failure to inspect half the  
17 animal research facilities in New York and California during  
18 the period of the investigation. Did you hear that testimony?

19 DR. BRAMSON: Yes, I did.

20 REPRESENTATIVE McHALE: Have you read that GAO  
21 report?

22 DR. BRAMSON: No, I haven't seen that. I do know  
23 what colleagues and my own experience here in the Common-  
24 wealth that we are visited between two and four times a  
25 year by APHIS, and these site visits generally take anywhere

8 1 from two to four days depending on the size of the facility.  
2 That they do an extensive site visit.

3 REPRESENTATIVE McHALE: You say two to four times  
4 a year?

5 DR. BRAMSON: That is correct.

6 REPRESENTATIVE McHALE: And so the inspections  
7 could be as little as once every six months?

8 DR. BRAMSON: That is correct.

9 REPRESENTATIVE McHALE: Let me suggest to you  
10 before you place the reliance and face that you do in APHIS  
11 that you get a copy of that GAO report. I believe it may  
12 be instructive for you. Thank you, Mr. Chairman.

13 CHAIRMAN DeWEESE: Yes, Mr. McHale. Anybody else  
14 have any comments or questions from the membership or the  
15 staff? I might add that ad hominem attacks are axiomatic  
16 in the legislative arena. I have been the recipient of  
17 innumeral barbs. So in spite of the electric performance of  
18 my pal here, thanks for coming, and I think we benefited by  
19 your testimony.

20 The next person to testify is Holly Hazard, Esquire,  
21 from Galvin, Stanley & Hazard, Washington, D.C. I will turn  
22 the mike back to Gerry.

23 MS. HAZARD: Thank you, Mr. Chairman, and my name  
24 is Holly Hazard. I am an attorney in private practice in  
25 Washington. I am here on behalf of the Doris Day Animal



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1 League and its 130,000 members nationwide and over 13,000  
2 members here in the State of Pennsylvania.

3 The Doris Day Animal League supports this bill  
4 in toto. However, I am going to focus on a few areas which  
5 I think I may have some more expertise and leave other  
6 areas to the other very able proponents of this legislation.

7 In the first area I want to get into, although  
8 reluctantly after last encountered, is the search warrant  
9 area. One of the statements that was made by the individuals  
10 who testified prior to me was that because Federal law is  
11 in effect, this issue is really being taken care of by the  
12 Federal agents responsible for compliance with the Federal  
13 Animal Welfare Act.

14 I would like to point out that that same law was  
15 in effect during the University of Pennsylvania's incident  
16 and other problems with that Federal statute as well as  
17 State statute and is currently the only law available at  
18 the Federal level for compliance with what we feel are very  
19 basic needs of the animals currently used by medical research.

20 The search warrant issue strikes at the very core  
21 of the enforcement capability of the anti-cruelty statute.  
22 Despite contentions that this will slow down or obstruct  
23 research in some way, it is important to note that the search  
24 warrant provision in the statute is no different than the  
25 search warrants currently available to law enforcement

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1 officials in virtually every other area of ciminal enforce-  
2 ment within the State of Pennsylvania and virtually every  
3 other state in the Union.

4 The search warrant provision will not grant a  
5 special right to those charged with enforcement capabilities  
6 of the anti-cruelty code, but will simply present them with  
7 the same tools afforded law enforcement officers in other  
8 areas to effectively bring those choosing to violate the  
9 statutes to courts of law.

10 Search warrants may only be issued under the same  
11 restrictions and guidelines that are set out under current  
12 Pennsylvania Criminal Code. Without probably cause, no  
13 search warrant would be issued.

14 If probably cause exists that cruelty is taking  
15 place within a research facility in the State of Pennsylvania,  
16 then law enforcement officials should be given the tools  
17 necessary to correct this wrong.

18 The disruption to a research facility will be no  
19 greater than the disruption to any other form of enterprise  
20 for which probably cause to suspect criminal evidence exists.  
21 The mere accusation of criminal activity by law enforcement  
22 personnel is not enough to obtain a warrant.

23 A search warrant can only be issued if an impartial  
24 and unbiased judicial officer concurs with the law enforce-  
25 ment personnel that probably cause exists that criminal

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1 activity is taking place. The purpose of this check is to  
2 protect citizens from overzealous law enforcement officials.

3 Animal research officials should have no greater  
4 constitutional rights than others. If they violate the  
5 criminal code, our government needs to have the enforcement  
6 tools necessary to prosecute them. If only legitimate  
7 research is taking place in a facility within the confines  
8 of the law as set forth by the State and Federal government,  
9 then no disruption will take place. If that is not the  
10 case, then research facilities have no cause to complain  
11 that their activities are being disrupted.

12 In the only criminal prosecution of a research  
13 laboratory to date in the United States which was the State  
14 of Maryland versus the Institute for Behavioral Research,  
15 the use of search warrants was an integral part of the  
16 prosecution.

17 In that case, the seizure of documents, biological  
18 samples, pharmaceuticals, and seventeen macaques presented  
19 the prosecutor with the evidence necessary to convict Dr.  
20 Taub of cruelty to animals under that state's anti-cruelty  
21 statute.

22 This research was never questioned by the U.S.  
23 Department of Agriculture of the National Institutes of  
24 Health previous to the prosecution of Dr. Taub, and was  
25 later found to be flawed and funding for the experiments was

1 stopped.

2 It is ludicrous for the research community to  
3 condemn attempts at obtaining search warrants for research  
4 of which there is no value to humans and which is cruel to  
5 animals on the grounds that this kind of research may be  
6 disrupted.

7 The research community claims that appropriate  
8 monitoring of research is currently being conducted by the  
9 Federal Government and specifically by the National Insti-  
10 tutes of Health and the Department of Agriculture. History,  
11 however, shows us that these programs have been largely  
12 ineffective in stemming even the most flagrant animal abuses  
13 in research and testing facilities.

14 In one of the most notorious cases in the history  
15 of the animal rights movement, the University of Pennsylvania  
16 was allowed to operate for over a decade with the tacit  
17 approval of the National Institutes of Health and the U.S.  
18 Department of Agriculture's Animal Welfare Inspection  
19 Program.

20 It was only through the illegal acquisition of  
21 tapes filmed by research scientists at this facility that  
22 that facility was seriously investigated and eventually  
23 closed by the Secretary of Health and Human Services. This  
24 research, clearly deserving of significant disruption, would  
25 have continued unabated had animal rights activists not called

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1 the status quo into question.

2 Had animal activists had the ability to obtain  
3 a search warrant, then significantly less disruption would  
4 have occurred at the laboratory.

5 In the most recent case brought to light in  
6 Pennsylvania, a firm known as Biosearch, Incorporated,  
7 which tests commercial, household, and other products for  
8 a number of nationally known product manufacturers, was  
9 inspected for compliance with FDA's good laboratory practice  
10 on no fewer than six occasions spanning the years 1979  
11 through 1986.

12 If the allegations brought forward with reference  
13 to this case are born out, then significant violations of  
14 Federal and State law have occurred. Yet, no provision  
15 exists under the Pennsylvania anti-cruelty statute to allow  
16 law enforcement personnel with the evidence -- To obtain the  
17 evidence necessary to adequately enforce the State's anti-  
18 cruelty statute.

19 Without the mechanisms necessary for adequate and  
20 appropriate prosecution of individuals choosing to violate  
21 the State anti-cruelty statutes, the law itself is a sham.  
22 Prosecutors are no less in need of material evidence when  
23 prosecuting anti-cruelty cases than they are in the area of  
24 drugs, theft, or any other criminal provision of the Pennsyl-  
25 vania Code. I urge this Committee to support this responsible

1 and needed section.

2 I brought with me for those of you or anyone else  
3 who may not be familiar with it a search warrant. This is  
4 a search warrant that was issued in the IVR case. As you  
5 can see, it is not simply one page. It is not based on  
6 misinformed or allegations that cannot be supported by the  
7 individuals who brought this case to the attention of  
8 impartial and unbiased judicial officers in the State of  
9 Maryland and allow that search of that facility to take  
10 place.

11 The second point I want to bring out that I just  
12 learned of is that even if APHIS were appropriately inspecting  
13 and taking care of the problems in research facilities in  
14 the past, the Department has now suggested that reorganization  
15 may be taking place because of funding cuts and because of  
16 different priorities.

17 They will be cutting back significantly on the  
18 very few animal welfare inspectors that are now available  
19 to monitor the provisions of the Federal Animal Welfare  
20 Act. Even if it is not necessary for the State to take  
21 on this kind of a question in the past, it would certainly  
22 be more important in the future.

23 My next point is reference with Institutional Care  
24 Committees. The Federal Animal Welfare Act requires that  
25 each institutional care committee have one member who is a

1 doctor of veterinary medicine and at least one member not  
2 affiliated in any way with the facility and who can provide  
3 representation for the general community interests in the  
4 proper care and treatment of animals.

5 The Federal legislation states that the committee  
6 shall be comprised of at least three members. The Pennsyl-  
7 vania Bill would require that each committee have a member who  
8 is a representative of the animal care staff, a member who  
9 is a State enforcement agent, a member who is a representa-  
10 tive of an incorporated humane or animal welfare organiza-  
11 tion.

12 These two sections are complimentary. I know that  
13 the speaker who testified previously said it may need to  
14 set up some kind of a dual system. That it would be  
15 redundant. My reading of the Federal statute and what is  
16 proposed in this bill is not the case. What happened in the  
17 Pennsylvania statute is simply the outside committee member  
18 who needs to be someone who was actively involved in the  
19 Animal Protection Committee and not someone who had some  
20 kind of indirect association with the facility itself.

21 The Federal Act authorizes the Secretary to  
22 cooperate with the officials of Pennsylvania or other states  
23 in carrying out the purpose of the Federal legislation and  
24 of any state legislation on the same subject. There should  
25 be no problem with preemption of the theory of these areas.

1 Perhaps there should be another Federal statute.

2 Because the requirements of these committees are  
3 not in conflict and the Federal Animal Welfare Act encourages  
4 state action, the state law would not be preempted and  
5 would ensure strict compliance with the intent of the  
6 Federal statute.

7 This section of the Pennsylvania Bill will close a  
8 loophole in the Federal legislation that has been abused in  
9 several instances by research facilities throughout the  
10 United States. Numerous examples have come to light that  
11 evidence a need to define at least one outside member of the  
12 animal care committee as being from a humane organization.

13 University after university has abused the dis-  
14 cretion allotted by Congress in the 1985 amendments by  
15 allowing individuals closely associated with university  
16 research or other research facilities to serve as the  
17 outside member. If these committees are to function  
18 effectively, then it is imperative that individuals from all  
19 perspectives on the use of animals come together to discuss  
20 the research taking place at that facility.

21 The Pennsylvania law goes a long way toward ensuring  
22 that the clear intent of Congress to bring an outside member  
23 to these committees is indeed carried out by the research  
24 facilities themselves.

25 The final area I want to get into is the test that



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1 will be prohibited under the statute. Animal protection  
2 organizations have focused on the problems associated with  
3 the LD-50 test and the Draize test for over a decade. In  
4 the classical LD-50 test, substances such as oven cleaners,  
5 lipstick, and household cleansers are force fed to 100  
6 animals until 50 percent of them die.

7 In testimony in the U.S. House of Representatives  
8 on this issue this past May, Dr. Gerhardt Zbinden, who is  
9 a world reknowned toxicologist from the University of Zurich,  
10 stated that three fundamental problems exist in using the  
11 LD-50 test to predict product safety.

12 One is that the LD-50 test is not a biological  
13 constant and is dependent on many factors such as the age,  
14 sex, strain of the animals, nutritional state, and caging  
15 that may vary from animal to animal in the laboratory. That  
16 means that the test is just not reliable.

