SCAW Winter Conference

SCAW is sponsoring a two day conference, entitled *Advancing IACUC Education and Research Animal Well-being*, to be held in San Antonio, TX on December 10-11, 2001. Some of the topics to be discussed will be:

- Physiological Well-being of Nonhuman Primates: New USDA Policy and ILAR Guidelines
- Complying with PHS Policy and New USDA Policy II on Pain and Distress
- Update of Regulatory Burden Reduction
- New Refinement Technologies in Protocol Review
- In Defense of Literature Searches for Alternatives to Painful Procedures
- Rats, Mice and Birds
- A Work Session for New, Nonaffiliated and Nonscientist IACUC Members
- How will International Standards Drive U.S. Regulations?

The speakers are exceptional and the conference topics will help members of IACUCs in protocol review: principal investigators, attending veterinarians and animal care staff.

The conference is co-sponsored by the University of Texas Health Science Center at San Antonio and the Office of Laboratory Animal Welfare, NIH.

For the full program and registration information please visit the SCAW website at www.scaw.com

WARDS/SCAW Session at AALAS

Working for Animals used in Research, Drugs and Surgery and SCAW will sponsor a session titled *Recognition of Pain and Distress by Animal Care Staff* at the national meeting of the American Association for Laboratory Animal Science (AALAS) on October 23.

For the full program please visit the SCAW website at www.scaw.com

Inside...

| SCAW's May Conference Highlights | p. 2 |
| News from all over | p. 3 |
| Summaries from SCAW's May conference | p. 11 |
| Book Reviews | p. 13 |
SCAW’s Spring conference entitled, *Contemporary Practices for Research Animal Well-being/IACUC Responsibility* held in Baltimore, Maryland on May 17-18 had over 200 in attendance. Below are some pictures and comments from/about the conference. Some of the summaries from the conference are on the SCAW website and two are in this newsletter.
AALAS’ New Executive Director

By Dr. Richard Simmonds, President, AALAS

I am pleased to announce that Ann Tourigny Turner, PhD, CAE, has accepted the position of AALAS Executive Director. Dr. Turner's 20 years' experience in association management includes serving as Chief Executive Officer for both the National Rehabilitation Association and the American Society for Psychoprophylaxis in Obstetrics as well as management positions in the American College of Health Care Administrators and the Association of University Programs in Health Administration.

Her most recent professional activities include serving as Director of Education at the Oklahoma Community Healthcare Alliance, consulting for the Airborne Law Enforcement Association, and teaching at the University of Phoenix. She has to her credit numerous publications and presentations on association management and health care issues.

Her expertise in association management also has been recognized by the American Society of Association Executives by her selection to be an "Association Peer Reviewer" (roughly analogous to being an AAALAC site visitor) for the purpose of voluntary evaluation of member associations. In addition to her management skills, her ample experience in education should prove to be a valuable asset to the association.

Dr. Turner has stated that one of the most rewarding aspects of her career is the opportunity to collaborate with staff and volunteer leaders in evaluating, developing and strengthening educational offerings, and I feel confident the association will benefit from her expertise. Please join me in welcoming Dr. Turner to AALAS.

Tufts Animal Expo 2001

Press release from Tufts Animal Expo 2002 program

Tufts Animal Expo 2000 exceeded everyone's expectations. The intent during the inaugural year was to attract professionals in veterinary medicine, animal care, human health, animal welfare and protection and industry to attend an INCLUSIVE educational opportunity to benefit animals and all those who care for them. Over 4200 attendees - from all 50 states and 24 foreign countries - packed the Exhibit Hall, lecture rooms and laboratories, showing that Tufts Animal Expo is truly an international event!

Tufts Animal Expo 2001, to be held October 10-13 in Boston will build on their inaugural success and unique programs will continue to be added. The MEETINGS OF THE MINDS sessions were so popular last year that they are going to feature three new ones, one on each of the first three days. New this year, they are introducing WHAT’S HOT sessions at the very start of the conference, just prior to a NEW PLENARY SESSION with a keynote address by Samuel B. Ross, Jr., Ph.D., Executive Director Emeritus and Founder of Green Chimneys in Brewster, NY. Dr. Ross will explore with us the human-animal bond and its benefits.

The Program Advisory Committee, with input from Tufts many affiliates and endorsing organizations, has developed a diverse program. In response to the helpful feedback from attendees at last year's conference, they have added more hands on laboratories, expanded programs for veterinary technicians, and further developed the sessions that explore animal use in human health care and healing.

For more information please visit the website at: www.tuftsanimalexpo.com
Update on MUMS Bill of 2001
Letter from AVMA

In April 2001, the American Veterinary Medical Association (AVMA) Executive Board approved continued support for the passage and implementation of the Minor Use and Minor Species (MUMS) Animal Health Act of 2001.

The MUMS bill provides a unique pathway for approval and marketing of drugs used in minor species and drugs indicated for uncommon uses in major species (minor uses in dogs, cats, horses, cattle, swine, turkeys, chickens). In many respects it is similar to the human Orphan Drug Act of 1983.

