

COMMONWEALTH OF PENNSYLVANIA
HOUSE OF REPRESENTATIVES
COMMITTEE ON JUDICIARY

In re: HB 873
Animal Lab Testing

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Stenographic report of hearing held
in Room 8E, East Wing, Main Capitol
Building, Harrisburg, Pennsylvania

Thursday,
May 25, 1989
10:00 a.m.

HON. THOMAS R. CALTAGIRONE, CHAIRMAN
Hon. Kevin Blaum, Subcommittee Chairman on Crime
and Corrections
Hon. Gerard Kosinski, Subcommittee Chairman on Courts

MEMBERS OF COMMITTEE ON JUDICIARY

Hon. Michael Bortner Hon. Nicholas B. Moehlmann
Hon. Lois S. Hagarty Hon. Jeffrey Piccola
Hon. Richard Hayden Hon. Robert D. Reber
Hon. David W. Heckler Hon. Karen A. Ritter
Hon. Paul McHale Hon. Michael R. Veon
Hon. Christopher K. McNally

Also Present:

Hon. Thomas J. Murphy, Jr.
William Andring, Majority Counsel
David Krantz, Majority Executive Director
Mary Woolley, Minority Counsel
Mary Beth Marschik, Minority Research Analyst
Katherine Manucci, Committee Staff

Reported by:
Ann-Marie P. Sweeney, Reporter

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1 CHAIRMAN CALTAGIRONE: I'd like to open up
2 these proceedings. We're here to take testimony on the
3 animal rights legislation, House Bill 873, a public
4 hearing held by the House Judiciary Committee. I'm
5 Chairman Tom Caltagirone from Berks County. I'd like the
6 other members' presence so noted from the record. If we'd
7 start from my left with staff, and staff and members can
8 introduce themselves as we go around.

9 MS. MARSCHIK: Mary Beth Marschik, minority
10 Research Analyst.

11 REPRESENTATIVE PICCOLA: Representative Jeff
12 Piccola from Dauphin County.

13 REPRESENTATIVE REBER: Representative Bob
14 Reber from Montgomery County.

15 MR. ANDRING: Bill Andring, Democratic
16 Counsel for the committee.

17 REPRESENTATIVE MOEHLMANN: Representative
18 Nick Moehlmann, Lebanon County, minority chairman.

19 REPRESENTATIVE HAYDEN: Representative
20 Richard Hayden from Philadelphia County.

21 REPRESENTATIVE McNALLY: Representative
22 Chris McNally from Allegheny County.

23 REPRESENTATIVE KOSINSKI: Representative
24 Jerry Kosinski from Philadelphia County.

25 MS. MANUCCI: Katherine Manucci, Secretary

1 to the committee.

2 MR. KRANTZ: David Krantz, Executive
3 Director of the committee.

4 CHAIRMAN CALTAGIRONE: I'd like to start off
5 with just a couple of things. I've been asked to mention
6 that we are not allowed to bring any food, drink or any
7 smoking in this room, so I'd appreciate it if everybody
8 would abide by those rules. I'd also like to just say
9 that everybody will be afforded an opportunity to testify
10 that's on the agenda. I would hope that everybody would
11 conduct themselves in a decent, orderly manner and that we
12 get on with the business of what we're here for, and
13 that's gathering information for the edification and
14 benefit of the members of this committee so that we can
15 discuss this issue in an intelligent manner and we can
16 decide exactly what we have to do.

17 We'll start off with -- Representative
18 Murphy is going to make a statement, but prior to that,
19 Chief Counsel Bill Andring would like to enter several
20 documents for the record that have been sent to our
21 office.

22 MR. ANDRING: Just for the record, we've
23 received a letter from J. W. Pedigrue, M.D., Director of
24 the Neurophysics Laboratory of the Psychiatric Institute.
25 We've been provided a copy of the Journal of Toxicology,

1 Volume 8, No. 1, a special issue on a government industry
2 workshop on progress for its non-animal alternatives for
3 the Draize test. And the chairman has also communicated
4 with a number of Federal government agencies, including
5 the Consumer Products Safety Commission and Environmental
6 Protection Agency, asking them for their position on the
7 bill under consideration. When those are received,
8 they'll be distributed to the committee members and made a
9 part of the record.

10 CHAIRMAN CALTAGIRONE: And we do have
11 several pieces of correspondence both pro and con on the
12 legislation that is being submitted for the record, and
13 the court reporter does have that with her. Copies to be
14 distributed then at a later date for all the members.

15 (See appendix for copies of exhibits.)

16 CHAIRMAN CALTAGIRONE: At this time, I'd
17 like to recognize Representative Thomas J. Murphy, who is
18 the prime sponsor of House Bill 873.

19 REPRESENTATIVE MURPHY: Thank you, Mr.
20 Chairman. New microphones. I'll have to get used to
21 them.

22 Let me just say as a beginning that many of
23 you have received letters, as I have received, from a
24 variety of prestigious institutions and doctors from
25 around the State in opposition to this bill, and as I read

1 those letters I realized that many of them really did not
2 read the legislation and I think were responding to
3 information provided to them in the worst-case scenario.
4 If you read the legislation, I think you will see that
5 much of what they say is factually untrue and is in
6 reality not impacted by the legislation at all.

7 I have reintroduced House Bill 873 because
8 it addresses some of the concerns I and tens of thousands
9 of fellow Pennsylvanians have regarding the treatment of
10 laboratory animals undergoing experimentation and use for
11 product testing. House Bill 873 does not restrict medical
12 research. The measure addresses those areas where basic
13 animal protection in laboratories is either weak or
14 nonexistent. House Bill 873 deals with duplicate or
15 redundant research, cosmetic and commercial testing, and
16 student rights.

17 It also, for the first time, places research
18 laboratories under the search warrant provisions of
19 Pennsylvania law, search warrant provisions which every
20 other person, institution, and corporation in Pennsylvania
21 falls under. There are -- you each will receive a tape of
22 two Pennsylvania institutions that have been charged with
23 a variety of violations, one shut down, the University of
24 Pennsylvania Head Injury Laboratory. In each case, there
25 were repeated efforts to get public law enforcement

1 officials to investigate the alleged abuses in these
2 facilities without success because they did not have the
3 ability to use search warrant provisions to go in and
4 investigate, so they did not have the jurisdiction they
5 needed. That's the reason for placing every institution
6 in Pennsylvania under the search warrant provisions.

7 Let me remind you again that this measure
8 deals with unnecessary and duplicative research and seeks
9 to create checks and balances in the research industry.
10 Some will argue that any regulation of animal research
11 could have adverse effects on certain businesses. I do
12 not believe that commerce and industry have to rely on
13 animal killing and suffering to test their products. Just
14 like arguing that business can't survive without child
15 labor or the 12-hour day. Hundreds of companies produce
16 products without resorting to animal testing. Most
17 recently, Avon and Mary Kay Cosmetics, two very large
18 cosmetic companies, have announced that they no longer
19 will test their products on animals, that they have
20 developed other alternatives. This legislation continues
21 -- would continue to push industries that are not as
22 progressive as those two to develop those alternatives.

23 The simple fact is that the research
24 industry has a vested interest in the status quo, and
25 inertia makes all of us unwilling to change direction.

1 House Bill 873 helps to make that change.

2 The most controversial element of this bill
3 is to call for a ban on eye irritancy and acute toxicity
4 testing. These are two particularly painful tests used
5 for the development of household products and cosmetics,
6 and, may I add, are not involved in direct research,
7 medical research, or drug research, for that matter.
8 Despite claims to the contrary, the U.S. Food and Drug
9 Administration does not require tests which blind or kill
10 animals. There are a variety of personal care or cosmetic
11 products which are marketed without animal tests. It is
12 unacceptable that we inflict pain and suffering to test
13 lipstick and perfume when it is unnecessary.

14 House Bill 873 also addresses the
15 inadequacies and lack of timeliness in respect to Federal
16 inspections of labs. Some labs benefit from infrequent
17 inspections, some labs do not have to register at all.
18 Proposed Federal regulations call for even fewer
19 inspections.

20 Let me add that House Bill 873 also protects
21 the right of students who, for personal or religious
22 reasons, refuse to experiment on living subjects. Great
23 Britain did away with live animal experimentation in
24 medical school 100 years ago. It is not necessary to
25 force students to inflict pain or suffering in order to

1 learn.

2 My bill, ladies and gentlemen, is a modest
3 proposal. It is also almost like a sunshine bill for
4 thousands of creatures who will be subjected to pain, and
5 we have compromised to get the measure in its present
6 form. It's a good start.

7 I urge all of you to support this
8 legislation, but more importantly, I urge all of you to
9 listen closely to the testimony today. We've had one
10 other prior hearing last year, some of you might have
11 attended that. From that hearing I think a lot of people
12 had their eyes opened to this issue. I ask you to put
13 aside the ghosts that will be raised by some people in the
14 research community - ghosts that do not exist. I ask you
15 to listen to the testimony, both pro and con, and I think
16 you will come to the conclusion that this bill is a modest
17 step forward in creating the stewardship in Pennsylvania
18 over all living creatures that the Commonwealth ought to
19 have.

20 Thank you. Are there any questions?

21 (Whereupon, Representative Moehlmann assumed
22 the Chair.)

23 ACTING CHAIRMAN MOEHLMANN: Thank you,
24 Representative Murphy.

25 Are there any questions?

1 REPRESENTATIVE KOSINSKI: Mr. Chairman, I'm
2 sorry, no question. I'd like to make a motion, if in
3 order, to invite Representative Murphy to sit with us.

4 REPRESENTATIVE McNALLY: I thought Nick was
5 going to ask.

6 ACTING CHAIRMAN MOEHLMANN: Do you have a
7 question?

8 REPRESENTATIVE McNALLY: Yes, I did.

9 BY REPRESENTATIVE McNALLY: (Of Rep. Murphy)

10 Q. Mr. Murphy, as a matter of fact, one of the
11 issues most commonly raised in the correspondence that I
12 have received is that there is a great deal of, or at
13 least there is some Federal regulation of research
14 laboratories. Now, your bill would require institutional
15 care committees to be set up in each research facility and
16 would establish other regulations through the, I believe,
17 the Department of Agriculture. I think one argument that
18 is being made by the research community is that if
19 Pennsylvania adopts more rigorous standards, it would make
20 us, from a research and economic standpoint, less
21 competitive with surrounding States which would be
22 following less rigorous or what you would say then are
23 less rigorous standards at the Federal level.

24 First of all, you know, would you agree that
25 we would be at some competitive disadvantage? And this

1 would be particularly important since some of us would
2 like to rely on technology and the research and scientific
3 community as an engine for economic development.

4 A. First of all, Chris, if you read page 2 of
5 the bill you will see that it says that "License
6 required," and it says, "...for that purpose by the
7 Secretary of Agriculture, or by the Federal Laboratory
8 Animal Welfare Act." It doesn't say "and," it says "or".
9 So research facilities that are already licensed by the
10 Federal government do not have to also go get a license
11 from the Secretary of Agriculture.

12 Q. If you read page 3 it says that "Each
13 research facility shall form an Institutional Animal Care
14 Committee."

15 A. They are required to do that already under
16 the Federal law, so that is not duplicative.

17 Q. So that you -- in fact, you don't think that
18 there is any difference between this bill and Federal
19 regulations?

20 A. In -- there are some additional differences,
21 particularly the Federal legislation does not prohibit the
22 Draize or the L.D. 50 test. We would prohibit that. That
23 is not a research test, that is a product test. It's
24 product testing. It also grants rights to students. You
25 might remember a year or so ago a high school student in

1 California came close to getting expelled because she
2 refused to do vivisection on a frog. A few years ago in
3 Pennsylvania, students at the veterinarian school at the
4 University of Pennsylvania were threatened with expulsion
5 because they would not perform vivisection or routine
6 classroom procedures on dogs. Alternatives were
7 ultimately developed so that they could graduate, and they
8 both are veterinarians today. So that the bill does take
9 a step further, but I do not believe there's any
10 redundancy in the bill at all. Federal government
11 requires an animal -- institutional animal committee.
12 There is no reason why the institutions can't have one
13 animal care committee and suit the State and Federal
14 responsibility.

15 Q. But the fundamental argument here is that if
16 Pennsylvania's standards are more rigorous than those of
17 surrounding States, we have some disadvantage
18 competitively.

19 A. What is the disadvantage?

20 Q. Well, first of all, that if you want to do
21 research or engage in some scientific work that involves
22 or in which you may want to involve animal testing, you'd
23 be better off to go to New York or New Jersey or Maryland
24 or Ohio or West Virginia or some other State rather than
25 come to Pennsylvania where the restrictions and

1 regulations are more rigorous.

2 A. In regard to the L.D. 50 test and the Draize
3 test, you're probably correct, Chris.

4 Q. Okay.

5 A. In prohibiting those tests, that will be a
6 higher standard than other States will have. Other States
7 might be able to use those -- companies might be able to
8 use those tests in other States, and in fact it might be
9 cheaper than the high tech alternative. It is my belief
10 in the long run it will not be cheaper for them to use
11 animals.

12 REPRESENTATIVE KOSINSKI: Just a comment,
13 Representative McNally, sir.

14 In comment to you, Representative McNally, I
15 think that one part of high tech and one part of advancing
16 technology in the States is coming up with alternates to
17 animal testing, specifically with the L.D. 50 and the
18 Draize eye test. And we have some great research
19 institutes in this State, and it seems to me they are
20 being far outstripped by places like Johns Hopkins in
21 Maryland with the non-cruel ways to conduct these two
22 specific tests, which is one of the reasons Representative
23 Murphy's bill is a catalyst towards such high tech
24 research in these areas.

25 REPRESENTATIVE MURPHY: That's correct, and

1 in fact we have funded, through some State programs,
2 efforts to find alternatives to the use of animals in
3 research. So, Chris, if you're interested in Pennsylvania
4 being the high tech engine of the country, then you should
5 be for this bill because it pushes alternatives.

6 REPRESENTATIVE McNALLY: Well, I think a
7 more appropriate method would simply provide financial
8 incentives for advances in technology rather than putting
9 regulations and burdens on--

10 REPRESENTATIVE MURPHY: I think we do both
11 the carrot and the stick. We provide those financial
12 incentives to encourage people to develop those
13 alternatives also.

14 REPRESENTATIVE McNALLY: The reason I raise
15 the question is that I see a contradiction that this
16 Federal/State regulation problem doesn't hold water with
17 respect to animal welfare, but on fair labor standards,
18 and specifically the minimum wage, that was the argument
19 made for the working poor, that we shouldn't have a higher
20 State standard because that puts us at a disadvantage.

21 (Whereupon, Chairman Caltagirone resumed the
22 Chair.)

23 CHAIRMAN CALTAGIRONE: Representative
24 Hayden.

25 BY REPRESENTATIVE HAYDEN: (Of Rep. Murphy)

1 Q. Representative Murphy, you mentioned the one
2 lab at the University of Pennsylvania, and I think the
3 other major investigation was at the Biosearch
4 Laboratories?

5 A. Yes.

6 Q. Can you tell me, I never found out what
7 happened as a result of those investigations. The
8 Inquirer reports were almost a year ago. Can you tell me
9 what enforcement action, if any, was taken against
10 Biosearch?

11 A. The University of Pennsylvania Head Injury
12 Laboratory was ultimately shut down by the Federal
13 Government.

14 Q. Yeah, I'm asking--

15 A. I think Biosearch is still being
16 investigated by the Philadelphia district attorney. There
17 are, from what I understand, over 100 violations of
18 Federal animal cruelty laws alleged, and it's being
19 investigated. I do not believe that any charges have been
20 brought forth yet.

21 Q. So then as far as you know, it hasn't been
22 resolved?

23 A. No, it's not been resolved.

24 Q. The other question I have, and this is
25 picking up on Representative McNally's point about the

1 attempt to impose an additional State standard over and
2 above the Federal standard. I have -- unlike some of the
3 people, I got some letters and it appeared to me, you're
4 right, there are some people that didn't read the bill,
5 and I had a chance to read the bill and I looked at your
6 definition of research facility, I compared it to the
7 Federal Register's definition of research facility, those
8 laboratories and those research facilities which are
9 required to be licensed under the Federal act, and the
10 research facility definition which is in the proposed
11 rules of the Federal Register on March 15, 1989, proposed
12 very broad definition of what a research facility entails,
13 what would qualify as a research facility. But it also
14 said that the administrator "may exempt by regulation any
15 such school, institution, organization, or person that
16 does not use or intend to use live dogs or cats, except
17 those schools, institutions, organizations or persons
18 which use substantial numbers," and then it talks about
19 live animals, and that the primary function is for
20 biomedical research or testing. Then those particular
21 research facilities may not be exempted. But what it does
22 is it permits the administrator at the Federal level to
23 say, okay, there are certain institutions, primarily
24 schools, I would imagine.

25 A. Right.

1 Q. And then he publishes a list of those
2 schools which would be exempt. As I read your definition
3 of research facility in this bill, particularly when you
4 make specific reference to on page 5 of the bill
5 "elementary, secondary or postsecondary school that uses
6 or intends to use live animals in research tests or
7 experiments," it appears that what this bill contemplates
8 to do is to, despite the fact that at the Federal level
9 they saw some merit to looking at schools and whatever--

10 A. Right.

11 Q. --this bill then proposes to incorporate
12 every potential elementary school, every potential
13 laboratory, and every potential use of a live animal?

14 A. That's correct. It's an either/or. Either
15 you register at the Federal level or you will register at
16 the State level, but at some place there will be together,
17 between the two, there would be complete registration of
18 all facilities performing research.

19 Q. The other point, just my last question to
20 you, Representative, is on the issue of -- you speak about
21 a license requirement in the animal research facility,
22 Section 5511.1, and you just mentioned either/or. It
23 appears that what you're attempting to do is that if you
24 have a license under the Federal Laboratory Animal Welfare
25 Act, that you are still going to be subjected to separate

1 State regulations under subsection (b). Is that what you
2 contemplate? Even though you're licensed under the
3 Federal government, you won't need a separate State
4 license or requirement but you will have to adhere to
5 State license and regulation?

6 A. Yes.

7 Q. Okay, thank you.

8 REPRESENTATIVE HAYDEN: Thank you, Mr.
9 Chairman.

10 CHAIRMAN CALTAGIRONE: Thank you,
11 Representative Murphy.

12 I'd like to note for the record that
13 Representatives Hagarty, Blaum, Ritter, Heckler, Veon and
14 Chief Counsel for the minority, Mary Woolley, is also
15 present with us.

16 I'll go to the next witness, Dr. Fredericka
17 Heller.

18 REPRESENTATIVE KOSINSKI: Could I make a
19 motion, Mr. Chairman, to invite Representative Murphy to
20 sit with us today?

21 CHAIRMAN CALTAGIRONE: Certainly. If he
22 would care to come up, he is welcome.

23 Doctor.

24 DR. HELLER: I'd like to thank the members
25 of the House Committee on Judiciary for allowing me to

1 speak today in support of House Bill 873. My thanks also
2 to Representative Murphy for sponsoring this legislation.

3 I am a physician with a private practice in
4 obstetrics and gynecology in Reading, Pennsylvania. As a
5 medical professional, I am concerned that there be
6 legitimate and sufficient regulations on the scientific
7 community to insure that the sacrifice of laboratory
8 animals is professionally defensible and humanely
9 conducted. Section 5511(a) of this bill provides the
10 State with the authority to license and monitor animal
11 laboratory facilities, and to enforce humane standards of
12 care in these laboratories. While some researchers resent
13 any increase in legislation and regulation, the reality,
14 to my mind, is that existing laws do little to protect
15 laboratory animals. Many species are exempted from the
16 regulations for the Animal Welfare Act. Enforcement of
17 minimal animal care codes is inadequate, partly because
18 the Department of Agriculture's inspection division is
19 underfunded and understaffed to control the large
20 quantities of laboratories and research facilities that
21 we're talking about.

22 As we mentioned earlier this morning,
23 shocking abuses of animals have been exposed at
24 institutions in Pennsylvania and across the nation. The
25 State has both the right and the obligation to monitor and

1 regulate the treatment of laboratory animals so that
2 future tragic and embarrassing cases, like the highly
3 publicized animal abuse at the University of
4 Pennsylvania's Head Injury Laboratory and the Bioresearch
5 Cosmetic Testing Facility, can be avoided. I might add
6 here that I am a graduate of the University of
7 Pennsylvania School of Medicine, extremely proud of my
8 alma mater, and very embarrassed about what happened
9 there. It would not have happened if this bill had been
10 enacted prior to that time.

11 As a consumer and mother of a 7-month-old, I
12 am concerned about the safety of cosmetics and household
13 products. As an obstetrician, needless to say, I don't
14 have to tell you about malpractice and giving pregnant
15 women medications which might cause malformations in a
16 fetus. I know that animal tests can never assure that a
17 product will be safe for human use because animals differ
18 so significantly from humans. I might refer here to the
19 famous thalidomide case, of which I'm sure you're all
20 familiar back in the '50's where thalidomide had been
21 tested on animals, it was given to humans who were
22 pregnant, and I believe some of the local public education
23 channels have recently done very exhaustive research on
24 what happened to the pregnancies that were involved.
25 These children had something called phocomelia, where

1 their limbs did not develop. Many of them died. Animals
2 were used to test that medication. It's one of many that
3 can be referred to. It did not transfer to humans, that
4 information.

5 Because of these differences, animal tests
6 are of little or no use to emergency physicians in the
7 management of cases of accidental exposures and
8 poisonings. Instead, doctors rely on case reports,
9* clinical experience, and experimental data from clinical
10 trials in humans. And we joke about, did you test it in a
11 rat? What happened to the rat? What happened to the
12 rabbit? Because we all know, it makes no difference what
13 happened in those animals. What matters is when we give
14 it to a human and what we see after the human ingests it
15 or comes in contact with the product. And that's what we
16 all pay attention to. As an obstetrician, obviously I
17 won't give a drug to a pregnant woman that's killed 30
18 rats, but on the other hand, I certainly won't give a drug
19 to a pregnant woman that did not kill 30 rats but caused a
20 major malformation in children of women given the drug who
21 were carrying a pregnancy. So you really cannot, and we
22 don't as physicians, use that information in our clinical
23 activities. And I think you can ask any physician that
24 and they'll give you that answer.

25 One need only look at the shelves in a local

1 grocery or pharmacy to know that there are hundreds of
2 products on the shelves and in the market which cause
3 irritation and damage if they're splashed in one's eye,
4 exposed to the skin, or swallowed. Clearly, the animal
5 tests haven't kept those products off the market. They're
6 still there. We know how to deal with them, for the most
7 part, if they are accidentally swallowed, et cetera.
8 Irritancy and acute toxicity tests on animals have little
9 relevance to human experience. Frankly, I don't feel that
10 they are of much clinical value and they are a senseless
11 waste of animal lives.

12 I think it's time to reform our cruel and
13 archaic consumer product testing. Remember, it was
14 developed in the '40's. I hope we've advanced beyond the
15 '40's.

16 To go on to another section of the bill, the
17 right to exercise one's religious or moral convictions I
18 feel is a basic tenet of the America political system, yet
19 some students who have declined, for ethical reasons, to
20 participate in animal experimentation or training
21 exercises have been harassed. I, myself, as a student at
22 the University of Pennsylvania, as I mentioned, in medical
23 school was exposed to animal experiments for my
24 educational benefit. I objected to them then, I object to
25 them now, and I feel that they need to come under closer

1 scrutiny. Florida and California have enacted legislation
2 to protect a student's right not to participate in animal
3 experimentation, and Pennsylvania should follow their lead
4 by enacting Section 5511.1(e) of this bill.

5 Thank you again very much for the
6 opportunity to testify. I urge that you all vote in favor
7 for this bill. I don't feel it's going to be an economic
8 hindrance. I think you're going to find that consumers
9 will support the idea of humane testing and eliminating
10 useless testing, such as the Draize testing, which we
11 really don't pay much attention to.

12 One of my patients this morning,
13 incidentally, as I went around to see her, she had a
14 lovely baby boy last night, said to me, "Where are you
15 going?" And I said, "I have to leave for Harrisburg.
16 It's a long drive and I can't stay and talk very long,"
17 and I explained to her what I was coming out to do. She
18 said, "I won't use products that have been tested on
19 animals using the Draize test, and I would prefer to buy a
20 product which has been tested in either animals, if
21 necessary, done in a humane fashion, or not use useless
22 and senseless tests." The public, the general public, is
23 very much aware of that, and I strongly feel that is not a
24 damage to consumer buying. I think that's a benefit that
25 we look at it and treat it sensibly.

1 Thank you very much.

2 CHAIRMAN CALTAGIRONE: Doctor, we have some
3 questions yet.

4 We had a little bit of a problem and that's
5 why I was distracted here for a second.

6 Doctor, I apologize.

7 DR. HELLER: I'm sorry. You upset my son.

8 CHAIRMAN CALTAGIRONE: You can bring him up
9 here.

10 Representative Hayden.

11 BY REPRESENTATIVE HAYDEN: (Of Dr. Heller)

12 Q. Thank you for your testimony, Doctor.

13 In response to your point that animal tests
14 are of little or no use to emergency physicians in the
15 management of cases of accidental exposures and
16 poisonings, I received a letter yesterday from a Dr.
17 Anthony R. Temple, who is a member of the Board of
18 Directors of the Delaware Valley Regional Poison Control
19 Center. He is a pediatrician and a medical toxicologist.
20 It appears from his CV here that he's had extensive
21 practice in the field of poison control issue, and he
22 shares your concern that there are some tests that are, at
23 least on the surface, perhaps to be unnecessary or perhaps
24 to be inhumane on balance as to what the actual value and
25 merit of those tests are when we compare to what the

1 utility is in the scientific community. But he does
2 conclude that "unfortunately, reliable evaluation from the
3 acute toxicity of cosmetics and household products still
4 requires some animal testing," and he says he "knows of no
5 reliable way to evaluate the acute toxicity of cosmetic
6 and household products without some use of animal test
7 results."

8 And then he mentions here your point about
9 the lack of correlation between animal ingestion or animal
10 use with respect to the human population. He says that,
11 he talked about "most exposures to household products
12 occur with children who are less than 6 years of age,
13 while the products are being used. Seventy-five percent
14 of the potential incidents happen while the products are
15 in use." And he says, "Fortunately, most exposures at the
16 present time are of minor or no consequences. The fact
17 that these incidents are rarely life-threatening is not an
18 accident...as a result of careful medical scrutiny, the
19 nature of risk of exposures to the product and the fact
20 that careful, considered animal testing is being conducted
21 by the consumer products industry today."

22 And then he goes on to cite the American
23 Association of Poison Control Center position, an act of
24 March 11, 1988, which "opposes legislation that would
25 limit the humane use of animals to provide acute or

1 chronic toxicity data until such time as reliable
2 non-animal alternatives exist to provide such data."

3 But the reason I read this, I think it makes
4 both your point and the point of others in the community
5 which is that we should strive to achieve alternative
6 tests, but at least from the point of those -- of some
7 practitioners in the field, we're not at that point yet
8 scientifically--

9 A. And I don't disagree with that. I would say
10 that that physician and myself are very close. I would
11 suspect that if we sat down and talked, we'd agree. I
12 don't think that no animal testing is the answer, but I
13 think that there are certain tests which are totally
14 useless, and most of us would agree on it; that there may
15 well be over testing, there may well be substitutes. And
16 I think we need to look for this. And really, I agree
17 with everything you just read there from that physician.
18 I don't disagree with it.

19 Q. Thank you, Doctor.

20 CHAIRMAN CALTAGIRONE: Jerry.

21 BY REPRESENTATIVE KOSINSKI: (Of Dr. Heller)

22 Q. First of all, I just want to point out, and
23 we keep repeating this, that the focus of the hearing
24 today is the Draize test and the L.D. 50. Could you give
25 us any specifics on those, Doctor?

1 A. Specifics. The Draize test, for example, is
2 done on rabbit eyes and I believe also--

3 Q. But the medical benefits or the benefits as
4 such?

5 A. Well, for example, in the Draize -- I'm
6 sorry, I won't be able to give you product names because
7 I'm not a researcher, but the Draize test itself has been
8 used on some animals and found to not cause a problem in
9 the rabbit and then found to cause a problem in a human,
10 so it has -- I'm sorry I can't give you product names, but
11 it certainly has been shown that that is true. It's not a
12 very good test scientifically. And again, I don't perform
13 this test but, and never would, but it's the kind of thing
14 where one -- six animals are used and if two show a
15 response, therefore it's a positive. If only one shows a
16 response, it's not a positive. Well, that's not really
17 very good scientific method, and I think any researcher
18 would tell you that.

19 Q. Doctor, did you come here of your own free
20 will today? You're not getting paid by any organization?

21 A. Absolutely not. I had to leave my private
22 practice to do so.

23 Q. Thank you.

24 CHAIRMAN CALTAGIRONE: Chris.

25 BY REPRESENTATIVE McNALLY: (Of Dr. Heller)

1 Q. Dr. Heller, I'd like to call your attention
2 to a magazine that my wife and I subscribe to, it's
3 Discover magazine, it's a popular science type of
4 magazine, and in this month's issue there was one
5 particular article, a brief note about a study done by a
6 group at McMaster University in Ontario. And if I can
7 briefly describe the experiment, it was based on the
8 classic Pavlov's dogs experiment. "The study, a joint
9 effort by psychologists and immunologists, used Pavlovian
10 techniques to manipulate the immune systems of rats.
11 Pavlov had trained his dog to associate food with the
12 sound of a ringing bell. The McMaster researchers trained
13 rats to associate injections of an allergen with a humming
14 fan and flashing strobe lights. On three occasions, two
15 groups of rats were given an allergy-provoking shot in
16 conjunction with this disco treatment, but on the final
17 day, only one group was injected with the allergy-causing
18 substance, although both were exposed to the noise and
19 flashing lights. Remarkably, both groups had an allergic
20 response. Blood tests confirmed that rats in both groups
21 had high levels of an enzyme that is released when the
22 immune system triggers an allergic attack. It is the
23 explosive release of such enzymes and other chemicals
24 themselves the symptoms of an allergy - swelling,
25 inflammation, and excess mucous."

1 Now, I think in your testimony you describe
2 that this bill would prevent inhumane treatment of animals
3 that are being tested. Now, under this bill, could a
4 person on the institutional care committee, construing the
5 statutes and regulations both Federal and State, conclude
6 that the injection of rats with an allergy-provoking
7 substance is inhumane and that in fact if someone in
8 Pennsylvania wanted to repeat the experiments done in
9 Ontario, that it's redundant?

10 A. All those things certainly could be referred
11 to. However, I think that many physicians know that
12 allergy responses can be provoked by emotional upset. If
13 you, Pavlovian-wise, train an animal to know that they're
14 going to break out with hives when they see the flashing
15 lights and they are injected, you can subsequently give
16 them the flashing lights and they probably will turn out
17 -- the histamine release will occur. That can be caused
18 by emotional stimulation, and allergists can tell you that
19 as well. Is that a useful test? I think that a committee
20 can determine whether or not it is. I can't tell you what
21 studies have been done along those lines.

22 I'm sure, however, that if that were determined
23 to be a useful study to pursue or to follow, that a
24 committee would say, fine, go ahead and do that testing.
25 We need that information. It needs to be done in a humane

1 fashion. I don't see why it should inhibit studies. I
2 think it would eliminate 16 different people doing the
3 same thing in an erratic manner because, you know, you can
4 do testing to try to achieve the same point, but if
5 everybody's doing the testing in a different fashion, you
6 can't compare the data. So it might even help us to put
7 data together that would be more useful.

8 For example, let me use your example. If I
9 use 30 rats and the next experimenter uses 30 rabbits and
10 the next experimenter uses 30 mice and the next one uses
11 30 monkeys and the next one uses 15 rats and the next one
12 uses 20 monkeys and the next one uses 5 mice, you cannot
13 compare those results. So perhaps if we have closer
14 scrutiny of the testing being done, you'll end up with
15 better data being found and humane treatment can go on,
16 you know, you may eliminate some of the tests that are not
17 considered useful.

18 Q. Well, Doctor, it just seems to me that
19 you're comparing apples and oranges so that, you know,
20 this bill is supposed to be about humane treatment, not
21 about the validity of research.

22 A. I agree with you. You asked me about the
23 validity of research in that particular instance.

24 Q. I asked you whether you think this is
25 inhumane and whether--

1 A. I don't think it's inhumane unless it's
2 unnecessary, and if it were being done simply one group
3 enjoyed doing this thing and it's been done in 50 other
4 places, then it becomes inhumane.

5 Q. Well, I suppose, I am not certain about it,
6 apparently you believe that the Draize test and L.D. 50
7 tests are presumptively that there is an irrefutable
8 presumption that the L.D. 50 test and Draize test have no
9 validity and regardless of how useful the results may be,
10 we shouldn't perform those tests?