17 The LD-50 test reflects only the lethality of the  
18 test animal and does not predict non-lethal effects of poison  
19 or information on the reversibility of toxic effects. That  
20 means we are not getting information on what we might use  
21 as an antidote to problems should they occur in testing  
22 products.

23 The third point that he brought out is that animals  
24 suffer a great deal of pain and anxiety and the information  
25 gained from the animal is a minor practical or clinical

1       significance.

2               He pointed out in his closing statement that the  
3       overwhelming majority of professional toxicologists agree  
4       with the scientific concepts outlined in his testimony and  
5       also that many public health officials and regulatory  
6       agencies are very much in favor of using more humane methods  
7       for the determination of acute toxic hazards of chemicals.

8               My final point deals with the Draize eye irritancy  
9       test. That has been much discussed. I won't go into the  
10      safety factors any more except maybe one point. That is  
11      that in testimony in a different hearing this past summer  
12      in the House of Representatives, it was noted that 47,000  
13      people were sent to hospitals in 1987 from injuries from  
14      cosmetic problems. These are cosmetics that had the Draize  
15      test completed on them prior to being marketed.

16              What the Government and manufacturers want is  
17      not to determine whether or not products are safe and then  
18      to make a decision as to whether they should or should not  
19      be placed on the market, but to make a determination as to  
20      how these products should be labeled. Products are labeled  
21      in terms of whether they are relatively non-toxic, moderately  
22      toxic, or highly toxic.

23              This kind of generalized information for the  
24      purposes of labeling can be obtained without resorting to  
25      this barbaric experiment. Federal Government regulators do

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1 not require that animal tests be used for product marketing,  
2 although no one would dispute that they encourage it.

3 The Government requires that industry appropriately  
4 label their products for the precaution necessary for  
5 consumers and workers. If alternatives are available that  
6 can predict human reactions to eye irritants, then the  
7 continued use of this test is unnecessary. Many such  
8 alternatives have been suggested for the Draize test.

9 The Draize eye rabbit test and the LD-50 test  
10 should be eliminated from all product protocols as inhumane  
11 and unnecessary to assess product safety. The Doris Day  
12 Animal League urges this Committee to vote House Bill 1554  
13 favorably out of this body. Thank you very much.

14 (Whereupon the audience applauds.)

15 REPRESENTATIVE KOSINSKI: Counsel, will you kindly  
16 submit a copy of the search warrant for the record, please.  
17 Questions?

18 REPRESENTATIVE McHALE: Yes, Mr. Chairman. In  
19 your professional opinion, does the search warrant provision  
20 in House Bill 1554 violate in any way the search and seizure  
21 provisions of the 4th Amendment?

22 MS. HAZARD: Absolutely not. That would go to the  
23 general search warrant provision under the Pennsylvania Code  
24 which I assume does not either because it merely says that  
25 as laid out in the Pennsylvania Code, the search warrants

1 would be extended to research facilities.

2 REPRESENTATIVE McHALE: During earlier testimony,  
3 Dr. Bramson placed considerable faith in the Animal & Plant  
4 Health Inspection Service, APHIS. At the time the video  
5 tape was made at the University of Pennsylvania, was APHIS  
6 in existence?

7 MS. HAZARD: Yes, sir, it was.

8 REPRESENTATIVE McHALE: Has there been any change  
9 in the operation of that agency since that time?

10 MS. HAZARD: Since 1984?

11 REPRESENTATIVE McHALE: Yes.

12 MS. HAZARD: As a result of what happened at the  
13 University of Pennsylvania and a number of other institutions,  
14 the agency has made some strides towards at least increasing  
15 the number of inspections. I believe at that time it was  
16 less than two a year. Now they are trying to get up to  
17 four a year which to many of us --

18 REPRESENTATIVE McHALE: Is minimal.

19 MS. HAZARD: -- minimal, yes. But given their  
20 current efforts of re-organization, we suspect that the  
21 minimal enforcement that was taking place when that report  
22 was authored will probably not be in existence too much into  
23 the future.

24 REPRESENTATIVE McHALE: Do you agree with Dr.  
25 Bramson that the proposed state agency created as a result

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1 of House Bill 1554 would be an unnecessary duplication of  
2 APHIS?

3 MS. HAZARD: Absolutely not. Another point on  
4 that, aside from that APHIS has not been particularly good  
5 at monitoring the Federal statute, the State Agency would  
6 also have the ability to monitor under the Anti-Cruelty  
7 Code which is not under the jurisdiction of the Federal  
8 Government and not under the jurisdiction of APHIS. It  
9 would definitely not be duplicative even if APHSIS were  
10 appropriately monitoring.

11 REPRESENTATIVE McHALE: Would you be able to  
12 obtain a copy of the GAO report referenced by Dr. Barnard  
13 concerning the relative ineffectiveness?

14 MS. HAZARD: I think I got a copy of that report.

15 REPRESENTATIVE McHALE: Would you today allow  
16 Dr. Bramson to take a look at that?

17 MS. HAZARD: I would give him a copy, yes.

18 REPRESENTATIVE McHALE: Thank you, Mr. Chairman.

19 REPRESENTATIVE KOSINSKI: Further questions? I  
20 think Dr. Bramson is gone.

21 MS. HAZARD: I will mail him a copy.

22 REPRESENTATIVE McHALE: Thank you.

23 REPRESENTATIVE KOSINSKI: Mike Edmiston, Chief  
24 Counsel.

25 MR. EDMISTON: Counsel, my understanding of the

1 search warrant provision in Pennsylvania statute is that  
2 it has its base in a provision of the Model Penal Code, a  
3 provision that recommended that the Model Penal Code's  
4 elements as to cruelty to animals not be deemed applicable  
5 to accepted veterinary practices and activities carried on  
6 for scientific research. Now, clearly that element of the  
7 Model Penal Code is not the same thing as an exception from  
8 vulnerability or availability to search warrants.

9 But I am wondering whether or not in your work  
10 in the development of your testimony you have taken a look  
11 at the Model Penal Code and taken a look at other state  
12 statutes around the country to determine whether or not  
13 the Model Penal Code provision exists in cruelty to animals'  
14 section or for that matter, whether similar search warrant  
15 exceptions exist in other state statutes.

16 MS. HAZARD: I am not familiar with the Model  
17 Penal Code. Also, I am not a Pennsylvania attorney. I may  
18 not be the most appropriate person to answer that. I do  
19 know, however, that this is -- Related to the other part of  
20 your question, there are other states who do allow a humane  
21 investigator and law enforcement personnel to have the  
22 opportunity to obtain a search warrant if that is necessary.

23 I have no evidence to suggest that that has in  
24 any way been disruptive of legitimate research in that  
25 state. I am really not qualified at this point to comment

1 on the code itself.

2 MR. EDMISTON: Thank you.

3 REPRESENTATIVE KOSINSKI: Thank you. We are going  
4 to take a five-minute recess.

5 (Whereupon the hearing recessed from 2:27 P.M. to  
6 2:36 P.M.)

7 REPRESENTATIVE KOSINSKI: May I call the meeting  
8 to order. Chairman DeWeese.

9 CHAIRMAN DeWEESE: Just one comment or question  
10 I should say before our next witness. I wanted to ask  
11 Representative Murphy if he had any idea how many of these  
12 products were Pennsylvania products and what kind of economic  
13 simulation is going on in the state to your knowledge  
14 vis-a-vis some of these products that are designed and  
15 marketed and used without the animal experimentation.

16 REPRESENTATIVE MURPHY: As far as I am aware of,  
17 none of the products are Pennsylvania manufactured products.  
18 It seems to me a market can be created for them, and I think  
19 -- And I have seen in recent advertising more advertising  
20 focus on these kinds of products in the past few years.

21 REPRESENTATIVE KOSINSKI: Next up is Dr. Harry  
22 Rozmiarek, Director Laboratory Animal Resources, University  
23 of Pennsylvania. Doctor.

24 DR. ROZMIAREK: Thank you. Mr. Chairman, members  
25 of the committee, and committee staff, my name is Harry

1 Rozmiarek. It is pronounced exactly the way Mr. Kosinski  
2 pronounced it.

3 I am a veterinarian. I am an immunologist,  
4 Diplomate in the American College of Laboratory Animal  
5 Medicine. I was a member of the Committee on Care and Use  
6 of Laboratory Animals, the National Research Council which  
7 wrote the 1985 revision of the NIH Guide for the Care and Use  
8 of Laboratory Animals.

9 I have been a Professor of Laboratory Animal  
10 Medicine and Director of Laboratory Animal Resources at the  
11 University of Pennsylvania since January, 1987. Previous  
12 to 1987, I had a similar position at the Ohio State Univer-  
13 sity.

14 I feel that I should depart from my testimony for  
15 a moment and respond to Mr. McHale's question as to whether  
16 the situation in animal care has changed from 1984, when  
17 the tapes were taken at the University of Pennsylvania. I  
18 am pleased to report that there was an extensive investiga-  
19 tion at the University of Pennsylvania. There were very  
20 significant changes to the animal care program. My position,  
21 my entire department did not exist at the University of  
22 Pennsylvania prior to 1987.

23 Since 1987, the University of Pennsylvania has  
24 hired no less than 10 veterinarians to fill my department.  
25 These veterinarians with specific training and devotion to



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1 laboratory animal medicine. They have responsibility for  
2 assuring animal care and welfare throughout the University  
3 of Pennsylvania.

4 I present this testimony as a specialist in  
5 laboratory animal medicine and an individual devoted to the  
6 highest possible level of animal care and welfare in bio-  
7 medical research, and have the support and backing of my  
8 institution in these comments.

9 I am quite concerned about House Bill 1554, and  
10 feel that as currently written, it would be extremely  
11 detrimental to biomedical research and teaching, and could  
12 cause difficulties for our state. It is redundant, expensive  
13 at best, and perhaps impossible to implement, assumes total  
14 incompetence in current animal use practices, compromises  
15 educational integrity, and would lower the level of animal  
16 care and animal welfare in our state. Let me be more specific  
17 about each of these concerns.

18 The idea of licensing in this bill is vague as to  
19 whether the institution or the individual is to be licensed.  
20 If the institution is to be licensed, it is a duplication of  
21 the registration already required under the Federal Animal  
22 Welfare Act and currently being accomplished by the United  
23 States Department of Agriculture.

24 If it refers to the individual, it poses a monu-  
25 mental problem as to what the licensing is to address.

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1 The licensing of individuals to conduct procedures as  
2 practiced in some parts of Great Britain has been shown  
3 to be extremely cumbersome and ineffective, and is quite  
4 expensive to both the Government and institutions involved.  
5 It has not resulted in a higher level of animal welfare in  
6 that country than in ours, but it has led to more active  
7 animal rights activities and security problems.

8 To charge the state with promulgating regulations  
9 to govern handling and care of research animals is a direct  
10 duplication of provisions already present in the Federal  
11 Animal Welfare Act, the Public Health Service Policy, and  
12 current NIG Assurance provisions.

13 For an update of current animal welfare policies  
14 and guidelines, I would refer you to the 1987 publication  
15 attached to the written copy of my testimony. The proposed  
16 inspection by state agents directly duplicates the Federal  
17 inspection now being carried out by agents of the Animal and  
18 Plant Health Inspection Service of the USDA. This inspection  
19 program has served a valuable function and a thorough function  
20 as was pointed out. It is currently undergoing reorganization  
21 to improve its efficiency and effectiveness.