The AVMA has initiated three methods to educate and inform AVMA members and others affected by this legislation:

A brochure and folder to inform veterinarians, Congress and AVMA customers (animal owners) of the impact of the MUMS bill;

An Information-and-Action-Network (MUMS-IAN) to inform all interested parties of the MUMS progress and;

AVMA is in the process of developing a MUMS website to provide educational information to their members and others. This website will be accessible from their home page www.avma.org

RDS Email News Service

The number of animal procedures carried out last year rose to 2.71 million, the Home Office announced. This represents a 2.2% (58,000) rise on 1999. The number of procedures involving genetically modified animals rose by 70,000 or 14% to 582,000 last year. The statistics will be published in full on Thursday 26 July.

Home Office Minister Angela Eagle, in her first public statement on animal experimentation since taking office, said: "The use of animals remains key to the development of scientific research that can lead to new medicines or test the safety of new chemicals. However, their use must be regulated and the UK has the toughest legislation in the world. Under this legislation, even taking a blood sample is recorded as a procedure and included in the statistics published today. In addition we remain committed to applying the three Rs principle in relation to animal testing."

The Animal Procedures Committee published its annual report today. It reports on the progress last year of subcommittees on cost-benefit, biotechnology, openness, and research on alternatives. The APC also examined other issues including training in microsurgery, enhancing public confidence in Home Office investigations and reporting of infringements.

Announcing publication of the Report, the APC chairman Professor Michael Banner also emphasised "widespread misunderstanding" of the mild nature of most animal procedures: "it is plainly not commonly understood that most scientific procedures do not cause grave suffering to animals, and that even taking a blood sample is a procedure under the Act."

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At First International Symposium, Experts Endorse Principles and Guidelines
Ottawa, 16 July 2001
News Release from ICLAS

The first International Symposium on Regulatory Testing and Animal Welfare was held in Quebec City, Canada on June 21-23, 2001 and brought together 160 experts from 22 countries from North and South America, Europe, and Asia. The experts included representatives from national research and regulatory agencies, universities, and industry involved in chemicals, pesticides and drug safety testing. Representatives from European, Canadian and US animal welfare groups also participated in the discussions.

The symposium was organized by the International Council for Laboratory Animal Science (ICLAS) and the Canadian Council on Animal Care (CCAC), with the help of the Organisation for Economic Co-operation and Development (OECD) and of many sponsors.

The intention of the International Symposium was to provide a platform to promote and harmonize more humane methodologies for the testing of chemicals and biological products in an effort to improve the welfare of animals used for safety testing.

Keynote presentations on the safety assessment process by representatives from the Food and Drug Administration, USA and the National Centre for Health Protection of Consumers and Veterinary Medicine, Germany, set the stage for subsequent scientific presentations. Breakout Groups focused on acute local and systemic toxicity testing, subchronic and chronic toxicity and carcinogenicity testing, the use of non-rodent species in testing, animal care practices, safety and potency evaluations of biologicals, and animal use oversight.

The main objective of the Symposium was to develop or identify best practices to minimize or eliminate pain and distress for animals used in safety evaluation and testing procedures. Another objective was to find ways to improve communications among regulated industry, animal welfare enforcement authorities, and regulatory authorities that require safety evaluation and toxicity testing. In fulfilling the main objective, there was unanimous agreement on the following principles and available best practices that should be implemented now by all user countries:

- there is an unequivocal link between good animal welfare and quality science;
- integrated testing schemes that incorporate non-animal methods are available for skin and eye testing and should be used now;
- the conventional LD_{50} (median lethal dose) test should be replaced with alternative methods that use fewer animals and that involve more humane endpoints;
- for any given testing procedure, elimination of pain and distress should be a higher priority than reducing the number of animals used;
- guidance documents on humane endpoints published by the CCAC (http://www.ccac.ca/english/gdlines/ endpts/appopen.htm) and by the OECD (http://www.oecd.org/ehs/ehsmono/index.htm) are recognized as effective refinement tools to minimize existing and potential pain and distress; scientifically validated more humane endpoints are available for vaccine and other biologics testing (e.g., rabies, pertussis, tetanus, diphtheria and other vaccines) that should be used by all sectors;
- guidelines developed by OECD to promote more humane methodologies for the testing of chemicals and by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are reducing animal use by eliminating redundant testing;
- data sharing and training programs should be put in place quickly to assist regulators, toxicologists and others to be comfortable with the new tests;
- animal care practices (cage floors, social housing, environmental enrichment) that improve animal welfare without jeopardizing the scientific design must be implemented; and
- Institutional Animal Care Committees serve a critical role in facilitating high quality safety testing and ensuring the best possible animal welfare.

Ecotoxicology was identified as an area where we have yet to begin to apply the Three Rs, given the increasing emphasis put by national governments on testing for chemicals in the environment and...
the resulting increase in use of fish and birds with no in vitro alternatives being developed yet. Another area in need of dialogue and deliberation is the rapid transfer of the latest science and technology to improve testing methods. The need to scientifically validate new methods and practices was emphasized, with recognition of two organizations that have now been established to carry out such work: the European Center for the Validation of Alternative Methods, and the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods.