11 A. I don't think those results are useful, and
12 that's what I'm saying. If testing--

13 Q. They are not useful per se?

14 A. Right, and I don't think that anyone,
15 really, very many people are going to tell you that the
16 Draize test is very useful.

17 Q. So that all the people who are doing the
18 Draize test and L.D. 50 are simply wasting their money?

19 A. I believe so. I think testing can be done,
20 scientific testing can be done, but the Draize test really
21 isn't a very good scientific test. So the information you
22 get is not going to be very useful. If you do a test
23 well, if you do it scientifically with a scientific
24 method, I think that's a term that we all grew up with,
25 you'll get good data. If you use a test that's not very

1 useful, your data is not going to be very useful.

2 CHAIRMAN CALTAGIRONE: Representative Veon.

3 REPRESENTATIVE VEON: Thank you, Mr.

4 Chairman.

5 BY REPRESENTATIVE VEON: (Of Dr. Heller)

6 Q. Doctor, thank you for being here today. I
7 wanted to follow up on your point that you made just in
8 the last couple of sentences about the Draize test not
9 being necessary. Well, I have various documentation from
10 really these three agencies, all of which are dated 1988.
11 Maybe you can shed some new light if this has changed, but
12 I have a letter from the FDA, I have a letter from the
13 EPA, and a letter from the U.S. Consumer Products Safety
14 Commission who obviously all have varying regulatory
15 functions in testing of products. It is my understanding,
16 at least reading these letters and very specific questions
17 asked them in response to the bill in New Jersey that if
18 the Draize test is necessary in their specific regulatory
19 areas. All of them have a different area, of course, and
20 that the answer from all three of them was yes. This was
21 letters in response to the bill in New Jersey. And I can
22 give you the specific question and answer they gave, which
23 was rather lengthy, but the question is, is the Draize
24 test necessary to perform your regulatory function? And
25 these letters say yes, but these were 1988 and I wonder if

1 you had--

2 REPRESENTATIVE KOSINSKI: Mr. Chairman, is
3 the person, Representative Veon, who wrote that a medical
4 doctor?

5 REPRESENTATIVE VEON: No, Ph.D.,
6 Commissioner of Food and Drug.

7 REPRESENTATIVE KOSINSKI: Ph.D. It doesn't
8 say what his Ph.D. is in, it doesn't have any background
9 of medical research. What are the things--

10 REPRESENTATIVE PICCOLA: Mr. Chairman, I
11 object to Mr. Kosinski interrupting Mr. Veon in his
12 questioning. Mr. Kosinski will have the opportunity to
13 ask questions when he's duly recognized. I think the
14 procedure of a public hearing is to let each member ask
15 questions--

16 CHAIRMAN CALTAGIRONE: Certainly.

17 REPRESENTATIVE PICCOLA: --and not to be
18 cross-examined by the members.

19 REPRESENTATIVE KOSINSKI: We'll carry on the
20 debate later on this afternoon at our taping, Jeff.

21 REPRESENTATIVE PICCOLA: I'm looking forward
22 to it, Jerry.

23 CHAIRMAN CALTAGIRONE: Thank you, gentlemen.

24 REPRESENTATIVE VEON: I understand the
25 gentleman, Mr. Kosinski's question, and the answer in each

1 of these cases may be yes, may be no. I'm not sure.

2 What I'm trying to get to, obviously, is
3 that they attempted to articulate an official position of
4 the Food and Drug Administration, the Environmental
5 Protection Agency, and the Consumer Products Safety
6 Commission, and each of them have tried to articulate an
7 official position.

8 BY REPRESENTATIVE VEON: (Of Dr. Heller)

9 Q. And I just wanted to follow up on that,
10 based on your question, and you may or may not be familiar
11 with this, I didn't mean to put you on the spot, but if
12 you have some opinion as to their positions, I'd be
13 interested in hearing that.

14 A. Well, yes, I do, and it's the same thing
15 I've been saying, I think. The testing has been done for
16 years. It really hasn't helped us physicians make
17 decisions about how to treat exposures, all right? It
18 doesn't always cross. The information that you get from
19 the animal does not always cross to the human, okay? The
20 Draize test, in particular, the scientific community I
21 think would say that it is not a very scientific test.
22 It's -- it doesn't give you very good data. It's too
23 subjective. So that you have three commissions or people,
24 I don't know who those people are that you're referring
25 to, saying that perhaps they're administrators, perhaps

1 they work for the EPA, I assume, and are paid by the EPA.
2 They're not the physicians like myself who are out in the
3 front lines. Now, I'm not an emergency room physician, so
4 routinely I do not treat poisonings, but as a physician, I
5 certainly do get an awful lot of phone calls. An
6 obstetrician gets a lot of phone calls about medications.
7 What can I take? What should I avoid? And we don't use
8 the information gotten, for the most part, from animal
9 testing, particularly the Draize test, to tell people what
10 to avoid.

11 Q. I appreciate that from a perspective of a
12 member who is trying to make up his mind on this issue. I
13 guess the point I'm trying to make and wanted to get some
14 feedback from you on was that these are official positions
15 of three Federal regulatory agencies who are telling State
16 legislators that these tests are necessary for us to do
17 our job as we attempt to regulate these products, as
18 Congress directs us to do. So I'm trying to get some
19 feedback here, and I know that there are other folks who
20 will be testifying today that maybe can elaborate on that,
21 but I think that would be, at least for this member, an
22 important point as to their official position, how that
23 relates to our role and job as State legislators in trying
24 to determine how we ought to vote on this issue, and I
25 appreciate your--

1 Professor of Veterinary Medicine from Penn State
2 University, and Director of Laboratory Animal Services.

3 DR. FERGUSON: Mr. Chairman, members of the
4 committee. My name is Frederick Ferguson, and I am a
5 Professor of Veterinary Science and Director of Laboratory
6 Animal Resources at the University Park Campus of
7 Pennsylvania State University.

8 My statement this morning is a result of my
9 concern about the potential impact of House Bill 873 on
10 the research environment in the Commonwealth of
11 Pennsylvania and my concern about the poor cost/benefit
12 ratio of this legislation in light of other existing and
13 pending regulations and laws.

14 The use of animals in the advancement of
15 scientific knowledge has provided many important
16 contributions of which we are all beneficiaries. A prime
17 example of this is the fact that a majority of the
18 significant research advances made by the Nobel laureates
19 alone in medicine and physiology in the last 88 years have
20 depended to some degree on the use of animals. I suspect
21 that each of us can identify some of these contributions,
22 such as the development of the polio vaccine, or the
23 definition of the genetic complex associated with tissue
24 transplantation, that have positively impacted on our
25 lives.

1 The use of vertebrate animals in research is
2 a very complex societal issue which, through the years,
3 has required public assurance that animals used for these
4 purposes are provided proper care and handling. Since the
5 early 1960's in the United States, the need for this
6 assurance has resulted in considerable legislative and
7 regulatory activity that is impacted on the use of
8 animals. An eminent danger, I believe, of this activity
9 is that future research which would improve the health and
10 well-being of both animals and man may be seriously
11 impeded by excessive regulation.

12 House Bill 873, amending Title 18, Crimes
13 and Offenses of the Pennsylvania Consolidated Statutes,
14 regulating animal research and providing penalties, has
15 the potential to have a significant negative impact on
16 research throughout the Commonwealth of Pennsylvania.

17 Now, I'm not going to go through in detail
18 the rest of the things in my statement because of the time
19 involved, but I would like to, first of all, express some
20 of my specific concerns about this bill. And some of
21 these have already been discussed.

22 This bill duplicates many Federal statutes,
23 regulations, and guidelines pertaining to the care and use
24 of animals for research purposes. As a result, I feel it
25 would necessitate or require unnecessary expenditures of

1 both money and labor by research organizations within the
2 Commonwealth, and in addition, by the Pennsylvania
3 Department of Agriculture. I think the economic impact
4 would be considerable, and I think it's extremely
5 important that this be carefully evaluated before this
6 bill is passed.

7 My second concern is, and again, this has
8 been addressed already this morning, if the purpose of
9 this bill is to license those organizations not covered by
10 existing Federal laws and regulations, this should be more
11 clearly stated. Persons and organizations covered by
12 related Federal laws and regulations should be excluded
13 from the provisions of House Bill No. 873.

14 My third concern is that as proposed, this
15 bill presents no support for the improvement of the
16 Commonwealth research environment. In contrast, a bill
17 which would support funding to improve existing animal
18 research programs would be well received. Funds could be
19 effectively and very constructively used for improving
20 research programs and facilities for primary housing, for
21 creating of personnel involved in care and use of animals
22 throughout the Commonwealth.

23 There are, and I've listed in my statement,
24 a number of the areas where I feel there is duplication.
25 Specifically, there is, I think, in terms of licensure or

1 registration; concerns about humane handling, care and
2 treatment; inspections, both unannounced and announced;
3 the training of researchers; technicians in attendance;
4 and the formation and role of the institutional animal
5 care and use committee. The specific existing and pending
6 laws and regulations I've proceeded to describe here, but
7 basically they include the Animal Welfare Act, which was
8 first passed initially in 1966 and subsequently has been
9 amended three times, and presently we have regulations
10 related to the 1985 amendment that are pending and should,
11 in fact, been in effect if things move as they are
12 intended sometime this summer.

13 Briefly, the regulations that are pending
14 indicate that institutions covered by the Animal Welfare
15 Act must have an institutional animal care committee
16 consisting of three members, one of which is a
17 veterinarian, the second member has to be a
18 non-institutional affiliated person who is able to
19 represent the public and the community. This committee
20 must review all protocols involving the use of animals and
21 make semi-annual inspections of animal care and use
22 locations. It has to provide reports, both to the
23 institutional officials, and items of noncompliance must
24 be reported to the United States Department of
25 Agriculture.

1 The second bill that impacts on research
2 that is in existence is the Health Research Extension Act
3 of 1985. This act changed the Public Health Service Act
4 and included in it a number of things, again, that are
5 duplicated in the bill that we're considering this
6 morning, and I won't go into all those. They are listed.

7 One of the specific things that the Public
8 Health Service Act amendment required was the protocol
9 review process by an institutional committee. And I've
10 listed on one of the pages the kind of things that go into
11 that protocol review process. This protocol review
12 process has required institutions to set aside a great
13 deal of professional time in committee service to review
14 these protocols, but the protocol review includes, for
15 example, the requirement that it must include a detailed
16 description of the proposed use of animals, and I think
17 the important word there is "detail". It has to identify
18 the species, the strain, age, sex, numbers of animals.
19 Numbers of animals is very important. It has to justify
20 the use or the rationale for the use of animals. It has
21 to indicate veterinary care provisions that are available
22 for these animals. It has to describe the housing
23 conditions that these animals will be maintained under.
24 It has to provide an assurance of what the training and
25 qualifications of the personnel doing the work is. It has

1 to describe the use of analgesics, anesthetics,
2 tranquilizers, and restraint that may be necessary in
3 carrying out a particular project. And finally, it has to
4 describe the methods of euthanasia.

5 Now, another document that first evolved in
6 the early 1960's was the "Guide for the Care and Use of
7 Animals," which was produced through the Public Health
8 Service. It's an NIH publication. It's been revised
9 repeatedly. It's been termed a living document in the
10 sense that it's meant to respond to changes that are
11 occurring as far as research activities nationally, and I
12 think it has done a very good job of doing this. And I do
13 believe that most institutions and organizations doing
14 research on animals do use this guide as an important
15 basis for providing them with things to relate to as far
16 as projects and research activities.

17 There are a number of other legal and
18 regulatory provisions that impact on the use of animals -
19 the Endangered Species Act, the Marine Mammal Protection
20 Act, and certainly the Good Laboratory Practice
21 Regulations.

22 Now, as far as enforcement and
23 implementation of all of these various regulations, there
24 are a number of systems already in place that have this
25 responsibility and carry out these functions. They

1 include the Animal and Plant Health Inspection Service,
2 the Public Health Service, a number of other Federal
3 agencies such as the Food and Drug Administration. There
4 are also -- there is also a nonprofit organization called
5 the American Association for the Accreditation of
6 Laboratory Animal Care that many institutions participate
7 in within this State and nationally.

8 Under the Animal and Plant Health Inspection
9 Service activities, which is part of the USDA, unannounced
10 inspections are carried out by a Federal employee to make
11 sure that institutions do comply with requirements of the
12 Animal Welfare Act. Research facilities have a number of
13 obligations under the act and have to be able to provide
14 the information that these inspectors require.

15 With the changes in the Public Health
16 Service Act, the Public Health Service has instituted a
17 program of unannounced inspections to research animal care
18 and use programs. In addition, granting agencies' review
19 teams where there are animals involved with research
20 projects very frequently will ask to look at the animal
21 facilities and review the programs in place that are
22 important as far as the care and use of laboratory
23 animals.

24 The American Association for the
25 Accreditation of Laboratory Animal Care carries out

1 inspections for those institutions that are involved with
2 it, and it uses a Public Health Service Guide and the
3 Federal Animal Welfare Act as a primary reference document
4 for its peer review process.

5 And finally, within the State of
6 Pennsylvania, under Act 225, the Dog Law, research
7 facilities using dogs are inspected by a representative of
8 the Pennsylvania Department of Agriculture.

9 The next item in my statement related to
10 licensure, and this has been addressed to some extent
11 already. The concern is that I don't believe that the
12 bill clearly indicates just who should be licensed and who
13 shouldn't be licensed, and also who then will be covered
14 by the State enforcement through the United States
15 Department of Agriculture, should it exist.

16 In summary, it's been over 35 years since
17 work with monkey and human kidneys have enabled the growth
18 of human polio virus in cell culture. I think a lot of us
19 here perhaps were alive at the time that polio was a very
20 serious disease in the world, and it isn't anymore.
21 Animals were important as far as that research is
22 concerned. Today we're confronted with other diseases -
23 AIDS disease, Lyme Disease. We and those to follow us,
24 including animal populations, will undoubtedly be
25 dependent upon the special benefits that are provided by

1 the use of animals and human surrogates to improve the
2 quality of our lives. We are obligated to protect the
3 privilege of using animals in research, however, I think
4 we must also protect the resultant benefits by not
5 overregulating research in the Commonwealth of
6 Pennsylvania. I think what we have to consider seriously
7 when we look at this bill is whether or not the
8 expenditures that could result really are necessary in
9 light of what already exists.

10 Thank you.

11 CHAIRMAN CALTAGIRONE: Thank you.

12 Jerry.

13 BY REPRESENTATIVE KOSINSKI: (Of Dr. Ferguson)

14 Q. Doctor, how much would this cost Penn State
15 specifically?

16 A. We're talking about the State bill now?

17 Q. Um-hum.

18 A. Penn State, specifically, I'm not sure,
19 quite honestly, it would cost us a whole lot.

20 Q. A whole lot. How much is a whole lot?

21 A. I can't put a figure on it, okay?

22 Q. Could you get that information to me?

23 A. I possibly could, yes. We do, since I think
24 as I said, we already have many of these things in place.
25 They duplicate. I think some of the areas of costs that

1 would be involved with this would be if there are
2 additional inspections, additional paperwork, and
3 additional bureaucracy to be superimposed on an already
4 pretty substantial one.

5 In addition to that, I think what I'd be
6 more concerned about as a taxpayer in the State of
7 Pennsylvania is the cost that's going to be incurred to
8 the Pennsylvania Department of Agriculture. It's going to
9 be substantial.

10 Q. But you can't identify the cost. See, you
11 used the term "substantial" a lot--

12 A. I can't. I wish I could.

13 Q. --but as a legislator, we have to deal with
14 specifics.

15 A. I'm not an economist. I'm sorry.

16 Q. If you could get me those figures, I'd
17 appreciate it, because I don't want somebody to give us
18 information that is faulty.

19 A. One of the difficulties, I might say, with
20 providing that kind of figure, just as it has been with
21 the Federal laws, is that until we see the regulations,
22 there's really no good way to give you a fair projection,
23 and in fact with the regulations that exist for the United
24 States Department of Agriculture right now, we've seen
25 figures of a billion dollars, we've also seen figures of

1 \$2 billion to \$4 billion. We don't know.

2 Q. Okay. Have you ever appeared in front of a
3 Federal legislative body?

4 A. No, I have not.

5 Q. On such legislation?

6 A. No, I haven't.

7 Q. Do you know the standard or the stand Penn
8 State took on whether they wanted tougher Federal
9 standards or lessened Federal standards in this area?

10 A. I'm not sure what you're asking me.

11 Q. Has Penn State lobbied the Federal
12 government for either tougher standards in these areas or
13 lesser standards in these areas?

14 A. I don't know that we've lobbied either way
15 on some of these things. I think in fact where there has
16 been some concern about what the content of a particular
17 bill or piece of legislation is, there has been some
18 lobbying done, yes.

19 Q. Okay, you don't know which way, though?

20 A. I would guess in most cases it was against
21 any kind of additional bureaucratic concerns, you know,
22 that might be projected.

23 Q, But you still say in the broader
24 philosophical question that the Commonwealth can send you
25 \$220 million a year to support your university, but we

1 shouldn't have any say in what goes on in that particular
2 university?

3 A. No, I'm not saying that.

4 Q. Okay. One thing I want to correct the
5 record on. Page 1, concern 3, "the Bill presents no
6 support for improvement of the Commonwealth research
7 environment." I am somewhat insulted, as a legislator who
8 sits on the Education Committee and who's been to Penn
9 State -- I am a Penn State grad -- on a number of
10 occasions to help fund a number of your projects,
11 including the microbiology lab. You're familiar with
12 that, Doctor?

13 A. Yes, I am.

14 Q. We've helped with that, and we've helped a
15 lot, and we've helped with the Ben Franklin Partnership

16 A. What I'm referring to here is specifically
17 those things that impact on the use of animals.

18 Q. Well, would the microbiology lab impact on
19 animals?

20 A. It may very well in terms of research, but
21 it certainly hasn't impacted on things that we might do
22 directly in terms of providing things for the animals that
23 are used in that research.

24 Q. The term you use is "Commonwealth research
25 environment".

1 A. Well, perhaps I should have changed that. I
2 do go on there to discuss the specifics of what I was
3 talking about.

4 Q. Because we've been very good in a number of
5 programs that way, and it takes me a bit aback when I'm
6 told that we're not.

7 A. There's no doubt about that. I think
8 Pennsylvania State University appreciates that.

9 CHAIRMAN CALTAGIRONE: Representative
10 Murphy.

11 BY REPRESENTATIVE MURPHY: (Of Dr. Ferguson)

12 Q. Doctor.

13 A. Yes, sir.

14 Q. Your testimony really very much focused on
15 the potential redundancy between Federal and State law,
16 and I assume that's a legitimate concern, and let's, for
17 the moment, assume that we address that by amendment of
18 the bill and put together so that they fit nicely in State
19 and Federal regulation. Can I assume that you have no
20 opposition to the search warrant provisions? Removing the
21 exclusion of research laboratories in the search warrant
22 provision?

23 A. Well, I, quite honestly, don't want to get
24 into the search warrant provisions. I think there are
25 some other people here that will discuss it as far as what

1 the concerns are. I would say that where my concern would
2 be would relate specifically to who is involved with doing
3 the searches and what is the outcomes of the searches.

4 Because I can think of instances where there is research
5 going on and maybe more so in terms of what's going on for
6 the benefit of animals where, say, there are genetic
7 models of, and I know based on experience that in visiting
8 other research facilities around the country and
9 veterinary schools and so on where there is this kind of
10 research going on where we're trying to understand better
11 disease processes in animals, it's extremely important
12 that the people that would come in and look at this
13 process or look at what's going on be able to make a
14 judgment, I think, of how it relates to whatever
15 determination they might make. In other words, the
16 research or the scientific part of the activity, I think,
17 has to be a part of any evaluation of this type that would
18 go on.

19 Q. You understand the search warrant provisions
20 are the same that you live under today as an individual in
21 the Commonwealth of Pennsylvania?

22 A. That may very well be, you know, but I don't
23 have a problem with that if that, in case, is a fact. But
24 I think we have to look very carefully at how it's worded
25 and what would come out of something like this.

1 Q. I understand that.

2 The L.D. 50 and the Draize test, Doctor, do
3 you have any problem with prohibiting those? In fact,
4 does Penn State University conduct the L.D. 50 or the
5 Draize test?

6 A. On occasion -- they wouldn't conduct an L.D.
7 50, that I'm aware of, or a Draize test, per se.

8 Q. So you have no involvement with those tests
9 and that part of it would not impact you at all?

10 A. I can't say that. It could potentially
11 impact us. Certainly we have a biotechnology institute
12 and we have people who possibly could be doing things
13 where this kind of test may be necessary. It is not
14 something I think that anyone enjoys having to do. It is
15 something I think that has been referred to here this
16 morning that on occasion, at least as far as the
17 information we have available, doesn't have a substitute.

18 Q. And finally, Doctor, if the Federal
19 regulations have been adequate, why did the University of
20 Pennsylvania Head Injury Laboratory happen, Biosearch, the
21 kind of abuses happen, or why have there been any number
22 of other instances around the country where there have
23 been actions taken against facilities, prestigious
24 facilities regulated by the existing Federal law, as you
25 say, are adequate and they've been found to be seriously

1 inhumane in significant violations to existing statutes?

2 A. I'm not sure of the relevance of your
3 question for several reasons.

4 Q. The relevance, Doctor, is that you're
5 telling us that existing regulations are adequate.

6 A. Well, let me say something.

7 Q. Let me finish, Doctor. You quoted that in
8 1985, in fact some of the existing regulations -- most of
9 the existing regulations that you say are adequate --
10 covered what went on at the University of Pennsylvania.

11 A. What year did the thing at the University of
12 Pennsylvania happen?

13 Q. 1985. Biosearch was 1988.

14 The Institute of Behavioral Research in
15 Maryland was 1986 and '87.

16 A. I'm not sure about those dates, okay?

17 Q. I am.

18 A. Okay. Well, if in fact they are, I'd like
19 to check those dates and make sure that they get entered,
20 because I think they are important. There have been some
21 changes in the Federal regulations that have resulted from
22 these, and I'm not going to sit here and tell you that
23 there aren't instances where problems may occur, okay?
24 It's like anything else. It's the same reason we've got
25 drunken drivers and people die because of it. I'm not

1 going to say that doesn't happen. I'm saying that we do
2 have some extremely good regulations in place. We've got
3 some regulations pending that are going to impact
4 tremendously on us, and I think to superimpose on this
5 some additional things at this time, you know, isn't
6 necessary.

7 CHAIRMAN CALTAGIRONE: Representative
8 Hagarty.

9 REPRESENTATIVE HAGARTY: Thank you.

10 BY REPRESENTATIVE HAGARTY: (Of Dr. Ferguson)

11 Q. I'm trying to understand the Federal and
12 State regulations you're referring to. Are you indicating
13 that -- I thought that I heard the sponsor say when he
14 testified that those institutions that are now federally
15 regulated would not be required to be State regulated. If
16 that's the case, do you have any objection to State
17 regulations?

18 A. That was one of the concerns that I had in
19 my statement.

20 Q. But if that were clear, and I think that's
21 what the sponsor said, you then have no concern about
22 State regulations as long as--

23 A. It depends on what those regulations are and
24 what they pertain to. Okay? Because I think that some of
25 the things that are here go beyond what presently exists

1 as far as Federal regulations are concerned, and I think
2 we have to look at those very carefully.

3 Q. I see. You support Federal regulations, you
4 support an amendment, but you don't support State
5 regulations going beyond them, is that my understanding?

6 A. That would depend. No, I'm not saying that.
7 I'm saying I think we have to look at what those State
8 regulations are that we're talking about and what they
9 address.

10 Q. Okay, I understand your answer. Could you
11 tell me, I don't know, what types of institutions are not
12 covered by Federal regulations?

13 A. Secondary schools, I believe, are not
14 covered. There are some exclusions based on the species
15 of animals that are used. This particular law, 873,
16 covers all vertebrate animals. The Federal law doesn't at
17 this time. It covers warm-blooded animals. Some of the
18 Federal regulations do cover vertebrate and other
19 guidelines and so on do cover vertebrate animals. There
20 are some organizations that are excluded.

21 Q. That aren't covered. All of the regulations
22 and laws that you refer to, are they Federal? Throughout
23 your testimony you refer to the various existing
24 regulations and laws. Are they all Federal?

25 A. They're all Federal except for the State Dog

1 Law which exists.

2 Q. I'm familiar with that. And I have one
3 other question. I do not intend to prohibit research that
4 is necessary for medical improvements, and so I'm curious,
5 what specifically, what specific language in this do you
6 see that will harm the use of animal research or impede
7 the use of animal research for medical advances?

8 A. I think the problem really is the fact that
9 the bill isn't that specific.

10 Q. But that's not legitimate.

11 A. I know that.

12 Q. You can't tell me that a tone of a bill has
13 the effect of law and is going to prohibit research. And
14 so what I've said, and I've said it to the other people
15 who have talked to me about this is, tell me what in here
16 do you think will impede research? Or if not, what
17 language do you need to change?

18 A. I think any time that we superimpose
19 additional regulations on the process of research, we're
20 going to impede research.

21 Q. So there's nothing specific in here though
22 that you think will impede the use of animal research in
23 medical advances?

24 A. Oh, I do think there is.

25 Q. What?

1 A. I think once we start superimposing
2 additional requirements on the researchers doing
3 experimentation, and we've already done that with some of
4 these Federal laws and new Federal regulations. There's a
5 great deal of time that's required by our faculty at Penn
6 State, for example, that goes into this process.

7 Q. But I'm not going to vote -- I don't vote on
8 Federal rules. All I want to know is if this only applies
9 to institutions that aren't now covered by Federal
10 regulations, other than the two specific tests that we've
11 heard about, what specifically in here will impede
12 regulations? Not what Federal regulations have done.

13 A. Okay, I didn't understand your question
14 then.

15 Q. I don't vote in the United States Congress.

16 A. If you're excluding those covered by Federal
17 regulations, then I can't speak to that specifically, but
18 because, for example, our university and most of the major
19 research organizations in the State of Pennsylvania are
20 covered by existing Federal regulations.

21 Q. Thank you.

22 CHAIRMAN CALTAGIRONE: Representative
23 McHale.

24 REPRESENTATIVE McHALE: Thank you, Mr.
25 Chairman.

1 BY REPRESENTATIVE McHALE: (Of Dr. Ferguson)

2 Q. Doctor, I listened carefully as you answered
3 the questions presented to you by Representative Murphy,
4 and I didn't understand your answers in their entirety.
5 You indicated that subsection (d) on page 3 of the bill
6 could have an adverse impact on potential research and
7 other related activities at Penn State, and what that
8 section says is "Prohibited tests.-- A person may not
9 subject a live animal to an eye irritancy test, including
10 the Draize eye irritancy test, or use a live animal in an
11 acute toxicity test, including the L.D. 50 test," and I
12 emphasize now, "for purposes of testing cosmetics or
13 household products."

14 How could that conceivably impact upon Penn
15 State?

16 A. Well, if we're talking specifically about
17 that, I would guess that it probably would not directly.
18 I can't speak--

19 Q. How would it indirectly?

20 A. Indirectly, it's possible that there may be
21 something that is developed--

22 Q. Does Penn State test cosmetics?

23 A. No, it doesn't.

24 Q. Or household products?

25 A. No, it doesn't, but there is the possibility

1 that something that could be developed at Penn State would
2 ultimately end up in that role as far as the use is
3 concerned.

4 Q. When was the last time Penn State conducted
5 those kinds of tests specifically for purposes of
6 evaluating cosmetics or households products, as the bill
7 is currently limited? When was the last time you engaged
8 in that kind of research?

9 A. I can't even -- not in my experience at Penn
10 State, which has been considerable.

11 Q. So you've had no past experience?

12 A. Right. If we're talking particularly about
13 Penn State, okay, but this bill doesn't talk just about
14 Penn State. It talks about--

15 Q. May I limit that? The question from Mr.
16 Murphy had to do with Penn State. You appear before us
17 today based on your credentials at Penn State.

18 A. No, I don't. I'm really appearing here as
19 an individual and not necessarily as a representative of
20 Penn State.

21 Q. That was going to be a later question that I
22 was going to present to you.

23 A. Okay.

24 Q. But at this point, the question was raised
25 by Representative Murphy as to how this would impact upon

1 Penn State. We, as State legislators, are concerned about
2 that because Penn State is obviously one of our finest
3 State institutions. You implied, if not stated, in your
4 earlier answer that that section would impact upon Penn
5 State. I'd like to know how?

6 A. I can't honestly say that the potential
7 doesn't exist that it would, okay?

8 Q. If you could amplify that and tell us how
9 cosmetic testing and household product testing, using
10 these types of toxicity tests, could impact upon Penn
11 State?

12 A. Okay, let me give you a for instance.

13 Q. Please.

14 A. See, one of the things that is obviously
15 occurring at many educational institutions throughout the
16 country and throughout the world is that there are a
17 number of initiatives that relate industry and
18 universities, academic institutions. And I think the
19 possibility does exist, could exist, I'm not saying it
20 will exist, that there may be something that would be
21 developed for those purposes that would ultimately -- for
22 example, the patenting, okay that would ultimately develop
23 in terms of patenting that could be dependent on something
24 that might be inferred as far as this kind of testing,
25 toxicity testing. Certainly the University of Wisconsin

1 has benefited through the years tremendously, its research
2 program has benefited tremendously, from something that
3 we're all familiar with called Warfarin. It was named
4 that because it came from Wisconsin Alumni Research
5 Foundation. Warfarin, as you may or may not know, is a
6 retinocide. The University of Wisconsin has acquired a
7 great deal of money for its research programs because of
8 the use of that product, because of the patent rights
9 associated with that product.

10 Q. But to the best of your knowledge, this type
11 of testing has never previously occurred at Penn State?

12 A. Not that I'm aware of.

13 Q. And to the best of your knowledge, there are
14 no current plans for such testing at Penn State?

15 A. That's true.

16 Q. Well, I think that's a different answer, at
17 least implicitly a different answer, from the one that you
18 gave Representative Murphy a bit earlier.

19 A. Okay, well, in a sense I may have
20 misunderstood Representative Murphy's question, because
21 again, I hope that my intent is, I think, to answer these
22 questions more as it relates to the environment in Penn
23 State.

24 Q. Well, we're talking about a bill, not an
25 environment. I look at the patch that you're wearing,

1 "Animal Research - We All Benefit." Frankly, I agree with
2 that statement, but that's not the issue under
3 consideration in this legislation. It's not a question
4 whether animal research can potentially benefit human
5 health. It can. I think that's quite clear. And for
6 that purpose, I support it. But when I look at subsection
7 (d), which is limited to the testing of cosmetics and
8 household products, I think that's a very different issue.

9 A. But you're talking about a specific
10 subsection here and what it relates to--

11 Q. That's correct.

12 A. And what I'm talking about or what I was
13 speaking to was the whole bill here.

14 Q. I think you're speaking philosophically and
15 we're speaking texturally. We're addressing a certain
16 specific piece of legislation, not a broader social issue,
17 and I don't want to take up a great deal of time.

18 A. Right. You're addressing a particular part
19 of that piece of legislation right now. I think other
20 people here are more qualified to address that issue and
21 will as the morning or the day goes on.

22 Q. The second section, "Refusal to participate
23 in experimentation.--No employee or student who refuses to
24 participate in experimentation, research, or teaching
25 methods involving dissection or vivisection shall be

1 penalized for refusal to participate based upon the
2 individual's fundamental beliefs." Do you object to that?

3 A. I don't object to that.

4 Q. Are you aware, you were speaking earlier in
5 terms of the redundancy that you allege to exist in this
6 proposed legislation, proposed statute, are you aware of
7 any other State or Federal law which gives this kind of
8 protection based on the beliefs of conscience held by an
9 individual student? Would this be redundant?

10 A. I can't speak to that. It's not something
11 that I'm that well-informed on, quite honestly, so I'd
12 rather not address it.

13 Q. But to the best of your knowledge, as you
14 sit here today, you're not aware of any other Federal or
15 State law that grants this kind of protection, are you?

16 A. No, I'm not.

17 Q. All right, my final question is, you
18 indicated earlier that you do not appear as a principal
19 spokesperson today on behalf of Penn State, that you
20 appear in a private capacity. The credentials, however,
21 that identify, you indicate that you're the Director of
22 Laboratory Animal Resources at the University Park Campus
23 of the Pennsylvania State University, but you've not been
24 directed to appear today on behalf of Penn State, have
25 you?

1 A. No, I have not.

2 Q. How did it come that you did appear before
3 us today? Are you representing any other organization?

4 A. No, I'm here as much representing myself and
5 my concern.

6 Q. I don't mean to draw any conclusions, but I
7 see that you're wearing the same patch, the same badge,
8 worn by most of the other corporate interests sitting in
9 our audience. Is that a coincidence?