22 I would be happy to respond to that in more detail,  
23 that is, if the committee wishes after my testimony is  
24 completed. Certification of individuals who handle live  
25 animals is already being accomplished by the American

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1 Association for Laboratory Animal Science through a nationally  
2 and internationally recognized certification program for  
3 laboratory animal technicians and technologists at three  
4 different skill levels. This program has certified over  
5 20,000 laboratory animal technicians since its inception and  
6 I suggest we not try to duplicate its process in our state but  
7 participate in it and benefit from it. Many institutions  
8 in Pennsylvania already recognize and encourage such  
9 certification.

10 In 1987, the Public Health Service Policy required  
11 an institutional animal care committee with broad responsi-  
12 bilities for animal care and use at each institution  
13 receiving Federal funding. In 1988, this year, the USDA  
14 required a similar committee for each institution using  
15 animals and increased the depth of its responsibility.

16 Of the nearly 1000 protocols reviewed at the  
17 University of Pennsylvania during the 1987-1988 year, approxi-  
18 mately 90 percent were returned to investigators for minor  
19 revisions or clarification, and approximately 5 percent were  
20 disapproved, tabled, or returned to investigators for major  
21 revision.

22 These committees have had a significant effect on  
23 increasing the consciousness and responsibility of all  
24 institutions and individuals who use animals throughout the  
25 country, and we should endorse and promote their continued

1 existence. Let us learn and benefit from this change in  
2 animal welfare policy and not try to duplicate it.

3 Large numbers of individuals are employed in this  
4 state to care for and handle laboratory animals, and they  
5 play a very important role in assuring that the most knowledge-  
6 able and skillful animal care practices are used at all times.  
7 The participation of these skilled and trained individuals  
8 is essential and sometimes critical to the functioning of a  
9 good research team.

10 The proposal to allow any employee to refuse to  
11 participate without penalty would be similar to allowing a  
12 train conductor to leave his station without notice or signi-  
13 ficant reason. We would then be put in the position of hiring,  
14 training and paying people to do critically important work,  
15 and then not being able to depend upon them. This provision  
16 could have devastating effects upon good biomedical research.

17 The proposed legislation would eliminate the present  
18 law's ban on issuing search warrants for premises where  
19 scientific research is being conducted. We should not allow  
20 vital research to be subjected to unnecessary or obstructionist  
21 searches. To grant sweeping police powers over important  
22 scientific endeavors to any society or association which is  
23 incorporated in this state could be very unwise.

24 Many members of such groups lack reasonable knowledge  
25 of the physiological or psychological needs of animals, have

1 a preconceived bias of the nature or value of animal related  
2 research, and all too frequently have a history of acting  
3 irresponsibly.

4 To allow such people to search buildings and  
5 seize data which they do not understand would be of no value  
6 to animals, but would be a serious threat to good scientific  
7 research. I suggest that we build upon and attempt to comple-  
8 ment the Federal Inspection Service and assurance provisions  
9 already in place, and use other qualified public officials  
10 only where such provisions do not already apply.

11 I should depart again from my testimony and point  
12 out that neither the University of Pennsylvania nor I object  
13 to search warrants where search warrants are applicable, but  
14 we are concerned that when that search is conducted, that  
15 there be qualified people who understand what they are  
16 searching for to be included in those searches. That is the  
17 intent of that paragraph.

18 Even the definition of an animal as a "Living  
19 vertebrate that is separated from its natural environment"  
20 is impossible to interpret and must be clarified. What is a  
21 natural environment for an inbred mouse which has been living  
22 in a laborator for 100 or more generations? It differs  
23 significantly from a field mouse living in the wild. The  
24 same could be said for many other species of animals.

25 Animal welfare and laboratory animal medicine and

1 science have matured and changed significantly over the past  
2 20 years. Practices, policies, and guidelines which have  
3 been implemented over the past 5 years have had a tremendous  
4 impact on the sensitivity of scientists and biomedical  
5 research institutions in this country, and the level of animal  
6 welfare has been raised significantly.

7 While the provisions in this bill might have been  
8 applicable in the mid 1960's, many are not consistent with the  
9 changes that have occurred in recent years, and their attempt  
10 to duplicate many good practices and guidelines which we  
11 would do well to build upon.

12 I would welcome the opportunity to answer questions  
13 to clarify my comments.

14 REPRESENTATIVE KOSINSKI: You are going to have  
15 some from me. First of all, I think you confuse the search  
16 warrant issue. It is somewhat arrogant in your testimony.  
17 In fact, you are arrogant, not somewhat, in stating that  
18 unqualified people would not be allowed to search the  
19 facility. Anytime a search warrant is issued, the judicial  
20 officer who executes that search warrant, who issues the  
21 search warrant, must include that. Am I correct, counsel?

22 MR. EDMISTON: (Nods head affirmatively.)

23 REPRESENTATIVE KOSINSKI: That is one of the parts  
24 of the search warrant that the issuing authority would look  
25 at, and it almost reeks of academic ivory towerism when you

31 1 come in and state that people outside of the University  
2 could not be knowledgeable about this. Second, how good  
3 was Ohio State University as far as animal laboratories,  
4 Doctor?

5 DR. ROZMIAREK: I went to Ohio State University  
6 because it has some problems. Those problems were in many  
7 cases addressed -- In all cases addressed and proper pro-  
8 cedures put in place. I think Ohio State University was a  
9 rather good university in assuring that good animal care was  
10 going on.

11 REPRESENTATIVE KOSINSKI: Could that be because  
12 Ohio has a similar law as the one we are considering today?

13 DR. ROZMIAREK: Ohio's law does not provide the  
14 provisions that I am objecting to if you read carefully.  
15 The licensing -- The provisions that I feel that we should  
16 build upon from situations that already occurred, the  
17 licensing, the certification.

18 REPRESENTATIVE KOSINSKI: And are procedures there  
19 exempting such research facilities from search warrants?

20 DR. ROZMIAREK: No, they are not to the best of  
21 my knowledge. Can I clarify?

22 REPRESENTATIVE KOSINSKI: By all means, please.

23 DR. ROZMIAREK: I do not intend nor does the  
24 testimony to say I object to a search warrant. The concern  
25 is that individuals participating in that search must be

1 understanding of what it is they are searching for. If they  
2 are seizing animals and data, we are very concerned that they  
3 should be knowledgeable with what it is they are seizing.

4 REPRESENTATIVE KOSINSKI: That is specified in the  
5 search warrants though.

6 DR. ROZMIAREK: I must admit my ignorance, but I  
7 will say I took that paragraph to two attorneys for assurance  
8 that it was not in the wrong legal sense, and their comments  
9 are incorporated in that paragraph. I agree with basically  
10 what you are saying.

11 REPRESENTATIVE KOSINSKI: Are they attorneys for  
12 the University?

13 DR. ROZMIAREK: One was a University attorney and  
14 one was not.

15 REPRESENTATIVE KOSINSKI: They didn't come to  
16 this attorney because I would have filled them in on reality.  
17 I don't think too many attorneys are familiar with this type  
18 of legislation and how it applies to animal rights.

19 Now, a few other comments. I do object to you  
20 saying while provisions of this bill might be applicable in  
21 the mid 1960's, they were certainly applicable in 1984 to  
22 your facility.

23 DR. ROZMIAREK: To the University of Pennsylvania,  
24 most definitely.

25 REPRESENTATIVE KOSINSKI: That was four years ago.



1 What we see consistently is if we do not legislate it, such  
2 practices continue. That is why we are here today considering  
3 a bill. Also, as a person who is concerned about animal  
4 rights, I am somewhat upset that you have a comment that  
5 such laws led to more active animal rights activities in  
6 this country. There is nothing wrong with that, nothing  
7 wrong whatsoever.

8 DR. ROZMIAREK: There is nothing wrong with the  
9 activities that query and object to the inappropriate use  
10 of animals. There is something wrong when there is vandalism  
11 and destruction of property involved with animal rights at  
12 these institutions.

13 REPRESENTATIVE KOSINSKI: I agree with you there.  
14 Animal rights activities, you can't hook up the two. Ninety-  
15 nine point nine percent of the animal rights activists I  
16 know are much more law-abiding than institutions who refuse  
17 or try to lobby to be exempted from laws that we are  
18 accounting for.

19 (Whereupon the audience applauds.)

20 REPRESENTATIVE KOSINSKI: Please. Representative  
21 McHale.

22 REPRESENTATIVE McHALE: Thank you, Mr. Chairman.  
23 Doctor, I appreciate your earlier extemporaneous comments  
24 that were at least in part responsive or intended to be  
25 responsive to my earlier questioning regarding changes. You

1 indicated that since your tenure at Penn, there have been  
2 significant changes in the department; is that correct?

3 DR. ROZMIAREK: Since, and the decision to bring  
4 this sort of organization to Penn happened before my tenure  
5 there. So, I wish to not take credit for that since my  
6 tenure. It was a major reorganization by the University,  
7 a decision to do this prior to my joining the University  
8 of Pennsylvania.

9 REPRESENTATIVE McHALE: Doctor, I am encouraged  
10 somewhat to hear those comments. However, that wasn't my  
11 question. When I addressed the question to the earlier  
12 witness, I asked her if there had been any changes at APHIS,  
13 not at Penn, since the time of the occurrence at the  
14 University of Pennsylvania. And based on her response at  
15 that time, I am not convinced that there have been significant  
16 changes made at APHIS since the time of the occurrence we  
17 saw on video tape.

18 DR. ROZMIAREK: I would like to comment on that  
19 just a bit.

20 REPRESENTATIVE McHALE: Well, I simply want to make  
21 it clear that was the earlier question. Your response is  
22 interesting, but not in direct response to the question I  
23 raised.

24 DR. ROZMIAREK: My response was to the question you  
25 raised immediately following the video tape.

1 REPRESENTATIVE McHALE: All right, sir. You had  
2 another comment you said you wanted to expand on.

3 DR. ROZMIAREK: Yes, sir. Concerning the Animal  
4 and Plant Health Inspection Service, there have been con-  
5 siderable problems, and the USDA Animal Plant and Health  
6 Inspection Service has undergone and is in the midst of  
7 beginning complete reorganization.

8 REPRESENTATIVE McHALE: Did you hear Dr. Bramson's  
9 testimony?

10 DR. ROZMIAREK: I did.

11 REPRESENTATIVE McHALE: He places considerable  
12 faith in APHIS.

13 DR. ROZMIAREK: There is movement within APHIS to  
14 give some assurance that there will be a program in the  
15 foreseeable future. I must admit that I concur that there  
16 are significant loopholes in the Health Inspection Service.  
17 The fact that they don't -- The fact that they do not include  
18 rodents is a significant problem. I think that should be  
19 addressed.

20 REPRESENTATIVE McHALE: On that context, it seems  
21 clear that an effective state agency would not be a duplication.  
22 We don't have an effective Federal Agency at the present time.

23 DR. ROZMIAREK: We have laws on the Federal book.

24 REPRESENTATIVE McHALE: I am not talking about law.  
25 I am talking the effects of the execution of these laws. Does

1 APHIS effectively execute the law at the present time and  
2 in recent past?

3 DR. ROZMIAREK: At this moment, there are loopholes  
4 in APHIS' inspection service, I must admit.

5 REPRESENTATIVE McHALE: Thank you.

6 DR. ROZMIAREK: At the same time, I would ask the  
7 question as to resources that it would take to duplicate the  
8 Federal law by state law. The problem as I see it is not  
9 in the Federal law. Is in the implementation and lack of  
10 resources perhaps being the major source of that lack of  
11 implementation.

12 REPRESENTATIVE McHALE: At least at the present  
13 time most of us cannot affect what happens in the United  
14 States Congress. We can, however, affect what happens in the  
15 state legislature. If Washington fails to act, we have a  
16 moral duty to do so. That is where I think we stand today.

