



# ACNP Bulletin

American College of Neuropsychopharmacology

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## The President's Council on Bioethics

The President's Council on Bioethics has issued its first report: "Human Cloning and Human Dignity, an Ethical Inquiry."



**Paul McHugh**  
Member, President's Council on Bioethics  
Chair, ACNP Ethics Committee

The President's Council on Bioethics has issued its first report: "Human Cloning and Human Dignity, an Ethical Inquiry." This account – available on line at [www.bioethics.gov](http://www.bioethics.gov) – documents the ethical deliberations of the council in its six-month study of Somatic Cell Nuclear Transplantation (SCNT).

The text reveals considerable agreement over policy amongst the diverse council members. They unanimously recommended that the use of human SCNT for reproduction (cloning for baby-making) should be banned. And the members unanimously recommended enforceable regulations for fundamental human SCNT research as with stem cell production or basic cellular biology.

The council divided, though, over how to bring regulation to human SCNT research and ended by offer-

ing two different policy proposals. Ten members formed a small majority supporting a legislative moratorium of four years in human SCNT work – a moratorium for more animal research, more discussion of the ethical issues of this practice, and for time to set up the regulatory processes that all favored. Seven members of the council formed a sizeable minority a) favoring the eventual establishment of a system of oversight and regulation but b) in the meanwhile approving the use of human cloned embryos and the stem cells and tissues derived therefrom "without substantial delay." Here I report my reasons for joining the majority in this matter.

I argued in council that SCNT – a major discovery in cellular biology – has implications needing careful assessment but that a strong argument in favor of proceeding with human SCNT rests upon the view that cells rather than new human beings are what are initially emerging with this process. These cells can be viewed as tissue culture extensions of the donor of the somatic nucleus and thus can be legitimately used in certain ways by interested scientists and physicians.

But even when one accepts this argument as to the nature of SCNT products, several concerns over proceeding without delay into widespread human SCNT research remain. These concerns are serious enough, I believe, for the American public,

including its scientific members, to insist that they be addressed – even delaying human research until appropriate regulatory responses are in place. The concerns are three.

First: If human SCNT is to proceed unchecked then many human eggs will be needed as "ingredients." Thousands may be necessary to satisfy unregulated demand and therefore many hundreds of women may be carried through the process of hormonal preparation and laproscopic egg harvesting. Do we really want to make egg factories out of large numbers of women? What are the dangers to their health and well-being. How can we avoid coercing them?

Second: Although the cellular disaggregation of the early products of SCNT seems licit given the assumption with which we began, these embryonic products could be implanted in a uterus and grown further to where organ formation appears. Would the point-of-view that permits cellular disaggregation of the early products of SCNT, also apply and permit organ disaggregation of the fetus derived from the same source? If not, why not? And if not, how will enforceable regulations be developed?

Third: Although the council and the National Academy of Science both proposed a ban on SCNT for reproduction, neither called attention to a most serious concern for humankind tied to this issue –the possible pro-

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duction of a genetic anomaly that would then pass from generation to generation. This concern is obvious on noticing that Dolly has a little lamb.

It took nearly 300 attempts with sheep SCNT and uterine placements to get Dolly. Some injuries to the genome inherent within SCNT led to fatal genetic abnormalities in all the others.

The concern though lies with the live birth. Just as one cannot be sure that Dolly is genetically sound, a human counterpart may carry, because of the cloning procedure, some pathogenetic mutation such as a trinucleotide repeat rendered unstable by the process. This mutation will pass - and perhaps expand - down the generations as with Huntington's Disease, myotonic dystrophy, and the like. Such a contamination of the human gene pool may take several generations to come to light. This issue needs much more public discussion than it has received.

These three concerns, I believe, are sufficiently serious for cellular biologists to gather and propose solutions. The vetting of research plans restricting access to human eggs to highly qualified laboratories may reduce the numbers of eggs required. Perhaps animal ova can replace humans in many studies. Some legal limit to the growth of SCNT aggregates and an enforcement policy with teeth may preclude uterine implantations and

thus both the inducement to dismembering of fetuses and the path to reproduction. An international effort to ban reproductive cloning as one bans slavery and genocide may reassure everyone that the human gene pool is safe.