10 A. No, it's not, because I guess I agree with
11 what the badge says, so.

12 REPRESENTATIVE McHALE: All right.

13 Thank you, Mr. Chairman.

14 CHAIRMAN CALTAGIRONE: Thank you.

15 Representative Heckler.

16 REPRESENTATIVE HECKLER: Thank you, Mr.
17 Chairman. I have just a few questions and an observation.

18 BY REPRESENTATIVE HECKLER: (Of Dr. Ferguson)

19 Q. I understand, and it is frequently the case
20 with scheduled hearings with long lists of witnesses, that
21 the folks are going to advocate one view of an issue or
22 one position on a bill to sort of break down their subject
23 matter, and it's plain that that's occurred here, but at
24 the risk of taxing you further, Doctor, I would ask -- I
25 mean, frankly, one of the provisions of this bill that

1 jumps out at me is the elimination of the prohibition on
2 the issuance of search warrants to people about whom we
3 have no particular guarantee of training who are officials
4 of associations for the prevention of cruelty to animals
5 to conduct searches at biomedical research facilities. If
6 that, and I won't ask you to deal with it at length, there
7 are some other witnesses going to, but would that repeal,
8 looking at that part of the bill alone, if we simply took
9 that language out of existing cruelty to animals law,
10 would that have an impact on Penn State, and if so, what?

11 A. If you took the wording that already exists
12 in the bill out? Is that what you're saying?

13 Q. No, no, I'm sorry. The law right now, the
14 cruelty to animals law, contains language which says no
15 search warrant -- first of all, contains a body of
16 language authorizing issuance of search warrants to agents
17 of cruelty to animals, associations for the prevention of
18 cruelty to animals and similar organizations incorporated
19 under the laws of the Commonwealth. At the end of that
20 authorizing section, there is a specific prohibition.
21 That prohibition says, "No search warrant shall be issued
22 based upon an alleged violation of this section which
23 authorizes any police officer or agent or other person to
24 enter upon or search premises where scientific research
25 work is being conducted by, or under the supervision of,

1 graduates of duly accredited scientific schools or where
2 biological products are being produced for the care or
3 prevention of disease." This bill proposes to take out
4 that prohibition, thereby authorizing agents of such
5 organizations to obtain the issuance of search warrants
6 upon the allegation that cruelty to animals is occurring
7 in those facilities. Those search warrants would
8 authorize the seizure of those animals as evidence of
9 those alleged violations. Would that impact on Penn
10 State, and if so, how?

11 A. Yes, I think it has the potential to do
12 that, because I think it has the potential to result in
13 someone coming in and examining animals that are being
14 used in particular kinds of research studies that may have
15 conditions that because of the backgrounds of the people
16 that would be doing or carrying out the search warrants,
17 they wouldn't be able to understand exactly why those
18 animals are there and what their purpose is in terms of
19 value, and some of these animals are extremely valuable.

20 Q. My next question, the institutional care
21 committees which would be required under this legislation,
22 and as I understand it, Federal law and regulation already
23 requires in those institutions which are federally
24 regulated the existence of such a committee, is that
25 correct?

1 A. That's correct.

2 Q. This bill mandates that one of the members
3 of any such committee be a member who is a representative
4 of an incorporated humane or animal welfare organization.
5 Is that presently a requirement under Federal law?

6 Q. That is not presently a requirement under
7 Federal law.

8 A. If this additional requirement were viewed
9 to impact upon Penn State, even though it is federally
10 regulated, upon the passage of this legislation, do you
11 have any opinion whether that provision would impact upon
12 Penn State, and if so, how?

13 A. Again, I think it has the possibility of
14 impacting significantly. Until you've been involved with
15 the committee process that has evolved, our committee, for
16 example, and I use it as an example, but I think it
17 probably reflects what's going on nationally and in other
18 areas within the State. Our committee meets weekly, or
19 part of our committee meets weekly, possibly sometimes for
20 three to four hours in the form of subcommittees to
21 consider protocols or projects that are being submitted.
22 The committee itself meets once or twice a month, and the
23 time involved there usually is a good part of an
24 afternoon, it involves, in our case, as many as 14 or 15
25 faculty members. There's a lot of time involved with it.

1 The process is slow, it's done carefully. I think if we
2 inject on top of this some people whose intent may not be
3 directed at or be of the opinion that animals should be
4 used for research, that the potential for harassment of
5 these committees and the time expended and so on could
6 expand considerably.

7 Q. Well, let me ask another question along
8 those lines. One of the -- certainly one of the broad
9 philosophic objectives of this legislation is to make sure
10 that somebody is counting the cost to animals, is not just
11 saying, gee, it would be interesting to do this and not
12 looking at the sacrifice that is being made by the animals
13 who are being used for that. Of the present -- in other
14 words, at Penn State you have such an institutional care
15 committee. All right, is there any -- what members of
16 that committee are likely to count the cost to animals,
17 are likely to be an advocate, if you will, in that process
18 for moderation for the animals' point of view, if you
19 will?

20 A. We have on our committee at Penn State right
21 now, and again, this may not parallel other institutions,
22 we have five veterinarians on our committee. We have a
23 person that is an ethicist, a non-scientist, a
24 philosopher, we have an outside member of the community at
25 large that is not affiliated with Penn State University,

1 and these people are, along with the members of the
2 committee, I might add, the other scientists that are
3 involved with this committee are, I think, extremely
4 concerned about the use of animals, how they're used,
5 numbers, why they're being used, and so on. The process
6 is a good process. It's been an interesting process, but
7 it is a time consuming process.

8 Q. To what extent are either the deliberations
9 of that body or the written protocols or whatever is
10 formulated by that body the public record?

11 A. I think that's probably going to vary from
12 organization to organization. The specific deliberations
13 certainly are available through the various agencies that
14 are involved with enforcement. As far as, you know, are
15 they published or this kind of thing, I'm not aware they
16 are. They may be for some organizations.

17 Q. Well, it occurs to me that in looking at
18 ways to try to address the legitimate interests of all
19 sides of this issue, that one of the ways to address some
20 of the concerns of those concerned about animals would be
21 to provide some access at least to the results of that
22 process and some ability to challenge decisions which
23 emerge from that process which would seem not to be --
24 would seem to be egregious or not supportable
25 scientifically, and that's why I'm wondering if the

1 Federal procedure creates that opportunity for somebody in
2 some local ASPCA or some other organization to say, fine,
3 decisions 1 through 15 we think are legitimate, but
4 decision 16 is not appropriate. Is there any such
5 procedure at this point?

6 A. I don't know if there's any such procedure
7 as far as specific protocols are concerned. I think
8 indirectly, you know, this exists. One of the things that
9 definitely exists, the environment that we have today as
10 far as research is concerned, I think both as far as
11 industry is concerned and academic institutions, it's not
12 easy to get research dollars, and when research dollars
13 are given to someone, they're looked at very carefully by
14 a peer review process. The animal end of things is
15 definitely looked at in this process of the peer review.

16 REPRESENTATIVE HECKLER: Thank you, Doctor.

17 The one observation I would have is that
18 I've heard now about the University of Pennsylvania Head
19 Injury Lab. I really don't know exactly what practices
20 were going on there which caused its closing. I hope
21 maybe before the end of the day we'll hear, but I think
22 this committee in our hearings about the possible
23 toughening of the drug laws last week is certainly aware
24 that we are imposing ever more Draconian legal sanctions
25 upon crimes like the sale of drugs or the commission of

1 violent crimes, and we don't seem to be stopping them. I
2 don't know that you can conclude because incidents of
3 misconduct, if in fact the situations that are being cited
4 involved misconduct, because they occur that the way we're
5 going to solve them is to pass additional sanctions.

6 Thank you.

7 (Whereupon, Representative Moehlmann assumed
8 the Chair.)

9 ACTING CHAIRMAN MOEHLMANN: Thank you, Dr.
10 Ferguson. You may be dismissed.

11 DR. FERGUSON: Thank you.

12 ACTING CHAIRMAN MOEHLMANN: Finally, I
13 imagine.

14 We will call now the next witness is Dr.
15 Marvin Kraushar. Is he here?

16 While he's making his way to the witness
17 table, I might observe for the members of the committee
18 that we are now one hour behind schedule and I imagine
19 there are witnesses on our schedule who are placing some
20 reliance on that schedule. I'm not suggesting to any
21 member that he not ask a question that he has, or at least
22 I'm not admitting to asking any member that he not ask a
23 question that he has, but if you would, please be
24 cognizant of the schedule. It will help us. Thank you
25 very much.

1 Please proceed, Dr. Kraushar.

2 DR. KRAUSHAR: Thank you very much, ladies
3 and gentlemen. Let me introduce myself to you. I'm an
4 ophthalmologist, I'm an eye surgeon. I'm Clinical
5 Professor of Ophthalmology at the University of Medicine
6 and Dentistry in New Jersey, and an Associate Clinical
7 Professor of Ophthalmology at the Mount Sinai School of
8 Medicine.

9 And before I give my presentation, I feel
10 compelled to relate to you a little story which just
11 popped into my mind after hearing the testimony before me.
12 I was a late arrival and I don't know how many people have
13 spoken in front of me or who will be speaking behind me.
14 I was a pitcher for my college team in baseball and one
15 day I was having what I thought was a particularly good
16 day, but evidently the umpire behind the plate didn't
17 agree with me, and at one point I asked him if we were
18 watching the same game. I said, "I just threw three
19 perfect curve balls and you called every one of them a
20 ball." And he looked at me and he said, "Son, if you can
21 learn to throw that pitch, you'll be in the major
22 leagues." And I responded, "If you learn to call it, we
23 can both be in the major leagues."

24 I have done animal research in the past. I
25 wholly support it. It has saved countless lives and I'm

1 certain in the future will save countless more, and it
2 definitely has a place in our society. But unfortunately,
3 it has no place in this bill. This bill is not talking
4 about research for humans for biomedical research. We're
5 talking about things like mascara, eyeliner, toilet bowl
6 cleaner, things like that. And I've testified at meetings
7 like this before, and usually there's somebody else who
8 will come and testify that they've had 20 cancer
9 operations or they are on chemotherapy for whatever and
10 they are in favor of animal research. As a physician,
11 I've dedicated my life to helping human beings, and I have
12 empathy for these people, I sympathize with them and I
13 think they are absolutely correct that animal research has
14 a definite place. However, it has no place in this
15 discussion today. It is just not germane to this bill.

16 Now let me get on to what I have to say.
17 I'm a member of the Board of Governors of the New Jersey
18 Academy of Ophthalmology. I am not speaking as a Board of
19 Governor member, I'm speaking for myself. There are four
20 parts to this bill which I have read, and I can see that
21 three of them are self-evident. I can't conceive anybody
22 would have a serious or reasonable complaint about any of
23 them.

24 As an ophthalmologist, I'm here today to
25 speak mostly about the Draize test. Basically, the main

1 argument that the household products and cosmetic industry
2 seems to have in favor of this test is that it's better
3 than nothing. Well, I think it's worse than nothing. I
4 don't know how many of you ever saw the movie "The Third
5 Man." It was a good spy story, a very interesting movie.
6 Basically, it had to do with a gentleman who was taking
7 penicillin and diluting it so he could sell it and make a
8 killing on the market, and actually what he did was made a
9 killing in the hospitals because patients with infectious
10 diseases that needed penicillin were given this drug which
11 was tremendously diluted to the point where it was doing
12 very little for them and they died. Well, that's what the
13 Draize test is doing for research. It is discouraging
14 attempts at finding other means of research.

15 First of all, there are no Federal agencies
16 of which I am aware that require the Draize test
17 specifically for testing household products and cosmetics.
18 And more importantly, the Draize test is one which is old,
19 archaic, and does not accurately correspond to findings in
20 the human eye, and because of this, you can't extrapolate
21 it to what's going to happen to human beings. So
22 basically what we need is something a little better.

23 The cosmetic and the household products
24 industry have three main points of complaint with respect
25 to our legislation. They need something that -- they need

1 a product that will be safe and has to be tested. They
2 need legal protection in case somebody has an accident
3 with their product, and I can understand both of these,
4 and they say it will cost money, which is true. But this
5 is really no excuse because it's a small part of the
6 budget of any of these large companies.

7 As far as legal protection goes, they say
8 that they need something such as the Draize test so that
9 if something happens, they can always say, well, here's
10 the test. We have tested it, we've done the best we
11 possibly can. And I understand their point, but relying
12 solely on the Draize test, which is what many people are
13 doing, discourages investigation of other media and other
14 tests which are valuable in helping us test toxicity in
15 the human eye. I can tell you I, as an ophthalmologist in
16 practice for 20 years, have never ever in my life
17 consulted the Draize test results before prescribing any
18 medication for any of my patients. I don't know anybody
19 who has.

20 But getting back to household products and
21 cosmetics, as far as I am concerned, what we really need
22 is to have more tests done of a non-animal type which
23 accurately correspond to the actual result in the human
24 eye, and this will really, truly protect humans who, after
25 all, are our main concern.

1 I will be happy to answer any questions you
2 may have.

3 ACTING CHAIRMAN MOEHLMANN: Thank you, Dr.
4 Kraushar.

5 Representative Heckler.

6 REPRESENTATIVE HECKLER: Thank you.

7 BY REPRESENTATIVE HECKLER: (Of Dr. Kraushar)

8 Q. Mindful of the Chairman's injunctions
9 notwithstanding, I have just a few questions for you,
10 Doctor. You have focused your testimony on section (d), I
11 believe, of the act which speaks to the prohibition of
12 Draize and L.D. 50 tests, and you've stated very clearly
13 that this has nothing to do with medical research. You
14 may have heard my questions to the prior witness. Do you
15 have any opinion about the impact which authorizing agents
16 of organizations for the prevention of cruelty to animals
17 to execute search warrants at medical research facilities,
18 do you have any opinion as to whether that might impact on
19 medical research?

20 A. I can see it impacting on medical research
21 in only a minor way in that if violations are found, it
22 will cost these laboratories some money to correct the
23 violations, but I see no reason not to have legislation
24 because of that.

25 Q. Well, are you familiar at all with the

1 process of the execution of a search warrant? I mean, let
2 me ask you, did you know that was in the bill before you
3 came here today?

4 A. Yes.

5 Q. Okay. And are you familiar with the process
6 of the execution of a search warrant?

7 A. As a layperson, basically I am, yes.

8 Q. So that if these folks who did not have or
9 at least are not required to have any particular
10 scientific training or familiarity with the activity which
11 would be occurring at the facility were to enter the
12 facility with legal authority and seize animals contained
13 there, you don't think that would -- that doesn't strike
14 you as particularly troublesome?

15 A. Not as particularly troublesome, no.

16 Q. But you would agree that we're talking about
17 something that impacts on medical research as opposed to
18 just Tidy Bowl?

19 A. In that respect, yes.

20 Q. Thank you. That's all I have.

21 ACTING CHAIRMAN MOEHLMANN: Representative
22 Hayden.

23 BY REPRESENTATIVE HAYDEN: (Of Dr. Kraushar)

24 Q. Doctor, other than the Draize test, are you
25 aware of any other eye irritancy tests which are currently

1 being used either, let's talk about the cosmetic industry
2 or through research laboratories in general, and I'll
3 define eye irritancy test as it is defined here in the
4 bill, which is described as "Any experiment involving the
5 placing of a substance in an animal's eye to measure its
6 irritating effects".

7 A. Yes, I'm familiar with a number of them, but
8 as opposed to taking up your time at this juncture, Dr.
9 Barnard, who will be testifying after me at some point
10 today, will be talking about that specifically, and I
11 think he is better equipped to give you the more concise,
12 appropriate answers to that question.

13 Q. Okay, the question I have is, all those
14 other range of tests which exist out there for eye
15 irritancy tests, do you think we should ban all of those
16 tests also?

17 A. Well, if they don't use animals, and most of
18 them don't--

19 Q. Well, as I read this definition, I'm
20 limiting it to as it's defined in the bill, which is "any
21 experiment involving the placing of a substance in an
22 animal's eye to measure its irritating effect".

23 A. If there is no viable alternative, I can see
24 using it. Under the present state of my knowledge, I am
25 not aware that there are not viable alternatives.

1 Q. We may hear from Dr. Barnard, but my concern
2 with that particular reference in the bill is that in fact
3 we are not here only talking about the Draize eye test or
4 the L.D. 50 test. The way this bill is written, we're
5 talking about every eye irritancy test, as I just read the
6 definition, and every acute toxicity test, so that's one
7 of my concerns is that if the language remains as is, we
8 would be banning all of those ranges of options, which I'm
9 not prepared to say whether we should or shouldn't, but
10 that's one of my concerns.

11 Thank you.

12 ACTING CHAIRMAN MOEHLMANN: Representative
13 Bortner.

14 REPRESENTATIVE BORTNER: Thank you, Mr.
15 Chairman.

16 BY REPRESENTATIVE BORTNER: (Of Dr. Kraushar)

17 Q. Doctor, during your course of study to
18 become a physician, starting with high school and through
19 college and medical school, did you ever dissect any
20 animals, reptiles, organisms?

21 A. Yes.

22 Q. And do you think that was helpful in part of
23 your training?

24 A. Not really.

25 Q. You don't think so?

1 A. No, I don't.

2 Q. So, I mean, as far as you're concerned, it's
3 perfectly possible to become a medical doctor and other
4 physician without ever having cut apart any kind of
5 animal, reptile, and so forth?

6 A. Absolutely. As a matter of fact, my medical
7 school, Tufts University, doesn't use this in medical
8 school at all anymore. They have animal models which they
9 use for dissection.

10 Q. And that was true -- is that typical or
11 common with most medical schools?

12 A. I can't honestly say, but I can tell you
13 from what I have heard, I've begun making inquiries about
14 this, that's how I know specifically about my medical
15 school, and the head of animal research at my medical
16 school wrote me a long, two- or three-page letter about
17 this maybe seven or eight months ago where he implied, and
18 again, he's implying now, I don't have any hard statistics
19 on it, that close to a third of the medical schools in
20 this country do the same at this point, and the number is
21 growing yearly.

22 Q. Would you feel the same way about a cadaver?

23 A. No, that's totally different.

24 Q. Could you explain to me why?

25 A. Yes. A cadaver is a dead person. Painless.

1 Q. I understand that, but you can also dissect
2 dead animals, can you not?

3 A. I suppose you can, but it depends on how
4 they get dead. I wouldn't want to have to kill an animal
5 first to say it's dead.

6 Q. Well, I didn't suggest that. I'm asking you
7 a question, whether you think these are valid teaching
8 methods.

9 A. At the present time I can only go by what my
10 medical school goes by, and they're the experts with
11 respect to teaching, and they don't use it.

12 Q. Well, are you aware that this bill would
13 allow a student to refuse to participate in any teaching
14 methods involving dissection or vivisection?

15 A. I am not only aware of it but I support it.

16 Q. Well, in your opinion, would that also
17 involve dissecting cadavers or other dead animals or
18 invertebrates, reptiles?

19 A. I suppose it would, and I don't see what
20 harmful effect that would have. I can't understand
21 anybody going, say, to a medical school who would refuse
22 to dissect a cadaver. A cadaver was not sacrificed in any
23 inhumane manner, and you certainly aren't going to be able
24 to treat a human or do surgery on a human if you haven't
25 done some dissection to learn the anatomy.

1 A. I see no problem with that. If you're
2 talking about a high school student refusing to dissect a
3 frog or a grasshopper, I don't see anything wrong with
4 that.

5 Q. When you say you don't see anything wrong
6 with it, you don't see anything wrong with permitting
7 somebody to make a decision or you don't see anything
8 wrong with doing it?

9 A. I don't see anything wrong with permitting
10 somebody to make a decision not to do it. There are
11 animal models available for high school laboratories as
12 well to show them the anatomy.

13 Q. And you would feel that that would also --
14 I'm not sure about your answer in the medical school.

15 A. My answer in medical school is I feel it
16 would be appropriate in medical school to dissect a
17 cadaver because people are not, to my knowledge,
18 inhumanely killed in order to obtain cadavers. And number
19 two, the person is going to be dealing with the human body
20 for the rest of their life, it's important to have an
21 intimate knowledge of the anatomy of the human body. If
22 there were, I suppose, a way to have a superb model of the
23 human body, then you wouldn't even have to dissect that
24 either, as a matter of fact, but I can only tell you that
25 when a child is dissecting a grasshopper, to be honest

1 with you, I don't see what relevance that has to the rest
2 of their life that they can't learn from looking at a
3 plastic model of a grasshopper or something similar.

4 Q. Well, it sounds to me like your answer on
5 the medical school, in the medical school situation is
6 different.

7 A. Absolutely.

8 Q. This bill doesn't make that distinction, and
9 I'm trying to make that point.

10 A. Well, the bill may not make a distinction,
11 but I think it would be hard put to find a medical student
12 who has geared many years of his life to going to medical
13 school who, when confronted with a cadaver, would complain
14 that it is an inhumane act to dissect a cadaver.

15 REPRESENTATIVE BORTNER: I don't want to
16 continue this any longer. I have no further questions at
17 this point.

18 ACTING CHAIRMAN MOEHLMANN: Representative
19 Veon.

20 REPRESENTATIVE VEON: Thank you, Mr.
21 Chairman.

22 BY REPRESENTATIVE VEON: (Of Dr. Kraushar)

23 Q. Doctor, first of all, I appreciate you
24 focusing in on the important parts of this bill, and I
25 think that's helpful to us as a committee and I appreciate

1 that for the sake of time also. You had mentioned that --
2 I believe you mentioned this, correct me if I'm wrong,
3 that you're not aware of any government agencies that
4 require the Draize testing?

5 A. For households products or cosmetics.

6 Q. Yes. I have again, and I mentioned this
7 before, you weren't here, I have letters here from the
8 Food and Drug Administration, from the Environmental
9 Protection Agency, and Consumer Products Safety
10 Commission, all of which of course regulate different
11 areas of consumer products and the testing of those
12 products.

13 A. Forgive me for interrupting, sir.

14 Q. Sure.

15 A. In the interest of saving you time, Dr.
16 Barnard will be the person who can really speak to that
17 question much more accurately than I.

18 Q. All right, I'll reserve those for him.

19 Just for the record, in your opinion on
20 this, this bill clearly includes rats and rodents and it
21 would be -- you would be in favor clearly in making sure
22 that rodents and rats are included in this bill?

23 A. Yes.

24 Q. And if you could just comment, I guess, on
25 the juxtaposition of at least what would be most people's

1 thought in society of attempting to rid themselves of
2 rats, setting traps, et cetera, et cetera, in their homes,
3 outside their homes, and juxtaposition that with
4 attempting to include that species or those kinds of
5 animals in this bill. Do you have just a comment on that?

6 A. Having been born and raised in New York
7 City, where we have our own share of rats, two- and
8 four-legged, there are considerable problems with rat
9 populations biting children, causing disease, et cetera.
10 I think that is certainly in the public interest to
11 eliminate them wherever it's appropriate. With respect to
12 dissecting an animal in a laboratory or with respect to
13 experimenting on one where there are non-animal
14 alternatives which are viable, I don't see any
15 relationship between those two examples you have given me.

16 REPRESENTATIVE VEON: Thank you, Mr.
17 Chairman.

18 Thank you.

19 ACTING CHAIRMAN MOEHLMANN: Representative
20 McNally.

21 REPRESENTATIVE McNALLY: Thank you, Mr.
22 Chairman.

23 BY REPRESENTATIVE McNALLY: (Of Dr. Kraushar)

24 Q. Doctor, I'd like you to address a question
25 that I had earlier begun to discuss with Dr. Heller. It

1 was her opinion, and apparently you would agree, that the
2 L.D. 50 test and the Draize test are not useful per se,
3 they have no utility whatsoever, they ought to be banned
4 entirely, at least for household and cosmetic products
5 testing, is that correct?

6 Q. Certainly with respect to household and
7 cosmetic products, yes, I agree.

8 Q. And yet there are -- you would concede that
9 there are companies, institutions, which actually perform
10 a Draize test and an L.D. 50 test for household and
11 cosmetic products?

12 A. Yes.

13 Q. And then you would also agree with Dr.
14 Heller that these companies and institutions which are
15 performing this test are simply wasting their money?

16 A. Oh, they are probably making a lot of money.

17 Q. Yet they could make more simply by cutting
18 those costs. I mean, if these tests are invalid and
19 non-effective and apparently costly and have absolutely no
20 utility, provide no useful information, are not valid for
21 clinical purposes, treatment purposes, why do they do it?
22 Why do they waste all that money?

23 A. I'm not saying that they don't provide
24 appropriate data. What I'm saying is that there are
25 non-animal tests which can provide similar data.

1 Q. So that in fact you would not agree with Dr.
2 Heller and maybe you'd retract your statement before that
3 these tests are not useful per se and in fact they do
4 provide useful information, is that correct?

5 A. It's a question of how useful it is compared
6 with what's being done and what's going on. I'm sure
7 there must be some useful information that comes out of
8 these tests, but I'm not aware of any information along
9 those lines which cannot be reliably duplicated by
10 non-animal tests, and that is my point here.

11 Q. Okay. And then we get really down to a
12 philosophical question and the tone of this legislation,
13 because this is, I think, by your own -- the admission
14 that these tests are useful and that they provide
15 appropriate data, now we're talking about a philosophical
16 question: Should we test animals? And the argument that
17 I would make, and maybe you can respond to it, is that so
18 long as the treatment of animals is not done for a
19 sadistic purpose, that is, merely to inflict pain, if it
20 is done, if a test or experiment is performed in order to
21 accumulate useful information, that is a legitimate
22 purpose and a legitimate function. You simply are
23 quibbling over how they acquire that information and, you
24 know, and if there's a less costly or a more effective
25 test or experiment, maybe my Republican friends on the

1 committee can help me out with the economics. It seems to
2 me that the market theory would state that some company is
3 going to use the less costly method and get a competitive
4 advantage and make more money and drive other people out
5 of business. Eventually, if we let the free market run
6 its course, then we're going to eliminate these tests that
7 you say are unnecessary or less effective?

8 A. You want me to respond to that?

9 Q. If you can.

10 A. I don't think I'll have any trouble.

11 Basically, these tests may provide useful
12 results. It just is incomprehensible to me how everybody
13 can't understand the fact that you can get the same
14 results from a non-animal test that is just as reliable,
15 why should you do it to animals? If you can't get the
16 same results, that's another story. But there are
17 reliable and responsible non-animal tests that can produce
18 the same results. We're not saying that these tests
19 produce results which are unnecessary or non-useful,
20 although many of them do. I'm sure you're aware of the
21 fact, and having done research I know it myself, and
22 having done animal research I know it myself, that there's
23 a great deal of duplication that goes on in laboratories,
24 and I am not here to insinuate that the people who use
25 animals in laboratories are doing so to get their kicks or

1 are doing so because they can't think of anything else to
2 do. What I'm saying is that the people who are using
3 animals should use animals if there is no viable
4 alternative, if they are not duplicating results that are
5 done somewhere else, and as long as they can't get the
6 same results out of either a non-animal test or using a
7 lower order animal. I see no reason to use animals for
8 tests where you can use non-animal tests which can produce
9 the same results. I can't see why everybody in the world
10 doesn't feel the same way. That just makes common sense.

11 Q. If I could just ask one final question
12 briefly. Why do we discriminate between higher order
13 animals and lower order animals, vertebrates and
14 invertebrates?

15 A. Well, to my knowledge, things such as worms
16 have a much higher tolerance for pain and indeed feel no
17 pain if you cut them in half. If you cut a rabbit in
18 half, it hurts.

19 ACTING CHAIRMAN MOEHLMANN: Chris, here
20 comes some help with the economics.

21 Representative Reber.

22 REPRESENTATIVE REBER: Thank you, Mr.
23 Chairman.

24 I'd be glad to help the Representative out
25 with more than just economics.

1 BY REPRESENTATIVE REBER: (Of Dr. Kraushar)

2 Q. Doctor, the student at your alma mater,
3 Tufts, during his matriculation, when's the first time
4 he's going to drop a scalpel on a living organism, if he's
5 been working on models?

6 A. You mean a living organism or a human being?

7 Q. Let's start with a living organism.

8 A. Well, let me put it this way, the first time
9 I dropped a scalpel on a human body was my first day in
10 medical school.

11 Q. Okay, I understand what you did, but they
12 didn't have the model syndrome in effect at that time.

13 A. Oh, yes they did.

14 Q. Were they using that exclusively?

15 A. You're missing -- let me just finish. The
16 first day I dropped a scalpel on a human body was my first
17 day in medical school when we began to dissect a cadaver.

18 Q. That's not a living.

19 A. What's the difference? It's the same thing.
20 It's a human body.

21 REPRESENTATIVE REBER: I rest my case, Mr.
22 Chairman. I have no further questions.

23 ACTING CHAIRMAN MOEHLMANN: The difference
24 was that you asked the question as you asked it.

25 Does anyone else have any--

1 DR. KRAUSHAR: Pardon me, but I would like
2 to respond to that, if I may.

3 The difference is that I, when I go to
4 medical school, I'm not training to be a grasshopper
5 doctor, I'm not training to be a frog doctor, I'm training
6 to be a human physician, and when I dissect a human
7 cadaver, it's the same thing as far as touch of tissues,
8 feeling sensation and getting experience as it is to
9 dissect a human body when they are alive.

10 REPRESENTATIVE REBER: Doctor, with all due
11 respect, I, as a patient, would prefer to have the psychic
12 mentality existing in the doctor that is performing that
13 operation on me to know that he has already had the
14 opportunity to emotionally, psychologically, et cetera, et
15 cetera, and I'm not a medical doctor, I don't know the
16 terminology, but I think we all get the point. There just
17 seems to me to be somewhere along the line where there has
18 to be that nexus between the individual who is performing
19 something knowing that he is performing something on
20 something other than a cadaver, and it's to that extent
21 that I feel some of the implications in this legislation,
22 not necessarily the prohibited test sections relating to
23 cosmetics or households, but sitting here listening to the
24 testimony as it was given to Representative Bortner during
25 his questioning of you, and some of the other witnesses in

1 the way this is going, it's beginning to shock my sense of
2 consideration as to where this may ultimately lead. Maybe
3 not where it's at right now, but where it's going to go.
4 And it's that kind of thought that I think we have to,
5 from our perspective sitting up here, consider, and that's
6 the only reason I ask the question. And I do apologize.
7 I didn't mean to be curt with you in regard to your
8 response initially as to the living organism.

9 DR. KRAUSHAR: Let me explain to you that
10 when a medical student or a doctor in training is first
11 given a scalpel to use on a living human body, he does not
12 start out with brain surgery. When he does this, this is
13 done in a very gradual manner, after observing literally
14 hundreds of operations at which he has assisted, and you
15 are worked into this little by little. And usually, to
16 anyone who is acquiring skills in surgery, by the time you
17 get to do your first operation, it's not that you sleep
18 all night thinking, "Oh, my gosh, I've never done this
19 before. I wonder how nervous I'll be, what kind of a job
20 I will do." Basically, anybody who is worth anything, by
21 the time that day comes, his attitude is, well, it's
22 finally here. This is what I've been waiting all my life
23 for to do. And by that time you have been cutting
24 sutures, wiping blood, retracting, doing all kinds of
25 things, and the small, little basic things that you are

1 given in the very beginning are things which do not
2 require great degrees of skill. You just don't walk in
3 some day from medical school and you're given a knife and
4 say, here, operate on this man's brain, or something like
5 that. So I hope you will feel better, God forbid if you
6 should need surgery some day, that the doctor who is
7 operating on you, if it may be his first case in private
8 practice, that you're not the first living thing he's
9 touched with his scalpel.

10 REPRESENTATIVE REBER: I'll just have to
11 check his diploma to see is if it's from Tufts or not.

12 DR. KRAUSHAR: I hope you're fortunate that
13 it is.

14 ACTING CHAIRMAN MOEHLMANN: Thank you, Dr.
15 Kraushar. That concludes the questioning.

16 REPRESENTATIVE McHALE: Mr. Chairman?

17 ACTING CHAIRMAN MOEHLMANN: I beg your
18 pardon, Paul.

19 Representative McHale.

20 REPRESENTATIVE McHALE: Thank you, Mr.
21 Chairman.

22 BY REPRESENTATIVE McHALE: (Of Dr. Kraushar)

23 Q. Doctor, do all cosmetic manufacturers use
24 the Draize eye test or the L.D. 50 test?

25 A. I haven't any idea. Dr. Barnard will

1 probably be able to give you more information on that.
2 Oh, excuse me, I can tell you. Absolutely not. Avon,
3 which is probably, to my knowledge, the largest producer
4 of cosmetics in the United States, has given the test up
5 and they no longer use it.

6 Q. Doctor, the last hearing that we had in
7 Pittsburgh, if I recall the testimony correctly, and I
8 don't recall the name of the witness who provided it, at
9 least one individual testified that L'Oreal no longer uses
10 these kinds of tests.