A highlight of the Symposium was the open communication that occurred among regulators, the regulated community and animal welfare representatives, from the podium and in all breakout group discussions. The International Organizing Committee concluded that the international mix contributed to this openness and that it set the stage for the expectation that this openness will continue.

In order to foster improved communications, participants will be forwarded summaries of presentations and breakout group reports by September 2001, and proceedings will be published in the Spring 2002 issue of the Institute of Laboratory Animal Research Journal, a publication of the US National Academy of Sciences. Finally, the results of the Québec Symposium will be presented at the August 2002 Fourth World Congress on Alternatives and Use of Animals in Life Sciences to be held in New Orleans, USA.

Further information on the program of the Symposium will be found at the following addresses: www.ccac.ca and www.iclas.org

New Research-Animal Protections Barred at Agriculture Department

Source e-mail from AMP
By Ron Southwick
Chronicle of Higher Education
July 13, 2001

The House of Representatives Committee on Appropriations has quietly approved a measure barring the U.S. Department of Agriculture from using its funds to extend protection to rodents and birds used in laboratory research.

The stipulation would specifically forbid the agency to widen the Animal Welfare Act to include birds, mice, and rats in the 2002 fiscal year. College lobbyists are cheering the move.

The House panel included the measure in the Agriculture Department’s appropriations bill for 2002, which the committee approved last month.

Last year, lawmakers signed off on language prohibiting the agency from regulating birds, mice, and rats in 2001. The Animal Welfare Act is the primary federal law regulating animals used in research.

College administrators have argued that expanding the law to include birds and rodents will cost institutions millions in additional paperwork. Officials at animal-rights groups said they were bitterly disappointed with the House bill’s language.

"We will work to see that it is removed," said Martin L. Stephens, vice president for animal research at the Humane Society of the United States. The Humane Society has joined with other animal-protection groups to lobby for the expansion of the Animal Welfare Act.

Research advocates are working to see that the Senate, which also must approve the Agriculture Department's spending, agrees to a similar provision, said Anthony Mazzaschi, assistant vice president for research at the Association of American Medical Colleges. College lobbyists are asking Sen. Herb Kohl, the chairman of the Senate Appropriations subcommittee that oversees the Agriculture Department, to include similar language in the Senate version of the spending bill.

Senator Kohl, a Wisconsin Democrat, supported the provision that kept the department from expanding the Animal Welfare Act this year, Mr. Mazzaschi noted. However, animal-rights groups are likely to find a senator willing to sponsor a bill to expand protection to birds and rodents, particularly with Democrats controlling the Senate, Mr. Mazzaschi said.

The Department of Agriculture agreed to develop new regulations to include birds and rodents last fall. The agency took that step to settle a lawsuit filed by the Alternatives Research and Development Foundation, a group that promotes finding ways to avoid using animals in laboratory studies.

The foundation and animal-protection groups contend that it is especially important to protect birds and rodents, because nearly all animal-based research involves mice and rats.
EURCA
Press release from EURCA

Background
The idea of a EUropean Resource Centre for Alternatives to using animals in higher education (EURCA) first arose in 1998, during a workshop on alternatives to the use of animals in higher education sponsored by ECVAM (The European Centre for the Validation of Alternatives in Medicine). This original idea has been progressed by David Dewhurst and Jan van der Valk who have now successfully obtained funding to turn the idea into reality.

Aims of EURCA
· to actively promote the use of alternatives to using animals in higher education (HE);
· to provide a mechanism for effective dissemination of useful information about alternatives to using animals in HE;

These aims will be achieved by:

Establishing a Resource Centre - a collection of electronic alternatives and taking this to relevant scientific meetings in Europe where it would function as a drop-in advice centre for teachers.

Assembling a group of academic teachers who actively use alternatives to take responsibility for disseminating information about alternatives to other teachers in the European community.

Creating a collection of alternatives and making these available to teachers

Carrying out site visits to demonstrate good practice in the use of alternatives.

Setting up an Internet website with an expansive information database on alternatives, demonstration versions of alternatives, evaluations, links to users etc.

Activities of EURCA
The planned functions of EURCA would be to:
· set up a content-rich web-based database of selected ('tried and tested') alternatives to using animals in HE
· assemble a collection of quality alternatives (CAL, video, models, using humans rather than animals to teach experimental science etc) and make them available to teachers for evaluation
· actively disseminate information about alternatives by taking the resource centre to major international scientific meetings
· offer advice to teachers on good practice in using alternatives based on the experiences of teachers who have implemented alternatives at universities throughout Europe
· encourage and promote the findings of evaluative studies on the effectiveness of alternatives in HE
· establish a European network of teachers actively using alternatives to share experience

For more information contact:
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OECD Guidance Document No. 19
Electronic copies of the document: Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation are available free of charge on the OECD Webpages at www.oecd.org/ehs/test

Public Policy Position
GlaxoSmithKline has a position statement on their website explaining their policies on animal research. To view this position please go to...

http://corp.gsk.com/tomorrow/animals.htm

7th National Symposium on Biosafety
The symposium titled Managing Risk in Animal Care and Use will be held January 26-30, 2002 in Atlanta, Georgia.