But I fear scientists will not move quickly towards these regulations unless their attention is seized. Hence my vote for a moratorium.

Remember that this Council has only "pulpit powers" not legislative powers. It cannot impose, it can only propose; but in so proposing it calls forth discussion from all interested parties in the American public. Cellular biologists and other scientists should listen to the proposal of the council's majority for a moratorium in human SCNT research.

I think they will agree that reasonable concerns exist in this domain. How they should answer is debatable. But I believe the best response to the council's proposal for a legislative moratorium is not to write protesting letters to all and sundry - as though one were fighting a lunatic fringe - but for the scientific community and especially for the NIH to make a coherent counter-proposal. This could well include a self-imposed moratorium - sufficiently long but no longer than needed - to answer these and other concerns about human SCNT and to put in place protective regulatory procedures. ♦



**The American College of  
Neuropsychopharmacology  
on the World Wide Web**



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## From The Editor

**Charles B. Nemeroff, Editor-In-Chief**

There have been many changes in Neuropsychopharmacology in the last six months - some have undoubtedly been evident to you, as for example, the change in the cover. Others are less evident but no less important in attaining our goal of being ranked as the best journal in our field.

The move of Neuropsychopharmacology to Nature Publishing Group is an exciting evolution for the Journal and the American College of Neuropsychopharmacology. The addition of our journal will enhance Nature Publishing Group's cluster of high quality Neurology, Neuroscience, Psychiatry and Pharmacology titles.

Neuropsychopharmacology will continue to publish the highest quality original research in areas of clinical and basic science that advance our understanding of the brain and behavior, especially as related to the molecular, cellular, physiological and psychological properties of agents acting within the central nervous system and the identification of new molecular targets for the development of the next generations of psychotropic drugs. In view of the interdisciplinary nature of the field, particular emphasis is placed on studies that address the biological substrates of normal and pathological behavior, the nature, etiology and pathophysiology of neuropsychiatric disorders, biologically relevant aspects of the epidemiology, diagnosis, and treatment of these disorders, and the basic mechanisms by which psychopharmacological agents exert their effects. With a remarkably energetic team of field editors and new publishing arrangements, this internationally successful journal will continue to publish the leading research in this rapidly evolving field.

One of the reasons we are so delighted with Nature, is the ability to transition almost immediately to a fully electronic and web-based peer review system. This will allow for both submission of manuscripts and review to occur electronically, which will ultimately markedly reduce the time to publication.

Clearly the view of the journal by both ACNP members and non-members is on the rise, as evidenced by a marked increase in the number of manuscripts submitted for publication. Moreover, the journal's impact factor increased in 2001 from 4.579 to 4.715; it is ranked by the Scientific Citation Index as 6 of 81 (top 7.5%) psychiatry journals, 11 of 186 (top 6%) pharmacology journals and 28 of 198 neuroscience journals (top 14%). My goal is to further improve these rankings over the next few years.

At the summer meeting of the field editors, several changes in the journal were discussed and ultimately adopted. First, the large increase in manuscripts submitted has necessitated an increase in the size of the journal. We plan on publishing 170 pages per issue in a new, more efficient page layout. The net result will be a 33 percent increase in the amount of material we can publish. We will therefore maintain our high quality without incurring an unwanted delay in time to publication. Second are changes in the categories of manuscripts submitted. Our mainstay is, of course, primary research reports. We have eliminated the Brief Report section. If you wish to submit a short report, please do so - it will be reviewed and placed with the other research reports. We will continue to publish state of the art reviews (Perspectives). We wish to add two new categories of manuscripts: (1) Controversial Topics in Neuropsychopharmacology will be brief, point-counterpoint papers published together on cutting-edge topics in the field. Each author will provide a 3-4 printed page manu-

script summarizing their position. Please send recommendations for authors and topics that would be suitable for this section; (2) complicated case studies - in response to the view expressed by several of our members that the journal was very neuroscience/basic science focused and not as clinically based as it should be, we have introduced this series in which complicated cases are described and then discussed in detail. Please consider contributing to this section.