11 A. It's possible. I don't know about that.

12 Q. I'll save those questions for perhaps some
13 other witnesses who might appear later.

14 We also heard testimony at that last
15 hearing, and I guess I'm asking you to confirm it if in
16 fact you're familiar with this subject area, that much of
17 this testing is done not for purposes of accumulating data
18 related to human safety in an affirmative sense, but
19 rather that much of this data was compiled using the
20 Draize test and the L.D. 50 test solely for purposes of
21 providing a defense by the cosmetic manufacturer in a
22 subsequent products liability suit, and from a moral
23 standpoint, I see two very different perspectives on that.
24 Are you familiar with that at all?

25 A. I mentioned that prior in my introduction.

1 I certainly understand cosmetic companies wanting to
2 protect themselves with respect to products liability, and
3 think they should, and I think you can help with them with
4 that because at this point all I have to say is, well, we
5 can use the Draize test because it's been around for 40
6 years and it's better than nothing. If you can give them,
7 by your law in Pennsylvania, a reason not to do the Draize
8 test so that if there is a question of product liability
9 and somebody who is suing them says, well, you didn't use
10 the Draize test, and they can say, well, we can't use the
11 Draize test but we're using so-and-so because the Draize
12 test is prohibited by law, you have given them that
13 protection against product liability lawsuit.

14 Q. Well, perhaps some of the other witnesses
15 will be able to comment on that.

16 A. Maybe.

17 Q. I think Representative McNally raised a good
18 point, and that is if the data is valid, why not collect
19 it? Your rebuttal I think is equally valid, and that is,
20 if we can find a way to do this without harming animals
21 while simultaneously compiling equally valid data, why not
22 take the more humane approach? As a corollary to that, we
23 ought to recognize, as at least based on the testimony
24 that I've heard previously, much of this testing takes
25 place not for purposes of protecting human beings but

1 rather to have reams of data in order to provide a defense
2 in a subsequent product liability suit. I think those are
3 distinctions that we ought to be familiar with.

4 REPRESENTATIVE MCHALE: Thank you, Doctor.

5 Thank you, Mr. Chairman.

6 ACTING CHAIRMAN MOEHLMANN: Thank you, Dr.
7 Kraushar. Appreciate your having taken the time and come
8 the distance that you have to appear before us.

9 Dr. Robert Gordon.

10 DR. GORDON: I'm Dr. Robert Gordon,
11 Associate Professor of Surgery at the University of
12 Pittsburgh, and a senior transplant surgeon at the
13 University of Pittsburgh Health Center Hospitals. I'm
14 also a member of the Institutional Review Board of
15 Presbyterian University Hospital. The IRB reviews and
16 approves all hospital research projects involving human
17 subjects, and one of the criteria in which the IRB relies
18 most heavily upon is the prior demonstration in animal
19 models of the safety and efficacy of proposed methods
20 before human use is attempted.

21 I'm going to read into the record some
22 remarks which I have prepared with Dr. Thomas Starzel, the
23 Chief of Transplantation at the University of Pittsburgh.
24 I'd also like to say that I'm here today at the invitation
25 of the University Administration, who asked Dr. Starzel to

1 appear before you today but unfortunately he could not be
2 here because he's in Europe speaking at a congress.

3 In looking at some of the animal rights
4 literature and some of the motivation for recent
5 legislation, it seems to me that there are three
6 underlying themes, and I've heard these repeated over and
7 over, both in the testimony from witnesses on both sides
8 of the question as well as from your own questions this
9 morning, and they are, one, it's fundamentally immoral to
10 use animals in research. We look down our noses at the
11 lower species and we take advantage of them, and I think
12 Representative Murphy has been quite straightforward in
13 saying that that is not his purpose in sponsoring this
14 legislation, and I sense even from the members of the
15 committee who seem favorably disposed of the bill that
16 they also are not supporting this legislation with the
17 viewpoint of banning medical research on animals, and that
18 most of you understand how much medical progress is
19 dependent on that.

20 The next level to which we move is that
21 whatever is done with animals should be done for a
22 specific purpose, it should be well-thought out, it should
23 have the objectives clearly stated so that we can assess
24 whether or not it's worthwhile taking advantage of another
25 species for our own benefit. This is a more difficult

1 area. And the third level is, there's a better way. We
2 don't need to use the animals.

3 Level one is not an issue today, but as one
4 of the Representatives stressed, he's concerned that it
5 might become an issue if this legislation passes and the
6 animals rights people get their foot in the door, what
7 will come next? Because the ultimate agenda is to stop
8 animal research. And if we do that, we're going to
9 potentially arrest medical research in the United States.
10 And I acknowledge that this legislation will not do that.
11 That is not what this legislation is designed to do.

12 Now, transplantation is a field in which
13 there have been extraordinary advances made public
14 recently, and you're all aware of what's happened with
15 that. And it may seem at times that this has been sudden,
16 but in fact it's not sudden at all. It's occurred over a
17 30-year period of painstaking research, almost all of
18 which was done on animals. I think it fair to say that I
19 would not be a transplant surgeon were it not for animal
20 research because there would be no organ transplantation.

21 All of the surgical techniques that we use
22 in liver transplant today, which is my special area of
23 interest, were developed in the animal laboratory. The
24 venous bypass pump that is now routinely used for liver
25 transplantation and it has enabled us to make the

1 operation available to many more high risk patients than
2 we were in the past was all worked out in the animal
3 laboratory before it could be safely applied to patients.

4 The methods of organ preservation that we
5 now have that have extended our preservation time for
6 livers from only six hours to better than a day were all
7 developed and tested in animal models both at the test
8 level and at the whole animal model.

9 Immunology, the immune system discipline
10 that is the science that is the basis not only for
11 transplantation but much of contemporary cancer research,
12 is highly dependent on animal research, and I'm sure you
13 know this. Most of the Nobel prizes that have been
14 awarded in biology and medicine in the last 30 years were
15 related to animal research, and certainly all the prizes
16 in immunology are based on fundamental research with
17 invertebrate animal strains where conditions can be
18 studied that are impossible to study in humans, but the
19 principles learned are directly applicable to humans.

20 I'd like to spend just a few moments to talk
21 about cyclosporine, because in many ways it's an ideal
22 drug to talk about the problems we face. The researchers
23 looking for cyclosporine were looking for an antibiotic.
24 They were not looking for an immunosuppressant drug. And
25 had they not tested this drug in animal models looking for

1 various effects of the drug, they would have missed what
2 is essentially a modern miracle drug, much like penicillin
3 was. So it disappointed them in one regard, but because
4 they were persistent and tested it in a variety of models,
5 they discovered another even more beneficial effect.

6 Furthermore, cyclosporine, like most drugs,
7 is far from perfect. It's full of toxic effects, and its
8 toxic effects do differ in different animals, but as we
9 moved up and learned to use the drug in animals and
10 eventually moved into higher species and humans, we've
11 learned how to avoid some of the dangerous effects this
12 drug can have in humans.

13 The doctor who testified at the beginning
14 stated that thalidomide wasn't prevented by animal
15 research, but how many thalidomides have been prevented by
16 animal research? That's the real question. Sure, one or
17 two slipped through. Nothing is perfect. She said she
18 doesn't worry about how many rats died, she worries about
19 what it does in the patients. She's lucky. Because some
20 rats died, she's not having to use a lot of things that
21 might hurt her patients. That's the point. I do worry
22 about when the rats die, and so does the FDA, who wouldn't
23 allow cyclamate on the market because it caused cancer in
24 rats.

25 The discovery of cyclosporine, like

1 penicillin, demonstrates that science is not as well
2 planned as we would like it to be and never will be. It's
3 a very delicate balance between what we think of as
4 deliberate pursuit of knowledge and serendipitous
5 observation that comes from having asked another
6 intelligent question and getting a surprising answer.
7 Many of the discoveries for which the Nobel prize have
8 been awarded are intelligent accidents.

9 Animal rights activists demand that we predict
10 what the results of our investigations are going to be,
11 and we try to do that. We have to justify them to get
12 funding, but we don't always know, and some of the most
13 stunning advances in basic animal research have been
14 applicable for human benefits in ways that none of us
15 envisioned during the initial studies. I think you have
16 to remember the unpredictability of scientific research.
17 It's a very important part of the scientific method.

18 You can see from just these few examples
19 that there's virtually no aspect of transplantation that
20 has not depended for its development on animal research,
21 and we can go on through the whole litany and I won't bore
22 you with that. You know about all the things that have
23 come about from animal research. Some of them have been
24 cited by other people.

25 Given the recommended changes in human

1 lifestyle that we think about today - don't smoke, eat in
2 moderation, exercise, avoid excessive use of alcohol -
3 many of these principles were demonstrated to be valid in
4 animal models where the conditions could be controlled and
5 these factors could be identified.

6 My concern with the legislation really
7 concerns two provisions. I'm sympathetic to the viewpoint
8 that a school child should not be forced to dissect a frog
9 if he doesn't want to. I agree with the people over there
10 who think not only is it victimization of the frog, it's
11 victimization of the kid, and that bothers me.

12 I agree with the doctor that most people who
13 get to medical school aren't going to be too concerned
14 about dissecting a cadaver, although I have to tell you
15 what my very first day in medical school involved. I
16 stood before the cadaver, not too thrilled to be there but
17 willing to go through it. My lab partner showed up, shook
18 my hand and said he was leaving to go to Columbia Law
19 School because he didn't want to go through it, and that's
20 what he did.

21 REPRESENTATIVE REBER: He specializes in
22 malpractice?

23 DR. GORDON: Hopefully on our side.

24 My concern is that the legislation proposing
25 to establish executive authority to build regulations and

1 set up State inspections and everything not only is
2 duplicative of Federal efforts at the present time which
3 are considerable, and the minimum cost estimates I've seen
4 of the Federal legislation are a billion dollars, and
5 there have been more astronomical estimations, but the
6 Public Health Service says a billion dollars. That, in
7 effect, is a 17-percent cut in available moneys for
8 Federal research at the present time, and at a time when
9 RO 1 grants are being funded at the lowest levels and
10 there are more rejections of good RO 1 grants than ever
11 before, that's a very significant impact. So I don't know
12 what the cost is going to be, which one of the
13 Representatives asked, but let's take 1/50 of \$1 billion,
14 since we are one State. It could be considerable
15 depending upon what the executive branch decides to do
16 when you unleash them.

17 You said that it wasn't legitimate to ask
18 what the consequences were. Well, I've seen what the
19 consequences were of the Organ Transplant Act. A whole
20 Federal bureaucracy's been set up, years and millions of
21 dollars have been spent and we have yet to demonstrate
22 whether or not that legislation has benefited one single
23 patient. There are enormous consequences to setting up a
24 regulatory agency and a regulatory mechanism both in cost
25 and in the effectiveness with which we have to function

1 and can function. The paper work and bureaucracy involved
2 today in writing a research grant proposal, the committees
3 that have to approve it, IRBs, animal use, radiation
4 safety, pharmacology, infectious disease, are enormous,
5 and you're proposing now another layer at the State level.
6 Think about it. If it's necessary and you can convince us
7 it's necessary, then you should do it. But I'm not
8 convinced at this point in time this is something you
9 really intend to do.

10 A lot has been said about the sanctions
11 proposal, and the question is, why should medical research
12 not have this same coverage under the law? Why shouldn't
13 they be subject to this? Everybody else is. Nobody has
14 phrased it the other way. Why would they exempt it? The
15 reason is so as not to disrupt a medical research project
16 that might be seeking an extremely valuable answer and be
17 in the process of making that discovery but have their
18 material seized, the project completely disrupted, and the
19 chance to finish the project probably destroyed without
20 any guilt having ever been established. That's the
21 reason. I'm all for having things investigated that need
22 to be investigated, and if somebody is smashing animals'
23 heads open inappropriately, then they deserve to be
24 punished for it. But I also am not foreseeing animal
25 rights activists, the ones especially on the more fringe

1 elements who will make a great fuss, target some
2 laboratory and have their work subject to search and
3 seizure when it may not at all have been justified. And
4 I'm not saying that the people here are necessarily
5 representing that fringe. I'm not accusing Representative
6 Murphy of promoting that sort of thing, but it could
7 happen. You're setting up a mechanism that could become a
8 great tool for harassment. You know about the cases of
9 arson and willful destruction of property that have
10 occurred in laboratories in the United States already.
11 There are fringe elements out there and there are some
12 very vociferous people who will use this as a weapon
13 against research. How you guarantee that legitimate,
14 justifiable, proper research will not be inappropriately
15 disrupted by being subject to this search and seizure,
16 that's the question I ask you to consider.

17 As far as all these special tests and the
18 cosmetic industry is concerned, that's not my area of
19 expertise. My only concern would be if the FDA said to
20 me, we want an L.D. 50 before you can use cyclosporine in
21 a patient. I'm stuck. I've got to do what the FDA wants
22 or the patient can't get to have the drug. That would be
23 my only concern. Whether or not it's appropriate for
24 mascara, there are other people here who are more
25 qualified to testify about that than I am. It's these two

1 things that bother me in particular - setting up the
2 regulatory mechanism which could be expensive, and even
3 though it's not targeted at what you would consider
4 important, acceptable, justifiable medical research could
5 nevertheless have a significant impact on it.

6 Thank you very much for your attention this
7 morning.

8 ACTING CHAIRMAN MOEHLMANN: Thank you, Dr.
9 Gordon.

10 Are there questions from the committee?

11 Representative Bortner.

12 BY REPRESENTATIVE BORTNER: (Of Dr. Gordon)

13 Q. Thank you, Dr. Gordon.

14 Very quickly, Dr. Kraushar, I believe,
15 testified that in his opinion there was very little value
16 in dissecting of animals I think he said for two reasons,
17 one, he is not being trained to be a frog doctor, there is
18 no value in that; and secondly, that there are models
19 available which can give exactly the same effect. Do you
20 agree with that?

21 A. Not entirely. I don't think it's essential
22 for a high school students to do dissection if they don't
23 want to. I mean, I'm sympathetic to the view of not
24 forcing somebody to do something that might be emotionally
25 traumatic for them, and for children, it's a sensitive

1 issue.

2 From the standpoint of a surgeon and
3 watching what's happened to medical training, the reason
4 why the dog surgical laboratories are disappearing is they
5 simply are too expensive. It's one of the most expensive
6 facilities to maintain in a hospital. But the fact is
7 that the average intern coming into a surgical residency
8 program today is grossly underskilled technically compared
9 to what they were 10 years ago, so much to point that we
10 have had to ask them to come to Pittsburgh two to three
11 weeks ahead of time to go through a surgical training
12 course before we can let them in the operating room. They
13 can't even tie knots differently. The cadaver is not the
14 same as living tissue. It's not even close. I learned
15 anatomy in the operating room. I would venture to say
16 that I could have actually become a surgeon without ever
17 having touched a cadaver, and my anatomy professor is
18 probably turning over in his grave right now, but I
19 learned anatomy in the living tissue, and the dog
20 laboratory, for me, was much more valuable than the
21 cadaver dissection in terms of seeing, learning, feeling,
22 sensing tissue and how to handle it. The young surgeon
23 coming into training today is grossly underskilled that we
24 are having to put them through an animal experience for a
25 few days to get them at least on a reasonable grounds to

1 start work in the human operating room.

2 Q. Would you feel then that this section that
3 permits the refusal to participate is not a particularly
4 important or significant part of this legislation?

5 A. I don't object to that legislation as it
6 applies to school children, I don't object to that
7 legislation as it applies to -- I think if somebody has
8 religious grounds for which they don't want to do it, the
9 Constitution covers that, as far as I'm concerned.
10 Whether or not you want to reinforce that with a State
11 regulation doesn't really bother me. I don't believe in
12 forcing people to do things they don't want to do. We
13 don't force people to do operations on patients that they
14 don't believe the operation should be indicated for, even
15 if I think it should be. That's not the way medicine
16 works, at least not in our institution. So I don't have a
17 great deal of trouble with that.

18 Q. Okay, thank you very much.

19 REPRESENTATIVE BORTNER: Thank you, Mr.
20 Chairman.

21 ACTING CHAIRMAN MOEHLMANN: Representative
22 McHale.

23 REPRESENTATIVE McHALE: Thank you, Mr.
24 Chairman.

25 BY REPRESENTATIVE McHALE: (Of Dr. Gordon)

1 Q. Doctor, initially I found myself in
2 agreement with what you were saying. You began your
3 testimony by establishing three criteria that I thought
4 capably laid out the various arguments. You indicated
5 first of all that the issue can be analyzed on the level
6 of the need for and justification of animal testing in
7 general. You quickly said that's not the issue before the
8 committee today, and that Representative Murphy made that
9 quite clear.

10 You then went on with two other criteria,
11 secondly, the question of a valid purpose for any animal
12 experimentation, and thirdly, you talked about
13 alternatives. Now, those were the three criteria. You
14 then spent almost the entire remainder of your testimony
15 focusing on the first criterion, which by your own
16 admission has nothing to do with the bill in front of us.
17 You spoke at length, and I think articulately,
18 intelligently, regarding the need for animal testing in
19 general. I agree with that, but I don't think that's the
20 issue before us, as you stated at the beginning of your
21 testimony.

22 What I'd like to do is bring you back to the
23 two remaining criteria which are in fact relevant to what
24 we're doing today. Subsection (d), prohibited tests, has
25 to do with the Draize test and the L.D. 50 test with

1 regard to the testing of cosmetics and household products.
2 Do you oppose that ban?

3 A. I have no position on that. As I think I
4 stated, my comments were all linked, and those three
5 principles overlap is the problem I have. As I said, I
6 don't have any specific position on that test. That test
7 does not impact on me as a clinician very much. I don't
8 do those tests. Whether or not they are required of me
9 depends upon what the FDA would say to me if I was trying
10 introducing a drug for human use.

11 Q. I think it's fair to say that that provision
12 in subsection (d) is a central provision of the bill.

13 A. Yes, it is.

14 Q. And you have no position on it?

15 A. Right. On that specific test I don't. If
16 somebody can prove that there's a better way, fine. Then
17 let's do it a better way. My concern about the bill
18 concerns the provisions that deal, as I stated, with
19 setting up a regulatory arm in the executive branch of the
20 State government--

21 Q. And you're opposed to that.

22 A. --to regulate research laboratories, at a
23 time when the Federal government is talking about a
24 billion dollars of expense to do that very thing.
25 Representative Murphy says he's not targeting the medical

1 research laboratory, but that part of the legislation
2 could. It depends what the executive branch decides to do
3 once you pass the bill.

4 Q. So what you're saying is we should refrain
5 from taking action in the hope that the Federal government
6 will take effective action in the same area?

7 A. Correct. And if they don't, you're free to
8 reconsider it, obviously.

9 Q. All right, the third provision, and I agree
10 with you, the general provisions regarding animal testing
11 and the search warrant provisions related to that are
12 centrally important to that bill, but I guess the point
13 I'm trying to make is that there are at least two other
14 sections that I consider centrally important, one of them
15 being the L.D. 50 and the Draize test, you have no
16 position on that.

17 A. Right.

18 Q. The third section that I think is centrally
19 important has to do with the refusal to participate in
20 experimentation, and you support that provision, if I
21 understand your earlier testimony.

22 A. Yeah. I am not for coercion of people,
23 basically, and to me, I don't force medical students to do
24 things that they are morally opposed to doing.

25 Q. All right, then if I understand your

1 testimony, you're opposed to the provisions that would set
2 up a broad-based regulatory system?

3 A. Correct.

4 Q. You have no position with regard to the L.D.
5 50 and the Draize test?

6 A. Correct.

7 Q. And you support the right to refuse to
8 participate in experimentation involving animals?

9 A. Right. I guess the only concern I would
10 have about that is if you got some student who is really
11 -- or have such an individual who started to objecting to
12 all kinds of willy-nilly silly things. I mean, if
13 somebody doesn't want to do a dissection of a live animal,
14 I don't have a problem with that. I don't think they
15 should be forced to do that. But if they start objecting
16 to drawing blood from the patient, starting IVs, hanging
17 blood in the hospital because it involves a puncture of a
18 blood vessel, then I would start to wonder why this person
19 is in medical school to begin with.

20 Q. If we eliminated the broad regulatory
21 provisions in the beginning of the bill and simply had a
22 flat ban on the Draize test, the L.D. 50 test, and we
23 provided the right of conscience to refuse to participate
24 in experimentation, would you oppose the bill?

25 A. No, I personally would not oppose the bill.

1 Q. All right. The only final and brief comment
2 that I--

3 A. You haven't discussed the sanctions part.

4 Q. Admittedly, and I understand to you that is
5 an important sanction.

6 You made reference to fringe elements with
7 regard to animals rights activists, and clearly there are
8 such elements. I don't believe they are represented here
9 today. I think that the folks today who are supporting
10 this bill are very much mainstreamed. But let me just
11 very briefly comment that I was deeply affected by a film
12 that I saw at the last public hearing of this committee
13 considering the predecessor of this bill when that hearing
14 took place in Pittsburgh not too long ago. I was stunned
15 and sickened by the video tape of what was going on at the
16 University of Pennsylvania. And so what I would point out
17 to you, while agreeing that there are some fringe elements
18 among animals rights activists, there are also radicals
19 and fringe elements who until recently were wearing white
20 coats and unnecessarily smashing animal heads in
21 laboratories and laughing about it. And I say that to you
22 not for dramatic effect. I have seen those films and I've
23 been sickened by them. So as we look to the possibility
24 of extremists, we ought to recognize that that
25 possibility, indeed that reality, has existed on both

1 sides of this issue.

2 A. Well, I'm sure you're right, and I'm sure
3 if--

4 Q. Have you seen that film, by the way?

5 A. I have not seen that film, but I'm sure if I
6 had I would be equally sickened by it.

7 Q. I would recommend that it be more than a
8 theory for you and that you take the time to view it,
9 because I was aware of it intellectually as well before I
10 saw it. I was, nevertheless, profoundly affected by it
11 once I had an opportunity to view it, and I strongly
12 recommend it to you.

13 A. The question is, though, will the Federal
14 legislation that's on the books and is likely to be on the
15 books provide the weapons necessary to eliminate that sort
16 of thing?

17 Q. We don't know.

18 A. We don't know yet.

19 Q. We have a responsibility independent of the
20 Federal government.

21 A. I mean, this is one sensational example. I
22 could have come in here with a movie of something that
23 would, in the words of my 12-year-old son, have grossed
24 you all out, okay? And what you would be watching is a
25 liver transplant of a human being.

1 Q. No, no, this is quite different.

2 A. I said to you that this is a terrible,
3 sensational thing that should never have happened and
4 apparently they were closed down, which is what should
5 have happened.

6 Q. Not at all comparable to a liver transplant.
7 We're not talking about the essential blood that's
8 involved in the dramatic impact of surgery. We were
9 talking about people in this film who were needlessly
10 slaughtering animals at one of the most prestigious
11 educational institutions in the country, let alone this
12 State, who were doing so under the least scientific of
13 circumstances, and literally laughing about it. So all
14 I'm saying to you is as we look to and condemn radicals on
15 one side of the issue, we ought to recognize that
16 radicalism has existed on both sides.

17 Thank you, Mr. Chairman.

18 A. Well, I accept that. I accept that there
19 are individuals on both extremes of the question who go
20 too far.

21 Q. You made a reference to only one side.

22 A. And I'm sure that there are examples of
23 abuse, and I would like to see those stopped. But what I
24 am concerned about is establishing a system that will do
25 much more than that, that will really make it difficult to

1 conduct things that I'm sure that you as an individual
2 really don't want to see impaired. That's what I'm--

3 Q. I support animal research when it's
4 necessary for human health and safety. I'm not sure that
5 I support animal research when it's to produce a new shade
6 of eyeliner.

7 REPRESENTATIVE MCHALE: Thank you, Mr.
8 Chairman.

9 ACTING CHAIRMAN MOEHLMANN: Representative
10 Veon.

11 BY REPRESENTATIVE VEON: (Of Dr. Gordon)

12 Q. Mr. Chairman, just briefly, Representative
13 McHale, in my opinion, left out one provision that to me
14 is important in the bill, and that's the search warrant
15 provision, and you had touched upon that briefly, and he
16 was listing those things that perhaps you might be willing
17 to agree with and could you support the bill on that
18 basis. If you could just reaffirm your position on search
19 warrants, since it seems that that clearly could have some
20 impact on medical research as much as any other provision
21 in the bill? If you could just clarify that?

22 A. Well, I think there was a very good reason
23 why medical research was exempted from that provision,
24 namely not to -- the problem is that once you disrupt an
25 experiment with a search and seizure action, you very

1 likely ruined any chance of recovering that experiment or
2 those materials. And it's fine if you've ruined something
3 that was unjustifiable or was criminal activity or
4 whatever you want to call it, but it's not so fine if in
5 fact somebody has made an accusation that has never been
6 put through to a proper investigation, never been
7 conducted in such a way as to determine whether or not in
8 fact there was anything wrong, but in the process you've
9 destroyed whatever was being done. There's no provision
10 in here for how to protect a legitimate research
11 enterprise from not being totally disrupted and destroyed
12 by the investigative action. That's the problem I have
13 with the provision.

14 Q. I appreciate that. So with that in the
15 bill, you could not support the bill?

16 A. Right.

17 REPRESENTATIVE VEON: Thank you, Mr.
18 Chairman.

19 ACTING CHAIRMAN MOEHLMANN: I believe that
20 is the final question. Thank you very much, Dr. Gordon.
21 We appreciate your taking the time to be here.

22 DR. GORDON: Thank you.

23 ACTING CHAIRMAN MOEHLMANN: Dr. Neal
24 Barnard.

25 Have I correctly pronounced your name, sir?

1 DR. BARNARD: Yes, you have. Thank you.

2 Good afternoon, and thank you for allowing
3 me the opportunity to speak with you today. First of all,
4 my name is Neal Barnard. I'm a physician practicing in
5 Washington, D.C. Although I'm on the teaching faculty at
6 the George Washington University School of Medicine, I am
7 not representing that medical school here. Instead, I am
8 representing a group called the Physicians Committee for
9 Responsible Medicine, which is a nationwide nonprofit
10 group of physicians who are concerned about ethical
11 practices, particularly issues related to animal research.

12 Let me preface my prepared comments with a
13 few comments that I hope might be helpful with some of the
14 questioning that has gone on this morning. First of all,
15 the training of surgeons. Some of us labor under the
16 fantasy that if you want to do a tonsillectomy on a
17 6-year-old child, that you have to go into a dog lab and
18 take the tonsils out of a dog and then go back and do it
19 on a baby or a child and then you're safe. Or if you want
20 to take the appendix out of a young adult, that you go
21 take the appendix out of a rabbit or a monkey, then you go
22 into the human laboratory and do it there. This is not
23 the way surgeons are trained.

24 Surgeons are trained, first of all, one of
25 the big preoccupations of medical students in their

1 surgical rotations is tying knots. They do this on
2 styrofoam blocks or other synthetics. When they learn to
3 do that, they are often then allowed to sew up in a
4 non-cosmetic area of a person, as I did when I was in
5 medical school. Someone had a minor procedure done to
6 their leg and I was allowed to sew up and my knots were
7 checked, and if I was wrong, they were redone. In the
8 process of surgical residency, the reason it takes five
9 years and longer is because you are not taking shortcuts
10 through animal labs. You're assisting and observing. You
11 spend hours and hours holding retractors, just doing
12 nothing but watching, and finally you are allowed to
13 assist, and you're really an apprentice. You eventually
14 take over under close supervision. So anyone who tells
15 you that animal labs are the way a surgeon gains
16 competence, that person is misleading you. And I don't
17 care if we're talking about taking the tonsils out of a
18 person or transplanting a heart or doing a coronary artery
19 bypass graft. If you want to make a competent surgeon out
20 of a trainee, you do that in the operating room.
21 Supplementary cadaver labs are often offered. Animal labs
22 are not a part of that training at at least the most
23 sophisticated and prestigious training institutions.

24 Let me make another comment. Early in this
25 century, medical training at some institutions was not

1 something to be proud of. And I'm proud to say that the
2 medical community decided that a culling process was
3 necessary. Those medical schools that were not Class A
4 medical schools ultimately had to go out of business, and
5 I can tell you, there were a number of people who objected
6 to that. But we said, we will have one standard for
7 medical training in this country, and the others will be
8 culled. Medical education has to be standardized.

9 Now, that's true of medical practice, too.
10 Medical practice is regulated, and should be. There have
11 been times in our history where it was not, and I would
12 argue that it should be regulated strictly.

13 Human research at one point in this century
14 was not well regulated. That's why black men were allowed
15 to die of syphilis while the white doctors knew that this
16 was going on and did not treat them because they were
17 doing a study. That is why a number of people had sham
18 surgical procedures where no curative procedures were
19 done, they were sewed up and data was gathered. But now
20 it's closely regulated and everyone knows that that was an
21 important move.

22 Animal research is largely unregulated in
23 this country, and the same culling process that we brought
24 to medical training and to medical practice and to human
25 research has to obtain in animal research. We have to

1 have a minimal floor of behavior.

2 Now, some people will say, well, it's like
3 drunk driving, it's like anything else. You know, some
4 people will misbehave in any system, and I would say
5 that's exactly correct, and those are the individuals
6 we're talking about. Can you imagine if we didn't have
7 laws to deal with drunk drivers? Some people will drive
8 drunk. Let's not have a law. Some people will abuse
9 animals in laboratories. If I, as a citizen, am concerned
10 that an animal has been and is being abused in a
11 laboratory, shall I bring that information to the Animal
12 Liberation Front and say, break in, or shall Pennsylvania
13 decide that I can legally bring that information to a
14 judge, to a law enforcement officer who can consult and
15 get proper -- reach a reasonable decision and issue a
16 search warrant? I think it's precisely because there has
17 been no provision made for that sort of investigation that
18 we see people taking the laws into their own hands, as I
19 would were drunk drivers not taken off the street. I can
20 tell you, I would break the law to stop that person. Why
21 not for any of these other things that we have agreed are
22 egregious?

23 Do Federal laws take the place of State law?
24 Certainly not. Someone said, well, we have AWAC and we
25 have ALAS and these other accrediting agencies. Whoever

1 mentioned that failed to mention to you that most of the
2 laboratories in the United States are not AWAC accredited.

3 The Animal Welfare Act. Yes, it's there.
4 Yes, it's supposed to cover all warm-blooded animals, but
5 when it was written into regulations, and still to this
6 day, it does not cover at least 90 percent of the animals
7 used in research. Laboratories that only use rats, mice,
8 and the other animals that are not covered by the
9 regulations of the Animal Welfare Act do not even have to
10 register with the U.S. Department of Agriculture. They
11 are not subject to inspection. The Office of Technology
12 Assessment in 1986 said, "This frustrates the intent of
13 Congress, but the Federal law has never been upgraded, and
14 State law should be," we should rectify that whole.

15 Moreover, the inspection system is a joke.
16 The General Accounting Office in 1985 released a report
17 showing that those States with the biggest labs,
18 California is number 1, New York is number 2, they went
19 through a year's worth of records and found that over half
20 the labs in those States had never been inspected, period,
21 during that entire year. Were those animals well-treated?
22 Who knows? There is no study that shows that they are.
23 So the current Federal laws are very minimal. They don't
24 do a good job. A State has to have its own standard, and
25 in my view, the University of Pennsylvania is a great

1 argument for State regulation, because how embarrassing
2 for Pennsylvania to have this occur here and to have the
3 Secretary of HHS, Margaret Heckler, have to step in and
4 say, you can't regulate it yourself, Pennsylvania; the
5 Federal government is going to do it for you. And it
6 wasn't anyone in Pennsylvania who shut that lab down, it
7 was Margaret Heckler. That should have been able to be
8 resolved quietly on a local level, and this would allow
9 that to occur.

10 Let me then comment on the Draize test. The
11 Draize test is not a safety test, it is not used as a
12 safety test. When something is dropped into a rabbit's
13 eye and it causes irritation, that does not keep products
14 off the market. It is not a screen in that sense. Take
15 Clairol's products, for example. Go to the store, go to
16 the drugstore and pick up Clairol Loving Care hair color.
17 You will read on the side that if you get this in your
18 eye, it will cause blindness. Blindness. Not eye
19 irritation, not might hurt - blindness. Now, do you think
20 Clairol's Loving Care would pass the Draize test?
21 Certainly not. It would fail. Is it marketed anyway? It
22 certainly is.

23 The Draize test is part of a labeling
24 provision, it's part of the labeling routine, but it is
25 not a safety test. If you look at Clairol's

1 semi-permanent hair colors, they are described in the
2 following terms: Three words, "CAUTION, eye irritant."
3 If you look at the Clairol's bleach powders they state:
4 "CAUTION, eye irritant. When the bleach powders are mixed
5 with hydrogen peroxide, the mixture may cause severe
6 irritation and possibly permanent eye injury...." Are
7 these legal? Sure.