17 Let me indicate on page 2 of your testimony, you  
18 indicate, and I quote, "The participation of these skilled,"  
19 and we are referring to employees, "and trained individuals  
20 is essential and sometimes critical to the functioning of a  
21 good research team. The proposal to allow any employee to  
22 refuse to participate without penalty would be similar to  
23 allowing a train conductor to leave his station without notice  
24 or significant reason." That is the end of your full quote.

25 Above and beyond the rhetoric that I think is

1       horribly overblown in that analogy, is in fact this kind of  
2       activity is essential and sometimes critical, why do you  
3       think that significant numbers of your employees would  
4       refuse to participate?

5               DR. ROZMIAREK: I don't think that significant  
6       numbers would. I think --

7               REPRESENTATIVE McHALE: How would we have a  
8       devastating effect?

9               DR. ROZMIAREK: It would have a devastating effect  
10       to the critical member of the surgical team performing a  
11       heart transplant in an animal would decide in the middle of  
12       the transplant that they chose not to conduct what their  
13       responsibilities was.

14              REPRESENTATIVE McHALE: Are you going to talk to  
15       your teams before the surgery begins?

16              DR. ROZMIAREK: Absolutely.

17              REPRESENTATIVE McHALE: How likely is it that the  
18       hypothetical you just described will in fact occur?

19              DR. ROZMIAREK: It is very unlikely. It is  
20       intolerable if it should happen once in the State of Pennsyl-  
21       vania in the next year.

22              REPRESENTATIVE McHALE: I find it extremely  
23       improbable. What this section does is provide a right of  
24       conscience to refuse to participate. I think reasonable  
25       people, and you should assume that most of your employees are

1 reasonable people, they are highly trained, will express  
2 any reservation to you in advance of a critical moment. To  
3 rely upon an extremely hypothetical, and then to buttress  
4 it with overblown rhetoric in order to deny a right of  
5 conscience I think doesn't correspond to the real world  
6 characteristics of your own employees. Thank you, Mr.  
7 Chairman.

8 REPRESENTATIVE KOSINSKI: I have one comment here.  
9 We must go to catch a plane, so the first comment is along  
10 with the University of Pennsylvania, Pittsburgh, and a number  
11 of other institutions where all this lobbying for more money  
12 and we are shown these great computer centers, I cannot  
13 understand why we can't have computer testing models in some  
14 of these areas. I know that sometimes it would be an impossi-  
15 bility for all of the areas.

16 Second, before I leave, I would like to turn the  
17 meeting over to Representative Murphy, who will continue  
18 with the afternoon agenda. Thank you.

19 REPRESENTATIVE MURPHY: Representative DeLuca.

20 REPRESENTATIVE DeLUCA: Thank you. I just have one  
21 comment to make. The reason we are here today and the reason  
22 this bill is being introduced is because the Federal Government  
23 hasn't done their job, number one. It hasn't done its job  
24 in a lot of issues. To have the law doesn't do us any good  
25 if they are not enforced. Money is not appropriate if we

1 don't have the right people under the department. For the  
2 state not to get involved in a situation like this is  
3 horrendous when we have the problems out there. Do you agree  
4 we do have a problem out there, or don't you?

5 DR. ROZMIAREK: I agree there is a significant  
6 problem in implementation of the Animal Welfare Act, absolutely.

7 REPRESENTATIVE DeLUCA: It is not being addressed  
8 by the Federal Government. All the testimony I hear and  
9 from other letters I get in my office seems to be it is not  
10 being addressed. How do we force the Federal Government to  
11 implement that type of regulation, to address these laws?

12 DR. ROZMIAREK: At this point --

13 REPRESENTATIVE DeLUCA: You said to expand on the  
14 Federal legislation. How do we do that?

15 DR. ROZMIAREK: I think we need to address the  
16 loopholes in the Federal implementation.

17 REPRESENTATIVE DeLUCA: How do we do that?

18 DR. ROZMIAREK: One of the points I wish to make  
19 is there has been reorganization and an entirely new unit.  
20 It is called the Animal Welfare Inspection Unit within the  
21 USDA. A new director takes office next month. I am anxiously  
22 awaiting that unit and how it will implement that responsi-  
23 bility.

24 REPRESENTATIVE DeLUCA. I understand.

25 DR. ROZMIAREK: I am enthused by that.

1           REPRESENTATIVE DeLUCA: Let me say that if we find  
2 deficiencies in the Federal regulations, we know how fast  
3 Congress can act. It will be therefore another 15, 20 years,  
4 if we wait for them. Don't you think it behooves us on the  
5 state level to address this type of inhumane problem?

6           DR. ROZMIAREK: I think addressing the problem is  
7 not a wrong issue at this time. I think we should be  
8 assuring that we are addressing all of the problems that  
9 might be incorporated in that address. The other thing that  
10 I really think has been missed, and that is the very recent  
11 changes in animal assurance policies by the Public Health  
12 Service which impacts understandably only on those agencies  
13 who wish to be in a position to receive Federal aid.

14           The Animal Use Review Committee in its current  
15 statute was only put into effect in 1987. The USDA did not  
16 get on that -- Did not enforce that and make it a requirement  
17 until 1988. That is very recent.

18           REPRESENTATIVE DeLUCA: I understand that. But  
19 should we permit it to let what we have seen on this screen  
20 happen?

21           DR. ROZMIAREK: Absolutely now. I do not condone  
22 that, nor should anyone.

23           REPRESENTATIVE DeLUCA: That is why we are trying  
24 to stop it with this type of legislation. Thank you.

25           (Whereupon the audience applauds.)



41 1 REPRESENTATIVE MURPHY: Doctor, I have three  
2 questions. One is why did that happen at the University of  
3 Pennsylvania?

4 DR. ROZMIAREK: The University of Pennsylvania at  
5 that time had a totally decentralized animal care program.  
6 There was not a University-wide policy on animal care. It  
7 was by department, by unit, by college, by school.

8 It allowed individual departments and individual  
9 units to police, to implement, and in fact endorse and  
10 manage their own animal care program. That means that the  
11 expertise was not there in all departments.

12 Any time you have that kind of decentralization  
13 over an issue that requires some kind of expertise to  
14 administer, clearly without delusion of quality --

15 REPRESENTATIVE MURPHY: Were you at the University  
16 of Pennsylvania at the time?

17 DR. ROZMIAREK: No, I wasn't.

18 REPRESENTATIVE MURPHY: But there were allegations  
19 prior to people having to take illegal action to make this  
20 public. I am assuming there were professional doctors and  
21 others who had heard those allegations and yet nobody acted.

22 DR. ROZMIAREK: There was no person with credentials  
23 and with expertise in a position of authority to stop what  
24 was going on. That was the significant problem. That is  
25 there at this time and has been.

1 REPRESENTATIVE MURPHY: Does it not reflect the  
2 Old Boys' network that exists in every other institution  
3 that we are aware of?

4 DR. ROSMIAREK: In 1984?

5 REPRESENTATIVE MURPHY: Yes.

6 DR. ROSMIAREK: That is a possibility. I am not  
7 sure that exists in every other institution. I think that  
8 is coming to a halt very quickly. I think the NIH provisions  
9 on animal care assurance are what is dropping that.

10 REPRESENTATIVE MURPHY: That was my next question.  
11 Thank you for the lead-in. I guess I would like to get my  
12 sense of courses that the more intensive Federal regulations,  
13 your efforts to better police the care of animals and the use  
14 of animals all came about because of in part external pressure  
15 from animal welfare people who have an interest insuring that  
16 you do the job more efficiently and better. Would you concur  
17 with that?

18 DR. ROZMIAREK: If you read the publication that I  
19 authored in the back of my testimony, I say that very directly.

20 REPRESENTATIVE MURPHY: So clearly for the people  
21 here and others who have left, clearly they played an  
22 important role in changing the perception of your profession  
23 in society in the care and treatment of animals?

24 DR. ROZMIAREK: Even the vandalism and break-ins  
25 have played a role in raising the consciousness and having

1 people looking into their own programs, absolutely.

2 REPRESENTATIVE MURPHY: To the extent the legisla-  
3 tion like this continued to raise your consciousness and  
4 others in your profession like yours plays a very important  
5 role?

6 DR. ROZMIAREK: The fact we are here talking about  
7 it is very valuable.

8 REPRESENTATIVE MURPHY: Finally, in the search  
9 warrants, Doctor, I guess it is beyond me why you would fear  
10 a search warrant. If your neighbors thought you were doing  
11 something illegal in your home and there was enough evidence  
12 that he could convince the Court to issue or for the authori-  
13 ties to issue a search warrant, your house could be searched,  
14 and yet you are exempt from that -- Your laboratory is  
15 exempt from that very action. We are not talking about any  
16 difference in degree here. We are talking about the very  
17 same standard for what it would take to get a search warrant  
18 to search your house versus your lab. Why would you fear  
19 that?

20 DR. ROZMIAREK: I would have no problem with  
21 bringing knowledgeable people of any part of society into the  
22 laboratories and have they tour the laboratories and view  
23 any of the experimentation going on. I have invited --

24 REPRESENTATIVE MURPHY: We are not talking about  
25 knowledgeable people touring the laboratory. We are talking

1 about a lab employee or somebody who has reason to believe  
2 that there are violations of the law taking place in a  
3 laboratory going to a police officer or some law enforcement  
4 officer, that law enforcement officer going to the courts and  
5 getting a search warrant. If you look at this search warrant  
6 issued in Maryland, it is very, very specific in its allega-  
7 tions in the charges that were made.

8 That basically would be the very standard that would  
9 have to be enforced if I wanted to get a search warrant to  
10 search your house. So how can you oppose that process for  
11 laboratories?

12 DR. ROZMIAREK: The opposition I had was to the  
13 language that implies to me that members of Animal Welfare  
14 Societies, Incorporated, in the state would conduct, seize,  
15 and remove data and animals. If I am being instructed by  
16 the legal people here that that would not be a possibility,  
17 then I have no problem.

18 REPRESENTATIVE MURPHY: Doctor, if there was a crime  
19 being committed, a police officer enters your home and seize  
20 whatever he needs or she needs to prove that you committed  
21 a crime, why should you be held to any less standard in your  
22 research laboratory?

23 DR. ROZMIAREK: I don't think I am suggesting that  
24 we are.

25 (Whereupon the audience applauds.)

1 REPRESENTATIVE MURPHY: I think you are. I think  
2 you are. If you are manufacturing drugs in your house,  
3 Doctor, and you are using your stove and your sink to do  
4 that, and they represent evidence, a police officer can take  
5 your stove and sink as proof of your actions. If animals  
6 are being abused in a laboratory, it is in violation of the  
7 law, would you oppose a police officer seizing those animals  
8 for evidence?

9 DR. ROZMIAREK: Absolutely not. I would ask for  
10 the assurance they be cared for properly.

11 (Whereupon the audience responds.)

12 REPRESENTATIVE MURPHY: Understand that we are  
13 asking for no more or no less than what is the law for  
14 everybody else in this Commonwealth. No more, no less.

15 DR. ROZMIAREK: I hope you understand that I do  
16 not stand in opposition to seizing.

17 REPRESENTATIVE MURPHY: So we can assume the  
18 University of Pennsylvania will notify the legislature of  
19 their support for the certain provision?

20 DR. ROZMIAREK: With the exceptions of the pro-  
21 visions that are prepared in my testimony. There are several.

22 REPRESENTATIVE MURPHY: Thank you. Further  
23 questions?

24 REPRESENTATIVE ITKIN: I don't want to belabor the  
25 issue, but I think it is very, very important. The question

1 of cruelty to animals and whether or not University facilities  
2 should have special exemption to commit cruelty to animals.  
3 I think that really goes to the crux of the issue.