The sessions will include:
Risk Assessment
Facility Design
Work Procedures and Occupational Health
Decontamination
Hot Topics and Late Breakers

For more information call 207-490-1076 or visit www.eagleson.org

SCAW is a co-sponsor of this symposium.

IRWC Conference
The International Wildlife Rehabilitation Council (IRWC) is holding its annual conference in Lake Buena Vista, Florida on November 14-17, 2001.

For more information please visit www.irwc-online.org
IACUC Meeting

IACUC: The Charge & The Challenge 7 will be held on Friday, November 9, 2001 at the Merrill Lynch Conference & Training Center, Princeton, New Jersey. The program will feature Eric Dezenhall, author of Nail 'em!, Confronting High-Profile Attacks on Celebrities and Business, 16 workshops, and regulatory updates. For registration, contact New Jersey Association for Biomedical Research at 908-964-9449 or on the web: www.njabr.org

NTP Update

The NTP Report on the Endocrine Disruptors Low-Dose Peer Review is now available and comments are being solicited.

This report is based on the Endocrine Disruptors Low-Dose Peer Review held October 10-12, 2000, in Research Triangle Park, NC.

To view the report and for additional information please visit the NTP web site at http://ntp-server.niehs.nih.gov under “What's New”

What's New at ILAR

Volume 42 (2) of ILAR Journal — Animal Models of Hepatitis

This substantive issue contains a comprehensive group of articles on various models used to study the known human types of hepatitis from A through E. Given the current reliance on nonhuman primate models for hepatitis, a common theme emphasized repeatedly throughout the issue is the need for better and more practical small animal models with particular emphasis on hepatitis C research needs.

To obtain a copy of this issue or a subscription through the ILAR Associates program, contact the Journal office email: ilarj@nas.edu or visit our website (http://www.national-academies.org/ilar).

AVMA Animal Welfare Forum

The American Veterinary Medical Association's 12th Annual Animal Welfare Forum on "Pain Management" is being held in conjunction with the American College of Veterinary Surgeons annual symposium. The forum will be held at the Hyatt Regency in Chicago, IL on Sunday, October 14, 2001.

Topics include: pain in companion, lab and agricultural animals; ethics when dealing with animal pain; alternative therapies; challenging pain management cases; similarities and differences between pain in human neonates and animals.

For additional information: Darci Reagan, AVMA, 1931 N. Meacham Road, Suite 100, Schaumburg, IL 60173, ph: 800-248-2862 ext 211 e-mail: dreagan@avma.org

SCAW Publication

NOW Available

Performance Standards and Animal Welfare: Definition, Application, and Assessment - Parts I & II addresses the definition, development and evaluation of performance standards in research animal facilities. This publication is based on SCAW conferences held in Baltimore in 1997 and 1998. Editors of this publication are: Jan Gonder, DVM, PhD, Robert Smeby, PhD and Thomas Wolfe, DVM, PhD. Please visit the SCAW website at www.scaw.com for ordering information. The cost is $25.00 per copy which includes shipping and handling in the U.S. Foreign addresses require $7.00 additional for postage and handling.
The American Association for Laboratory Animal Science (AALAS) is presenting the second annual Management and Technology Conference on February 7-9, 2002. The objective for this conference is to provide attendees with sessions that will enhance their skills in both management and technology topics and offer valuable networking opportunities. The conference will take place at the Peabody Hotel in Memphis. With the Mississippi River as its backdrop, Memphis provides a diverse array of museums and area attractions.

For more information: The AALAS website at www.aalas.org will be the place to get complete program details. Click on the M&T icon from the home page to take you to all the relevant registration forms, housing information, exhibitor information, and session descriptions. To request a conference brochure, call 901-754-8620.

2002 M&T Affiliate Sponsors:
Scientists Center for Animal Welfare
Laboratory Animal Management Association
Canadian Association for Laboratory Animal Science

### European Parliament Approves Sales Ban on New Cosmetics Tested on Animals

**Source e-mail from AMP by Constant Brand, Associated Press Writer**

Brussels, Belgium (AP) — The European Parliament voted in April 2001 to impose a sales ban on all new cosmetic products that have been tested on animals.

The 626-member European Union assembly meeting in Strasbourg, France, easily voted in favor of some 30 amendments that strengthen existing EU rules on cosmetic products.

An immediate ban would take effect on products for which alternative testing exists, if EU governments give their approval to the new legislation.

The proposed rules would phase in a ban by January 2005 on all new cosmetic products — including make-up, shower gels, shampoos and creams — using ingredients tested on animals, even if alternative tests have not been developed.

The ban would also apply to all imports of animal-tested cosmetics...

The proposed new legislation comes after three years of political wrangling between the European Parliament and the European Commission which postponed an earlier ban that was to have gone into effect in 1998.

The EU executive said it delayed the ban because there was a lack of alternative testing for cosmetic manufacturers. It fears the proposed ban could be challenged at the World Trade Organization by the EU's trading partners arguing the ban was a trade barrier disguised as animal welfare.