8 If you look at Clairol's Metalex hair dye,
9 it is called an eye irritant. The aerosol hairsprays are
10 described as potential eye irritants. All these would
11 fail the Draize and they are all marketed anyway. So
12 anyone who tells you, your children are safer if they get
13 something in their eye because we Draize tested it, is
14 utterly false. The Draize test is not used in that way.

15 Someone might say, well, then why is the
16 Draize test even used? Well, before we get to that, let
17 me point out that the Draize test, even if it were used as
18 a safety test, is wholly inadequate for the purpose. The
19 Draize test, the definitive study on the Draize test, was
20 published by John H. Draize in 1944, and there's almost
21 nothing that was the state of the art in 1944 that we are
22 still saying we just couldn't do better in 45 years. In
23 1948, the Draize test was four years old and at about that
24 point the sawdust started falling out of the transmission
25 of the Draize test, so to speak. It was in that year that

1 histamine was found to pass the Draize test, it doesn't
2 hurt rabbits, but even a very dilute solution can cause
3 irritation in the humane eye. Selenium sulfide caused no
4 reaction in the rabbit test, but in humans it caused
5 irritation and inflammation in the eye. 2.5 percent
6 cresol caused just a mild reaction in rabbits, severely
7 irritating in the human eye. There are certain detergents
8 that are well known and well described in the scientific
9 literature that caused no reaction in the rabbit eye but
10 are extremely damaging to the human eye. A 5-percent soap
11 solution caused no reaction in the rabbit eye but was
12 quite irritating to the human eye.

13 Why so many difference between test results
14 and clinical experience? The reason is that rabbits are
15 not used because they are a good model of the human eye.
16 The reason that rabbits are used is that they are small,
17 they don't fight back, they have large eyes, and they are
18 easy to work on. The cornea of a rabbit is 30 percent
19 thinner than a human cornea. They have a third eyelid
20 that can sequester compounds that you're testing. They
21 tear in far less volume of tears has produced -- the pH of
22 the tears, the acidity is 10 times different than in a
23 human. The reason that rabbits are used, again, is
24 because they are docile, they are easy to manipulate, and
25 they have large eyes. Is that science? No, it's

1 convenience, but, you know, researchers aren't going to be
2 using Pit Bulls to do their Draize test on. They want an
3 animal that they can handle, that their technician isn't
4 going to get torn up. The Draize test is hardly state of
5 the art science.

6 Researchers at Carnegie-Mellon stated the
7 following: They reviewed Draize test procedures, they
8 found that not only were the results quite variable from
9 one institution to another, but that some compounds seemed
10 quite irritating in some labs and not very irritating in
11 other labs using precisely the same test, the Draize test,
12 and they stated, and I quote, "It is suggested that the
13 rabbit eye procedure should not be recommended as standard
14 practice in any new regulations."

15 Okay, alternatives. What are the
16 alternatives, and are they state of the art? Could we
17 move to them now? The answer is, there is no finish line
18 for the validation process. There is no date by which
19 some stamp is put on the Draize test and it's declared
20 obsolete and others are validated. Companies that use
21 these tests have to make their own decisions. Avon has
22 already made its decision. The validation process is over
23 for Avon, and they've accepted a method that's produced by
24 the National Testing Corporation in Palm Springs,
25 California, that's called the Eytex method. It uses a

1 combination of proteins and other ingredients that
2 simulate the structure of the human eye. When you test an
3 ingredient on this product, this testing product, if it
4 causes a cloudiness, then it's likely to be an irritant.
5 Avon said, fine, no more Draize. That's good enough for
6 us.

7 Noxell, which makes Noxema, Cover Girl,
8 other products, they have accepted a method called the
9 agarose diffusion method. It's a simple test. You take a
10 glass dish, put a layer of cloned cells on it. No animals
11 are killed. A layer of cloned cells, and you put a
12 cushion of agarose, which is a derivative of agar, on top
13 of that, then you put what you're testing on top of that
14 cushion. If the cells are killed, it's an irritant. This
15 test is slightly more sensitive than the Draize. In other
16 words, it's slightly more cautious, and Noxell, as I
17 mentioned, has accepted this, so why couldn't other
18 companies come along and do much -- precisely the same
19 thing? The reason that some of them don't is not because
20 they have doctors rushing in and saying, oh, but the
21 Draize is the best. They have teams, rather, of lawyers
22 saying, if you're sued you want to stick to the standard
23 of practice. You'd better be doing what the other
24 companies are doing. And if the company says, yeah, that
25 makes sense, then they continue the Draize test, and if,

1 as Avon did, as Noxell did, as Benaton did, as Elizabeth
2 Taylor when she marketed her perfume did, they said,
3 baloney. We don't need the Draize test. And there is
4 good reason for that, because there have been court
5 decisions where animal tests did, in fact, not protect the
6 manufacturer.

7 There are other methods in Pennsylvania.
8 The chorioallantoic membrane test was developed, as you
9 probably know, by Joseph Leighton and Ruy Tchao. This
10 uses an ordinary chicken egg where you make a window in
11 the shell, remove that piece of the shell and there's a
12 small membrane under the shell that has blood vessels in
13 it and reacts very much like the human eye. And the nice
14 thing about all of these tests is they are so much cheaper
15 than the Draize that you can do them over and over and
16 over and over again, so there is not this problem of
17 interlaboratory disagreement.

18 Also, at Ohio State, Jerald Silverman
19 recently published on a tetrahymena method, which uses a
20 protozoan, single-celled animal that is quite a good test
21 and also slightly more sensitive than the Draize test.

22 If these are acceptable to some of the
23 largest manufacturers, why not -- why can't all of the
24 manufacturers go along? And I think ultimately they will.
25 I certainly hope.

1 My favorite alternative, by the way, to the
2 Draize test is what I call selective validation. We have
3 to notice that this bill is not talking about penicillin,
4 it's not talking about surgical eye drops, it's talking
5 about cosmetics, it's talking about household products.
6 These are things we bring into our home, we buy over the
7 counter, and if a child ingests those or splashes them in
8 the eye, a responsible company doesn't put something in
9 there that the emergency room doctor has never seen
10 before. You rush the child to the emergency room and say,
11 no one ever used this before, it's new, it's only been
12 Draize tested, that's it. And as you know, in the Draize
13 test they don't use antidotes, do they? Good luck, Doc.
14 Can you save my child's vision? The responsible companies
15 say, we are going to use things that if they have to be
16 caustic, at least they'll be things that at least we know
17 what they are, we're familiar with these things. That way
18 you can save a child's vision, you can save a child's life
19 if you need to.

20 Let me comment just briefly in finishing
21 about a couple of the other provisions of the bill. The
22 right of the student to refuse. Published in the
23 September 1988 Journal of Medical Education, which is
24 published by the Association of American Medical Colleges,
25 the results of a survey done of every American medical

1 school, and we found that there are many medical schools
2 that use no animals at all in their required curriculum.
3 Tufts is only one, but there are others. Ohio State,
4 Michigan State, University of Michigan, University of
5 Washington, State University of New York at Stony Brook,
6 and in this State, Hahneman. Hahneman used to have 15 dog
7 surgeries, today it has zero.

8 Are animals needed? Certainly not. But
9 what about those schools that think it's a good idea?
10 There are many of those schools that still have an animal
11 lab in physiology, pharmacology, one course or another.
12 There's no uniformity about it, but some of them have some
13 of these labs. At virtually all schools they are
14 optional. In other words, if a student objects, the
15 provision is made for them not to participate. Just as we
16 would never take a medical student and say, this woman
17 wants an abortion and you must do it. Because we
18 recognize that some people will not want to perform an
19 abortion. Some will think that's a good idea, but the
20 point is, you don't force a student to do an abortion.
21 Likewise, if a student says, I object to killing animals
22 needlessly, why should they be forced to? And it's a
23 recognition of this need that Tufts Veterinary School has
24 followed suit and now has precisely such a track. You can
25 be a competent physician without doing that. I should

1 think you should be able to get through college, through
2 high school, through junior high, without having to kill
3 animals. And again, this isn't banning that, it's simply
4 saying that those students who have an objection based on
5 their fundamental beliefs, that that, at least, should be
6 respected.

7 Let me conclude at that point and see what
8 questions there may be, if there are any.

9 (Whereupon, Chairman Caltagirone resumed the
10 Chair.)

11 CHAIRMAN CALTAGIRONE: Questions from
12 members?

13 Dave.

14 REPRESENTATIVE HECKLER: Thank you, Mr.
15 Chairman.

16 Doctor, you have provided further evidence
17 for my suspicion that lawyers are the root of all evil in
18 the world.

19 REPRESENTATIVE McHALE: Thank you,
20 Counselor.

21 REPRESENTATIVE KOSINSKI: I'll sue you for
22 defamation of character.

23 REPRESENTATIVE HECKLER: Well, we'll start
24 with you, Jerry.

25 REPRESENTATIVE HAGARTY: We have seconds

1 over here.

2 BY REPRESENTATIVE HECKLER: (Of Dr. Barnard)

3 Q. At any event, you obviously testified about
4 this matter on a national basis and are somewhat familiar
5 with this issue nationally. I'm inclined to agree with
6 many of the things you're saying. As I may have indicated
7 in earlier questions, I am very concerned about the search
8 warrant provision.

9 A. Um-hum.

10 Q. I have an extensive background in law
11 enforcement and I worked with agents of our local SPCA
12 when I was a prosecutor, very successfully. Are there
13 States in which some appropriate agency, whether that
14 would be the Department of Agriculture or some agency that
15 is going to be able to exercise some judgment, some degree
16 of judgment, as to the medical bona fides of a particular
17 facility or particular procedure are empowered to conduct
18 investigations and in appropriate cases execute search
19 warrants?

20 A. In the State of Maryland, a search and
21 seizure was conducted on the Institute for Behavioral
22 Research.

23 Q. Do you know who did that?

24 A. The police did that.

25 Q. Okay.

1 A. A warrant was obtained based on evidence
2 that the animals were cruelly treated. In fact, that was
3 the case. The animals were cruelly treated. To my
4 knowledge, that's the only search that has ever occurred
5 in the United States. And in fact that was, I think, a
6 case of exactly what you need. You need to have a legal
7 provision whereby that can occur. There was no abuse of
8 the system there. People who were familiar with that case
9 brought their case not, again, to the Animal Liberation
10 front or someone else to go in and steal the animals, but
11 rather to duly empowered authorities who could get
12 appropriate consultations as they saw fit.

13 I think the question is a good one.
14 Obviously, if someone is totally in the right and their
15 animals are not being cruelly treated they would not want
16 them to be subject to a seizure unnecessarily. But again,
17 currently, there is no provision whatever whereby one can
18 make that judgment, and this law, as I understand it,
19 would simply allow duly empowered individuals to make that
20 judgment, and I assume that would mean a judge.

21 Q. Well, you don't know how search warrants are
22 issued and executed in Pennsylvania, and we don't have the
23 time to educate you on that point, but I can assure you
24 that what goes into the -- there is no built-in guarantee
25 of any critical analysis of the factual accuracy of what

1 goes into the warrant, and in fact the issuing authorities
2 for the vast majority of the search warrants which are
3 issued are not learned in the law. But, again, since
4 lawyers are the root of all evil, that may not mean
5 anything.

6 A. Well, if that's so, I hope that some steps
7 are made to rectify that because obviously if someone
8 searches my home without proper cause or any Pennsylvania
9 resident's home without proper cause, I would hope there
10 would be recourse.

11 Q. Well, that's it. The remedy is, in most
12 cases, a motion to suppress, and so that the evidence that
13 they've seized, even if they find contraband or evidence
14 of a crime, the evidence is then suppressed and the
15 charges against you end up being dismissed. The
16 difficulty that I experienced particularly where we're
17 talking about medical research facilities is the damage
18 which we've heard, and which it's only common sense and
19 which we certainly heard from other witnesses, the damage
20 that's going to be done in the process.

21 The other point that as a prosecutor, former
22 prosecutor, what occurs to me is that in the vast majority
23 of cases, let's say I'm convinced that there's a
24 laboratory in my jurisdiction that is doing terrible
25 things, things that are plainly inhumane and things that

1 once I look into it and talk to qualified experts I'm told
2 can't possibly be justified on any scientific basis. My
3 very last resort in building a case is going to be to go
4 in and seize whatever animals are involved. I may very
5 well want to go in and have my people take pictures, I may
6 very well want to go in and have -- what I may very well
7 want to do is subpoena records, subpoena people to testify
8 before the Grand Jury. I may very well want to have some
9 undercover person go in to gather evidence or, more
10 appropriately, simply demand that the lab be inspected by
11 appropriate people.

12 Again, you're not necessarily the person
13 with whom this will be resolved, but I think it needs to
14 be said that you're right, we shouldn't have people
15 seizing something they believe to be wrong. I didn't have
16 the opportunity to see the film that so affected
17 Representative McHale, but we don't want people being
18 aware of these activities and not having anyplace to go
19 within the criminal justice system. My suspicion is that
20 the criminal justice system, certainly any district
21 attorney who has access to an investigative Grand Jury,
22 could deal with those situations without a search warrant
23 provision.

24 A. My concern is, having seen that film, and I
25 would recommend that to anyone because that was recent

1 history in this State. It was a case that was not ignored
2 by people concerned about animals. People who are
3 concerned about the treatment of those animals tried to
4 get duly empowered investigations and inspections of that
5 laboratory, and because there was no provision under the
6 law to allow that, cruelties occurred that if you see that
7 tape, you will be utterly convinced that something has to
8 change. There has to be a provision not for the law to
9 abuse this but for at least a mechanism or duly empowered
10 officials to take action.

11 What disturbs me, I'm not an attorney, I'm a
12 physician, and what disturbs me is that some physicians
13 would like to be above the law, and I don't believe that
14 that's proper. They would like you to have faith in them
15 almost as sort of deities. I think it's a mistake.

16 Q. I'm certainly ascribe to that. Is it your
17 understanding that the situation at the University of
18 Pennsylvania was taken to the district attorney's office
19 in that city before and without any avail?

20 A. I'm not sure if it went to the district
21 attorney or not. Others could comment on that, but I do
22 recall that the Humane Society was trying to gain access
23 to do a proper inspection and was not allowed to do so.

24 Q. Thank you.

25 BY REPRESENTATIVE McNALLY: (Of Dr. Barnard)

1 Q. Doctor, I just have two questions for myself
2 and one for Representative Veon, who had to leave.

3 First of all, you mentioned that I believe
4 Noxell and Avon now use non-animal tests for their
5 products?

6 A. That is correct.

7 Q. Is that correct?

8 A. That's correct.

9 Q. You also said that the Draize and L.D. 50
10 tests do not prevent eye irritants from being put on the
11 market, is that correct?

12 A. That's -- a great deal of government data
13 would show that there are eye injuries with products, in
14 spite of the use of these tests.

15 Q. Okay. And so are you now saying that Noxell
16 and Avon do not sell products that irritate the eye or
17 that are toxic? All of their products are non-toxic?

18 A. I was not intending to say that, no.

19 Q. Okay, so that in fact, the alternative tests
20 are no more effective than the Draize test and L.D. 50
21 test in keeping eye irritants and toxic substances off the
22 market?

23 A. It was not my intention to imply anything of
24 that type. That's correct.

25 Q. Secondly, you also--

1 A. However, I might point out that if a company
2 makes a decision that something that -- all the tests do
3 is they show irritancy or non-irritancy. A company can
4 then decide to market them or not as they see fit.

5 Q. Okay. You said that--

6 A. Actually, let me modify that, if I could.
7 As I mentioned earlier, a couple of these tests are more
8 sensitive than the Draize, so there is some possibility
9 that if a company were interested in marketing safe
10 products, that if they were to make this shift, they would
11 perhaps have a slightly higher standard.

12 Q. All right. And so returning again to the
13 Draize and L.D. 50 tests, you mentioned, I think, that
14 these tests are performed, at least in your opinion,
15 because they are hedged against liability in products
16 liability suits, is that correct?

17 A. That's an impression on my part. I have
18 often scratched my head wondering why anyone would
19 continue to do this sort of thing that has been so
20 resoundingly criticized in the technical literature, and
21 that's the best explanation that I can come up with

22 Q. Well, wouldn't an acquisition of information
23 for the purpose of providing a hedge against liability,
24 isn't that a legitimate function?

25 A. It seems to be one that some of the

1 companies feel is important.

2 Q. Well, in any event--

3 A. It's not one that I'm interested in as a
4 physician, no.

5 Q. Well, perhaps the shareholders are
6 interested in it.

7 A. Well, but that's not a reason for the Draize
8 test.

9 Q. Sure it is.

10 A. That's not a reason to be forced--

11 Q. Certainly. So long as a test or an
12 experiment is not performed for an illegitimate purpose,
13 and just an example of an illegitimate purpose is simply a
14 sadistic purpose. If you're doing it to protect yourself
15 against liability, you're doing it to obtain information,
16 to learn, it may be gruesome, an unpleasant thing to do,
17 but that's a legitimate function.

18 A. No, I don't believe it is, because first of
19 all, some courts have ruled that just because they did
20 these tests, that does not remove corporate liability.
21 Number two, perhaps it's worth saying what an L.D. 50 is.
22 You take a rodent, a dog, a cat, or any other animal and
23 you feed them things that if you but put them on your
24 kitchen floor they wouldn't go nowhere near. They don't
25 naturally want to eat lipstick, Scope mouthwash, Gillette

1 Liquid Paper correction fluid. And what do you do? You
2 force feed it to the animal day after day after day. And
3 L.D. 50 means "lethal dose 50 percent". The test does not
4 end until half of them are dead. The other half will wish
5 that they were dead because they have been force fed a
6 near toxic dose of a household product or a cosmetic.
7 Again, we're not talking about lifesaving drugs. We're
8 talking about commercial products. This test is at its
9 worst when the products are not terribly toxic, say
10 mouthwash, because again, the test doesn't end until half
11 of them die. So you force feed larger and larger amounts,
12 and at that point they may die for hemorrhage or bloating.
13 It is a revolting test, and any company who says, hey
14 liability reasons, let's poison some dogs, some cats, some
15 rodents, I find that an absolute effrontery of even basic
16 ethical principles.

17 Q. Well, as I say, I think that I would
18 disagree. I think that if you're doing it to acquire
19 information to protect theirself against liability, that's
20 a legitimate function.

21 A. Well, I'm happy that a number of the other
22 companies have disagreed and are moving away from these
23 tests.

24 Q. Well, and that's a judgment that they are
25 entitled to make.

1 A. Well, but the citizens of Pennsylvania and
2 the citizens of the United States should be able to say
3 there are some things that are beyond--

4 Q. I think there are some citizens here that
5 say that they should be allowed to perform those tests.

6 A. Well, I'm sure that those people will say,
7 and rightly, we want cancer research, don't we? We want
8 heart disease research, don't we? We want diabetes
9 research. We want burn research. Happily, none of those
10 are mentioned in this bill.

11 Q. Yeah, they are. Not specifically the
12 prohibited tests, but in every other section of the bill
13 they are included.

14 A. Well, I imagine that those here advocating
15 for cancer research would say, if some person engaging in
16 cancer research is cruelly treating animals, and there's
17 good evidence of that, shouldn't they be subject to some
18 measure of the law? Currently, they are not, and I'm sure
19 they wouldn't argue against that. At least I would hope
20 not.

21 Q. Well, Representative Veon asked me to ask
22 you, he has three letters, one from the U.S. Consumer
23 Products Safety Commission, one from the Department of
24 Health and Human Services, and one from the Environmental
25 Protection Agency. In summary, they all state, at least

1 with respect to the Draize test, that the Draize test is
2 necessary, that it is valid. In fact, the U.S.
3 Environmental Protection Agency states, "Although there
4 are non-animal test systems which screen for various
5 aspects of ocular and acute toxicity, none of them has
6 been validated to ensure that it accurately mimics
7 responses in the intact animal."

8 A. Do you have the date on that letter, sir?

9 Q. Those are all 1988. June 1988, March '88,
10 and I think this one is May 1988.

11 A. Well, one of the things that's happened in
12 that intervening 11 months is that Avon has decided that
13 whatever those -- whatever interpretation one might make
14 of those, that they are not legally required to do this
15 test. Likewise, Noxell has done the same. Companies such
16 as Nexxus, which makes hair products in every hair salon,
17 Paul Mitchell, these are widely available and never Draize
18 tested, never L.D. 50 tested, never animal tested in any
19 way, and the reason is this: That all of those letters
20 that you've read, including FDA letters and so forth, some
21 people have chosen to interpret that as requiring these
22 tests. That is an incorrect interpretation. There is no
23 pre-market animal testing required of any cosmetic or
24 household product.

25 Now, if you are manufacturing an ophthalmic

1 solution, perhaps, maybe that's a different subject
2 because that's not a household product and that's not a
3 cosmetic. But in that case, the FDA might have a
4 different kind of jurisdiction, different set of
5 regulations. When you're talking about these two areas,
6 there is no pre-market animal testing required, and that's
7 why these companies can do what they're doing. I mean,
8 otherwise, wouldn't Avon, Noxell, Paul Mitchell and all
9 those other companies been in royal trouble?

10 REPRESENTATIVE McNALLY: Thank you, Mr.
11 Chairman.

12 BY REPRESENTATIVE HAYDEN: (Of Dr. Barnard)

13 Q. Doctor, I'd like to continue our focus on
14 the L.D. 50 test and the Draize eye test. I have
15 reference here in the Federal Register to the classic L.D.
16 50 test, or the classic. Is there any difference between
17 that and just for reference to the L.D. 50 test?

18 A. Those could be viewed as synonymous terms.

19 Q. Okay. Our bill makes a reference to
20 precluding any eye irritancy test or any acute toxicity
21 tests.

22 A. Yes.

23 Q. And if you heard my question to the
24 physician before from New Jersey--

25 A. I did.

1 Q. --are you aware of any other eye irritancy
2 test other than the Draize test which is used for purposes
3 of determining toxicity?

4 A. Other eye irritancy tests that might be
5 used, in my judgment, would probably be variants on--

6 Q. Wait a second.

7 A. Well, let me finish--

8 Q. I didn't ask in your judgment, I asked if
9 there are any out there which are currently used by
10 anybody in the scientific community.

11 A. I understand your question, and I think to
12 give you a proper response would be as follows: Were this
13 bill to simply ban the Draize test, period, all that a
14 person would have to do is say, well, what's a Draize
15 test? You have to put something in a rabbit's eye and
16 watch it for three days. If it's an irritant, watch it
17 for three weeks and leave it at that. All you do is you
18 change that protocol very slightly and you're not doing
19 the Draize test anymore, are you? You're doing some other
20 eye irritancy test and getting away with really getting
21 around the intent of the law. At least that's my
22 understanding in reading this, that they're trying to say
23 you shouldn't just do that. It's like banning high
24 velocity rifles by banning the M-16. You just switch to
25 the AK-47.

1 Q. Which is something they are going to do
2 federally anyway, by the way.

3 A. But to directly answer your question,
4 really, the Draize test is the test that's used, and any
5 other test would be simply a variant of that, to the best
6 of my knowledge.

7 Q. But when we refer to the Draize test, we all
8 have a general accepted body of scientific knowledge as to
9 what the Draize test entails. Are there any -- what I
10 mean to ask, and I assume that the Draize test primarily
11 involves rabbits, since the pictures that I've seen from
12 most people, are there other tests involving eye irritancy
13 tests which, through the use of administration of some
14 sort of chemical compound in an eye primarily of any other
15 kind of animal, be it a lower order animals, an
16 intermediate level animal?

17 A. Other animals have been used. Draize
18 himself, in his 1944 report, had a picture of several
19 stocks all in a row, three contained rabbits, as I recall,
20 one contained a dog, a puppy, a juvenile dog. Eye
21 irritancy tests have been done on primates as well,
22 particularly monkeys. These, I assume, would also be
23 prohibited under the law. So the other species of which
24 I'm aware of, dogs and monkeys.

25 Q. Your statement that the -- at least this

1 applies to the FDA -- that the FDA does not require the
2 L.D. 50 test as a determination of toxicity as accurate.
3 In fact, the reference I have in the Federal Register said
4 that in 1985, the agency revoked its only regulatory
5 requirement for the test, eliminating the requirement of
6 the classical L.D. 50 test. So the statement -- there has
7 been a lot of misinformation about the L.D. 50 test, but
8 that is certainly an accurate statement. That is not a
9 prerequisite to marketing a product for FDA approval. But
10 I do have a concern that within the same reference to the
11 Federal Register of October 11, 1988, there was a petition
12 filed by the ASPCA and 20 cosponsors. I wonder if your
13 organization was one of the cosponsors of that petition,
14 which asked for a clarification by the FDA as to their
15 specific protocol with respect to the L.D. 50 test, hoping
16 and urging for actually a statement of policy as to what
17 the alternatives that were to be accepted and basically
18 pushing for an elimination of the L.D. 50 test as an
19 accepted test by this particular agency, the FDA?

20 A. The FDA was hedging its bets for quite a
21 while saying that obviously it's not a very good test, but
22 they weren't going to specifically make any language about
23 it, and more recently they did give a clarification, but
24 the point here is that I've been concerned about the L.D.
25 50 beyond just the cosmetic and household product issue.

1 The L.D. 50 is a terrible test for drug evaluation. It's
2 almost useless. And unfortunately, the testing procedures
3 for drugs may be different from cosmetics and household
4 products, but for cosmetic and household products only,
5 which is what this bill addresses, no animal tests are
6 required pre-market by FDA or anyone else.

7 Q. I think that's accurate to state that, but
8 although the FDA went as far to say that the scientific
9 community agrees that the classical L.D. 50 test is not
10 necessary for determining acute toxicity--

11 A. Right.

12 Q. --I also have a letters here from Dr. Gerald
13 Levy, the Professor and Chairman of the Department of
14 Medicine at the University of Pittsburgh, in which he says
15 he shares your concerns about the Draize eye test and the
16 acute toxicity test L.D. 50 which have all been abandoned
17 as relatively useless tests, there seems to be a
18 substantial amount of scientific literature which has
19 rejected the utility, actually, of the L.D. 50 test, yet
20 even with this petition the FDA refused, although you said
21 they hedged and in fact they sat on this petition for two
22 years before they issued this advisory opinion. They
23 still did not ban it as one of the acceptable methods of
24 determining toxicity.

25 A. That's correct. What they're saying is that

1 they don't want it, they're not asking for it, but if you
2 want to run it in Pennsylvania, that's your business.

3 Q. And they said the same thing before the
4 Maryland Governor's Task Force--

5 A. That's correct.

6 Q. --to Study Animal Testing in your home State
7 on April 17, 1989, in which they went through the whole
8 realm of alternative types of tests like in vitro tests,
9 some of the other tests that you made reference to, but
10 they still came to the conclusion that as it stands now,
11 many years of further research and broad advances on all
12 fronts of toxicological, medical, and related scientific
13 disciplines will be required to replace animal testing
14 methods with non-animal techniques. So once again, you
15 know, I think we agree that the FDA --the point is where
16 the FDA is?

17 A. No, I don't think that -- no, I don't agree
18 with you on that.

19 Q. Well, my interpretation of the FDA statement
20 before the Maryland Governor's Task Force a month ago,
21 less than a month ago, and the FDA's position here in the
22 Federal Register was that although the L.D. 50 test is not
23 required, that they will accept L.D. 50 test results for a
24 product which they are trying to get through FDA for
25 marketing purposes. They're not recommending it. They're

1 not telling you that they're required, but they will
2 accept it.

3 Q. Those would not be cosmetics or household
4 products, which is what this bill is limited to. The FDA
5 is the Food and Drug Administration, and the drugs and so
6 forth that they are evaluating may well be L.D. 50.
7 They're not asking you to, but they will accept L.D. 50
8 data for pharmaceuticals, for drugs. They will.

9 Q. Okay.

10 A. And they don't ban this. I don't know if
11 they ban any other animals tests either.

12 Q. With respect to the use of all alternative
13 tests, the L.D. 50 tests, are there other toxicity type
14 tests that the alternatives to the L.D. 50 tests out there
15 which involve other animals engaged to try to achieve the
16 same kind of result that the L.D. 50 test talks about?

17 A. Any sort of animal is subject to the L.D.
18 50. So it's not a question of certain animals used in
19 L.D. 50 versus other animal tests. Any species of animals
20 would be subject to the L.D. 50.

21 Q. You mentioned -- you made reference to the
22 fact of not having the opportunity to have access to
23 medical laboratories, and I think you made a valid point
24 that nobody is above the law, and I think anybody here
25 would want to do that, but I also have a concern about the

1 way the bill is drafted. There is no requirement that,
2 for instance, a physician or a veterinarian or someone of
3 that kind of medical training be the type of person who is
4 authorized to go and obtain a search warrant, based upon
5 information that that particular qualified individual
6 finds. The fact that the Federate Human Societies of
7 Pennsylvania sent us a letter that said that they're
8 concerned about the bill, though they support the Draize
9 eye test feature and the L.D. 50 feature, their concern
10 is that the majority of human agents appointed by duly
11 incorporated humane societies do not have the scientific
12 expertise required to enforce those changes, and I think
13 those are some of the -- I mean, this is somebody from
14 part of the group which would be expected to help
15 enforce the law if in fact it passed. So would you
16 support a requirement, if in fact this bill, was enacted
17 on the search warrant end that there be some minimum
18 educational requirement similar to the type of the
19 committees that are formed under the Federal law that you
20 have some knowledge about animal research before these
21 people could have access to the search warrant provision
22 in the bill?

23 A. I would think some provision of that sort
24 could be written into the regulations that are
25 promulgated. One could say that someone with scientific

1 training had to go in with that team, or whatever. I
2 guess that would be up to the persons writing the
3 regulations and they could take that into account.

4 Q. Thank you, Doctor.

5 CHAIRMAN CALTAGIRONE: Representative
6 McHale.

7 BY REPRESENTATIVE MCHALE: (Of Dr. Barnard)

8 Q. Doctor, I think you testified that the
9 Draize test was first developed in 1944?

10 A. It was developed actually considerably
11 earlier than that, but the definitive study was published
12 in that year.

13 Q. When was the L.D. 50 test developed?

14 A. Prior to that. I believe it's a World War I
15 era test.

16 Q. Doctor, one of the previous witnesses
17 testified that he supported animal research because of the
18 advances that such research had produced in the field of
19 liver transplants and immunology. I, too, support that
20 type of research. In your opinion, if we were to ban the
21 Draize test and the L.D. 50 test, both of which are now
22 approximately a half century old, do you think there would
23 be any adverse impact on advances in modern medical
24 technology?

25 A. No, I can't imagine that it would impact

1 adversely in any way on research.

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

4 CHAIRMAN CALTAGIRONE: I don't think there
5 are any further questions. You can be excused.

6 Okay, it's been taking a little bit longer
7 than I anticipated. If the members could just restrain
8 themselves a little bit of the questioning, we do have a
9 lot of excellent testimony yet to come and we are very far
10 behind in the schedule of witnesses.

11 I'd like to call Dr. David Meinster and
12 Arnold Raphaelson next, and if Steve Carroll would also
13 join in in order to speed things up. I'd like to take
14 those three next. And then the next three would be
15 Hazard, Dunayer, and then Stephens. And we'll roll it a
16 little bit like that and then you can all offer your
17 testimony and then open it up for the members to offer
18 questions.

19 So if Steve Carroll would come up, Dr. David
20 Meinster, and then Arnold Raphaelson. State your name for
21 the record, if you want to go left to right, however you
22 want to start, and make your presentations, and then when
23 you complete, the three of you, then we'll open it up for
24 questions from members.

25 MR. CARROLL: Okay. We'll start with me, I

1 guess.

2 Yes, my name is Steve Carroll, and I'm the
3 Executive Director of the Incurably Ill for Animal
4 Research. Our membership are people in the country who
5 have major health problems, people who want to get well,
6 want to get on with their lives, and people who hope that
7 medical research will make that possible. I think in
8 respect for the time that we're running over today, I will
9 skip past the first page of my testimony which talks about
10 some of the advances that we've seen in medicine, because
11 I think everybody that's here is aware of that already.
12 Suffice it to say that modern medicine has come a long way
13 in the last 50 to 100 years, but we must not forget that
14 we still have a long way to go. That there still are
15 diseases that need cures and there still are new surgical
16 techniques that need to be discovered, and that there
17 still are new pharmaceutical drugs that need to be
18 developed, and that medical research, about 45 percent of
19 which requires animals, is aggressively working towards
20 reaching those goals.

21 We also need to be aware that this marvelous
22 progress that we've seen is being threatened by a small
23 and vocal group of people who believe that a rat is a pig
24 is a dog is a boy, that they're all the same. That quote
25 is from Ingrid Newkirk, the National Director of People

1 for the Ethical Treatment of Animals, or PETA, one of the
2 largest animal rights organizations in this country. And
3 make no mistake about it, there are a lot of people who
4 are very vocal who want to put an end to all animal
5 research.