I have received a large number of gratifying positive comments from many ACNP members about the new cover of the journal. Nature has agreed to keep the format similar. The cover illustrations are not linked to an article published in the journal. As such, I would be delighted to receive your best illustrations for use of the journal cover. Please consider sending me brain imaging, immunocytochemistry and any other illustrations you consider appropriate. The Emory faculty would appreciate your help here as I have relied heavily upon them for cover illustrations.

On a troubling note, several ACNP members and even a few members of the editorial board have declined our requests to review manuscripts for the journal. This is an absolute requirement for editorial board membership - it is not honorific in any way. Moreover, ACNP members should recognize that reviewing manuscripts for our journal is part of the requisite service to our college.

I have been privileged to have a superb managing editor, Jen Mahar, nine talented and hard-working field editors and the support of the ACNP President and Council. I am even more enthusiastic about Neuropsychopharmacology than I was when I accepted the Editor-in-Chief position and hope that you, the membership, are equally enthusiastic. Feel free to contact me at any time concerning the journal. ♦

## ACNP Hosts Congressional Briefing on Violence and Severe Mental Illness

### Frankie Trull, Policy Directions

On Tuesday, April 30, 2002, the ACNP hosted its second congressional briefing entitled Violence and Severe Mental Illness: Can it be Prevented? Earlier this year, ACNP held its inaugural briefing on post-traumatic stress syndrome.

These briefings are designed to enlighten policy makers and other interested parties about issues on which the ACNP has particular expertise. Over time these briefings will raise the profile of the ACNP on Capitol Hill, educate policy makers about issues of importance to the ACNP, and establish the ACNP as a reliable and authoritative resource for key congressional and administrative policy makers. The ACNP chooses topics for its briefings on issues that have received recent news coverage as well as issues that are being debated by the Congress or federal agencies.

The April briefing focused on violence and severe mental illness. The Andrea Yates case brought unprecedented attention to this issue which led to increased interest among the general public as well as policy makers. The briefing was moderated by William E. Bunney, Jr. M.D., the Della Martin Chair of Psychiatry at the College of Medicine, University of California at Irvine. To set the stage for the briefing, Dr. Bunney made several broad and significant observations about mental illness. He noted that suicide is the third leading cause of death for people between the ages of 18 and 44. About 30,000 people commit suicide every year. Interestingly, the incidence of homicide associated with individuals suffering from a mental illness or disorder is about a third lower than suicide.

Dr. Bunney explained that effective treatments are available to those suffering from a mental illness. "The success and the efficacy, for example, of lithium in manic-depressive illness is extraordinarily similar to the success of insulin in diabetes." Bunney also noted that there are remarkable new research strategies and opportunities in the field of mental

illness. New imaging techniques that permit researchers to look into the brain are providing promising new insights into better understanding of these illnesses. Additionally, the search for the genes that cause mental illness has greatly improved. Bunney said that "in the past we have been able to look at one gene at a time. Now, there are strategies for looking at over 30,000 genes. . . . And the hope is that these research strategies . . . will lead to new treatments and eventually to prevention."

The first expert speaker was Dr. John Mann, head of the Neuroscience Division at the Columbia University College of Physicians & Surgeons. Dr. Mann discussed the inter-relationship of suicide and violence, why that inter-relationship exists, and the implications for prediction, treatment and prevention. Dr. Mann explained that suicidal behavior and violent behavior towards others often co-exists. Individuals who are prone to these behaviors have very powerful, very aggressive feelings coupled with a predisposition to act on powerful feelings. He said that this combination of a psychiatric disorder together with strong emotions and a lack of behavioral self-control "results in sometimes devastating circumstances." Mann noted that suicide falls disproportionately on young people. After discussing several of the factors that lead to suicidal tendencies, including reduced serotonin levels in the brain, as well as environmental influences, Dr. Mann told the audience that there are several treatments available that are "uniquely effective at reducing

the risk of suicidal behavior in psychiatric patients independent of how well they affect the primary psychiatric illness." Mann completed his remarks by stressing the importance of patients continuing with these treatments, noting that these are chronic conditions that should not go without treatment.