The Pain & Distress Report, published by The Humane Society of the United States, is a newsletter that provides IACUCs and others in the field of laboratory animal science with up-to-date information on issues regarding pain and distress in laboratory animals. Each Pain and Distress Report includes information on policies and perspectives, resources and services, recent publications, summaries of articles from the technical literature, upcoming conferences, pain and distress statistics, attitudes and public opinion, and helpful websites. Current and previous issues of the newsletters can be viewed at www.hsus.org/programs/research/p&d_rep.html

To begin receiving electronic copies of the newsletter via e-mail, please write to ari@hsus.org or call 301-258-3041.
Study Finds Inconsistency in Animal Research Reviews
July 27, 2001, Contact: Scott Plous, Email: splous@wesleyan.edu

MIDDLETOWN, CT—Results from a study published in the July 27 issue of Science suggest that the approval decisions made by university animal use committees in the United States are unreliable when it comes to experimental procedures involving animals.

Funded by the National Science Foundation, the study was conducted by Scott Plous of Wesleyan University in Middletown, CT, and Harold Herzog of Western Carolina University in Cullowhee, NC.

The investigation, which took three years to complete, compared judgments made by 50 randomly selected animal care and use committees drawn from U.S. colleges and universities. To assess the consistency of approval decisions, 150 recent research proposals from these institutions were each independently evaluated by two different animal care and use committees.

The results showed that approval decisions were statistically unrelated. In most cases, proposals that were disapproved by one committee were approved by the second committee.

The study also explored whether reviews were more reliable when the experiment involved certain types of animals or procedures. For example, reliability was assessed for proposals that involved dogs, cats, and primates, or for experiments involving drugs, surgery, animal pain, or death. Even in these cases, independent reviews did not agree beyond chance levels.

"The people who serve on animal use committees have been put in a difficult situation," Plous says. "They try hard to make good decisions, but they aren't given the kind of detailed, standardized guidelines necessary for a reliable review."

Herzog agrees: "As an animal researcher, I was surprised by the results. These committee members are smart, dedicated people. If the reliability of their proposal reviews is at chance levels — literally, a coin toss — then the review system needs to be fixed."

Plous and Herzog hope their results will prompt a reevaluation of the way animal research proposals are approved. Similar reevaluations have taken place with respect to research on human participants, but the approval process for animal research has been largely unchanged since Congress first mandated it in the mid-1980s.

Under U.S. law, most research institutions must establish an animal use committee to review proposed experiments and assure they meet federal guidelines. If a proposal fails to meet federal guidelines, the committee is required to reject it or call for changes before the experiment can take place.

To see a copy of the Science article, go to this address:
http://www.sciencemag.org/cgi/content/full/293/5530/608?ijkey=UiT530KdhBkj&keytype=ref&siteid=sci
You can also view supplementary material on the Science web site at:
http://www.sciencemag.org/cgi/content/full/293/5530/608/DC1

Mutant Mice
NIEHS News List e-mail

The National Institute of Environmental Health Sciences announced the establishment and funding of five research centers to develop and breed mice with key genetic variations similar to those of humans.

The centers will provide the special, mutant mice for scientists throughout the National Institutes of Health, of which NIEHS is a part, and to other research programs as well, to help scientists study how human bodies repair environment-damaged DNA and control their cell's life cycles.

For the rest of the story, see http://www.niehs.nih.gov/oc/news/mocts.htm

IACUC 101 in Connecticut

On October 16, 2001, the Applied Research Ethics National Association (ARENA) in conjunction with Yale University, the NIH Office of Laboratory Animal Welfare (OLAW), Southern New England AALAS, Bayer - Pharmaceutical Division, Bristol-Myers Squibb, Boehringer Ingelheim Pharmaceuticals, Inc., and Pfizer will present ARENA IACUC 101. IACUC 101 is a full day didactic and interactive course. Participants will receive an extensive Resources Manual plus other valuable reference materials and information. The session will be held in New Haven, CT on October 16, 2001. Announcement and registration information are posted at:
http://grants.nih.gov/grants/olaw/Yale.htm
Transgenic Research and Animal Welfare
by Dr. Dennis Johnsen, Clinical Professor
University of Washington School of Medicine

Transgenic and gene knockout research, heavily dependent on the use of mice, represents one of the most exciting and rapidly growing areas of science today. Growth in the use of mice at the University of Washington, estimated to be about 20% each year over the last decade, is a unique phenomenon in the use of animals in research today. Almost all of this growth can probably be attributed to the revolution that is occurring in genetic research. While the research community has pointed out that the numbers of animals used in research involving unrelieved pain are relatively small, these numbers have typically not included rats and mice. It is clear that genetic manipulation can result in pain and distress such as the morbidity and mortality that occurs from their increased susceptibility to infection or the experimental induction of a number of "designer" diseases. If the numbers of mice used in genetic research were to be included among all animals reported to be used in research, and pain and distress assessed according to standards typically used for those larger species reported upon, the totals, at least in absolute terms, would not be small.

The impact on the institution of this growth has been substantial. Most obvious are increases in the amount of space dedicated to holding mice (more and more at the expense of housing other species), staffing for animal care and veterinary services, staffing for the animal care and use committee (IACUC), purchase of ventilated rodent barrier housing units and associated equipment, and the provision of a completely new transgenic service to support the genetic research effort. The institution has been forthcoming in meeting these needs for personnel and space. Avoiding trouble and doing things right is an important objective, recognizing both public ambivalence towards genetic research and its heavy dependence on animal use.