6 While there are many of these activists who
7 openly will say that that is their ultimate goal, there
8 are others who realize that they will never get a law
9 passed outlawing the use of animals in research. So they
10 direct their efforts towards making research requiring
11 animals prohibitively expensive, cumbersome, and overly
12 restrictive. And oftentimes, these people hide their true
13 intentions of ending all animal research behind a false
14 facade of animal welfare concern. Now, these people are
15 patient. They're willing to make one small step at a
16 time. There's an old saying that you can start with a
17 3-foot long tube of salami, but no matter how thinly you
18 cut the slices, if you keep cutting away, eventually it's
19 going to disappear.

20 The bill that you are considering today is
21 not a thin slice. It would cut away a large chunk of
22 medical research. It would needlessly increase the cost
23 of conducting research, leaving less money to fund
24 productive projects. It would needlessly divert the
25 researchers' time away from the laboratory, and it would

1 needlessly place a burden on the Commonwealth of
2 Pennsylvania. And it would provide the animal activists
3 with additional means to disrupt research.

4 IIFAR is concerned about House Bill 873
5 because it would affect the medical future of our members
6 throughout the country. Pennsylvania is home of several
7 prestigious research facilities and progressive
8 pharmaceutical companies. When something new is
9 discovered in Pennsylvania, that discovery isn't held
10 within the Commonwealth's boundary. It's shared
11 throughout the world. I have chronic osteomyelitis, and
12 I'm waiting for a more effective treatment, but I don't
13 know where that might come from in the future. It may
14 come from California, Iowa, Florida or Pennsylvania. But
15 I don't want to see Pennsylvania removed from that list of
16 possibilities.

17 873 would direct the Secretary of
18 Agriculture to promulgate regulations governing the humane
19 housing, treatment, and care of laboratory animals. These
20 same items are already a part of the Federal Animal
21 Welfare Act. They are already required. You have asked
22 in questions earlier how this would affect, have a
23 negative effect on research. Well, the USDA has already
24 spent four years working on developing these regulations
25 to implement the last amendments to the Animal Welfare

1 Act, which the wording is almost identical to your bill.
2 During that four years, the research community has had to
3 work very closely with them to make certain that these
4 laws are at least something that can be lived with. And
5 that, in itself, is damaging research. This hearing today
6 in a small way is impeding research because we have
7 doctors and we have researchers that are here today
8 instead of in their labs where they should be. And I
9 think that you also need to ask yourselves if you really
10 want to put your Department of Agriculture through four
11 years of coming up with regulations that are already --
12 that are a duplicate of what is already there in the
13 Federal government.

14 873 would also allow the issuance of search
15 warrants for alleged violations, and I hope that everybody
16 here really realizes what this could -- what type of a
17 Pandora's box this could open up. Animal activists around
18 the country have repeatedly abused every means possible to
19 disrupt research. They have filed lawsuits in countless
20 States around the country, they have challenged zonings on
21 new research facilities. Now, they've never won these,
22 but they don't need to win to succeed what their ultimate
23 goal is, which is to disrupt research. If they can get
24 institutions and companies to divert money into court
25 costs, if they can get researchers to walk out of their

1 labs to testify at a hearing, they have succeeded in what
2 they are setting out to do. So you can be assured that if
3 873 becomes law the way that it is, that there will be
4 some activists that will allege violations almost daily,
5 wreaking havoc among the research community and wasting
6 the Commonwealth's time and resources as well. And here
7 again, the Federal government already has means of
8 protecting laboratory animals. Both the NIH and the USDA
9 already investigate complaints about improper lab animal
10 care.

11 I think that one item that everybody is
12 especially concerned about and wants to see followed
13 through on is prevention on how to prevent diseases and
14 disorders and injuries in this country. Well, one of the
15 provisions in this bill would be very damaging for that,
16 and that is the ban on eye irritancy and toxicity testing,
17 because one of the ways that injuries can be prevented and
18 are prevented in this country is through the information
19 that's learned through product safety testing, so that
20 emergency room physicians know how to treat somebody who
21 comes in with a substance in their eye, so that consumers
22 can make an educated choice when they go to the store by
23 how the product is labeled. They can tell whether it's
24 dangerous or not so that these types of accidents can be
25 prevented.

1 Now, I'm not a scientist and I really can't
2 speak on the scientific worthiness of these tests, but I
3 don't think many of you are scientists either, but I do
4 think that you have a high level of common sense and
5 reasoning, and I tend to think that I do, too. And it
6 sure seems to me that after hearing testimonies from
7 people on both sides of this issue who have said that the
8 non-animal alternatives that are being purported as taking
9 the places of these tests are less expensive, it sure
10 seems to me that profit-oriented companies would try to do
11 whatever they can do to lower their costs, and if they
12 were less expensive and they did offer the same
13 prevention, that they would use it. It also seems to me
14 that it might be very dangerous to the health of members
15 of the Commonwealth and of the whole country to
16 legislatively prohibit certain types of tests.

17 There are several provisions in this bill,
18 other provisions that are also equally damaging, but time
19 is short and there will be others here today that will be
20 addressing these topics in more detail, so I'll pass on
21 them. I simply ask that you carefully think about what
22 many of those provisions could do to medical research if
23 they were abused. I also suggest that you ask yourselves
24 just who would benefit and who would suffer as a result of
25 the passage of this bill. Would the laboratory animals

1 really benefit? No, I don't think so, because the
2 protection that's offered to them under 873 is already
3 there through the Federal government. It's the animal
4 activist who would benefit by the passage of this bill
5 because it would give them additional ways to disrupt
6 research, moving them one step closer to their ultimate
7 goal of stopping all use of animals in medical research.
8 And would it be the research community that would suffer
9 because of this bill? Not really. Researchers,
10 scientists and animal caregivers are going to continue to
11 get paid every week, whether they are filling out forms,
12 whether they are testifying in hearings, or whether they
13 are working in their laboratories. The pharmaceutical and
14 consumer product companies will continue to safety test
15 their products, if not in Pennsylvania then elsewhere, and
16 if it costs more money, they can just pass it on to the
17 consumer.

18 No, it will be the citizens who will be the
19 losers, especially those who have an immediate need for
20 improved medical treatment. We are the losers when the
21 price of drugs raise. We are the losers when the
22 researchers have to spend time away from their lab, and we
23 are the losers when the precious research dollars are
24 needlessly wasted on duplicative layers of regulation.

25 I thank you for your time.

1 CHAIRMAN CALTAGIRONE: Thank you.

2 DR. RAPHAELSON: Mr. Chairman, I am Arnold
3 Raphaelson. At my left is David Meinster. We have
4 prepared our testimony jointly. We are both professors of
5 economics at Temple University, with particular interests
6 in health economics.

7 We are here to testify today in part about
8 an economic study that we performed that was sponsored by
9 the Philadelphia Drug Exchange a few years ago. The Drug
10 Exchange membership is composed of the major drug
11 manufacturing and distribution firms in Pennsylvania. But
12 we want to stress that our testimony need not reflect the
13 official views either of the Drug Exchange or of Temple
14 University.

15 Clearly, some members of the Drug Exchange
16 are very much concerned that House Bill 873, if enacted,
17 will cast a shadow over the future of pharmaceutical
18 research in Pennsylvania. If their concerns materialize,
19 it's clear that drug firms could, with relative ease, as
20 was just noted, conduct their research elsewhere.

21 Research and development are very important
22 for the health care industry. R&D has been responsible,
23 as has been noted here already, for many dramatic advances
24 in therapeutics, and we see this all around us. In 1987,
25 it's estimated that one and a half billion prescriptions

1 were filled in the United States, and in 1988, about \$8.5
2 billion in over-the-counter, that is nonprescription
3 products, were credited with saving \$24 billion in
4 physicians' fees and lost work time. All of us are agreed
5 that we want these benefits to continue from the
6 laboratories, and these benefits are more apparent than
7 some of the conditions and the institutions that have
8 provided the discoveries behind them. We should recognize
9 that it is possible if we don't see to that environment
10 that we could lose them from Pennsylvania. And we often
11 assume that the big advances in medicine come from distant
12 nonprofit institutions, but the truth is that most new
13 drugs come from drug companies, and Pennsylvania is very
14 important in this field.

15 In the Federal publication U.S. Industrial
16 Outlook, 1989, the U.S. drug industry, as a whole, is
17 cited as having about \$50 billion in worldwide sales,
18 including exports and products made abroad. There was a
19 favorable international trade balance, one of the few for
20 the United States, with \$3.79 billion in exports and \$3.65
21 billion in imports, despite the fact that there is an
22 estimated \$2 billion loss to patent pirates.

23 That publication cited several factors as
24 important to the prosperity of the industry, including its
25 contributions to meeting national health goals, especially

1 with an aging population that has growing health needs.
2 And crucial also is the number of new products developed.

3 The publication cites four questions that
4 are said to guide the industry spending for research and
5 development. First is, will the new product satisfy a
6 medical need? Second is, does the industry have the
7 competence to develop the product within a reasonable
8 length of time? Third is, will the product bring about a
9 significant therapeutic improvement? And fourth, will the
10 demand justify the expenditure? Well, the industry's
11 responses to those questions are measured by the total
12 spending of about \$6 billion on research and development
13 in 1988. \$5 billion of it spent in this country, a
14 billion dollars spent abroad. In 1987, 16 of the 21 new
15 drugs approved by the U.S. Food and Drug Administration
16 were developed in the United States, and the Outlook
17 publication goes on to say, quote, "New drugs can only be
18 developed if the R&D development is economically and
19 politically friendly and if there is some relief from
20 litigation once the new drug has been placed on the
21 market," closed quote.

22 The costs of R&D and the liability insurance
23 are very high. Competitive pressures have increased as
24 patents have expired and generics and nonprescription drug
25 sales have grown. As a result, some firms have stopped

1 developing and producing things like vaccines and other
2 high risk products. It's clear, just as the Eastman
3 Kodak-Sterling decision was to move to Pennsylvania from
4 New York State for a favorable research environment, it
5 can be moved from Pennsylvania to other States or to
6 foreign nations if that environment in Pennsylvania is
7 perceived as deteriorating.

8 Pennsylvanians may not fully appreciate how
9 much medical progress has been brought to life by members
10 of the Philadelphia Drug Exchange, by firms in the
11 Commonwealth. We know many of the major advances have
12 occurred and many of those have occurred within 100 miles
13 of Harrisburg in the research laboratories of less than a
14 dozen firms in the area. A few years ago, the two of us,
15 along with Erwin Blackstone, a third college in the
16 economics department at Temple, developed an economic
17 impact analysis relating the pharmaceutical industry, the
18 Philadelphia Drug Exchange, to the Pennsylvania economy,
19 and we produced a booklet of our findings. Dr. Meinster
20 will highlight some of those findings.

21 DR. MEINSTER: Very briefly, we found out in
22 almost every measure that Pennsylvania's drug industry was
23 growing in sales, in payroll, in capital expenditures and
24 in spending for research and development, and this was
25 during a period that much of Pennsylvania's basic industry

1 was in decline, with the resulting loss of people and
2 revenue.

3 Federal data show that during the period
4 1977 to 1982 that Pennsylvania-based drug industry sales
5 rose by 72 percent, which was about three times the rate
6 of Pennsylvania industry manufacturing and was even higher
7 than that of the rate for the drug industry nationally.
8 The drug industry is one of the fastest growing of
9 American industries, and Pennsylvania drug firms are among
10 its leaders.

11 In the same period, the drug industry's role
12 as a manufacturing employer grew in Pennsylvania in
13 percentage terms.

14 While capital investment in Pennsylvania
15 grew about 50 percent between 1977 and 1982, drug
16 companies' capital expenditures rose about 300 percent.
17 This rate of increase in Pennsylvania was 2 1/2 times the
18 rate for the industry nationally, and six times the rate
19 of increase in capital spending for all Pennsylvania
20 manufacturers.

21 While Pennsylvania's dollar payroll in total
22 manufacturing rose about 30 percent during the '77 to '82
23 period, the Pennsylvania payroll in drug manufacturing
24 rose 45 percent. It should be borne in mind that the
25 importance of the drug industry to Pennsylvania is

1 understated by manufacturing employment and payroll data.
2 The industry's ability to sustain employment during the
3 1981-83 recession is a case in point. In that period,
4 employment in the drug industry declined at a lower rate
5 and its sales in payrolls actually rose. By the end of
6 1983, Pennsylvania's drug industry sales at about \$3 1/2
7 billion represented almost 1 dollar in 11 of the State's
8 manufacturers.

9 In addition to the government data, we
10 surveyed eight drug manufacturing firms in Pennsylvania.
11 These firms contributed about \$23.5 million in State and
12 local taxes in 1983. In addition, the industry's
13 employees paid about \$22 million in State and local income
14 taxes.

15 These firms increased research and
16 development spending to about \$333 million in 1983.

17 The drug industry is renown for its support
18 of community and educational organizations in
19 Pennsylvania. Our survey found that they contributed
20 about \$1.2 million to colleges and universities in 1983,
21 the last year that we had the figures for, and about \$11
22 million to other institutions.

23 Much of these data will be updated as new
24 census information becomes available. We have obtained
25 some recent information on Pennsylvania firms' research

1 and development expenditures of possible interest to the
2 committee. For 1988, the six major firms operating in
3 Pennsylvania spent more than \$2.2 billion on research and
4 development. Sterling Drug Division of Eastman Kodak may
5 add \$150 million or more annually as its research and
6 development operations transfer to the Delaware Valley
7 from New York State over the next several years.

8 Clearly, the pharmaceutical industry is a
9 powerful economic, social, and cultural presence in
10 Pennsylvania. We feel sure that in considering any
11 legislation regulating that industry that you will
12 recognize the effects on that industry's ability to
13 continue and to expand its contributions to our economy.

14 Thank you.

15 CHAIRMAN CALTAGIRONE: Thank you.

16 Members.

17 REPRESENTATIVE HECKLER: Just one
18 observation, I'm sorry, for Mr. Carroll. I have some
19 direct -- there are family experiences which lead me to be
20 very favorably inclined toward some of your arguments, but
21 I would suggest to you that the camel's nose in the door
22 of the tent argument which we hear, whether it's from the
23 National Rifle Association who is convinced -- that while
24 you're smiling and nodding and I'm saying that I don't buy
25 it, and I don't think that this legislature should make

1 decisions on legislation on that basis. I think it's our
2 responsibility to review each piece of legislation on it's
3 own merits. I'm also not commenting on what I think the
4 merits of this legislation are, but I just want to make
5 the observation that I think that it's very important that
6 we look at the virtues or lack thereof of this legislation
7 and not say, let's stay out of this area because if we
8 outlaw Draize and L.D. 50 today, tomorrow we're going to
9 be turning the research labs over to the folks who believe
10 in animal rights. I don't think this debate is
11 well-served by taking that point of view.

12 MR. CARROLL: Well, I would agree with you,
13 but that wasn't actually the point of view that I was
14 trying to put across, and if I did, I'm sorry. What I was
15 trying to say is that there are areas in this specific
16 piece of legislation that could be abused and that you do
17 have the responsibility to look at that possibility, and
18 that's what I was trying to address, not necessarily the
19 fact that they could or would come back tomorrow. I
20 didn't mean to get into that at all.

21 REPRESENTATIVE McNALLY: I'd like to
22 address a question to the economists, the two gentlemen
23 that did the study.

24 We've heard some conflicting testimony
25 today, or what appears to be conflicting testimony, from

1 the proponents of this legislation as to the utility of
2 the L.D. 50 and Draize tests. Two, I think, witnesses
3 said that they thought that the L.D. 50 and Draize tests
4 had little or absolutely no utility whatsoever. Assuming
5 that they are correct and if Draize and L.D. 50 tests are
6 simply a waste of money, offering no benefits, could you
7 tell us how much money the pharmaceutical and household
8 and cosmetic manufacturers in this country or State spend
9 on specifically the Draize and L.D. 50 tests?

10 DR. RAPHAELSON: No. We have no information
11 on the amount of spending on those particular tests. If
12 we assume, as you've asked us to, that the tests serve no
13 purpose to them at all, we have the feeling that perhaps
14 with some lag of ongoing programs that they would be
15 discarded. The amount spent on these tests we have no
16 specific knowledge of. We have some global data with
17 respect to the firms that are Federal data and we have our
18 survey data which indicate amounts for R&D in general but
19 not for specific purposes.

20 DR. MEINSTER: I would like to reiterate a
21 point that you made earlier, and that is that these firms
22 are all in competition with each other, and if firms were
23 spending excess amounts on these kinds of research, it
24 would affect their profits and clearly they would stop
25 doing it. So I think the market in this kind of a

1 situation is a very powerful influence. If there were
2 cheaper and just as productive methods of achieving the
3 same results, I think the market would be that they would
4 switch to those tests.

5 REPRESENTATIVE McNALLY: So I guess, you
6 know, my concluding question would be that would the
7 household and, you know, to the best of your knowledge,
8 would the household and cosmetic industries and
9 pharmaceutical industries be a fairly competitive industry
10 where significant spending on, you know, wasteful
11 experiments would have an impact and might be felt in the
12 marketplace?

13 DR. RAPHAELSON: I think in general the
14 pharmaceutical industry would be regarded largely as an
15 oligopoly where there are several large firms rather than
16 as anything approaching the model of perfect competition.
17 However, the rivalry among those several large firms is
18 quite intense. Many of them are under very similar
19 pressures, including the liability pressures with products
20 and other elements that would lead them to continue the
21 research that would involve some tests. Whether those are
22 not, I have no idea. And the fact is that while they
23 strive to develop new products and get patents on them,
24 they are getting a great deal of pressure from other
25 firms, that is not just the large ones, in the production

1 of generics. I don't think that they are now in the
2 position of high budgets wasting money, and I don't think
3 that they would be spending it if they could not justify
4 such spending.

5 REPRESENTATIVE McNALLY: Thank you.

6 CHAIRMAN CALTAGIRONE: Any other questions?

7 (No response.)

8 CHAIRMAN CALTAGIRONE: Thank you, gentlemen.
9 I appreciate your testimony.

10 I would like to call next Holly Hazard, Eric
11 Dunayer, Martin Stephens.

12 MS. HAZARD: Thank you, Mr. Chairman, and
13 members of the committee. I submitted extensive comments
14 and I just want to, because there have been a number of
15 other people testify before me, touch on a few points that
16 I think have not been made very clearly and hope that you
17 will take the opportunity to read my comments in full if
18 you should need further information.

19 The first point that I want to address on
20 this bill, I'm Holly Hazard and I'm the Executive Director
21 of the Doris Day Animal League. We have approximately
22 30,000 members in Pennsylvania and about 300,000 members
23 nationwide. Our organization fully supports the
24 provisions as set forth in the proposed legislation.

25 The first area of legislation that I'd like

1 to discuss briefly is the search warrants provision. And
2 I hesitate to say that I am an attorney. I am not a
3 Pennsylvania attorney and I'm not familiar with your
4 judicial system as it might be different from other
5 States, but I believe that this is an important part of
6 the capability of any State to enforce the provisions
7 under its anti-cruelty statute. If the State's serious
8 about wanting the provisions of anti-cruelty statute to
9 include what goes on in a research laboratory, then one
10 important provision of this would be to allow those
11 individuals charged with that enforcement the opportunity
12 to go in and seize evidence and to investigate claims that
13 there may be some improprieties taking place if an
14 unbiased judicial officer feels that the individual has
15 made a sufficient case so that there are no constitutional
16 questions and so that there are not any violations of
17 someone's civil or constitutional rights taking place.

18 There should be, and I would hope that there
19 is in Pennsylvania, sufficient controls under the criminal
20 justice system so that we would not be in a position where
21 an advocate of animal protection who would not have
22 experience and who was not making claims that were
23 legitimate violations of the anti-cruelty statute, not
24 simply someone that didn't like the research that was
25 going on, would be able to go into someone's laboratory

1 and seizes animals any more than someone should be able to
2 go into my home and seize my animals because they didn't
3 like what I was doing if I was violating the anti-cruelty
4 statute.

5 With reference to your concerns that there
6 are things that go on in research laboratories that the
7 layperson may not understand and so therefore may
8 misinterpret as cruelty when cruelty is not actually
9 taking place, certainly people that go in and are in
10 charge with enforcement, are charged with upsetting
11 people's civil liberties and constitutional rights, should
12 be trained and should understand exactly the line that
13 they have to walk to insure that we protect the
14 constitutional rights of individuals, animal researchers
15 and others. I believe that that can be adequately done.
16 It's done in every other area of criminal jurisdiction and
17 criminal procedure, and certainly research laboratories
18 should be no different in trying to control those
19 safeguards.

20 With reference to one of the questions that
21 was asked, this is the last point I want to make on search
22 warrants, I have a letter here that I think was
23 distributed to members of the committee, if not it will
24 be, from Mr. Gary Francione, who is a professor of law at
25 the University of Pennsylvania in which he stated, and I

1 just want to read a couple of sentences, that he was very
2 heavily involved in the efforts to close the now infamous
3 head injury laboratory at the University of Pennsylvania
4 Medical School. As you know, that laboratory was closed
5 by the Public Health Service for violation of various laws
6 and regulations concerning animal treatment and
7 occupational safety. And this is the appropriate part,
8 "On several occasions I spoke to the Philadelphia district
9 attorney's office and tried to get an investigation of the
10 laboratory by local officials. On each occasion I was
11 told the search warrant exemption effectively precluded
12 such an investigation." If an exemption were not in the
13 law, perhaps the abuse of animals at the lab could have
14 been stopped years earlier.

15 So that was one instance in which we could
16 have stopped all the publicity and quite a bit of the
17 anguish that went on for the animals and for the people
18 involved in that case had there been an opportunity for
19 people to go through the legislative system.

20 The second point that I want to touch on
21 very briefly has to do with prohibiting the Draize and the
22 L.D. 50 tests for cosmetics and household products. First
23 of all, with reference to the testimony that came just
24 before with reference to drug companies in this State and
25 the impact that this legislation may have on them, with

1 reference to the regulatory requirements that may be set
2 up under this new law, certainly drug companies, if they
3 are using animals, would be affected, but with reference
4 to the Draize and the L.D. 50 test, the provisions of this
5 act and the intent of the act are only to include
6 cosmetics and household products and should have
7 absolutely no impact on the testing of new drugs in this
8 country and in this State.

9 The three arguments that you often hear in
10 opposition to prohibiting the Draize and L.D. 50 are that
11 these tests are required under Federal law, they are
12 required for safety and they are required because although
13 alternatives have been developed, they haven't been,
14 quote, "validated," unquote. I think that there's been
15 quite a bit of discussion as to the safety of the Draize
16 and L.D. 50 and also the alternatives available, so I
17 won't get into that much detail. With reference to the
18 Federal law, there are two agencies involved that have
19 jurisdiction, potential jurisdiction, over cosmetics and
20 household products. That's the FDA and the Consumer
21 Products Safety Commission, and several of the committee
22 members have referenced letters from these agencies
23 stating that they support the Draize test and the L.D. 50
24 tests and they believe that they are safe and effective
25 tests. I would say in response to that that there is no

1 question that the Federal government encourages these
2 tests, they accept the results of these tests, they do not
3 have a program in place to encourage alternatives, but
4 they do not require these tests. And if we have made an
5 effective case that products can be safely marketed, as
6 they are by over 100 companies in the United States,
7 without doing these tests, then the point that I wish to
8 drive home is that there is no Federal prohibition from a
9 company attempting to use the alternatives to these animal
10 tests. The FDA, in a statement that I think was
11 referenced earlier to a task force studying this problem
12 in Maryland, stated, quote, "Current law administered by
13 the FDA does not require the use of animal tests for
14 cosmetics." The FDA made a further statement in a letter
15 to Congresswoman Barbara Boxer in September of '88 which
16 said not only do they not require the data from this test,
17 but they could not obtain that data if such tests were
18 conducted. The FDA simply does not collect data on
19 pre-market evaluation of cosmetics prior to those products
20 being presented into the stream of commerce.

21 The Consumer Products Safety Commission
22 stated in the Federal Register notice as early as 1984
23 that neither the Federal Hazardous Substances Act, which
24 is the act in their jurisdiction, nor the commission
25 regulations require any firm to perform animal tests.

1 Again, this is not to say that they don't support these
2 tests but it's simply to say that if the opposition's
3 argument there that they would like to change but they
4 simply can't because the Federal government has them in
5 some kind of a stronghold, this is simply factually
6 incorrect.

7 The second safety arguments that industry
8 makes is that there are alternatives to these tests but
9 they have not been validated. Validation, as was
10 mentioned earlier by Dr. Barnard, is not some special
11 analysis that's done simply miraculously and everyone is
12 going to switch. It's a process and it's an evolution
13 towards more technologically advanced methods. The facts
14 are that alternatives to these tests do exist. Several of
15 the associations have gotten together and discussed at
16 least 14 of these alternatives. The problem is that
17 individual companies don't think that enough work has been
18 done, that the test has been repeated enough times so that
19 they feel comfortable with one kind of test or another.
20 There's a very simple solution to feeling uncomfortable
21 with the lack of validation, and that's simply to spend
22 the money on research that they need to spend to repeat
23 the test. There's no mystery to what needs to be done on
24 these alternative procedures, and several companies have
25 done that. Avon, for example, has and they have stated

1 that they have, quote, "validated" the Eytex system.
2 There is nothing to stop other companies from spending the
3 money to go ahead and do that.

4 As far as changing from the alternatives
5 that are available to validated alternatives which would
6 make the companies comfortable in switching, the only
7 problem with switching to these has to do with the lack of
8 commitment on the part of industry. The CTFA, the
9 Cosmetics, Toiletry and Fragrance Association, has stated
10 in the last year they have spent about \$5 million on
11 alternatives at the Johns Hopkins Center and other places,
12 but when you compare this kind of spending to the amount
13 of money that they spend on advertising, for example,
14 Proctor and Gamble last year spent about \$1 billion in
15 advertising, you can see that the amount of money and the
16 effort that they're putting into these alternatives is a
17 pittance.

18 We believe that the cosmetics and household
19 products firms are disingenuous in saying that they'd like
20 to switch over but that they have don't have the
21 opportunity or that the alternatives are not there. They
22 are there, several firms have switched over. Hundreds of
23 companies in this nation don't use these tests, and the
24 Federal government has not stopped them from manufacturing
25 or from marketing their products.

1 Thank you.

2 CHAIRMAN CALTAGIRONE: Next.

3 MR. DUNAYER: My name is Eric Dunayer. I'm
4 a veterinarian and I work for the Association of
5 Veterinarians for Animal Rights as their Curriculum
6 Modernization Coordinator.

7 Pennsylvania House Bill No. 873, Section
8 (2)(e), which concerns a student's right to refuse to
9 participate in a vivisection or dissection, holds personal
10 significance for me. I entered the University of
11 Pennsylvania School of Veterinary Medicine because I
12 wanted to pursue a career helping animals. I soon
13 learned, however, that certain requirements of the
14 veterinary school were in conflict with my moral code of
15 not harming or killing animals. Early in my second year I
16 was required to take a course in pharmacology, including
17 an associated laboratory. The laboratory exercises used
18 animals in a manner I considered cruel and unnecessary.
19 One lab consisted of injecting mice with an insecticide
20 and watching how they died. Another used a heart from a
21 freshly killed guinea pig to demonstrate the effect of
22 certain drugs on heart muscle. These labs demonstrated
23 already well-known principles.

24 A group of us realized that we could not, in
25 good conscience, participate in these laboratories. We

1 went to the instructor to express our misgivings and to
2 work out a mutually acceptable alternative, one that would
3 fulfill the course's educational goals without violating
4 our ethical beliefs. Instead, we were quoted school rules
5 specifying mandatory lab attendance and informed that no
6 exceptions were possible because the lab was absolutely
7 essential for the course. Rather than accept the
8 situation, we took our case to administrative officials.
9 After weeks of delay, we were ushered into a meeting with
10 a Robert Marshak, then dean of the school. Again we were
11 quoted school rules, but now the dean added his own
12 personal message. He told us that with our attitudes, we
13 did not belong in veterinary school and that he wished he
14 could identify people like us before we got to Penn.
15 Finally, if we refused to attend the lab sessions, we
16 could expect to fail the course. The administration's
17 threats so intimidated most of the students involved that
18 only Gloria Binkowski and I continued to refuse to attend
19 the labs. We learned the course material from
20 pharmacology textbooks, took the necessary tests and
21 waited for our grades. Although we hadn't attended the
22 labs, the instructor gave each of us an A for the course
23 based on our exams. The following year, the course no
24 longer included any animal lab, nor has it included one
25 since.

1 At the beginning of our third year, Gloria
2 and I were expected to take a required laboratory course
3 consisting of four surgical sessions on two healthy dogs.
4 In the first session, a dog is recovered from anesthesia
5 following surgery. In the second session conducted a week
6 later, the same dog is killed. The third and fourth
7 session repeated the sequence of the first two with a
8 second dog. Again we objected. We felt that it was
9 morally wrong to kill or maim a healthy animal. Gloria
10 and I approached the course instructor and asked to work
11 with him on a mutually acceptable alternative. Our
12 request was summarily dismissed.

13 We repeatedly appealed our case until we
14 were finally offered a so-called alternative. This
15 consisted of killing four healthy dogs rather than two.
16 These dogs, initially healthy, would be maimed as part of
17 practice surgery, then killed. In addition, we would be
18 expected to monitor other surgically maimed dogs during a
19 short recovery period, after which they, too, would be
20 killed. We were given an ultimatum: Accept this
21 alternative or fail the course and leave veterinary
22 school.

23 Gloria and I appealed to the president of
24 the University, hoping he would help us settle this matter
25 in a nonadversarial way. Instead, we were both failed,

1 barred from entering our final year of study, and faced
2 with certain expulsion unless we re-took this course under
3 the same conditions. At this point, our only recourse was
4 to file a lawsuit against the university to preserve our
5 right to complete our studies. After negotiations with
6 the veterinary school, we were allowed to fulfill our
7 surgical requirements with a morally and educationally
8 acceptable alternative. Gloria and I went on to complete
9 our studies and graduate with our class, in my case with
10 high honors. Soon after, we both obtained jobs practicing
11 veterinary medicine.

12 Unfortunately the resistance Gloria and I
13 encountered is not unique. Other students who have asked
14 for alternatives to animal labs have been threatened with
15 academic penalties. In 1987, a California high school
16 student went to court to preserve her right not to perform
17 dissection. That year, because of her case, the State of
18 California passed legislation to protect high school
19 students who object to classroom vivisection or
20 dissection. Currently, a New Jersey high school student
21 is awaiting the court's decision in a similar case. Some
22 professional and college students are even abandoning
23 their chosen careers because of intransigence of their
24 instructors and school administrators. Several years ago,
25 a veterinary student left the University of Georgia after

1 the school refused to consider a request for a humane
2 surgical alternative. In 1987, a medical student at the
3 University of Colorado requested an alternative to a dog
4 lab. The instructor threatened to fail her. When a
5 majority of her classmates signed a petition supporting
6 her stance, these students were accused of academic
7 misconduct. Finally, feeling she had no choice, she
8 participated in the laboratory, only to be so demoralized
9 by the experience that she subsequently quit medical
10 school.

11 What makes such incidents especially sad is
12 that in all instances, humane alternatives were available
13 -- alternatives that develop the requisite skills.
14 Because many students, as well as their instructors, seem
15 unaware of these alternatives, I recently accepted a
16 position as Curriculum Modernization Coordinator with the
17 Association of Veterinarians for Animal Rights. The
18 position involves identifying alternatives to the harmful
19 use of animals in education, in disseminating this
20 information to students and faculty. Literally hundreds
21 of anatomical models, patient simulators, films,
22 videotapes, and computer programs are available that can
23 substitute for animals in teaching laboratories. For
24 example, I recently viewed an excellent videotape on the
25 biology of frogs that can easily replace dissection. All

1 too often, animal labs continue simply because that's how
2 things have been done in the past. There is mounting
3 evidence that neither dissection nor vivisection is
4 essential to learning.

5 At the college and professional levels,
6 animal labs are becoming increasingly obsolete. A
7 professor of surgery at the Ohio State University's
8 veterinary school uses a foam rubber pad threaded with
9 slippery red ribbon to teach the hand skills needed in
10 tying off bleeding vessels. Many physiology professors
11 now employ computer simulations that can duplicate
12 cardiovascular, kidney, and other functions. A recent
13 survey conducted by the Physicians Committee for
14 Responsible Medicine shows that almost half of all medical
15 schools now use no animals in their physiology labs. If
16 half of these schools can teach physiology without animal
17 labs, why not the other half?

18 In addition to being unnecessary to the
19 learning process, animal labs have a negative
20 psychological effect on the students who participate in
21 them. Beginning with high school dissections, these labs
22 desensitize students to animal suffering. The teacher,
23 viewed as an authority figure, seems to be saying it's
24 okay to destroy life. For many students, animal labs are
25 both unsettling and demoralizing.