The second speaker was Dr. Zachary N. Stowe, Director of the Women's Mental Health Program at the Emory University School of Medicine. Dr. Stowe discussed mental illnesses that can occur following birth as well as ongoing illnesses and how they impact people at different points in time. He also discussed opportunities for public education that might help predict risk factors that assist in preventing some of the problems associated with these illnesses. Stowe noted that about 8-10 percent of new mothers will experience an episode of major depression. A much smaller percentage, about 1-2 out of a thousand, will experience the most severe form which is referred to as post-partum psychosis. Stowe explained that "post-partum illness probably begins during pregnancy and in fact that's why we miss it because we don't do much research in pregnant women."

Stowe said that one of the important things about post-partum illness is that it is preventable. We "can identify probably two thirds of the women who will have a post-partum event before they ever deliver." He cited a study that concluded that medicine had limited benefit, but contact and education during pregnancy reduced the risk of post-partum recurrent events



From Left to Right: Zachary Stowe, John Mann, Carol Tamminga and William Bunney

by about 60 percent. Stowe highlighted the importance of preventing or limiting post-partum events by noting that "over 20 studies show that if you do anything to mom's mental state it has an adverse effect on the child, typically effecting little boys more than little girls."

Stowe told the audience that "the best thing about maternal mental illness is that it's incredibly treatable. But if you don't identify it, you can't treat it. And if you don't teach people how to identify it, you still can't treat it. . . . We need more treatment studies. If you add up all the treatment studies in post-partum women it includes less than 400 total patients to date." In addition to more treatment studies, Stowe discussed the importance of doing much more to address the stigma associated with post-partum illness.

The final speaker was Dr. Carol Tamminga, Professor of Psychiatry at the University of Maryland School of Medicine. Dr. Tamminga spoke about psychosis and what we can do to treat it. She also discussed many of the new medications that are now available to treat psychosis.

Dr. Tamminga explained that we don't yet know what causes psychosis, but we do have effective treatments for it. She noted that in the last ten years we've had four new drugs introduced to treat psychosis and these drugs are very effective and have low levels of side effects. She said that pharmaceutical companies have become very interested in research in this area. "Not only have we had four new treatments in the last ten years but the drug company pipelines are full of new compounds that hold an awful lot of promise." She explained that "new compounds, new drugs to treat schizophrenia have to go hand in hand with a mental health care system that can really deliver those treatments to people who need them."

At the end of the presentations, the audience posed several questions about the science of mental illness, the adequacy of current treatment programs, and the implications for improving public policy in this area. Attendees included congressional staff, patient advocacy representatives, public health agency officials, and members of the press. ♦

## Update On The ACNP Website

James H. Meador-Woodruff

The ACNP website is now well into its third year, and continues to evolve. If you have not done so recently, log on and check out the many new features that we have been able to add over the course of the year. The website has undergone a significant revamping and has a number of new content areas and features designed to keep our membership informed about both news and scientific information. In addition, we have recently added a number of new features for our members designed to simplify some aspects of membership in the college.

As in previous years, a number of our publications are currently online on the ACNP website. Scientific publications that are available on the website include the Fourth Generation of Progress, which is a quite popular destination according to our monitoring of website activity. In addition, the Fifth Generation of Progress is currently online and accessible to individuals who have purchased the book. We were able to co-publish the book and the electronic version of the Fifth Generation of Progress in collaboration with Lippincott Williams and Wilkins, and a searchable version of the print version of the book is available online to those who purchased the print version of the book. We continue to host a rapid publication site for manuscripts accepted for publication in *Neuropsychopharmacology*. As soon as a manuscript is accepted for publication in the journal, we are able to have the article uploaded on the website in a citable fashion within 48 hours. Reviewing our user statistics, this also is a quite popular site on our website, with a large number of hits to the website associated with this area. The current issue and past copies of our quarterly bulletin are also available on the website.

We have recently expanded other non-scientific areas of the ACNP website. Information about membership and our travel awards may be found on the website, and we are rapidly moving toward on-line application for travel fellowships, membership, and promotion within the college. Poster and panel submissions, as well as registration for the annual meeting may all be done online. We most recently have added a "members only" area to the website, where a number of features are available behind a password protected area. All members were notified about this by a recent email. A number of you have already established your accounts, and I would encourage those of you who have not to do so. In this area of the website, you will find a searchable membership directory, you can pay your annual dues, and submit the name and contact information for your invitee to the annual meeting. We continue to develop other features, so check back often.