4 Certainly you have animal welfare organizations  
5 concerned about the commission of these kinds of violent  
6 acts against animals. The question is whether or not there  
7 is a certain standard of acceptance on the part of research  
8 and experimentation facilities that, yes, they are going to  
9 commit cruel acts on animals, and, therefore, any search of  
10 the facilities at any time is going to give rise to bona fide  
11 complaints of use of animals. Is that what really is con-  
12 cerned on the part of the University, that the way that they  
13 now conduct with the animals is going to be recognized by  
14 welfare and animal welfare authorities under today's standards?

15 DR. ROZMIAREK. Not at all. I feel strongly that  
16 the University as a place of higher learning has the  
17 responsibility of setting an example in animal care and not  
18 to fear normal good and welfare organizations and set an  
19 example.

20 REPRESENTATIVE ITKIN: Have you offered and  
21 volunteered and have animal welfare rights organizations view  
22 the University of Pennsylvania facility?

23 DR. ROZMIAREK: I have invited senior officials from  
24 the Animal Welfare Institute and the Humane Society of the  
25 United States to visit animal facilities that I have directed,

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1 and they have attended and visited.

2 REPRESENTATIVE ITKIN: This care -- This committee  
3 on care and use of laboratory animals which you claim to be  
4 a member, is that something that is statutorily created or  
5 required because of some law?

6 DR. ROZMIAREK: It is not. It is a committee that  
7 is created specifically to edit and come up with a guide for  
8 the care and use of laboratory animals which is an NIH require-  
9 ment, but not law.

10 REPRESENTATIVE ITKIN: NIH requirement?

11 DR. ROZMIAREK: Right, Public Health Service.

12 REPRESENTATIVE ITKIN: You are doing it because of  
13 some regulation which you are expected to perform. If you  
14 don't create that committee, there may be penalties imposed  
15 on the University?

16 DR. ROZMIAREK: No, sir, not at all. The require-  
17 ment by the Public Health Service is that institutions which  
18 wish to be considered to receive Federal aid must comply  
19 with public health policies for good animal care. It is a  
20 requirement if the institution wishes to receive Federal aid.  
21 It is not a Federal or state law.

22 REPRESENTATIVE ITKIN: How frequently does this  
23 Committee meet?

24 DR. ROZMIAREK: The committee meets approximately  
25 once every four or five years. Its sole purpose is to revise

1 the guide for the care and use of laboratory animals.

2 REPRESENTATIVE ITKIN: This committee only meets  
3 once every four to five years?

4 DR. ROZMIAREK: The committee met extensively from  
5 1983 to 1985 for the sole purpose of revising the guide. The  
6 new issue of the guide was published in 1985. Since 1985,  
7 the committee has not met.

8 REPRESENTATIVE ITKIN: What assurance do you have  
9 that one of the researchers are not abusing animals in his  
10 charge?

11 DR. ROZMIAREK: In my institution?

12 REPRESENTATIVE ITKIN: In your institution.

13 DR. ROZMIAREK: We have a staff of laboratory  
14 animal veterinarians that regular make clinical rounds  
15 throughout the institution. We have completely reviewed  
16 every research protocol. Before an individual may receive  
17 an animal at the University of Pennsylvania, that individual  
18 must present in writing to an Institutional Animal Use  
19 Committee on which I serve specific detail as to the number  
20 of animals, specifically what those animals will be used for,  
21 specifically how and whom and where that work will be done,  
22 and the reason that that work is essential, and must  
23 additionally specifically address any alternatives and why  
24 alternatives cannot be done for this specific work.

25 If those are not satisfied, that individual is not



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1 permitted to use animals at the University. That was not in  
2 effect in 1984.

3 REPRESENTATIVE ITKIN: That is an in-house  
4 committee?

5 DR. ROZMIAREK: It is an in-house committee. That  
6 sort of committee is mandated by Public Health Service  
7 provisions.

8 REPRESENTATIVE ITKIN: What I am saying is what  
9 others would have access to this information, or would you  
10 consider it proprietary?

11 DR. ROZMIAREK: Absolutely not. I would be willing  
12 to share our protocol forms and policies and the Public  
13 Health which is public record. The Public Health policy on  
14 animal care, the requirements for an institutional committee  
15 at institutions that wish to receive Federal aid.

16 REPRESENTATIVE ITKIN: So in other words, animal  
17 welfare rights organizations could be on the mailing list  
18 and receive these protocols?

19 DR. ROZMIAREK: Absolutely. The protocol form.

20 REPRESENTATIVE ITKIN: What is being intended to  
21 do and how to --

22 DR. ROZMIAREK: No. The protocol itself, the  
23 specific work that is going to be addressed, that is something  
24 that is provided to the committee. The committee has at the  
25 University of Pennsylvania not one but two outside individuals

1 who both happen to be on governing boards of the Humane  
2 Society. My concern with the Humane Society is not that we  
3 don't want them on our committee, my concern is that there  
4 aren't enough to go around. Good qualified people to serve.

5 REPRESENTATIVE ITKIN: You keep up bringing up  
6 qualified people like some say are biased and don't under-  
7 stand that you have to do certain things because they would  
8 lack the understanding. I don't understand what you mean by  
9 qualified, trained.

10 DR. ROZMIAREK: Perhaps qualified and trained  
11 isn't the right term. People without previous bias in their  
12 attitude.

13 REPRESENTATIVE ITKIN: You are concerned that they  
14 possess a lack of insensitivity?

15 DR. ROZMIAREK: Absolutely.

16 REPRESENTATIVE ITKIN: It goes on both sides.

17 DR. ROZMIAREK: I recognize that.

18 REPRESENTATIVE ITKIN: Thank you, Mr. Chairman.

19 REPRESENTATIVE MURPHY: Any further questions?

20 Mike.

21 MR. EDMISTON: Doctor, I just have a few questions..  
22 The first one is as to the element of the bill which would  
23 prohibit the LD 50 toxicity and Draize eye irritacy tests in  
24 the Commonwealth. Correct me if I am wrong, I looked over  
25 your testimony, and I have paid attention to what you had to

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1 say here today. I did not see any statement on that element  
2 of the bill and testimony, nor did I hear you say anything  
3 on that element of the bill. Am I correct in not seeing  
4 anything in the proposed statement?

5 DR. ROZMIAREK: Yes, you are.

6 MR. EDMISTON: Am I correct in not having heard  
7 you say anything on that provision of the bill today?

8 DR. ROZMIAREK: You are correct. I would be happy  
9 to comment if you wish.

10 MR. EDMISTON: Well, let me ask the question. Do  
11 you object in your official capacity as a representative of  
12 the University of Pennsylvania to the prohibition of those  
13 tests, prohibition of the performance of those tests in the  
14 Commonwealth of Pennsylvania?

15 DR. ROZMIAREK: As a representative of the  
16 University, I do not object. The University does not perform  
17 either of those tests. That is why I omitted them from my  
18 testimony.

19 MR. EDMISTON: I have another question, and it goes  
20 to the business of APHIS' reorganization. Reorganization,  
21 as I am sure you well know, can be a euphemism for just about  
22 anything. It means a change in the organization. Something  
23 like reform or various other words. When Attorney Hazard  
24 testified, she remarked about APHIS' reorganization and  
25 expressed some what I perceive as consternation that

1 reorganization may not produce a more vigorous APHIS. You  
2 seem to suggest otherwise. Have I misunderstood your regard  
3 for the potential in APHIS' ongoing reorganization?

4 DR. ROZMIAREK: No, you have not. I am encouraged  
5 by the reorganization because they created a unit who has  
6 the sole responsibility of animal welfare. They have had a  
7 unit of this kind before. In previous years up until the  
8 present time, the unit, the Animal Plant and Health  
9 Inspection Service, had as its name implied a responsibility  
10 for regulatory medicine, for plant medicine and services,  
11 and was deluded quite significantly by also having the  
12 responsibility for animal welfare.

13 I am encouraged by the unit which has the sole  
14 responsibility and by its title, the animal welfare responsi-  
15 bility. I am very hopeful they will take that seriously, and  
16 we will see significant changes in implementation.

17 MR. EDMISTON: Thank you.

18 REPRESENTATIVE MURPHY: Any further questions?  
19 Thank you, Doctor.

20 Oscar Moreno and Dr. Keith Booman are going to  
21 testify also.

22 MR. MORENO: Mr. Chairman, members of the Judicial  
23 Committee, ladies and gentlemen, my name is Oscar Moreno. I  
24 am the President of a small Consultant Toxicology company,  
25 and I want to thank you for the opportunity to address you

1 today on this very important issue, the use of laboratory  
2 animals for medical research.

3 This issue is one that pulls at our heart strings  
4 and our reasoning powers and, unfortunately, has polarized  
5 people into two sides, us and them. Both sides, I believe,  
6 can find merit in each others position except for a few  
7 unbending individuals who can see only black or white.

8 The problem is much too complex to try to solve  
9 overnight. Certainly, legislating certain parts of this  
10 problem out of Pennsylvania is not going to solve anything.  
11 It will just concentrate it elsewhere along with the jobs and  
12 tax base lost here.

13 But what I really want to tell you today is how the  
14 industry, our industry, has been evolving over the years and  
15 how I, being on the inside, see it. What is happening is an  
16 adjustment, a working towards a common ground that is bound  
17 to exist.

18 I have been in medical research for 37 years, most  
19 of that time in toxicology. I have gone through the spectrum  
20 of positions from technician to president and owner. I have  
21 worked for a large pharmaceutical company, in a University  
22 atmosphere during graduate school, and for a large consultant  
23 toxicology company as a Director.

24 I have personally done most of the tests in  
25 question and have supervised others. I think that my

1 experience is such that most toxicologists would attest to  
2 my expertise in this field.

3 The two tests which are targeted in this bill, and  
4 which have caused the most controversy, are the Oral LD 50  
5 and the Draize Eye Irritation.

6 The Oral LD 50 has been described as "stuffing  
7 enough chemicals down the throat" of several groups of  
8 animals to kill half of them. The correct terminology is  
9 "intubation of the animals" and the volume given to each  
10 animal is limited to one milliliter for a mouse and 5 or  
11 less milliliters for a rat.

12 There are exceptions to this, but generally, these  
13 are the working limits. An experienced technician can intubate  
14 an animal correctly with minimal trauma in a matter of seconds.

15 When I first started working as a technician doing  
16 LD 50 studies, we were doing hundreds of them, mostly in  
17 mice. This test, along with other screening procedures, was  
18 used to eliminate many chemicals from further studies. Chemi-  
19 cals showing some beneficial pharmacological effects were also  
20 tested in rats.

21 Other species, such as dogs, were only used when  
22 a chemical had shown sufficiently promising effects to merit  
23 extensive study. Once the company decided that a particular  
24 chemical would be developed further, the regulatory agencies  
25 required that more extensive tests be done to identify

1 potential hazards to humans.

2 This policy of testing most chemicals for oral  
3 toxicity has gradually changed. In some cases, chemical  
4 structures are studied and some assumptions are made, that  
5 similar structures may have similar toxicities.

6 Also, the number of animals used per group has  
7 changed from 10 animals per group down to 5 per group. The  
8 statisticians have devised methods of using 2 animals per  
9 group to give very close LD 50 approximations, certainly  
10 close enough for screening.

11 The regulatory agencies define a chemical as toxic  
12 if 5 grams per kilogram given orally will kill an animal.  
13 Ninety-five percent of chemicals tested are not toxic by this  
14 definition, and given one group of animals this dose suffices  
15 to identify its safety. If a chemical produces mortality at  
16 this level, then a lower level of 0.5 grams per kilogram  
17 is used.

18 These two levels include 99 percent of chemicals  
19 tested, and these "limits" identify the probably toxicity.  
20 These procedures have greatly limited the numbers of animals  
21 used.

22 Now the problem arises in submitting this informa-  
23 tion to regulatory agencies. Although they say that they  
24 do not now or ever really required an LD 50 in two species,  
25 in reality, when the data is submitted, it is not accepted.