1 Students who revere all life deserve
2 support, not censure. I believe that the State of
3 Pennsylvania should protect the rights of students whose
4 ethical beliefs prevent them from inflicting suffering.

5 I urge you to support a student's right to
6 refuse to participate in vivisection and dissection. I
7 also urge you to support the portion of House Bill 873
8 that prohibits the use of live animals to test cosmetics
9 or households products.

10 Last summer, the People for the Ethical
11 Treatment of Animals asked me to review conditions at one
12 toxicology lab, Biosearch in Philadelphia. Having worked
13 for several years in biomedical research, I am familiar
14 with proper housing conditions. In addition, I have a
15 Master's degree in industrial hygiene, with heavy emphasis
16 on toxicology. Even with this background, I was not
17 prepared for the conditions I found at Biosearch.

18 Gauze pads to be used had been laid out
19 directly beneath an air vent covered with thick deposits
20 of dust and grease. Animal cages were covered with dry
21 feces and animal hair. Guinea pigs were housed in
22 severely overcrowded conditions. But the chief cause of
23 animal suffering was not the housing conditions but the
24 toxicology tests themselves. Dying rats, subjected to the
25 L.D. 50 tests, lay among already dead cage mates. Many

1 rabbits being used in the Draize tests were clearly in
2 pain. In each case, one eye was swollen shut and oozing
3 pus. When we approached their cages, the rabbits shrunk
4 back in fear. When we held them to examine their eyes,
5 they thrashed so violently that we were able to only
6 examine one rabbit's eye closely. The membranes around
7 the eye were severely swollen; the cornea had become
8 opaque with a large ulcer. As a veterinarian, I
9 understood that the rabbit had been permanently blinded in
10 that eye.

11 The tests I saw being carried out at
12 Biosearch have no valid scientific purpose. The L.D. 50
13 was originally formulated in 1927 to standardize the
14 concentrations at which dangerous drugs such as digitalis
15 or insulin are administered. Today, more modern
16 techniques such as chromatography are used to establish a
17 drug's potency. In chromatography, for instance, a
18 mixture has its chemical ingredients separated out,
19 usually by machines, so that these ingredients can be
20 exactly measured. So the original justification for the
21 L.D. 50 no longer exists. In addition, it was a mistake
22 to believe that the L.D. 50 test on animals could
23 accurately predict a chemical's toxicity. Such factors as
24 the test animal's age, sex, breed, and living conditions
25 all contribute to wide variation in test results. In any

1 case, a particular species' reaction to a substance is
2 often completely different from another species' reaction
3 to the same substance, including, of course, that of
4 humans. The L.D. 50 is all but worthless for predicting
5 human reactions to a toxin.

6 The Draize test also fails to protect human
7 health. As it's been stated many times, the rabbits' eye
8 have different characteristics than human eyes, including
9 a third eyelid, a thinner and larger cornea, and virtually
10 inability to produce tears. This means that in the case
11 of some substances, the rabbits' eyes would react more
12 intensely than a human's, and in other cases it would
13 react less.

14 The L.D. 50 and the Draize do not protect
15 human health, nor are they required by law for cosmetics
16 and household products. These procedures are performed
17 solely to protect companies from liability. Companies
18 feel they would best protected in the case of a lawsuit if
19 they can say they've been using these procedures that have
20 become standard in the industry. Alternatives do exist.
21 Chemicals can be applied directly to tissue culture to
22 assess the substance toxicity. Computers can predict
23 toxicity based on a chemical's molecular structure. In
24 addition, there is a test tube alternative to the Draize,
25 the Eytex system that Dr. Barnard spoke about. Finally,

1 companies can use ingredients already known to be safe
2 from years of prior use. Over 100 companies already
3 manufacture their products without animal tests.

4 I urge you to protect both the American public
5 and helpless animals by banning the L.D. 50 and the
6 Draize. Animal suffering and a false sense of consumer
7 safety are the only legacies of these two tests. As
8 members of the Pennsylvania Assembly, you can set an
9 example for the entire nation by voting against procedures
10 that are wasteful, misleading and enormously cruel.

11 Thank you.

12 DR. STEPHENS: Good afternoon. I'm Dr.
13 Martin Stephens with the Humane Society of the United
14 States. The Humane Society is the nation's largest animal
15 protection organization, and I'm here today on behalf of
16 our many members in the State of Pennsylvania.

17 Before I summarize my written comments, I'd
18 like to briefly address a few points that have come up
19 during the course of the hearing. We've heard a lot about
20 duplication with this bill and Federal legislation that
21 already exists. And this pertains mainly to licensing,
22 and I would point out as an aside that licensing is a
23 misnomer. There's registration of facilities, not
24 licensing, which implies some kind of test that needs to
25 be passed before you can be approved and licensed.

1 There is a difference between simply
2 conducting animal research and having to submit to Federal
3 regulations. There are loopholes in the kinds of
4 facilities that have to comply with Federal laws. For
5 example, research facilities that don't transfer animals
6 in interstate commerce don't necessarily have to register,
7 and there are other loopholes having to do with exclusive
8 use of certain kinds of species, like birds, mice, or
9 rats. If you use too few cats or dogs in the eyes of the
10 USDA, then you may not have to register. If you're a high
11 school, you don't have to register, or if you simply
12 appeal to the USDA and the USDA approves based on various
13 other criteria, you don't have to register. So there
14 would be a need to register at the State level.

15 There are other provisions that aren't
16 duplicated at the Federal level. For example, the Federal
17 law mandates that a community member must sit on the
18 review board at each facility, but they don't specify any
19 criteria that that person doesn't necessarily have to be
20 with the Humane Society, whereas the State bill does
21 specify that, and that would get around the research
22 facilities who have appointed people to be their animal
23 protection representatives who couldn't care less about
24 animal protection. Those universities and research
25 facilities are inviting trouble, and there may be more

1 black eyes for the State of Pennsylvania because of that.
2 And, of course, there are other provisions, such as the
3 search warrant provision and the student's right provision
4 and the bans on the L.D. 50 and the Draize that would be
5 new to this bill.

6 We've heard a lot about overregulation, the
7 existence of massive Federal regulations, and I, for one,
8 am curious as to why the opponents of this bill fear State
9 knowledge of what's going on in their laboratories. They
10 seem to be opposed to the concept of State regulation.
11 They haven't seen the actual regulations yet. They're
12 opposing this bill on principle because they don't want
13 you to know what goes on in their labs. And they're
14 singing the praise of Federal legislation on Capitol Hill
15 that they are vigorously opposing at every step, and now
16 they're threatening lawsuits claiming that the new
17 proposed Federal regulations under the Animal Welfare Act
18 exceeds the statutory authority of the USDA. And now
19 they're decrying the head injury laboratory. Well, where
20 were they several years ago when they were exposed? They
21 were extolling, they were defending the university in many
22 cases, and they point to the NIH as one of the regulators
23 of the Federal government. The Director of NIH praised
24 the head injury laboratory as one of the finest
25 laboratories in the world when there was that expose.

1 These are the Federal oversight persons that they are
2 pointing to.

3 As I mentioned, they haven't seen the regs
4 yet. We don't know what the regs will be under this
5 legislation, if it passes. Let the opponents of this bill
6 come back in several months if this bill passes when the
7 regulations are proposed and let them find specific
8 regulations. Let them see them first before they open
9 their mouth.

10 And the search warrant. We've heard a lot
11 about the search warrant provisions. There's one
12 important point that hasn't been brought out yet, and that
13 is that if there are regulations because of this bill,
14 those regulations probably will resemble Federal
15 regulations which have to do with things like cage size,
16 feeding the animals, watering the animals, cleaning the
17 cages, et cetera. The Federal legislation has almost
18 nothing to say about the actual conduct of research - what
19 happens to the animal when you put it on the operating
20 table? And I would doubt that the State legislation would
21 have much to say about the actual conduct of research
22 likewise. So that means you don't have to have any
23 tremendous knowledge of animal research to go into a
24 facility with a search warrant and measure cage size, see
25 it built up with feces within a cage, see whether the

1 animal is so skinny that it apparently hasn't been fed for
2 the last three weeks. You can see those things. I fully
3 support training of the people that go in with search
4 warrants, but you don't necessarily need great scientific
5 knowledge to check on compliance.

6 Let me briefly turn to my written comments.
7 I have no intention of reading these or paraphrasing them.
8 Let me just summarize a few points.

9 Regarding the search warrant provision, for
10 example. Pennsylvania is like 28 other States that apply
11 their anti-cruelty statutes to research facilities. And
12 I've colored in these 28 States. They are all around the
13 country. There's no specific exemption for research
14 facilities. And I've colored Pennsylvania a different
15 color because apparently Pennsylvania is the only one of
16 those 28 States that don't allow delegated authorities to
17 get search warrants to apply the anti-cruelty statutes to
18 research facilities. And that's an important point.
19 Pennsylvania wouldn't be sticking its neck out as the only
20 State to allow search warrants for research facilities.
21 It's been done, and research flourishes in those other
22 States.

23 With licensing, there are something on the
24 order of 18 other States that have licensing of one form
25 or another of research facilities. Does that mean

1 research is crippled? No. Pennsylvania is one of only
2 five States, and I've drawn these in here, just five, that
3 has no form of licensing of research facilities.

4 As to the institutional care and use
5 committees that would be overseeing research at individual
6 facilities, sure, as I said before, there is a Federal
7 mandate for a community member to sit on those review
8 boards. That's one lone voice. Surely, even if that
9 person was a complete anti-vivisectionist, that person
10 would be in no position to stop what went on. But the
11 important point here is that if you appoint a
12 conscientious person to that committee, then that will
13 show the Commonwealth that there is an advocate for the
14 animals on that committee and that the spirit of this
15 mandate for a community member is not being blatantly
16 violated by the institution appointing representatives who
17 couldn't care less about animals to that position, and we
18 have examples of this.

19 I won't say much about the prohibitions on
20 the L.D. 50 and the Draize test. A lot has already been
21 said. Let me just point out that even the companies that
22 say that they couldn't market new products without animal
23 testing are grossly exaggerating their own internal
24 policies. Avon, for example, who now says that they are
25 not going to do any more animal testing, but when they

1 still were doing animal testing, said that fully 95
2 percent of their new products are marketed without new
3 animal testing. Okay, were they relying in part on old
4 animal testing? Yes. But fully 95 percent of the new
5 products, and this bill would affect only the new
6 products. It wouldn't require that companies go to the
7 store shelves and pull off all the animal-tested products
8 from the shelves. Just new products. 95 percent of those
9 products go to market without animal testing. The
10 companies are already heading to a point where they are
11 not going to be using animal testing anymore. Maybe
12 that's several years ago.

13 What we're saying is that this is a
14 political issue, we can do without a new brand of
15 cosmetic, a new brand of cleanser, within those several
16 years while you're trying to validate the alternatives.
17 This is a political issue. We want to put pressure on you
18 to increase the pace of progress, and that's what this
19 bill, that's what this prohibition, is really about, the
20 pace of progress. Industry says to the consumers that
21 write to them to express concerns, yes, we are heading
22 towards the day when we don't use animals in the labs for
23 purposes of testing these products, so they've already
24 agreed with our goal. This is a question of how fast they
25 move that way, and if Pennsylvania passes a prohibition

1 and if the several other States that are considering this
2 this year pass their prohibitions, that will really light
3 a fire under industry to let them know that we're serious
4 about this.

5 And finally, on the student's rights
6 provision, a lot of students turn to my organization, the
7 Humane Society of the United States, for counseling on
8 this. They don't want to participate in some of the
9 dissections or in the vivisections, and in our experience,
10 the vast majority of these cases are quietly resolved.
11 The only cases that you hear about in the news are those
12 that lead to confrontation where the schools are adamant
13 in not letting the students do an alternative project.
14 What we're saying is, avoid those confrontational
15 situations, avoid those ugly scenes and the bad publicity
16 and let students not get out of work but do other kinds of
17 work to satisfy those provisions.

18 Thank you very much.

19 CHAIRMAN CALTAGIRONE: Members?

20 Dave.

21 BY REPRESENTATIVE HECKLER: (Of Ms. Hazard)

22 Q. Briefly, Miss Hazard, I assume that you're
23 familiar with the bill?

24 A. Yes.

25 Q. Can you tell the committee what background

1 or training is required in Pennsylvania law for an agent
2 of and -- I'm sorry, the correct language, I believe it's
3 a humane society or other similar organization
4 incorporated in the Commonwealth?

5 A. I'm not a Pennsylvania attorney and I recall
6 reviewing that last year when we were discussing this
7 bill. I don't remember the specifics. I remember that
8 there's not a lot, if there is any. But I would point out
9 that there would be no more or less for, say, a police
10 officer who might go into a situation in a laboratory who
11 would not be--

12 Q. Well, maybe I didn't frame my question
13 correctly. Would you agree that there is no training
14 standard whatsoever for these agents either with regard to
15 the rules of criminal procedure, how they are to execute a
16 search warrant or in fact what they are liable to -- how
17 to interpret what they might find? There's no present
18 standard in law?

19 A. I believe that's the case, but as I said,
20 I'm not an expert in Pennsylvania law, but they would, of
21 course, have to go through some kind of judicial
22 proceeding to show that there is probable cause.

23 Q. That's correct.

24 A. Yes.

25 Q. Now, the one other question, we've received

1 some materials, among the body of things that have been
2 submitted by the various interested parties, that
3 indicates that the Maryland case, which the only one I've
4 heard cited where there was a search warrant executed
5 and I presume some animals seized, but that was thrown out
6 by the Maryland appellate courts on a theory that the
7 State law or State actions had intruded upon Federal
8 prerogative. Are you familiar with that?

9 A. I'm familiar with it. Actually, my law
10 partner was the prosecutor in that case, so I hope I can
11 get it correct what the decision of the court was. Dr.
12 Kalb was found guilty at the trial court level. The
13 Supreme Court of Maryland found that they did not believe
14 that it was the intent of the legislature to include -- it
15 didn't have anything to do with the Federal law, they
16 didn't believe that it was the intent of the legislature
17 to include research facilities under the State
18 anti-cruelty statute, so it would be a very similar
19 situation here. But I would point out that in the very
20 next session of the legislature, the elected
21 Representatives of that State came back and very strongly
22 turned around any misconceptions that the court might have
23 in that case about that, and now research institutions are
24 very clearly included under that statute.

25 Q. Okay, and are you aware of any case law then

1 nationally that suggests that there is a Federal
2 preemption?

3 A. Not only is there not any Federal
4 preemption, but under the Federal Animal Welfare Act, and
5 I can get you a specific cite, there is a section that
6 says that it is the intent of the Congress to work with
7 States in enacting legislation which would protect animals
8 under this law and not to preempt any State legislation in
9 this area.

10 REPRESENTATIVE HECKLER: Thank you.

11 MS. HAZARD: Thank you.

12 CHAIRMAN CALTAGIRONE: Chris.

13 REPRESENTATIVE McNALLY: A question for Dr.
14 Dunayer.

15 BY REPRESENTATIVE McNALLY: (Of Dr. Dunayer)

16 Q. I had asked this question earlier. Why do
17 we and why aren't we in this legislation to discriminate
18 between vertebrate animal and lower order animals?

19 A. Well, there's a feeling that lower order
20 animals are not capable of feeling pain, are not as
21 sentient, and it's more, I believe, a point of philosophy.
22 I don't see that we should. I mean, that's my personal
23 feeling. I believe that all animals, and I personally in
24 my own life, I don't make that distinction between
25 vertebrate and non-vertebrate, but I think, you know, as

1 everyone says, there has to be a point of starting.

2 Q. Well, you know, since we have to draw the
3 line, or perhaps we don't, but if we did, could we draw
4 the line between warm-blooded animals and cold-blooded
5 animals?

6 A. No, I don't think -- I know not because you
7 can look at a fish and you can find what would be
8 considered an organized brain in a fish with many of the
9 same types of structures that our brain has that we know
10 are involved with pain, and the same is true all the way
11 up the other cold-blooded animals, such as amphibians and
12 reptiles the same is true. We certainly know it's true in
13 mammals and birds. When you get down to below the level
14 of vertebrate, you don't have that sort of organization
15 where you can point to one structure and say, yeah, this
16 is a brain. But we are finding things, for instance,
17 earthworms were mentioned, and it's been found that
18 earthworms contain a substance called endorphins, which we
19 know in our own brains are used to soothe pain. So
20 there's evidence that maybe even down to the level of an
21 earthworm we're seeing evidence of pain reception and
22 therefore, you know, if you have pain, ways of getting
23 around it. So I don't personally feel it's a clear-cut
24 distinction between vertebrate and non-vertebrate. It's
25 getting hazier all the time.

1 Q. Well, now, if pain is the criterion, and
2 perhaps that's really the objection that we have in animal
3 testing is that it causes pain in an animal, would you not
4 have objections to animal dissection and experimentation
5 if, for example, we anesthetize the animal?

6 A. Well, I think pain is one criteria, and I
7 think there are other criteria you have to look at. You
8 have to look at whether this animal is what we, again,
9 consider conscious. We know that dogs and cats are
10 conscious. We know that they expect to get fed every day,
11 they expect to take their walks. So these are conscious
12 animals who we've grown to understand don't just live to
13 eat or drink or survive. They have other things that
14 they're interested in. I mean, we can't say they have the
15 level of a human being, but they do have a significant
16 interest in what their life is, and to deprive them of
17 their life simply because we think that we can do that
18 does not make it right. And if we base it simply on
19 physical things, then we can also take it without
20 thinking. I believe pain is one criterion, but I also
21 think we have to consider the animal as a whole, as a
22 sentient being, and not just dismiss it because we can say
23 we can take the pain away.

24 Q. Well, but we're not simply dismissing the
25 animal's life arbitrarily. It seems to me that in every

1 instance which, you know, which you have proposed to
2 eliminate or regulate these tests, experiments,
3 dissections, are being performed for a purpose which
4 benefits society. That is, to learn more about
5 physiology, anatomy, pharmacology. It's a scientific
6 endeavor, or in the case of a Draize test or L.D. 50 test,
7 as a hedge against liability to promote an economic
8 interest. And, you know, so it seems to me, and I really
9 don't understand why we shouldn't balance those social
10 benefits against the costs that to me you've described.

11 A. Well, I believe that when an individual
12 looks at these things, if there are alternatives
13 available, the humane individual chooses the alternatives.
14 The researchers say we don't want to kill animals. The
15 people who are doing the Draize and the L.D. 50 say, we
16 don't want to kill animals, we don't want to injure
17 animals. The people who are doing laboratories using
18 animals are saying the same thing, but yet when you
19 present there are alternatives, why doesn't the humane, if
20 they are truly humane, why don't they choose those
21 alternatives? I believe, as I've said and others have
22 said as well, that the Draize test, the L.D. 50 test, and
23 the use of animals in laboratories, the harmful use of
24 animals in teaching laboratories, let me make that clear,
25 can be replaced by alternatives that are humane. Now,

1 some of these are not necessarily non-animal alternatives.
2 Again, I'm going to talk specifically about laboratories
3 in teaching. Some may involve the use of animals, but
4 again, we have to say not in a painful way, not in a way
5 that takes their lives, takes the life of these animals
6 when there are alternatives. That, to a humane
7 individual, I believe, is not proper.

8 CHAIRMAN CALTAGIRONE: Thank you. Thank you
9 for your testimony.

10 I'd like to call next Dr. Keith Booman,
11 Robert Brady, and Dr. Thomas G. Davis.

12 MR. BRADY: Mr. Chairman, my name is Bob
13 Brady, and we've, at least at this side of the table, have
14 decided I will go first because I represent the cosmetic
15 industry, and I suspect the bulk of the questions may be
16 directed towards me. If you prefer a different order--

17 CHAIRMAN CALTAGIRONE: Go right ahead.

18 MR. BRADY: Okay. Thank you.

19 To begin with, I have passed out to you
20 copies of not only my testimony but a series of exhibits
21 which I'll refer to during the testimony.

22 As I said, my name is Bob Brady. I'm an
23 attorney from Washington, D.C., with the firm of Patton,
24 Boggs & Blow. Prior to my present position, I was General
25 Counsel and Executive Vice President of the Cosmetic,

1 Toiletry and Fragrance Association. Prior to that, from
2 1975 to 1983, I was an attorney at the Food and Drug
3 Administration and ended my career as Executive Assistant
4 to the Commissioner of Food and Drugs. I might add, for
5 the record, not the present commissioner nor the
6 commissioner that wrote the various letters that we're
7 taking about here.

8 The Cosmetic, Toiletry and Fragrance
9 Association is the primary association for the cosmetic
10 industry. It represents about 250 manufacturers of
11 finished products and 250 suppliers of packaging,
12 chemicals, other things that help develop the product. We
13 represent the vast majority of cosmetics distributed.

14 I'm going to spare you, obviously, reading
15 my testimony. I had also prepared a summary and I'm going
16 to spare you that. I almost don't quite know where to
17 begin because there were so many questions today directed
18 towards our use of the Draize and the L.D. 50, but let me
19 try to summarize my summary. I've got a few comments to
20 earlier, and then I think the most productive way would be
21 for you to ask questions.

22 I think there is much in common with
23 everyone in this room, and that is we want safe products.
24 Dr. Stephens said that that is, quote, "our goal of the
25 Humane Society." Well, I think it's industry's goal as

1 well. We're human beings. We want safe products for
2 consumers, and we want to do it in a way that is going to
3 minimize the use of animals and minimize the amount of
4 pain that those animals have to go through in order to
5 obtain safety data sufficient to establish that a cosmetic
6 that is going to be marketed nationwide will be safe for
7 all consumers.

8 Cosmetics are much more, obviously, than
9 mascara. They are shampoo, they are deodorant, they are
10 toothpaste, they are suntan products. Indeed, all of us
11 in this room, or most of us in this room, have used four
12 or five already today. I, myself, washed my hair this
13 morning, I brushed my teeth, I put on deodorant, and
14 although you may not believe it, I shaved. The point I'm
15 trying to make is that they are very useful products.
16 They are not frivolous products. They are clearly not
17 drugs, and I'm not trying to make that point, but I'm
18 trying to make the point that consumers in this country
19 want and deserve a wide array of consumer products, and
20 our industry provides that. Indeed, consumers buy 9
21 billion units of cosmetic products per year, and we want
22 to make sure they're safe.

23 I think this issue, albeit it's a political
24 issue, is also a scientific issue, and you legislators
25 have an extremely important task. It's a very emotional

1 task and it's a very complicated scientific task. As
2 you've heard all kinds of testimony today about
3 alternatives, whether they work, whether they don't work.
4 And while it certainly is political, I think it's got to
5 have a scientific base, and I urge you, while you listen
6 to my testimony, first of all, I'm a lawyer, I am not a
7 scientist. I am not going to give you an opinion as to
8 whether the Draize test works. What I'm going to do is
9 ask you to look at experts who are much more centrally
10 involved with the development of these tests and the
11 assessment of these tests. And while I certainly don't
12 impugn any of the testimony by the people who support this
13 bill, I'm not sure they are in the same position in terms
14 of their expertise as some of the people that I will be
15 referring to today.

16 As I said, it seems to me there are two
17 primary issues. What constitutes safety? And we've heard
18 a lot of discussion today about what the Federal law does
19 or does not require. The Federal law says that cosmetics
20 will be safe, otherwise the Federal government can seize
21 them, they can enjoin a company or they can prosecute a
22 company should a company distribute across State lines an
23 unsafe cosmetic. That's the same standard for foods,
24 drugs, everything else. The law does not state safety is
25 determined by the following 13 tests, but simply that is

1 true also for drugs, foods, and everything else. The
2 standard of safety, which I believe, and I haven't
3 checked, is probably the same standard that is in your
4 Pennsylvania Food and Drug Act, because I believe every
5 State has a mini-Food and Drug Act which has comparable
6 provisions, so I suspect that you have a food and drug act
7 here in Pennsylvania that has the same general standard.
8 Well, what do lawyers do and regulators do when they have
9 a general standard? They interpret that and they
10 implement it in a way based on generally recognized
11 principles of scientific standards. And now I'm going to
12 ask you to start looking at what I believe are the
13 appropriate experts on this question.

14 The first in my exhibits attached to my
15 testimony are four different letters from the present
16 Commissioner of Foods and Drugs, Dr. Frank Young. The
17 letters are -- I'm sorry, there's three letters and a
18 statement. They are in '88. The most recent statement
19 was in March of '89 to the Maryland commission looking at
20 the animal testing issue. Earlier there was a question
21 raised about whether Dr. Young was a Ph.D. or an M.D. and,
22 one, I'm not sure that that's relevant, but, two, he's
23 both. He is an M.D. and a Ph.D. He is also the former
24 dean of a medical school and probably one of the nation's
25 leading medical researchers during his time in medical

1 school. Dr. Young and the FDA make two points. The first
2 is, in their belief, animal tests, at some point in the
3 process of development of a product, and I'll come back,
4 at some point in the process, animal tests are necessary
5 in order to establish safety in their minds. Second
6 important point that runs through all of those documents,
7 and I urge you to read them carefully because this is an
8 extremely complicated scientific issue, the second point
9 is, is there an alternative today that is an absolute
10 replacement for the Draize test? And they say no.

11 We've had a lot of talk this morning about
12 various companies who are responsibly trying to meet the
13 concerns of the animal rights movement by trying to move
14 away from animal tests. I think that some of the
15 statements that have been made are not totally complete,
16 and that's another concern I have. There are a lot of
17 generalizations being made about the matter.

18 The FDA position is that there are a number
19 of screening tests that will allow companies to reduce the
20 number of animals they might need in order to establish
21 safety. Indeed, Noxell has been mentioned here several
22 times as doing away with animal testing. That's simply
23 not true. All their public statements are that their use
24 of a screening method called the agarose diffusion method
25 is meant to reduce their animal testing requirements by

1 about 80 percent. But it is not a replacement. It is a
2 screening test.

3 Another expert that I think you need to look
4 at very carefully, because he's devoted his professional
5 career to this, is Dr. Alan Goldberg, who is head of the
6 Johns Hopkins Center for the Study of Alternatives to
7 Animal Testing. The Johns Hopkins Center was set up in
8 large part by money provided by the soap and detergent
9 industry and the cosmetic industry in 1981. Its goals
10 were to get a basic research to find out and figure out
11 ways to get to alternatives. We would like alternatives
12 as well, we just simply don't think in some instances
13 they're here yet. In many instances we don't need animal
14 testing, and as we've talked about the companies that
15 market products that don't do testing on the finished
16 product. But I dare say that for any responsible company
17 to market a product today, there is some animal testing in
18 the history of the development of those ingredients. It's
19 simply -- and that's the position that the FDA is taking.
20 They're taking the position that you've got to, at some
21 point in the process, do some animal testing. But let me
22 go back to Dr. Goldberg. Dr. Goldberg, who as I said, has
23 spent the last 10 years as virtually the world's leading
24 expert on this subject, has testified and still states
25 that there is simply no test which is yet a total

1 replacement, a non-animal test which is a total
2 replacement, for the Draize eye test. Is the Draize eye
3 test perfect? Absolutely not. Is it an old test? Yes.
4 Could it be better? Of course. But it's simply at the
5 moment one test which helps provided data to companies to
6 establish the safety of products.

7 Second point that Dr. Goldberg makes, and
8 it's in my testimony, is that it would be what I call
9 toxicological malpractice for a scientist to rely totally
10 on non-animal tests at this time. Now, here's a man whose
11 whole career is dedicated to finding these tests. He
12 certainly has no incentive, as it is sometimes implied of
13 the cosmetic industry, not to do these tests. His goal is
14 to find these tests, as is industry's goal. Not only did
15 we fund and fund to a great extent the Johns Hopkins
16 Center a year ago patterning our activity after an earlier
17 program started by the Soap and Detergent Association, we
18 have taken 12 of the leading screening tests, and they are
19 all identified in my testimony and attachments, that
20 companies are using now to reduce the number of animals.
21 We've taken those 12 tests and we've started
22 scientifically validating them. The process of validation
23 so everyone can use that data as it develops will be
24 publicly available so everyone in this room can see it and
25 look at it.

1 Individual companies, as I said, are making
2 movements as fast as science will allow them to move, and
3 I think that's a very important point - as fast as science
4 will allow them to move they are moving to try to use as
5 few animals as possible. We in the cosmetic industry are
6 human, we also have children, and we don't want to use
7 animals in an unnecessary or painful way, if possible.
8 Are there people out there who do that? Sure. Are there
9 people who don't pay their taxes? Sure. Should you go
10 after tax evadors? Yes. Should you go after people who
11 abuse animals? Of course. But that's not really the
12 issue germane to this debate, in my mind. The issue is,
13 should you legislate the development of science
14 prematurely?

15 Now, why does the industry do these tests?
16 As I said, the Draize test is not perfect, but we're
17 moving as rapidly as we can to develop those alternatives,
18 and in the meantime, we want to make sure that not only
19 what you put on your face, your hair, what your wife puts
20 on her face or her hair, or what your children might
21 accidentally thrust in their eye is as safe as it possibly
22 can be. Product misuse in the cosmetic and household
23 product industry is a major concern. We want to make sure
24 that we've got all the data possible when little Johnny
25 accidentally pours my shaving cream in his eye that he

1 knows that when we call the Poison Control Center, which
2 we will absolutely do, they'll have the best data
3 possible.

4 Let's turn to the Poison Control Center.
5 There was testimony earlier today by an extremely
6 well-meaning obstetrician who said she simply doesn't use
7 that data, and she said she's the bottom line, and I'm
8 sure she is for obstetrics and gynecology. I submit to
9 you that the people who are truly the bottom line in terms
10 of accidental exposure, while I'm sure she gets plenty of
11 calls, are the poison control people and the emergency
12 room people. And what do they say about bills like this,
13 not in this State but other States? They absolutely
14 oppose legislating abandonment of the Draize test at this
15 time. It is a source of data that helps them establish
16 how to respond when a child or anyone has gotten a
17 substance in their eye.

18 Again, I come back to the point that when
19 you're assessing the science of this issue and the correct
20 medical practice and the correct regulatory stand, you
21 shouldn't rely on me. I'm an industry spokesman. I'm
22 paid by industry. Hopefully, I have an obligation to tell
23 you the truth, but you should rely on the best experts and
24 the most germane experts, and I submit the most germane
25 experts are Food and Drug administration, emergency room

1 physicians, poison control people, and people whom have
2 devoted their lives to the development and have the
3 incentive to develop non-animal alternatives.

4 And with that I'll stop and be glad to
5 answer any questions.

6 CHAIRMAN CALTAGIRONE: Thank you. I'd like
7 the other gentlemen to testify first.

8 DR. BOOMAN: Mr. Chairman, members of the
9 committee, my name is Keith Booman. I'm the Technical
10 Director of the Soap and Detergent Association. I am a
11 scientist. I have a Ph.D. in chemistry from California
12 Institute of Technology, 15 years of product development
13 at the Roman Haas Company research division laboratories
14 in Philadelphia, and then 18 years with the Soap and
15 Detergent Association in dealing with research on human
16 safety and environmental aspects of detergents and
17 detergent ingredients. The major responsibility that I
18 have right now is in evaluating non-animal tests for the
19 evaluation of eye irritancy. I'd like to say that the
20 basic reason that our industry is interested in this whole
21 topic is consumer safety, plain and simple. A company
22 that does not have a reputation for safe products,
23 products that are safe enough to use, does not live very
24 long. So it's important for us to be able to evaluate
25 acute toxicity, eye irritancy, and acute ingestion

1 toxicity reliably.

2 Our industry is an industry where the
3 products are widespread. Over a million pounds of laundry
4 product is used in this country each year. Thousands of
5 exposures, both with respect to accidental ingestion among
6 children 1 to 5 and accidental splashing of products in
7 the eyes of people who are using them. The bottom line is
8 that over these hundreds of thousands of accidents that
9 occur during the use and storage of these important
10 households products, life threatening events do not occur,
11 and that is solely based on the reliability of the testing
12 that we do. And if you're interested, I can go into
13 greater detail on how these tests are carried out in a
14 scientifically valid way.

15 As I indicated a moment ago, we are working
16 in a major effort in evaluation of non-animal tests for
17 eye irritancy. At this point in time, there is no
18 alternative that we can use for reliably evaluating acute
19 ingestion toxicity. The tests that we're evaluating, and
20 a number of them have been mentioned today, are ones that
21 scientists agree are not likely to be able to replace the
22 Draize test entirely. They will probably be able to
23 reduce the use, the reliance on animal testing,
24 considerably, but it does not seem possible to think in
25 terms of them eliminating reliance on animal testing. And

1 I'd like you to know that we are in continual contact with
2 the Federal agency scientists in CPSC, Consumer Products
3 Safety Commission, Food and Drug Administration,
4 Environmental Protection Agency, and as late as last week
5 in reviewing our program with them, the input that I got
6 back was that the input that you have seen in letters from
7 these agencies remains the same today as it was in 1988.