With respect to veterinary services, mice that are more valuable as well as more susceptible to infection, require both more attention to traditional "herd health" and preventive medicine measures as well as increasing the kinds of individual clinical treatment normally afforded to larger species. Problems posed by pathogens, both familiar old ones and ones newly recognized, are challenging the effectiveness of traditional diagnostic and control measures in animals with incomplete immune systems. Since they are on the "front line" of monitoring and surveillance, increased emphasis has been required to train both animal technicians and research staff to recognize and report signs of illness as well as to master the demanding discipline necessary to do laboratory work in a specific pathogen free environment (SPF).

One of the major areas of impact has been on the IACUC, whose secretariat has probably experienced the most growth as a unit in the last decade. Much of this is attributable to the growth of genetic research and assumption of responsibility for the rodent training function closely associated with it. It is often not possible to anticipate whether pain or distress will occur in mice in projects involving genetic manipulation. However, the committee is finding that it is possible to hold investigators accountable for early recognition and resolution of such problems and assuring that they are reviewed and approved by amendment of research protocols. Incidents involving deviation from protocols and the possibility of sanctions have been a relatively recent development and have been few in number - one or two per year. Typically they have involved both unanticipated morbidity or mortality and the failure of investigators to adequately monitor their animals. On the other hand, the numbers of requests for amending protocols based on experimental experience is on the rise.

Instituting monthly room by room morbidity and mortality reporting has been one of the most important developments in early identification and resolution of animal welfare problems. Originally launched to bring unanticipated deaths in larger species to the attention of the attending veterinarian, the reporting system was extended several years ago to include small rodents. The reports, which supplement open direct reporting channels when warranted, have been particularly useful in drawing attention to clinical problems that earlier...
might have escaped notice. Mice used in genetic research have come to be the focus of nearly all followup prompted by these reports. This followup normally involves discussions between the investigator concerned and the attending veterinarian which leads to requesting IACUC approval for an appropriately amended protocol.

For its part, the genetic research team is coming to recognize the mouse as more than just luggage for carrying genes. Based on increasing experience with the effects of gene insertion and deletion, investigators are increasingly being expected to address animal welfare concerns as well as to take on responsibility for the characterizing, phenotyping, and monitoring the animals that they create. The need to be trained to work with animals, something that might have been regarded as of little importance earlier, is now a requirement. Genetic research teams are having to cope with a tightening squeeze for space, the disruptive effects of inadvertent infection, the inconvenience and restrictions present in working in an SPF environment, and facing even more dire consequences if they do not. The importance to their research of the veterinary staff, the attending veterinarian as an ally in resolving animal health and welfare issues, and ultimately meeting IACUC expectations are things that all genetic researchers using mice are having to face up to.

It is likely that genetic research using animals will continue to grow as it has in the last decade. Mice will undoubtedly lead the parade but we will also see more use of other species. However, space - and appropriate space - will increasingly become a limiting factor. This limitation will likely force difficult decisions about discontinuation of lines of transgenic or knockout mice, improvements in cryopreservation technology, and disadvantageous movement towards greater use of off campus facilities. How investigators and the IACUC view animal welfare issues in small rodents, an area that probably has not been regarded with as much sensitivity as it deserves, will continue to evolve and the bar is likely to be raised. Despite how robust and promising genetic research presently is, the public is not entirely comfortable with it or with its dependence on research animal use. Institutions and the research community will need to be more proactive in promoting public understanding and support for this effort rather than hoping that trouble will not find them. This research is vulnerable if efforts to assure that pain and distress in the animals used in it are neither convincing or successful.

**Ultrasound Imaging in Rodents:**
**Overview of Principles and Applications**
*Dr. Robert W Coatney, Senior Staff Veterinarian GlaxoSmithKline*

Ultrasound imaging utilizes the interaction of sound waves with living tissue to produce an image of the tissue, or in Doppler based modes, determine the velocity of a moving tissue, primarily blood. It is most commonly used as a versatile, non-invasive diagnostic tool that is widely used and accepted in human and veterinary medicine. It has also been used as a research tool as the resulting dynamic, real time images can be analyzed to obtain quantitative structural and functional information from the target organ. Until recently these research applications were limited primarily to larger, non-rodent species. Advances in ultrasound imaging technology during the last decade have provided commercially available ultrasound systems with the spatial and temporal resolution to accurately obtain images of rat and mice hearts, kidneys and other target tissues including tumor masses. As a result, ultrasound imaging is being used more frequently as a research tool to image rats and mice, and particularly to evaluate cardiac structure and function. The developing technology of ultrasound biomicroscopy has even greater spatial resolution and has been used to evaluate developing mouse embryos and guide site specific injections into mouse embryos. Additional ultrasound imaging technologies including contrast enhanced imaging, and intravascular ultrasound transducers adapted for use transesophageally have been used in rats and mice. This presentation will provide a brief overview of the principles and formats of ultrasound imaging focused on the properties which are critical to imaging rodents. It will also provide examples of how ultrasound imaging has been used in research involving rats and mice. The use of non-invasive ultrasound imaging in research represents a significant refinement, as it can replace more invasive techniques, as well as a significant advancement in research techniques to study target organ structure and function in rats and mice.
Definition of Pain and Distress and Reporting Requirements for Laboratory Animals

Review by Dr. Marilyn J. Brown-Dartmouth College
Proceedings of the Workshop held June 22, 2000
Committee on Regulatory Issues in Animal Care and Use, Institute for Laboratory Animal Research
Copies are available directly from ILAR, 202-334-2590 or by fax at 202-334-1687. The cost is $15.