1           So what happens is that, to avoid this waste of  
2 time and effort, companies submitting chemicals for agency  
3 approval will get the necessary toxicity data and submit the  
4 whole package the first time.

5           Now, I was -- On this next statement, I am just  
6 going to ad lib here because I was warned don't use the next  
7 statement because people say we only use animals that will  
8 not fight back. That is just the point I make. I will say  
9 it anywhere. I don 't think I have ever seen cats used in  
10 oral toxicity. Cats have sharp claws and teeth, and people  
11 prefer not to work with them. Dogs are seldom used for  
12 LD 50 studies.

13           The study done with dogs is called the Maximal  
14 Tolerated Dose and is designed to find limits for use rather  
15 than death. Longer studies are done in mice, rats and dogs,  
16 primarily, but these are designed to define effects from  
17 prolonged use.

18           The Draize Eye Irritation is a test designed to  
19 use the rabbit eye as the model to identify products that  
20 might present a hazard to the human eye. The test material  
21 is instilled onto the rabbit eye, and the effects noted over  
22 a period predetermined by protocol. Regulatory agencies  
23 require varying times from 3 days observation up to 21 days  
24 if the results show damage to the cornea, such as an opacity.

25           This test has been in use since the late forties



1 and is one of the required tests for submission to regulatory  
2 agencies. Because it is the only reasonable test that gives  
3 any kind of related data to eye damage in humans, it has been  
4 extensively used.

5 Over the last few years, investigators have made  
6 many changes in protocols which reflect their concern for  
7 animals. However, these reduced animal protocols are not  
8 accepted by most regulatory agencies.

9 Fewer animals are being used in each test. Some  
10 investigators use three animals routinely, and in some cases,  
11 only one rabbit is used. In many cases when the investiga-  
12 tors know that the test material is very acidic or highly  
13 basic, an assumption is made that damage will result if  
14 instilled into the eye.

15 Also, if data exists that damage occurs to the skin,  
16 which is another test, the same assumption is made. To try  
17 to alleviate the possibility of pain, some investigators  
18 suggest the use of an anesthetic in the eye prior to instil-  
19 lation of the test material. This sort of a good news, bad  
20 news approach because although the initial pain is relieved,  
21 the protective mechanisms do not work to rid the eye of the  
22 offending irritant and may result in more severe and prolonged  
23 effects.

24 One more thing that is often used, at least in our  
25 laboratory, is the telephone. When we suspect that a test

1 article has potential to cause severe damage, we will treat  
2 one animal, and, if our suspicions are correct, we will  
3 contact the investigator and discuss the results with him.

4 In many cases, they will give permission not to  
5 treat any additional animal. If a result is seen late and  
6 we inform the investigator, the test may be stopped. In  
7 either case, the concern for the animal is paramount.

8 There are two main obstacles to eliminating the  
9 present tests used. The first, as I mentioned before, is the  
10 regulatory agencies which require, by law, that data be  
11 submitted to substantiate safety claims.

12 Secondly, alternative tests are difficult to devise  
13 and take years to develop and validate to the point where  
14 reliable data is available. To have the regulatory agencies  
15 accept the data from such alternative tests, will take years  
16 longer.

17 To all that I have said so far, of course, there are  
18 exceptions. There are some tests which are done when there is  
19 no need to do them, and maybe some are even done as a matter  
20 of policy. But these are few and certainly not the norm.

21 Finally, I want to say that contrary to some expressed  
22 opinions, scientists are just as human and humane as anybody  
23 else. We do care for animals, and even though we feel that some  
24 testing is necessary to save a life or the eyesight of an  
25 individual, we do care. Thank you very much.

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1 REPRESENTATIVE MURPHY: Are there questions? Mike.

2 MR. EDMISTON: I just have one question. Dr.  
3 Moreno, if House Bill 1554 were to be enacted and become  
4 law, what effect would it have on M.B. Research Labs,  
5 Incorporated?

6 DR. MORENO: It is a good part of business and  
7 certainly would make an effect, but it certainly would  
8 create other business and alternative tests, and we would  
9 adjust to it. I don't think things are going to happen  
10 overnight. I think if it is there, we will work with it.  
11 We are not there to break laws. We will work within the  
12 laws. We will stay there.

13 MR. EDMISTON: I have one other question. The  
14 provision of the bill that addressed the exception from the  
15 search warrant, do you have a problem with that?

16 DR. MORENO: That doesn't give me a problem as  
17 has been discussed today. It really -- I feel that the law  
18 is there to protect people. I feel it will not be abused.  
19 I really don't think that it will be abused or was intended  
20 to be abused in any way.

21 MR. EDMISTON: Thank you.

22 REPRESENTATIVE MURPHY: Doctor, I don't want to  
23 misread your testimony, in the undercurrent of your testimony,  
24 I feel that you would prefer not to use animals in research.

25 MR. MORENO: No. Well --

1 REPRESENTATIVE MURPHY: Or in testing.

2 DR. MORENO: I do feel that animals are useful,  
3 and they have a purpose in research. It has been shown  
4 over and over again. I didn't bring that up. I felt that  
5 there was no reason for it.

6 REPRESENTATIVE MURPHY: If you were able to use  
7 alternatives, it is to your interest to do that?

8 You would have no objection, you indicated?

9 DR. MORENO: I have no objection to any tests that  
10 are validated. Now, that are not validated and not shown  
11 to be validated -- It was brought up earlier that the FDA  
12 does not require this. I have a quote here from a previous  
13 -- When Maryland had their hearing, if you would allow me  
14 to read this. It is from Dr. Frank Young, Commissioner of  
15 the U.S. Food and Drug Administration.

16 He writes, "The FDA cannot condone the use of any  
17 potentially harmful substances in humans prior to preliminary  
18 testing in animals to provide reasonable assurance that it  
19 is not injurious to humans. The Draize Eye Irritation test  
20 is currently the most valuable and reliable for evaluating  
21 the hazard of safety of a substance introduced into or around  
22 the eye."

23 Now, the word currently there --

24 REPRESENTATIVE MURPHY: Doctor, let me just say  
25 you ought to hang around Government people more because that

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1 language did not say that use of animals is required.

2 DR. MORENO: I didn't say that it was. I said it  
3 is currently what they are using. I think the word currently  
4 is important because this is what is available now. We are  
5 willing to change.

6 REPRESENTATIVE MURPHY: Obviously if we prohibit  
7 the test, and enough states prohibit the test, it will change,  
8 Doctor.

9 DR. MORENO: I can live with that.

10 REPRESENTATIVE MURPHY: I understand that.

11 (Whereupon, the audience applauds.)

12 REPRESENTATIVE MURPHY: Thank you. I have no  
13 further questions.

14 MR. EDMISTON: The quote you just read from, can  
15 you identify that for us in a little bit more detail, please.

16 DR. MORENO: From the Legislation Bill S-109 which  
17 was considered in Maryland legislation. Dr. Frank Young.  
18 That is a letter written by Dr. Frank Young to the committee.

19 MR. EDMISTON: It has a date?

20 DR. MORENO: No, I don't see any date here in the  
21 paper that I have. It was written either this year or the  
22 latter part of last year.

23 MR. EDMISTON: Thank you.

24 REPRESENTATIVE MURPHY: Dr. Keith Booman, Technical  
25 Director of the Soap and Detergent Association.

1 DR. BOOMAN: Representative Murphy, my name is  
2 Keith Booman. The 144 member companies of the Soap and  
3 Detergent Association manufacture cleaning products and  
4 raw materials for cleaning products. These companies manu-  
5 facture over 90 percent of the cleaning products sold in the  
6 United States.

7 I am here in general sympathy for House Bill 1554.  
8 I am here opposing the clause that refers to the LD 50 test  
9 and the Draize test.

10 REPRESENTATIVE MURPHY: Why doesn't that surprise  
11 me.

12 DR. BOOMAN: It shouldn't be a surprise, Repre-  
13 sentative Murphy. Consumers in this country use about eight  
14 billion pounds of laundry detergent. It is in every house-  
15 hold. The most common household product that is accidentally  
16 ingested by children is laundry detergent and other cleaning  
17 products. It is incumbent upon our industry and on the  
18 Federal Government and all of us to know that an incident of  
19 accidental ingestion is not going to be a life-threatening  
20 event.

21 The only way that we have of determining that  
22 today is through variance of the LD 50 test. Not the original,  
23 crude LD 50. With variances of it such as the one Dr. Moreno  
24 has mentioned. The ones that use either single dose or a  
25 few doses that are judiciously selected.

1           We have no recourse at the moment to any other  
2 approach to doing that. As far as the eye test is concerned,  
3 the situation is somewhat similar. The pervasive nature  
4 of household products, household cleaning products, the  
5 incidents of accidentally ingesting these materials is an  
6 everyday event in the United States. It is extremely  
7 important that we and the Federal Government both have the  
8 ability to assess what the consequences of that is.

9           It is important for us to assess the consequences  
10 of it and to assess what sort of warranty the consumer needs  
11 to have in order to act appropriately. The Draize test has  
12 done that for us.

13           A remark has been made to the effect that many  
14 incidents do occur, and, of course, they do. And these  
15 products irritate to some degree or another, and they sting  
16 to some degree or another. But it is critically important  
17 to let the consumer know whether that event is something  
18 that is medically serious, whether it is something that is  
19 going to be irreversible.

20           Those are the basic things that product labels  
21 attempt to do today. It has done so very well by use of the  
22 Draize test over the last 40 years. We have avoided serious  
23 mistakes in putting products on the market. We have avoided  
24 serious mistakes with respect to warning the consumer what  
25 should be done or how serious a given incident actually is.

1           And a replacement for the Draize test is not  
2 available today.

3           Now, progress towards replacing the Draize test  
4 was the subject of the September 14, 1988, Joint Government  
5 Industry Workshop in Arlington, Virginia. It was held to  
6 learn about non-animal tests that might be applicable to  
7 cleaning products and review what remains to be done before  
8 non-animal testing to be used to reduce animal testing or  
9 evaluating human eye safety products.

10           I was co-chairman of the workshop. I would like to  
11 tell you about it.

12           The sponsors of the workshop included Federal  
13 Agencies charged with the responsibility for product safety,  
14 Consumer Product Safety Commission, the Environmental  
15 Protection Agency, the Food and Drug Administration. The  
16 workshop was also sponsored by the association that represents  
17 the manufacturers of chemical consumer product, our association,  
18 the Chemical Manufacturers Association, Chemical Specialties  
19 Manufacturer Association, the Cosmetic, Toiletry, and  
20 Fragrance Association.

21           The workshop attendees included 130 representatives  
22 from government, industry and academia, and animal rights  
23 and consumer organizations. The workshop included formal  
24 presentations from government, industry, scientists and  
25 panel discussion of the presentation, and audience questions.



1           The results of the FDA evaluation of non-animal  
2 tests for eye irritancy were presented. I managed myself  
3 that effort.

4           The following points were evidenced to all by the  
5 end of the workshop. No replacement for the Draize test has  
6 been validated. The response of the eye to chemicals is so  
7 complex that no single test can possibly replace the Draize  
8 test. Replacement of the Draize test with several non-animal  
9 tests, in other words, a battery of tests, may be possible  
10 but will require additional research. That research is in  
11 progress.

12           Validation of the replacement battery of tests  
13 cannot be carried out until the important component tests  
14 have been identified. While there are candidates for the  
15 cell toxicity component of eye irritations, the test for  
16 other components such as healing or for specific effects on  
17 the cornea, iris conjunctive have not been identified.