I am pleased with the progress that we have made with the website over the past three years. A significant landmark is that we will have had in excess of one million annual hits to our website for the first time this year! This is in large part due to the efforts of our Nashville web staff, including Jill Dybka, Chris Work and Jeevan Rose. This group has worked hard over the course of the year to redesign the website, and to continue to make it more useful and user friendly. Many of the changes that we have made to the website are in direct response to feedback that we have received over the course of the last year from the membership. Your opinions are important as we continue to develop the website. As always, I invite your feedback and comments. ♦

## ACNP and ECNP Develop a Second Exchange Program

**Oakley Ray**

For several years (since 1991) the ACNP and the European College of Neuropsychopharmacology (ECNP) have had an exchange symposium program. In recent years it has been funded on our side by an educational grant from Eli Lilly. The program fosters increased international communication on a number of topics.

The ECNP Executive Committee submits a panel which is reviewed by the ACNP Program Committee at its summer meeting. Sometimes suggestions are made to modify the symposium so it complements the other components of the Program.

The ACNP symposium is developed by the President of the College, and frequently, is highly similar to the President's Plenary at our December meeting. Because of the way in which the ECNP operates, Dennis Charney (ACNP President in 2003) has already had to submit his symposium for 2003 ECNP Congress in Prague, Czech Republic.

The ECNP recently suggested an Exchange Fellow program. They would select three young individuals who have been given Poster Awards at their meeting (this year in Barcelona, Spain, October 5-9). They would provide travel and housing for the 3 Exchange Fellows to attend our December meeting. The ACNP invites the Fellows to attend our meeting, waives the meeting registration fee, and allows them to present a poster. We will also include them in the special programs for the travel awardees.

For attendance at the ECNP meeting, the ACNP will support the travel and

lodging of three individuals selected by the Education and Training Committee from the ACNP Travel Awardees who have been competitively selected. The E&T Committee will develop a system for selecting "the best of the best" to be our Exchange Fellows.

This new program will run for three years as a trial. If everyone decides it's a success, or can be made a success, then it will be continued. The Exchange Fellow program certainly seems to have much going for it: the focus is on young people, and it involves international collaboration and exchange. Look for our first Exchange Fellows in December! ♦

## No More Lines

**Oakley Ray**

With all of our electronics and modernization there has always been one bug-a-boo about attending the Annual Meeting: the line at Registration.

Those lines will disappear for you this year if you pre-register. When you pre-register you will be sent two items in one envelope: your name badge and a distinctive card with your name on it.

When you arrive at the Caribe Hilton you can pick up a badge holder in the lobby. Put your badge on—and you have instant status as a bonafide ACNP 2002 Annual Meeting attendee! The badge enables you to attend all of the scientific and all of the social events—including the morning breakfasts and lunches. Without a valid name badge you will be excluded. Sorry, Council decided we've had too many gatecrashers in recent years.

You take the distinctive card with your name on it to the Congress Bag dispenser, hand it to one of the individuals waiting there and they will dispense one Congress bag to you. They'll probably also smile and thank you for pre-registering and simplifying everyone's life.

If you do not pre-register there will be the usual table with forms to fill out, lines to stand in while we check your credentials and your credit. Forewarned is forearmed.

There is one thing. If you do not bring your name badge (the one you will receive in the mail in October) to the meeting, there is another line where you can have a second badge printed—after we verify that you in fact have pre-registered.

It's so much easier and efficient to: Register in the privacy of your home or office and send it to the Secretariat by email or snail mail.

Receive your name badge and distinctive card via the US postal service before the end of October or, if after October, within two weeks of pre-registering.

Spend no time waiting in line. ♦

## House Bill Proposes Changes to Human Subjects Research

Frankie Trull, Policy Directions

Rep. Diana DeGette (D-CO) and Rep. Jim Greenwood (R-PA) introduced the "Human Research Subject Protections Act of 2002" (H.R. 4697) on May 9, 2002. The legislation is similar to a bill introduced by DeGette in the last Congress (H.R. 4605). The House of Representatives adjourned for its summer recess on July 26 without taking any action on this legislation. It is not clear whether the House will act prior to adjourning in October. Although there has been discussion of a companion bill in the Senate, no such legislation has been introduced.