8 I'd like the committee to know that our
9 industry is doing what I think all of society would hope
10 we would be doing, and that is reducing animal testing as
11 fast as we can. And in point of fact, over the last
12 decade, our industry has been able to reduce reliance on
13 the rabbit testing for eye irritancy by 87 percent and
14 able to reduce the reliance on animal testing in general
15 by 64 percent. But we are not at a point where we can
16 eliminate acute toxicity testing without compromising
17 product safety.

18 Now, the matter has been raised as to who
19 needs another cleaning product? I'd like to remind
20 Representative Caltagirone and the rest of the committee
21 that this legislature itself is in the process right now
22 of demanding new products from our industry. So one
23 cannot say that there is not a need for new cleaning
24 products. There is a need, you have expressed it, and I
25 can outline for you, if you wish, other areas in which we

1 are likely to need new products, improved products, in the
2 near future.

3 With that I would close. We must object to
4 this bill. We must develop reliable acute toxicity
5 information, and we cannot do that without limited animal
6 testing at this point in time, and we do not have the
7 possibility at this point in time of seeing our way clear
8 to testing without animals.

9 Thank you.

10 CHAIRMAN CALTAGIRONE: Thank you.

11 DR. DAVIS: Mr. Chairman and members of the
12 committee, I am Dr. Tom Davis, Vice President for
13 Worldwide Medical Affairs of SmithKline & French
14 Laboratories. I also practice medicine at Presbyterian
15 Hospital, which is part of the University of Pennsylvania
16 Medical Center. Here with me today is Ceil Hedburg, DVM,
17 Ph.D., from McNeil Laboratories; Richard Knauff, DVM, from
18 Wyeth-Ayerst Laboratories; Michael Kastello from Merck was
19 here but had to leave, unfortunately, and as counsel to
20 the Pennsylvania Pharmaceutical firms is Kathy Speaker
21 MacNett, Esquire, from the Harrisburg law firm of Buchanan
22 and Ingersoll.

23 Mr. Chairman, the pharmaceutical
24 manufacturers of Pennsylvania acknowledge that the
25 sponsors of House Bill 873 are motivated by a concern for

1 animals. We share those concerns. We believe that
2 research animals must be treated humanely. We believe
3 that research facilities must be staffed by well-trained
4 people, and we further believe that these facilities must
5 be inspected thoroughly and with adequate frequency by
6 competent authorities. But we also believe that the
7 environment in which research and development are
8 conducted must be free of excessive, sometimes redundant,
9 and/or conflicting regulation, and that enforcement of
10 humane animal care and use must remain in the control of
11 competent, professional authorities.

12 Now, our reading of House Bill 873 convinces
13 us that it would impose excessive, conflicting, and
14 sometimes redundant regulation and thereby cast a shadow
15 over the future of research in our industry. At this
16 point, I would like to just depart from the prepared
17 texts. It's late in the day and I will try to just make a
18 few points that we would like to see emphasized during
19 consideration of this bill.

20 The first refers to the search and seizure,
21 if I may call it that, and the way we read this bill is
22 that these search warrants may be taken out by people who
23 have no knowledge of the kind of work that goes on in our
24 laboratories. We do not like this approach. We are
25 subject to inspections from the Federal government. Those

1 people are trained, they come in and they know what they
2 have to look at and they understand what they are looking
3 at. We would object to having people come into our
4 laboratories who do not have that training, and this bill
5 does not specify that they must have that training.

6 Secondly, the bill includes all vertebrates,
7 and that's been discussed here. There is no way that we
8 can, at this point, do away with experimentation in all
9 vertebrates. We are constantly looking for ways to
10 decrease our reliance on animals, and anyone who says that
11 we are not does not understand what we are about. It's
12 already been mentioned that we are in business to make a
13 profit, and anything that will reduce our costs will help
14 us make a profit. Therefore, we are searching for ways to
15 reduce our reliance on animal experimentation.

16 The bill, on page 4, line 18, also has a
17 statement that is very disturbing. It is in the
18 definitions section and it defines acute toxicity test as
19 follows: "Any experiment involving the administration to
20 a live animal of a substance to screen for its relative
21 toxicity." Now, that doesn't say anything about
22 cosmetics, it doesn't say anything about household goods,
23 even though the bill is aimed at those items. That is a
24 very, very broad statement. To my way of reading it, it
25 covers all toxicity testing. We cannot exist unless we

1 are permitted to do the tests that we think are necessary
2 in order to get regulatory approval around the world.

3 You've heard a lot about the Draize test and
4 a lot about the L.D. 50s. We all have our opinions on
5 them. Most of them still use these tests, but
6 nonetheless, the important thing to remember is that we
7 are required by law not only in certain statutes here in
8 this country but also by other countries where we market
9 our products, we are required by law to do some of these
10 tests. The L.D. 50 is required in Japan. Japan is the
11 second largest pharmaceutical market in the entire world,
12 and we have to do it in order to get our compounds
13 approved there. And I might add that our industry is one
14 of the few that has a positive exchange in terms of
15 products between Japan and the United States, so it's very
16 important for us.

17 We think that there were already bills that
18 cover the primary intent of this one. We believe that if
19 there are moves to work on the Draize and the L.D. 50 and
20 to work on other items in this bill, the place to do it is
21 at the national level, so that we will be helped to carry
22 on our business without having to be interfered with on a
23 State-by-State basis.

24 Now, there have been a lot of war stories
25 told today and I hope you'll bear with me while I refer to

1 one more. In 1976, we introduced a drug called Tagamet.
2 It was a revolutionary drug for the treatment of peptic
3 ulcer disease. We went through 700 chemical entities
4 before we arrived at Tagamet. Only a very few of those
5 ever went into animal testing. Only a very few. It was a
6 long and expensive program that started back in the early
7 '60's. At the time of approval in this country, 600
8 people each month were dying from peptic ulcer disease.
9 Within a year, death from the complications of peptic
10 ulcer disease in the United States was almost unheard of,
11 and it's still the same today. If we had been under
12 inspection by some of the entities that are described in
13 this bill and if an unnecessary seizure leading to a delay
14 had occurred, thousands of people would have died while
15 this was waiting for its case to be worked out.

16 Finally, I'd just like to say that there
17 have been some implications that we are, in our
18 experimental work on animals, insensitive to their needs
19 and that we will continue to experiment on animals until
20 doomsday. This is absolutely not the case. A vote
21 against this bill is a vote for animal rights and animal
22 health rather than the other way around. We do not
23 believe that a vote against it is a vote for cruelty to
24 animals.

25 Thank you.

1 REPRESENTATIVE McNALLY: Just a question for
2 the last speaker.

3 BY REPRESENTATIVE McNALLY: (Of Dr. Davis)

4 Q. And I want to make sure I understood this
5 and that I'm clear about this. Did you state that the
6 L.D. 50 test is required in order for a product, a
7 pharmaceutical product, or other product, I suppose, to be
8 sold in Japan?

9 A. For us to get approval for our products, as
10 of this moment, an L.D. 50 is required. We are working to
11 get that changed.

12 Q. What about the Draize test?

13 A. I would refer to Dr. Knauff on that.

14 DR. KNAUFF: The Draize test is required for
15 ophthalmic products throughout the world.

16 REPRESENTATIVE McNALLY: Okay. And is it
17 required for ophthalmic products in the United States?

18 DR. KNAUFF: It is if that ophthalmic
19 product is in a plastic container, because they have --
20 the plastics that the containers are made out of have
21 tendency to leech out into the product and will cause eye
22 irritation, so that eye irritation is mandatory.

23 REPRESENTATIVE McNALLY: So the solution
24 that I used on my contact lenses this morning, would that
25 be tested on the Draize test?

1 DR. KNAUFF: Yes, sir. Yes, sir.

2 REPRESENTATIVE McNALLY: And Mr. Hayden also
3 informs me that the L.D. 50 test is required for products
4 sold in Canada, is that correct?

5 DR. KNAUFF: To the best of my knowledge it
6 is, yes.

7 REPRESENTATIVE McNALLY: That's it.

8 BY REPRESENTATIVE HAYDEN: (Of Mr. Brady)

9 Q. I have one question for Mr. Brady, and I
10 think it's a point that you made in the context of your
11 testimony which needs to be addressed again. You made the
12 statement that even for products which now advertise that
13 they use no animal testing for any of the contents in
14 their products, that, in fact, I have a brochure here
15 that's termed "Responsible Manufacturers," where it says
16 that -- mentions Nexxus and Paul Mitchell hair care
17 products and Elizabeth Taylor's Passion perfume have all
18 be marketed with no animal testing. Then it says, "Each
19 of those companies uses formulations whose safety is known
20 in advance, rendering animal tests unnecessary and
21 promoting consumer safety as well." And you made the
22 statement that somewhere in the history of the ingredients
23 primarily of these products that there had been some kind
24 of animal testing, and in many circumstances not knowing
25 what these individual ingredients are, I can't state, but

1 in many cases probably either the Draize eye test, if it's
2 used anywhere near the eye, or in some cases the L.D. 50
3 test?

4 A. Right.

5 Q. In fact, I was reading through some of the
6 literature presented to me by people on the issue which
7 made reference to isopropyl alcohol, which, looking at a
8 number of the household products, you know how it is, you
9 know, your kid's in the bathroom, you're trying to brush
10 his teeth and you end up reading all the ingredients on
11 the toothpaste and everything. I notice that isopropyl
12 alcohol appears in virtually every sort of household item,
13 hair care product, and I think it's even in toothpaste.
14 And I think it's in -- my wife uses this Nexxus stuff,
15 which, by the way, is only available at your -- not
16 available in your regular stores but only available in
17 your hair care places, and Nexxus has isopropyl alcohol in
18 it, and the information I received says that at some point
19 in the development along the lines of isopropyl alcohol
20 they used the Draize eye test?

21 A. Right.

22 Q. What I think it does is it makes the point
23 that if you take products which have already been listed
24 as -- and I know there's an industry reference to products
25 whose known safety within the industry, and you can take

1 those compounds who have already been through this testing
2 process, mix them in some formula, do some other testing
3 and predict to some certain degree of certainly what's
4 going to happen. But the point is, and I guess this is
5 for the R&D folks to your right, is that when they're
6 taking new compounds, compounds that have yet to have been
7 tested or compounds who have yet to have been mixed with
8 other products that have been tested, that you are, in
9 effect, creating a new product, something obviously that
10 you're going to try to get a patent for and make some
11 money off of, but that you need to do some kind of
12 analysis for this new compound that people have done years
13 ago for isopropyl alcohol, which is now included in a
14 number of these kinds of products which are being branded
15 as "responsible manufacturers".

16 DR. BOOMAN: Well, speaking for the
17 detergent industry, in the case of significantly different
18 combinations of old ingredients, all of which, by the way,
19 in our industry have some degree of biological activity,
20 is absolutely essential for us to do that.

21 REPRESENTATIVE HAYDEN: It doesn't require
22 necessarily a response, but I think that it is a point
23 that has been missed, I think, in the discussion up until
24 now.

25 MR. BRADY: Well, the cosmetic industry

1 reformulates products constantly. I mean, both the small
2 companies and the large companies. And there's an
3 enormous data base. Much of that data base, I might add,
4 as I point out in my testimony, is publicly available
5 through a program called the Cosmetic Ingredient Review,
6 set up by the CPFA, which makes all the commonly used
7 cosmetics ingredients, all the toxicity data is publicly
8 available and companies use that to avoid having to do
9 duplicative tests. Companies like Avon and Noxell and the
10 others also have enormous backlogs of human experience,
11 and the FDA has no objection when you make a slight
12 formulation change and you're comfortable with the
13 toxicological background of both the ingredients and the
14 finished product through a long history of human use,
15 remembering at the beginning of that human use there was
16 some animal testing. Then they don't require that you do
17 more animal testing.

18 REPRESENTATIVE HAYDEN: Thank you. I just
19 have one final question.

20 DR. DAVIS: Dr. Knauff can add to it.

21 DR. KNAUFF: One of questions that has been
22 raised here repeatedly is the alternatives that we are all
23 looking for. We have -- Noxell Corporation has been
24 expressed here. We are going to have a meeting on June
25 6th in Philadelphia, City Line, of all the institutions

1 that are studying alternatives, including Johns Hopkins,
2 New York University, Medical College of Pennsylvania, and
3 the people from Noxell. We are looking at these and we
4 want to find out exactly where they all stand. The people
5 from Johns Hopkins have 35 different studies out. We're
6 going to get a report on all of those, and we invite any
7 member of this committee to be at that meeting.

8 REPRESENTATIVE HAYDEN: That's either in my
9 district or right next to my district. Where is this
10 meeting going to take place?

11 DR. KNAUFF: It's going to be at the Adams
12 Mark Hotel.

13 REPRESENTATIVE HAYDEN: That's in my
14 district. Thank you.

15 REPRESENTATIVE McNALLY: My last question
16 for the industry representatives is with respect to the
17 refusal to participate in experiment, or I guess it's
18 really limited to dissection and vivisection. Both
19 students and employees are protected by that provision.
20 Do you have any objection to that provision with respect
21 to employees?

22 DR. DAVIS: With respect to employees, we do
23 not. Whenever we run into a situation like that, we have
24 the employee examine several offers for different types of
25 opportunities within the same area.

1 REPRESENTATIVE McNALLY: Thank you.

2 CHAIRMAN CALTAGIRONE: Dave.

3 REPRESENTATIVE HECKLER: Thank you, Mr.
4 Chairman.

5 BY REPRESENTATIVE HECKLER: (Of Dr. Davis)

6 Q. Dr. Davis, you've expressed some concern at
7 the definitions contained in the bill, well, specifically
8 the definition for an acute toxicity test. I would call
9 your attention to the fact that while both that test and
10 the definition of eye irritancy test makes no reference to
11 what substance or what the purpose of the test would be or
12 what substances would be used, that the prohibition which
13 is contained in (d) does limit the or prohibit the use of
14 either the Draize or L.D. 50 tests for purposes of testing
15 cosmetics or household products. Would you agree that
16 that prohibition would not impact upon medical research?

17 A. I'd agree from the standpoint of the
18 development of prescription medicines, but perhaps Dr.
19 Knauff can--

20 DR. KNAUFF: As long as it is strictly
21 limited to that and it doesn't become amended once it
22 reaches the floor.

23 REPRESENTATIVE HECKLER: Well, now we're
24 getting into the kinds of considerations that you folks
25 have to enter into in figuring how to lobby us. Again, I

1 repeat my earlier enjoiner that it seems that it's
2 incumbent upon us to look at the language as framed and if
3 we happen to conclude that we approve that language, then
4 to see to it that it doesn't get amended, but the old
5 camel's-nose-in-the-door-of-the-tent theory is not, in my
6 view, an appropriate way to look at the legislation.

7 Thank you.

8 CHAIRMAN CALTAGIRONE: Thank you, gentlemen,
9 very much.

10 We will next hear from Erik Hendricks, the
11 Executive Director of the Pennsylvania SPCA.

12 MR. HENDRICKS: Thank you for this
13 opportunity, Mr. Chairman, and my name is Erik Hendricks,
14 and I am the Executive Director of the Pennsylvania SPCA,
15 which is the oldest and largest humane society in the
16 State of Pennsylvania. Last year we served in 46 of the
17 67 counties of the Commonwealth from our 6 locations
18 around the State. We performed over 900 routine
19 inspections and investigated more than 3,500 complaints of
20 abuse or neglect involving animals. Unfortunately, even
21 though that sounds like a lot, it's really just a drop in
22 the bucket. We are just one small agency relative to the
23 11 million citizens in this State. We do what we can, but
24 it's still far from enough. However, I think our efforts
25 make a difference. I'd hate to think what the place would

1 be like without us and the other humane societies that are
2 working equally as hard in Pennsylvania.

3 Now, I don't think any legitimate research
4 institution could fear House Bill 873. We've heard many
5 comments about the search warrant authority and the
6 ability of those with that search warrant authority to
7 know right from wrong, so to speak, when it comes to
8 laboratory animals. Obviously, our agents are not
9 laboratory technicians, they are not technically trained
10 in that area, but it should be remembered that we are
11 really not going in to upset the process of the
12 experiment. We are going in to check into the care of the
13 animal basically outside of that experimental process. We
14 are interested in their housing, their feeding, their
15 watering, things of that nature. We leave the
16 experimental process to the animal care committees and to
17 the Federal and State regulatory authorities to decide
18 whether the experiment itself is a violation of any of
19 those rules, regulations, and guidelines. The exception
20 to that would be if we were told that a Draize test or an
21 L.D. 50 test was being performed and if those tests are
22 contained in a law prohibiting them, we would then look
23 into that particular area. Obviously, our agents would
24 have to be versed in what constitutes an L.D. 50 test or a
25 Draize test.

1 But I think that it should also be
2 remembered that just because humane agents and other
3 police authorities have that authority of the search and
4 seizure, that it doesn't mean that we're going to be
5 running into laboratories every day waiving papers at the
6 technicians and the doctors saying, you've got to stop
7 what you're doing, we're going to take over for the next
8 hour and possibly take over all your animals. There must
9 be probable cause, and that's a phrase that has caused all
10 sorts of anguish in the courts because one man's or one
11 judge's probable cause is another judge's non-probable
12 cause.

13 We don't take the search warrant authority
14 lightly. We do not assume we can get a search warrant.
15 We make sure that before we go to the trouble of procuring
16 a search warrant, which involves getting the okay from a
17 local district attorney and then from a judge, before we
18 go through all of that rigmarole, that we know that the
19 evidence that is being given to us to constitute probable
20 cause is valid. We are not going to put our reputation on
21 the line, and the individual agent involved is not going
22 to risk a criminal charge as well as an individual civil
23 charge on one case. He is not going to risk that. The
24 warrant process is not abused by any humane organization
25 that I know of. I have not heard of any charges against

1 any Pennsylvania humane society regarding an abuse of this
2 authority, and I don't expect that this particular area
3 should make any difference.

4 We have a very hot issue now other than this
5 laboratory work called factory farming. Pennsylvania is
6 one of the largest factory farming States in the country,
7 if not the largest. We have the search warrant authority
8 to investigate factory farming. You have never heard, or
9 at least I have never heard, of any farmer in Pennsylvania
10 complaining that we have abused our privilege and our
11 right under the search warrant authority by harassing his
12 operation with unannounced visits demanding to see his
13 animals or even threatening to take animals that are being
14 kept under these factory farming conditions. I bring this
15 up as an example of the fact that humane societies know
16 their role, know their responsibilities, and know that if
17 they abuse this authority that has been given to them that
18 they will lose all of the authority and that they will
19 then be toothless.

20 Now, it should also be remembered that this
21 authority is very limited. 5511 contains specific
22 subsections detailing certain violations. It's been
23 brought up several times today, Dr. Gennarelli's Head
24 Injury Lab at the University of Pennsylvania has been
25 brought up several times today. I happen to be quite

1 knowledgeable in that case because I served on a committee
2 that investigated it. I was appointed by the President of
3 the University of Pennsylvania. Unfortunately, the film
4 that was mentioned earlier today by Representative McHale
5 is good and bad, and I hesitate to recommend anyone seeing
6 it because it has been edited and it is not a total truth,
7 unfortunately. But the reason I bring this up is I doubt
8 that anything was going on in that laboratory, at least
9 from what our investigation showed, that would have
10 allowed a humane society in 1985, even with search warrant
11 authority, to go in and get a warrant because the
12 violations that were going on in that laboratory were
13 violations of Federal statutes and NIH guidelines, not
14 State law. So there would be no probable cause for a
15 humane society to go in under those situations.

16 The unfortunate aspect of this laboratory
17 inspection process is that the Federal government just
18 doesn't have enough money to pay for all the inspectors
19 that are required to do more than the once a year
20 inspections that are now going on. That is the problem.
21 That is why most laboratory owners, organizations, or
22 companies want to keep the Federal level of inspection the
23 way it is now. They'll talk about duplication and
24 redundancy, but the fact is, it wouldn't be redundancy
25 because inspections aren't being made, only because of a

1 shortage of manpower. The humane societies, while not
2 composing a lot of people, still have more manpower in
3 Pennsylvania than the USDA does or the NIH. We would be
4 an adjunct of sorts to their inspections, although we
5 would not technically be making routine inspections. We
6 could at least get into the laboratories when there is
7 probable cause, and if we ourselves see things that may
8 not been in violation of our own State statutes against
9 cruelty to animals, we may see violations of NIH
10 guidelines and USDA regulations which we could then report
11 to them. We could not enforce their regulations, but we
12 could act as a reporter to them, and we would be a
13 reliable witness for them to act.

14 As far as the Draize test is concerned, I
15 can only see one purpose for the Draize test in today's
16 world, and that is as a defense against potential
17 liability claims, and I think that by passing this law,
18 including the Draize test provision, that you do these
19 institutions and corporations a big favor. You rid them
20 of that need to come up with a defense in a liability case
21 saying that we use the Draize test. It would save them a
22 lot of money. The L.D. 50 test is always strange logic,
23 in my viewpoint. From a scientific standpoint, at least
24 the Draize test has a control, which is the other eye of
25 the rabbit. The control mechanism in the L.D. 50 test is

1 nonexistent. It's one of the cruelest tests ever devised,
2 and the fact that it survived so long is an embarrassment
3 to modern society.

4 Every time that I testify on an animal bill
5 or anybody seems to testify from the animal welfare side,
6 we're always up against dollars, and I've heard that same
7 argument many times today. You know, how much money is it
8 going to cost? I really don't think that it's going to
9 cost the corporations any money at all. It costs humane
10 societies more money because we will be probably doing
11 more work. We may have to hire some more agents, who
12 knows? We're not sure of that yet, but we're not saying
13 we can't do it. We'll go out and find a way to do it.

14 Logistically, I'm not certain if every
15 animal care committee really could have both a State
16 agriculture agent and a humane society representative on
17 it. I think that may be a logistical problem, but it's
18 one that is easily worked out, I believe. One way of
19 doing it is to have an either/or situation there rather
20 than both. We are representatives on the Animal Care and
21 Use Committee at the University of Pennsylvania. This
22 gives us a very good insight into what is going on at
23 Penn. Our representative is but one vote on that
24 committee of about -- I think there are about eight people
25 on the committee. But even if her vote can't overturn a

1 particular experimental process that she feels is really
2 not in the best interests of humanity, it at least gives
3 pause for thought for the rest of the committee, and in
4 many cases, we have brought up issues that have resulted
5 in experimental processes being refined to use fewer
6 animals, or in some cases even the committee has agreed
7 that there really is no meaningful purpose for that
8 experiment. But without a voice in the crowd, so to
9 speak, some of these things can be steamrolled right over,
10 and I think it is important for at least a one outsider to
11 be on these animal care committees, hopefully an outsider
12 with some humane interests so that there will be at least
13 some semblance of balance when it comes to making
14 decisions.

15 And that's about what I have to say on it,
16 although I could have said other things, but I don't want
17 to restate the obvious and what has already been mentioned
18 by experts in the field at today's hearing.

19 CHAIRMAN CALTAGIRONE: Dave.

20 REPRESENTATIVE HECKLER: Thank you, Mr.
21 Chairman.

22 BY REPRESENTATIVE HECKLER: (Of Mr. Hendricks)

23 Q. Mr. Hendricks, a couple of points. Your
24 organization is based in Philadelphia?

25 A. That's right.

1 Q. So that do you enforce the humane law of the
2 State outside of the city of Philadelphia?

3 A. We are statewide and we have five other
4 locations. We basically run almost across the State. We
5 go from Philadelphia out to Clarion, and in Clarion we go
6 even further west and north. Each of our branches is
7 located in rural areas, and from these locations, our
8 agents cover quite a large area, usually six or seven
9 counties from that branch.

10 Q. Okay. Well, I would call your attention to
11 the fact that while I have no doubt that the practice in
12 Philadelphia is that as a district attorney or assistant
13 district attorney must review search warrant affidavits of
14 probable cause, that is a local option provision under the
15 Rules of Criminal Procedure.

16 A. That's correct.

17 Q. And I do not believe that that option has
18 been exercised by all that many DAs.

19 A. It does vary from county to county. That's
20 for sure. The search warrant provision, a lot of the
21 reasons we can get a search warrant is the fact that we've
22 never abused the search warrant process. If we start
23 abusing it, if a lot of our warrants are found to be
24 faulty, you don't get that signature again.

25 Q. Well, I have to tell you that if the State

1 Police or somebody else or the DA's Association, of whom I
2 was formerly counsel, came in here and said, well, gee,
3 just lower the standard of probable cause a little bit
4 because if we abuse this we'll get into trouble, I don't
5 think that would get a very good reception.

6 A. I didn't say that.

7 Q. I hear you. The difficulty, I think, that
8 has been perceived by the legislature, however, is
9 figuring out just what amounts to probable cause and in
10 fact what amounts to cruelty to animals in the context of
11 research, and on that I'd like to come back. It seems to
12 me that your testimony really badly muddled together two
13 different concepts. One is the concept of inspection,
14 that someone would have the routine opportunity to go in
15 to a laboratory, another facility that was using animals,
16 and see what was going on, see how the animals are being
17 kept, see what is being done to the animals. Right now,
18 is it correct, that only the Federal government agents can
19 do that?

20 A. That's correct. I'll give you a
21 similarity--

22 Q. Wait, I haven't asked the question.

23 A. Okay.

24 Q. Okay. Under the proposed scheme of this
25 legislation as I understand it, there would be authority

1 given to the Pennsylvania Department of Agriculture to
2 regulate and at least implicitly to inspect these
3 facilities, and there would be authority given to you
4 folks as well as the police to get search warrants. Now,
5 do you anticipate, under this legislation, that you would
6 have the opportunity or your agents would have the
7 opportunity to conduct routine inspections?

8 A. Not at all. I'll give you the analogy. The
9 Department of Agriculture has a Bureau of Dog Law, as you
10 are well aware. The bureau has its own set of
11 regulations. It has its own set of people to enforce
12 those regulations. Those are the Dog Law Enforcement
13 Officers, or dog wardens, one in each county. That's a
14 very large body of regulations. We do not enforce those
15 regulations. Among the regulations is the inspection
16 process. If you take out a license for a kennel in the
17 State of Pennsylvania, you are agreeing to inspection at
18 any time by one of the dog wardens. You are not agreeing
19 to an inspection by a humane society official, and the way
20 I read this bill, this would be exactly the same. You
21 would be licensed by the Department of Agriculture and you
22 would be agreeing to inspection, during normal hours, by a
23 Department of Agriculture officer trained specifically for
24 that purpose. You would not be agreeing to inspection by
25 police officers or agents of the humane society. Not at

1 all. I'm sorry I muddled it. I'm trying to rush, I
2 think.

3 Q. Well, okay. If then we are anticipating in
4 this legislation establishing a cadre of people who know
5 what they're doing, who are familiar with the requirements
6 for the keeping and treatment of animals, why would we
7 want to give search warrant authority to agents of
8 organizations like yours?

9 A. We basically act as an adjunct. There's no
10 reason for us to exist, there is no reason for us to have
11 search warrant authority if the State of Pennsylvania
12 would give its State Police and local police more time to
13 take care of this body of law, this section of the law,
14 5511. The reason we do is it is because they have
15 prioritized criminal activity, and they consider 5511 to
16 be a very, very low priority, and they have just kissed it
17 off over to the humane societies. So basically we are
18 doing the work of the State, even though we are not paid
19 by the State. We're an adjunct situation here. All of
20 the humane societies do this basically without taxpayer
21 expense, and so I think the State should be happy we're
22 here.

23 Q. Are you aware that the Federated Humane
24 Societies of Pennsylvania have taken the position in a
25 letter written recently that they would not wish to see

1 the search warrant provisions of the legislation?

2 A. I've discussed it with Jill Erwin. I assume
3 she wrote the letter.

4 Q. Mr. Hancock did.

5 A. Oh, he's the president. All right. But I
6 discussed this with Jill Erwin, who is the legislative
7 chairperson of the organization, and we don't agree
8 completely, but it's a minor disagreement. I think that
9 you would find that in actual practice, humane societies
10 would probably not be very involved in going into
11 laboratories. I do not think we would get too many
12 warrants in practice. I think you would be -- the
13 authority we would have in theory, but I expect it would
14 be rarely used.

15 Q. One other point, and I apologize for
16 prolonging this, Mr. Chairman. You mentioned that the
17 situation at the University of Penn Head Injury Lab that
18 Representative McHale referred to earlier and which is
19 really one of the only two specific instances I've heard
20 cited today would not have been a case in which a search
21 warrant could have been issued. Why is that?

22 A. Well, as I said, we are empowered to enforce
23 a specific section of the law, the 5511 section.
24 According to everything that I saw during our
25 investigation of that laboratory, we had access to every

1 tape. We interviewed all the people who were involved
2 with the laboratory, from Gennarelli up and down. The
3 violations were technical violations for the most part of
4 NIH guidelines and certain USDA regulations, such as
5 smoking in the lab, using a scalpel that had fallen on the
6 floor. There were some things going on, shenanigans is a
7 good term, very unprofessional is what it was, and this is
8 what enraged many people more so than some of the other
9 things. The attitude that the researchers, who were
10 graduate students and post-graduate students, had had
11 apparently towards these animals. Gennarelli defended
12 this to some extent by saying this is gallows humor. And
13 I know what gallows humor is about because we kill many
14 thousands of animals each year, so I understand that when
15 you're in a situation that is so morbid it's difficult for
16 a human to survive under those conditions without trying
17 to find some way to lighten it.

18 Unfortunately for these researchers, these
19 young people who were the actual researchers in the
20 experiment, they were doing it all on videotape and taken
21 out of context. That can be very damaging. The
22 unfortunate part of the videotape was that it was taken
23 out of context in some cases. I see references all the
24 time to this tape in the media, and there are three
25 particular comments that are always made. One, that the

1 heads were smashed in, which is wrong. Two, that \$14
2 million was spent on it, which is wrong. One-sixth of
3 that went into the actual baboon aspect of the experiment.
4 The experiment had three areas of involvement. 50 percent
5 of the money went into clinical experiments using humans
6 who had been traumatized, brain damaged humans. The other
7 20 percent or about 30 percent, I guess it was, went into
8 an alternative, and they developed a wonderful
9 alternative, although you've never really heard about it,
10 using a certain kind of gel and high speed camera
11 techniques to mimic the action of the brain.

12 Basically, what was happening in that lab
13 was that an animal was immobilized in a device that had to
14 be -- the head had to be sort of cemented into this
15 device, and then the device was quickly moved. In other
16 words, I'll just show you what happened. The head would
17 go in a 5/1000 of a second from this position to this
18 position (indicating), or from this position to this
19 position in 5/1000 of a second. There was no crushing of
20 the head. It was a manner of acceleration forces, because
21 the brain is swimming inside of our skull in fluid to
22 protect it. What they were showing was the damage that is
23 done when the brain collides with the inside of your
24 skull, and that's where the damage comes from, which is a
25 problem which happens in automobile accidents and athletic

1 injuries. You can be in a seatbelt in your automobile and
2 your body can look perfectly fine because you didn't go
3 very far in the accident but your head may have gone from
4 this position to this position, and that can kill you or
5 cause -- well, in worst it can just make you a vegetable
6 or something in between. But that's what they were
7 studying. If you would believe some of the critics of the
8 lab, it sounded as if they were taking wide-awake monkeys
9 and taking hammers and smashing their heads in. The fact
10 is, they were using a certain kind of a drug that actually
11 did put the monkeys to sleep, but this dissociative kind
12 of anesthetic made them look like they were awake.

13 So if you take things out of context, you
14 can really make them look bad. And I'm not defending
15 Gennarelli's lab, I'm just defending fair play. You've
16 read my comments, I'm sure, that I was defending fair
17 play. I am not defending his lab. I am saying that it is
18 dangerous to assume that everything that you see in that
19 tape is just the way it's being presented. That tape was
20 edited by PETA, and they did it for their purposes only.
21 And there were bad things going on in that lab, but they
22 were mostly technical problems. I do not think that
23 anything in that lab was actually a violation of Section
24 5511, and that's why I say I doubt that the search warrant
25 would have really made a difference in terms of our

1 prosecuting that lab. It may have resulted in the NIH
2 investigating quicker because we could see violations of
3 NIH or USDA regulations and report to them, even though we
4 ourselves couldn't prosecute. That would be the
5 difference.

6 Q. Thank you very much.

7 CHAIRMAN CALTAGIRONE: Thank you for your
8 testimony.

9 MR. HENDRICKS: Thank you.

10 CHAIRMAN CALTAGIRONE: And I do want to
11 submit another piece for the record, and I want to thank
12 everybody for attending. The meeting is adjourned.

13 (Whereupon, the proceedings were concluded
14 at 3:40 p.m.)

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1 I hereby certify that the proceedings and
2 evidence are contained fully and accurately in the notes
3 taken by me during the hearing of the within cause, and
4 that this is a true and correct transcript of the same.

5 
6

7 ANN-MARIE P. SWEENEY
8
9

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