18           Validation of a battery of tests to the degree that  
19 animal tests will not be required to confirm the results can  
20 only happen when the relevance of the biological mechanisms  
21 that apply in the non-animal tests, those that occur in human  
22 eye irritation, are understood. We know little today about  
23 either.

24           For the near term then, non-animal tests can only  
25 be envisioned as reducing the amount of animal testing required.

1 Criteria for replacement battery of tests could not be  
2 developed at the workshop. How many mistakes can be  
3 tolerated from the new test battery for estimating human  
4 eye irritancy. Clearly that depends on how serious the  
5 mistakes are likely to be. At the moment, we do not know.  
6 More information is needed.

7 The Draize test itself is needed for validation.  
8 Well the purpose of the replacement for the Draize test is  
9 predicting human eye irritancy, the reference of chemicals  
10 with human data sufficient for use in validation does not  
11 exist. Banning the Draize test would set the validation  
12 process itself back years.

13 Important progress is being made. Government and  
14 industry are working together towards the goal of reducing  
15 the dependency on animal testing for evaluating safety. I  
16 think this workshop is evidence of that. The agencies agreed  
17 to our proposal to validation preceded by category of  
18 chemicals such as cleaning products.

19 As soon as the test battery for cleaning products  
20 is validated, for instance, the consumer product industry  
21 can use an alternative test battery for cleaning products.  
22 That is a big step in terms of the way Government is looking  
23 at it. Situations like this.

24 This means that alternative testing methods can  
25 be used much earlier. The effects of the test to every product

1 category had to be demonstrated before it could be used upon  
2 any product category.

3 In summary, a valid replacement for the Draize  
4 test does not exist. Replacing the Draize test is more  
5 complicated than previously thought. Reducing the use of  
6 animal testing should be possible near term, but generations  
7 of new Draize data will be necessary before progress can be  
8 made. Banning the Draize test now would be counter-productive.  
9 It would set the validation process back years. Thank you.

10 MR. EDMISTON: I think I only have three questions.  
11 I will know better when I hear the response. The first  
12 question I have relates to an observation you made early on  
13 in your testimony. It is an inference I have drawn from  
14 what you said.

15 I think you have suggested in your testimony that  
16 the prohibited tests as they are described in this bill are  
17 described with such a breath so broadly that in your opinion,  
18 they overreach. That variation in particular in the LD 50  
19 toxicity test would be prohibited by the language in this  
20 bill. You think those variations, generally describe the  
21 variations that should not be prohibited; is that correct?

22 DR. BOOMAN: Exactly.

23 MR. EDMISTON: The second question I have then is  
24 I don't believe I heard the same type of a suggestion as to  
25 the Draize Eye Irritency test.

1 DR. BOOMAN: That is also correct.

2 MR. EDMISTON: Further, the workshop, the September  
3 14 workshop, referenced by yourself, noted by some of our  
4 earlier witnesses today, in particular, by the Pharmaceutical  
5 Manufacturers Association, was a workshop, correct?

6 DR. BOOMAN: Correct.

7 MR. EDMISTON: It may come as a great surprise to  
8 you that I am an employee of the House of Representatives.  
9 It may not come as a great surprise to you that in that  
10 capacity, I hold this proceeding in particular high regard.  
11 However, it is a public hearing as part of the lawmaking  
12 process. However, when we walk out of here today, House  
13 Bill 1554 will not be law. I believe we all understand that.

14 So some might suggest that although this is a public  
15 hearing conducted consistent with Pennsylvania laws controlling  
16 it, it could be called kind of a workshop. Its authority  
17 is limited. It doesn't change the law.

18 So what I am getting to, if it is not more than  
19 apparent, is the suggestion that the excerpts cited from the  
20 various papers and statements at the workshop, though they  
21 would have some credibility in the analysis of some listeners  
22 and some observers, and conceivably in the industry and  
23 conceivably in the regulatory industry, the government, they  
24 are simply at this point statements. They are not authoritative  
25 expressions having the influence and the power of law. Correct?

1 DR. BOOMAN: Absolutely correct. They are at the  
2 same time the best statement that I can give you as to the  
3 summary of the state of thinking of the people in both  
4 government and industry to have a responsibility for  
5 assessing safety of the consumer products.

6 MR. EDMISTON: I understand that. Before you  
7 finish, I didn't ask the questions to be literal. Do you  
8 mean to undermine the workshop, its results, the participants,  
9 and those who looked at this issue carefully enough to have  
10 made an investment in it?

11 Please don't misinterpret the intent of the question.  
12 I wanted to have the point clarified.

13 DR. BOOMAN: Of course, It may be of interest and  
14 help to you to know that the proceedings will be published  
15 in the Peer Review Journal of Toxicology in the United States.  
16 It will have considerable weight in the scientific community  
17 as representation of the state of the art of the science of  
18 this matter today.

19 MR. EDMISTON: Thank you.

20 REPRESENTATIVE MURPHY: Doctor, a couple questions.  
21 These tests have been going on for approximately forty years.

22 DR. BOOMAN: That's correct.

23 REPRESENTATIVE MURPHY: Why do the tests have to  
24 continue? I understand if it is absolutely a new product with  
25 new ingredients. I guess as an undergraduate biology major,

1 I wonder why the tests have to continue if the ingredients  
2 in the products are essentially the same.

3 DR. BOOMAN: They don't, and they are not. I  
4 think the critical issue here from someone attempting to  
5 assess safety, has to do with new products or products that  
6 are --

7 REPRESENTATIVE MURPHY: I am talking about new  
8 ingredients in those products.

9 DR. BOOMAN: You are talking about new ingredients  
10 and new combinations of ingredients where interactions of  
11 a toxicological type are possible or likely. And that is  
12 always -- those two areas, a brand new ingredient and the  
13 dealing with new mixtures of ingredients --

14 REPRESENTATIVE MURPHY: They are the only time the  
15 tests take place?

16 DR. BOOMAN: To the best of my knowledge. In our  
17 industry, that is where animal testing is required.

18 REPRESENTATIVE MURPHY: So these products here  
19 are made from existing ingredients, and therefore, that's why  
20 they would not need animal testing?

21 DR. BOOMAN: Existing materials known to be benign  
22 where the possibility of interaction, toxicological interactions  
23 are judged to be non-existent.

24 REPRESENTATIVE MURPHY: So all the testing going on,  
25 you are telling me, is for new product development, new

1 ingredient development, the combination of new ingredients?

2 DR. BOOMAN: In our industry, you know, I am talking  
3 about our industry, obviously.

4 REPRESENTATIVE MURPHY: Right.

5 DR. BOOMAN: The place -- yes, existing products are  
6 not tested. Oven cleaners aren't tested. It is essential  
7 misrepresentation of the state of toxicology today to suggest  
8 that they are. I have already told you several times,  
9 Representative --

10 REPRESENTATIVE MURPHY: You indicated that the  
11 value of this information is obviously if somebody digests a  
12 product or gets it in their eyes, that there is treatment.  
13 How do you communicate the ingredients and the type of treat-  
14 ment necessary to doctors over the country?

15 DR. BOOMAN: Through the Poison Control Center,  
16 through a system of distributing information to the Poison  
17 Control Centers.

18 REPRESENTATIVE MURPHY: So companies do have that  
19 responsibility?

20 DR. BOOMAN: They do, indeed.

21 REPRESENTATIVE MURPHY: Regulated by the Federal  
22 government or voluntary?

23 DR. BOOMAN: The nature of the labels is regulated  
24 by the Federal government. The distribution of this  
25 information to Poison Control Centers and through poison techs

1 is voluntary, but it is something that all of the companies  
2 do.

3 REPRESENTATIVE MURPHY: Now, Doctor, finally, what  
4 if we gave you a couple years to get rid of this test, would  
5 that accelerate your efforts?

6 DR. BOOMAN: We are working as hard as we can,  
7 Representative Murphy.

8 REPRESENTATIVE MURPHY: You had forty years,  
9 Doctor. It seems you made a major step in the last five years.  
10 (Whereupon, the audience applauds.)

11 DR. BOOMAN: We have made a major step. If I  
12 might continue. What is foreseeable in the near term such as  
13 two years, is the possibility of drastically reducing the  
14 amount of animal testing that is required for the Draize  
15 test. It is highly unlikely in two years that it could be  
16 replaced completely.

17 I indicated to you earlier that the battery of tests  
18 that one might use has not been identified yet. The extent  
19 to which mistakes could and would be made by this battery  
20 not yet identified is obviously not known.

21 The tests that are envisioned at this point in time,  
22 regardless of what anyone might say, the mechanism relevancy  
23 of the test to the eye is not established and not understood,  
24 and the consequence of that is that one is not going to be  
25 able to rely one hundred percent on any of the tests that we



1 are currently working on.

2 REPRESENTATIVE MURPHY: That is certainly true for  
3 the test on the Draize test, the LD 50 test. There is not  
4 one hundred percent reliance. The transferability of the  
5 information you get from using the animals is not one hundred  
6 percent transferable to humans.

7 DR. BOOMAN: Your point is well taken. The point  
8 about the Draize test and the LD 50 test is that we understand  
9 the mistake rate. We understand --

10 REPRESENTATIVE MURPHY: Sometimes.

11 DR. BOOMAN: We understand --

12 REPRESENTATIVE MURPHY: That's not one hundred  
13 percent assurance, either, Doctor.

14 DR. BOOMAN: Obviously. Let me see if I can't be  
15 directly responsive to your question. We are not going to be  
16 able to answer your question until we understand what sort  
17 of mistakes will be made, are likely to be made. Are they  
18 mistakes that will be threatening to human eyesight, or will  
19 they be on this scale relatively trivial?

20 The answer to that question, Representative Murphy,  
21 is not with us today. It is not knowable until we have more  
22 information.

23 REPRESENTATIVE MURPHY: Doctor, unless you test  
24 the product on a human, it will never be knowable. You will  
25 never have one hundred percent assurance that the test of a

1 product, the results will be transferable or absolutely  
2 predicted.

3 DR. BOOMAN: Representative Murphy, I think we are  
4 hung up on the matter of ultimate and one hundred percent  
5 knowability.

6 REPRESENTATIVE MURPHY: Yes. We are not going to  
7 solve it today.

8 DR. BOOMAN: We don't want to get trapped in that.  
9 The point is that the sort of mistake rate we are going to  
10 accept has to depend on the sorts of mistakes that are likely  
11 to be made. We will be generating the information in the  
12 next two years that would allow you and us and everyone in  
13 this room to say, yes, that mistake rate is acceptable. It  
14 is good enough. But we are not in a position to do that  
15 today.

16 REPRESENTATIVE MURPHY: I hope you are. We  
17 intend to act on this bill. Thank you, Doctor.

18 DR. BOOMAN: Thank you.

19 REPRESENTATIVE MURPHY: Dr. Thomas Regan.

20 (Whereupon, the audience applauds.)

21 DR. REGAN: Let me begin by thanking you and the  
22 other members of the House Judiciary Committee for the  
23 opportunity to be here today. Having spent the formulative  
24 years of my life as a resident of Pennsylvania, my public  
25 school years as a student in Pittsburgh, where my parents and

1 most of my relations continue to live, and it sounds like  
2 they may be here. My college years were spent as a student  
3 at Thiel College in Greenville, Pennsylvania. Having this  
4 past, makes my being here on this occasion something of a  
5 homecoming. It renews my sense both of my roots and my pride  
6 in this great state, and of course, in this great city.

7 My profession, as you know, is in higher education.  
8 Specifically, I have been teaching in the Department of  
9 Philosophy and Religion at North Carolina State University  
10 since 1967. During my years in higher education, I have  
11 published scores of papers in professionally referred journals,  
12 on a broad range of contemporary moral issues, including the  
13 issue of our responsibility to animals.