This 118 page, paperback publication includes 14 presentations that were given at a workshop sponsored by the Institute for Laboratory Animal Research (ILAR), and the Office of Laboratory Animal Welfare (OLAW) of NIH. The purpose of this workshop was to provide input to the United States Department of Agriculture (USDA) in their consideration of the principles and definitions pertaining to the recognition and alleviation of pain and distress in laboratory animals. Most presentations were followed by a brief question and answer period. The final chapter is a Panel discussion with all of the speakers. The appendices include the APHIS/USDA Policy 11 and 12, proposed rulemaking, a glossary of abbreviations, a list of meeting participants, the meeting agenda and biographical sketches of the ILAR committee who organized the workshop.

After the introduction by Dr. Ralph Dell, ILAR, Dr. Ron DeHaven gives the USDA perspective on Pain and Distress. Dr. DeHaven reviews the draft definition of distress. He also recognizes that other methods of relief such as therapeutic agents, specialized nursing care, behavioral conditioning etc. may be used to ameliorate pain and/or distress and that a single procedure may be placed in the current Columns C, D, or E, depending on circumstances. There is an explanation of each of these columns, with examples. There is an encouragement to use retrospective reporting. In addition to the title topic, Dr. DeHaven provides thoughts on how IACUCs should review considerations of alternatives to painful and distressful procedures (Policy 12) and the inclusion of mice and rats in the AWA Regulations.

Dr. Nelson Garnett, OLAW, gives the Public Health Service (PHS) perspective in the next chapter. He also discusses Policy 12, mice and rats, the relationship of the pain and distress issue to US Government Principle IV and the Humane Society of the United States (HSUS) Pain and Distress Initiative. He urged the participants of the workshop to consider the following questions:

- Will proposed changes benefit animals? (a recurring question in subsequent presentations)
- Are they consistent with statutes/regulations?
- Do they "harmonize" agency standards?
- Do they achieve goals while minimizing burdens?

Dr. Kathryn Bayne, AAALAC, International, gives a veterinary behaviorist’s perspective on pain and distress, although she focuses on distress. Dr. Bayne begins with discussing the reasons it is difficult to define distress. She also discusses the advantages and disadvantages of using behavior as an assessment tool and need to determine whether changes in behavior are not only atypical but maladaptive. Dr. Bayne stresses the importance of having individuals who are knowledgeable and skilled in the interpretation of behavior as well as the importance that the assessment not be influenced by the personal biases of the observer. She believes that in a workable program for managing pain and distress, the IACUC plays a pivotal role in collaboration with the veterinarian, research staff and animal care staff.

Dr. G. F. Gebhart, a well-known scientist in the study of pain, discusses the notion of pain versus nociception. He classifies pain into protective pain and nonprotective pain. When defining stress and distress, Dr. Gebhart urges the use of the definitions from the 1992 NCR publication Recognition and Alleviation of Pain and Distress in Laboratory Animals.

Dr. Andrew Rowan, HSUS, discusses the four main segments of the HSUS Pain and Distress Initiative. These include commissioning an expert report; sending letters to IACUC, focusing on regulatory “shortcomings”, and encouraging more research and funding on how to assess and limit animal pain and distress. He stressed the importance of consistent reporting practices and suggested three grades of pain - minor, moderate and severe.

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In the next chapter, Pain and Distress Caused by Experimental Procedures - Is it Time for a Reality Check?, Dr. Alicia Karas, a veterinary anesthesiologist, discusses the limitations of prospective pain and distress categories and urges more observation and documentation to assure adequate reporting. She suggests that validation of categorization be done through periodic or random IACUC review of activities and outcomes.

Dr. Taylor Bennett, representing the American College of Laboratory Animal Medicine (ACLAM), was not supportive of changes to the existing policy because of his concerns that the USDA Animal Care Policies are de facto regulations with no mandated public comment period. Dr. Bennett points out that "pain and distress are medical care problems that first require detection, then determination of a cause (the diagnosis), and then alleviation (the treatment). The section of the AWA on the Attending Veterinarian and Adequate Veterinary Care is important in giving institutions the guidance needed to address the pain and distress issues. As agreed by other speakers, Dr. Bennett mentions the need for research into these issues.

Dr. Marcelo Couto, American Association for Laboratory Animal Science (AALAS), discusses the AALAS position paper on pain and distress. He covered evaluating pain and distress, alleviating pain and distress, training personnel and the roles of the veterinarian, IACUC and investigator.