14 I published more than fifteen books on these same  
15 issues, and have lectured on these topics throughout the United  
16 States, Canada, Great Britain and Europe, before groups of  
17 scientists, philosophers, lawyers, theologians, elected  
18 representatives, and other policymakers, educators and the  
19 general public.

20 I mention these facts, not to beat my own breast,  
21 but, rather, to suggest how and why my being here on this  
22 occasion is part of the pattern of my professional life that  
23 has led me and some others out of the academic's proverbial  
24 "ivory tower" and into the real world.

25 An important part of the real world concerns how

1 we educate our children. As a parent myself, I am under-  
2 standably concerned about the values my own children are  
3 taught in our society. And as an educator, I am keenly aware  
4 of how much of this teaching takes place in our grade and  
5 high schools and in our institutions of higher learning.

6 My own experience has taught me there is relatively  
7 little that elected representatives can do directly to try to  
8 shape the values young people learn, either in the home or  
9 in our places of worship.

10 Indeed, as a partisan of the ideals of the democracy  
11 on which our nation is founded, I believe there is little elected  
12 representatives should do in this regard.

13 Parents are rightly viewed as sovereign over their  
14 own home, and the cherished principle of the separation of  
15 church and state must always be honored. This leaves the  
16 field of public education as the one where elected representa-  
17 tives can and should endeavor to contribute to the values our  
18 children are encouraged to express in their lives.

19 This is the broader in which we should view the  
20 provisions set forth in Part (e) of Section 2 of House Bill  
21 No. 1554. The provisions state, in part, "No student who  
22 refuses to participate in experimentation, research or  
23 teaching methods involving vivisection of live animals shall  
24 be penalized for refusal to participate based upon the  
25 individual's fundamental beliefs."

1           In other words, a student's right of conscience is  
2 to be protected in the laboratory. The Commonwealth of  
3 Pennsylvania will not permit young people to be punished for  
4 refusing, as a matter of conscience, to do what they believe  
5 is wrong. Not only is this protection guaranteed by our  
6 Constitution, in my view, it also is well grounded in our best  
7 thought about moral development.

8           For what we aspire to do in our places of education  
9 is more than fill our students' heads with facts. We also  
10 are obliged to foster their growth as responsible, caring,  
11 autonomous persons. I have chosen these words -- "responsible,  
12 caring, and autonomous persons," deliberately, and I want  
13 to say a little about each of them.

14           "Responsible." Everyone involved in education  
15 acknowledges the value of responsibility in our students. The  
16 importance of this value is as basic as doing homework and  
17 as fundamental as being fully human.

18           We want our students not only to be responsible, but  
19 also to take responsibility. To understand that, when all the  
20 dust settles, they must finally be the ones who determine what  
21 they decide to do, as well as what they refuse to do.  
22 Ultimately, it is the student who must answer for what he or  
23 she does.

24           "Caring." There is a limit to the pursuit of  
25 selfishness. All the great moral traditions that have shaped

1 our nation's values speak with one voice on this matter.  
2 Especially in the case of those who are incapable of defending  
3 themselves, we recognize the value of empathy and the need for  
4 assistance.

5 The last thing we want in our places of education,  
6 therefore, are policies or practices that stifle the growth  
7 of care among young people. On the contrary, what we need,  
8 and what we should encourage, are policies and practices that  
9 foster and reward the growth of this great value, caring.

10 "Autonomous." If we are to hold our students  
11 responsible for their choices, we must also create opportunities  
12 for them to choose. To do so need not risk academic anarchy.  
13 It is not only possible, it is an actual fact that students  
14 can be given the liberty to make choices about what they will  
15 learn and how they will learn it, and that the granting of  
16 this liberty to them can advance, rather than retard, both  
17 the rate at which they learn and their enthusiasm for learning.

18 Moreover, by affording students a more extensive  
19 liberty, the authority traditionally vested in the teacher need  
20 not be compromised. For it is the teacher who, in the end,  
21 will and must evaluate the student's performance, just as it  
22 is the student who, in the end, will and must endeavor to meet  
23 the standards the teacher imposes.

24 My comments on the values of responsibility, caring  
25 and autonomy are not tangential to the issues before us.

1 Just the opposite. For what the provisions of the House  
2 Bill under discussion provide for is the nurturing of these  
3 three great values in the lives of students in Pennsylvania.

4 To exercise the liberty not to take part in vivi-  
5 section squarely places the responsibility in the hands of the  
6 student and, so, can assist in our efforts to teach students  
7 both that they are responsible for what they decide and must  
8 take responsibility for this. By granting them this liberty,  
9 moreover, we help them grow in their capacity to face and make  
10 difficult choices.

11 And by protecting them against punishment when they  
12 act from their own well-considered views about what is right  
13 and wrong, we send them a clear signal that our society places  
14 a positive value on caring about, having informed compassion  
15 for those who have been made to suffer and who lack the means  
16 to defend themselves.

17 In all these ways, and more, then, the provisions of  
18 the bill currently under discussion are on the side of those  
19 fundamental values, that it is an essential part of our system  
20 of education to impart, to foster the growth of our students  
21 as responsible, caring, autonomous persons.

22 Earlier, I mentioned the importance of the separation  
23 of church and state in our democratic traditions. Nothing  
24 I am about to say should be taken to challenge this essential  
25 separation.

1           It is important that we realize, however, that the  
2 issue before us is one that increasingly is commanding the  
3 attention of church leaders.

4           At a recent consultation of the World Council of  
5 Churches, which counts among its 305 denominational members  
6 the Baptist, Episcopal, Lutheran, Methodist and Presbyterian  
7 churches in America, and which included a representative of  
8 the Vatican, the very issue before us was a matter of the most  
9 serious concern.

10           The report issued from this consultation reflects  
11 this when it declares that, and I quote, "our children need  
12 to be sustained in their natural empathy with and compassion  
13 for animals, and this means that certain traditional practices,  
14 including in particular compulsory vivisection, will have to be  
15 altered."

16           This statement was unanimously adopted by an inter-  
17 national body of religious leaders from such disparate  
18 countries as Australia, Denmark, the United States, South Korea  
19 and South Africa. Clearly, the tide of world opinion, both  
20 secular and religious, is changing.

21           I am encouraged to have heard here today or not heard  
22 here today, in fact, any testimony given by any of the people  
23 to any objection to this part of this legislation. It would,  
24 of course, be a moral contradiction to acknowledge the  
25 importance of the values of responsibility, caring and autonomy



1 in the classroom, and deny their importance in the workplace.

2 It is one of the great merits of the bill before  
3 us that it does not do this. The protection the bill affords  
4 extends to anyone, whether student or employee, who refuses  
5 to participate in vivisection for reasons of conscience. In  
6 this respect, the bill exhibits admirable moral consistency.

7 There is much else in the bill's provisions which I  
8 would like to address in detail, but which the understandable  
9 limits of time make impossible. Allow me simply to make a  
10 few concluding general observations.

11 There is nothing in this bill that retards the  
12 advancement of science. What does retard the advancement of  
13 science is bad science, and the two product tests the bill  
14 would prohibit, the LD 50 toxicity and the Draize eye irritancy  
15 tests, are paradigms of just that, bad science.

16 Against, the only people I heard here today speaking  
17 in favor of these tests are people who I have reason to believe  
18 have some special vested interest in terms of capital invest-  
19 ment in the continuation of these tests.

20 Dr. Rozniarek of the University of Pennsylvania,  
21 thought himself at liberty to speak for the University in  
22 saying they had no objection to that provision of the document.  
23 Dr. Bramson and Dr. Adler, of the University of Pittsburgh,  
24 the University of Pittsburgh Medical School, again indicated  
25 no objection from the University on these particular provisions.

1 Dr. Moreno said they could live with it. They  
2 could adjust to it, no objections. Also, what I heard, then,  
3 the only thing I heard in terms of opposition were people  
4 speaking for what I would regard to be vested special interests.

5 Moreover, by increasing the accountability of  
6 scientists, the bill goes some way towards insuring that those  
7 who profess to serve the public interest are, as they should  
8 be, subject to appropriate public scrutiny, the need for which  
9 has been painfully documented by the videotapes it has been  
10 your responsibility to view. Citizens deserve a dollar's  
11 worth of good science for every dollar of theirs that is spent.  
12 The bill helps insure that they will get this.

13 On this question of APHIS, there is, and I will be  
14 pleased to make this available to the committee, a map that is  
15 designed to show what the reorganization of APHIS will look  
16 like if the recommendations go through. I can tell you that  
17 according to the statistics, there will be 59 inspectors to  
18 inspect 8200 sites. Now, we heard testimony here earlier  
19 today that some of these inspections last four days. Let's  
20 assume that is the case.

21 We have 59 inspectors inspecting 8200 sites at four  
22 days as the investigation. That's 140 sites per inspector.  
23 Let's assume they work fifty weeks a year, Each inspector will  
24 be able to inspect 56 sites of the 140 that would be parceled  
25 out. That means, out of the 8200, if this APHIS reorganization

1 plan goes through, that almost 5,000 of the sites will not  
2 be inspected.

3 I think that computes with the kind of statistics  
4 we already have. That in New York and California, something  
5 approaching fifty percent of the sites hadn't been investi-  
6 gated.

7 So, finally, there is nothing in the bill that  
8 threatens the public health. The prohibited tests are  
9 anachronistic left-overs from a period of science beyond  
10 which we should have moved decades ago. By taking the  
11 legislative initiative to move beyond them in the Commonwealth  
12 of Pennsylvania, you and your colleagues in the General  
13 Assembly will bring credit to the people of Pennsylvania and  
14 prove once again that, in comparison with others, Pennsylvania  
15 is a state that remains on the cutting-edge of informed,  
16 progressive thought.

17 Thank you very much.

18 (Whereupon, the audience applauds.)

19 REPRESENTATIVE MURPHY: You do your alma mater  
20 proud. I have no questions.

21 I want to comment that I thought your statement was  
22 a wonderful philosophic wrap-up of, I think, the spirit of which  
23 the hearings were held and the hopes of what we can accomplish.  
24 I think for everybody here, you spoke so eloquently of what  
25 this issue is about.

1           Let me just say that I think what you saw here  
2 today, thanks to Chairman Bill DeWeese, is a real classic  
3 example of democracy. Of people coming together trying to  
4 make a decision on a very difficult issue. Even people  
5 who use the test and perform research understand that we ought  
6 to be getting to move away from that.

7           I think Dr. Regan gave us a philosophic basic for  
8 which we should.

9           When all of you feel so helpless about changing the  
10 world, you should know that this hearing and other steps you  
11 have taken to make this hearing happen are really the steps  
12 in how democracy works.

13           With your continued support and continued effort,  
14 hopefully, Chairman DeWeese will vote this bill out of the  
15 committee and the full House will see it for a vote soon.

16           Thank you.

17           DR. REGAN: I know I speak for everyone here and  
18 also for most people who have been obliged to leave for a  
19 variety of reasons, in saying how much your leadership on this  
20 issue has meant to everybody in the Commonwealth of Pennsylvania.

21           We thank you very much.

22           CHAIRMAN DeWEESE: It is hard to enhance  
23 Representative Murphy's epilogue on today's event. I would  
24 like to commend everyone for the quality of the testimony and  
25 for the demeanor of the witnesses and the audience.

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This is a potentially incendiary subject in the public realms, and there was some trepidation among the staff and members as to what kind of an event this would be.

I think it has been edifying and worthwhile.

I would like to thank you on behalf of the House Judiciary Committee for being here and being part of our process.

I think this concludes our event. This event is adjourned.

(Whereupon, the hearing terminated at 4:04 P.M.)

I hereby certify that the proceedings and evidence taken by me in the above-entitled matter are fully and accurately indicated in my notes and that this is a true and correct transcript of same.

  
Susan L. Mears, Reporter