Dr. J. R. Haywood, representing the research investigator community, reiterated earlier messages about the importance that policies and regulations should benefit the animal. Dr. Haywood expressed concern about the increased regulatory burden and the resources it takes away from research. He also stressed that definitions and reporting should be kept "simple". He discussed the fact that the ethical issues in science become more complex as the science becomes more advanced.

Dr. Lynn Anderson presented an industrial perspective. In addition to the principles that the prevention and alleviation of pain and distress are legal and ethical imperatives, Dr. Anderson mentions that it is important for quality science. This is tempered with the idea that the risk of causing pain or distress in a small number of laboratory animals may be justified if the research benefits society by identifying ways to prevent humans and other animals from suffering. She discusses the sources of pain. She also recommended that the USDA adopt the definitions from the 1992 NCR document. Dr. Anderson did not support the use of a "mild", "moderate", "severe" categorization system because it would be even more subjective than the current system. Dr. Anderson outlined the shared responsibilities for the assessment of pain and distress.

Dr. John Harkness gave four introductions to talks with the titles: "My Life as a Rat"; "My Ignorant Colleagues"; "Rats and Your Cousins, I Love You"; and "Overwhelmed".

Dr. Victoria Hampshire discussed personal experiences with clinical pain management, study design, mitigation of scientific cofounders and long term gains to researchers and the public. She discusses distress as a culmination of minor events and urged awareness and treatment of those minor events as one method for minimizing distress. She identifies those events using a multidimensional risk model. Dr. Hampshire urges heavy reliance on teams of clinical veterinarians and technologists.

Dr. Robert Rich then discusses the use of laboratory animals in the postgenome era, discussing the predictable trends towards systems biology and the reduction of the heterogeneity of the animals used. The consequences of genetic breeding, the explosive creation of animal models of disease, will focus the research community on management rather than elimination of pain and distress. Dr. Rich advocates increased attention to and definition of experimental endpoints as a method to minimize pain and distress.

Dr. Christian Newcomer, also representing ACLAM, reviewed the original congressional testimony on the AWA to help the participants understand the intent of Congress regarding the alleviation of pain and distress. He also pointed out that in the span of the last 20-30 years, the vast reduction of endemic infectious diseases in lab animals has already eliminated a vast majority of the pain and distress and that this advance was only marginally aided by regulation. He points out that the structure is in place, IACUCs and institutional veterinarians, to tackle the remaining "thorny" pain and distress issues. Dr. Newcomer joined several of the speakers in urging the USDA to use the 1992 NCR document when developing definitions of pain and distress. He also mentioned several points of concern in the "aggressive agenda" of the USDA Animal Care Strategic Plan 2000.

This book is an important resource for institutional veterinarians, IACUC members, research staff and others who are interested in understanding this issues surrounding pain and distress in laboratory animals and the possible impact of the regulatory process on research.
This book contains the proceedings of the 38th scientific meeting of the Society for Laboratory Animal Science on the development and use of isolated perfused organs. This book includes papers by 23 contributors describing various aspects of the use of isolated perfused organs in the studies of topical drug bioavailability, irritancy, cytotoxicity, metabolism, vessel mechanics, gene expression, mediator release, and quality control to mention several of the topics covered.

The use of perfused organs is valuable in that studies can be performed in a more physiologic condition than can be done with the use of cell culture. These studies are also advantageous in that these organs can be obtained from the local abattoir (for most models described) at a modest cost thus reducing the need to use animals specifically bred for research. Of course, there is a limitation to the use of whole organ perfusion experiments and that is the limited time of viability of the organs after removal from the animal. Few studies can be continued longer than about seven hours.

Specific models described in this collection include the use of perfused eye, lung, heart, liver, kidney, ear skin, leg, and bovine udder. As an example, several papers describe the utilization of bovine udder to study bioavailability of topically applied drugs to the external skin and drugs applied intracisternally, thereby examining the effects of drugs applied to cornified skin and mucus membrane. Performing biopsies of the udder skin after completion of the experiments enabled the investigators to study irritancy and cytotoxicity caused by the drugs applied to the skin. The organ-specific advantages of using the other models are also described.

Overall I found the papers easy to read but the location of the papers within the book could have been improved to enhance the flow of information. As an example, the general paper describing the bovine udder model should have preceded the paper on the histology of the udder. In addition, the paper on quality control should have been at the end of the book instead of the middle. Nonetheless, this book is a fine review of the current (1998) use of isolated perfused organs in basic research.
Michael Hayre Deceased

Michael D. Hayre, D.V.M., a friend of SCAW for over a decade, died in a Memphis hospital on Wednesday evening, August 29. The day before, he had been hit by a car while he was jogging. Dr. Hayre never emerged from the coma caused by the accident.

Dr. Hayre, served for the past two years as Chairman of the Board of Directors of Americans for Medical Progress. Since June of 1999, Mike was also Vice President, Comparative Medicine and a member of the Executive Management Committee at St. Jude Children’s Research Hospital in Memphis, Tennessee. Prior to St. Jude’s he was Director of the Laboratory Research Center at the Rockefeller University in New York and an Associate Veterinarian at the Yorkville Animal Hospital.