The Human Research Subject Protections Act of 2002 would amend the Public Health Service Act to apply the Federal Policy for the Protection of Human Subjects or the "common rule" universally to all human research subjects. The Department of Health and Human Services (HHS) regulations (45 CFR part 46) apply to research involving human subjects conducted by the HHS. Although a part of HHS, regulations for Food and Drug Administration (FDA) regulated products may have different requirements (FDA regulations 21 CFR parts 50 and 56). When research involving products regulated by the FDA is funded, supported or conducted by FDA and/or HHS, both HHS and FDA regulations apply. DeGette's legislation seeks to "harmonize" the rules applying to all human research subjects whether regulated by HHS or FDA.

The compliance requirements as outlined in the bill include rules for informed consent and IRBs for all human subject research proposals. The legislation authorizes the Secretary of HHS to review the areas of differences including (but not limited to) the existence of a significant financial interest, research relating to

emergency interventions and requirements of the clinical investigators regarding the protection of human subjects.

The bill does not require an IRB accreditation policy; instead, the Secretary has discretion to determine if such an accreditation is needed. If the Secretary determines it is necessary, he is responsible for a biannual evaluation of the accrediting entity's performance. He has the authority to withdraw the recognition of the accrediting entity.

The legislation also leaves much of the regulatory authority to the Secretary. It would direct the Secretary to establish criteria to identify and monitor high-risk clinical trials and promulgate regulations outlining protocols for individuals with diminished decision-making capacity. In addition, the legislation allows the Secretary to establish additional protections if the Secretary determines that such protections are not in conflict with this legislation.

To view the entire bill, go to:

<http://thomas.loc.gov/cgi-bin/query/C?c107:./temp/~c107zgBpmj>

### Federal Agency Activities

#### OHRP

The Office for Human Research Protections (OHRP) issued a revised Institutional Review Board (IRB) guideline document on July 11, 2002. This document outlines the required elements of written IRB procedures and is intended to assist institutional officials responsible for preparing and maintaining written IRB procedures.

OHRP prepared this update in response to requests for guidance and clarification of written IRB procedures. The document serves as a summary of already implemented regulatory requirements and routine

guidance previously issued by OHRP. To review this document go to:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm>

#### NHRPAC

The National Human Research Protections Advisory Committee (NHRPAC) held its meeting on July 30-31. The next meeting is tentatively scheduled for late October. Issues involved with impaired decision-making including mental incapacity, consent of minors in pediatric clinical trials, and research with incarcerated individuals were the key topics of discussion.

A recurring question was whether it is a privilege to be included in a study, or better to be excluded. The pendulum has swung from being so protective of those who are mentally ill, mentally retarded, or incarcerated to questioning their right to be a part of a study where they may receive innovative and lifesaving therapies.

NHRPAC charged a "Workgroup on Decisional Incapacity" with considering the recommendations from the National Bioethics Advisory Commission's (NBAC) 1998 report on "Research Involving Persons with Mental Disorders." (To view this entire document online, go to:

<http://bioethics.georgetown.edu/nbac/capacity/TOC.htm>)

In a draft document, the workgroup discussed further recommendations and clarifications to the NBAC report. In general, the workgroup believes that IRBs should not unilaterally exclude individuals with impaired decision-making skills, but must exercise diligence in ensuring they (or their legal guardians) understand the level of risk involved in becoming a human research subject. ♦

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## CALENDAR OF EVENTS

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**December 8-12, 2002**

ACNP 41st Annual Meeting

For information:

ACNP Secretariat

2014 Broadway, Suite 320

Nashville, TN 37203

Tel: 1 615 322 2075

Fax: 1 615 343 0662

E-mail: [acnp@acnp.org](mailto:acnp@acnp.org)

Website: [acnp.org](http://acnp.org)

**September 20-24, 2003**

16th ECNP Congress, Prague-Czech Republic

For information:

Organizing secretariat:

Congrex Holland

PO Box 302

1000 AH Amsterdam

The Netherlands

Tel: 31 20 50 40 200

Fax: 31 20 50 40 225

**October 5-9, 2002**

15th ECNP Congress, Barcelona Spain

For information:

Organizing secretariat:

Congrex Holland

PO Box 302

1000 AH Amsterdam

The Netherlands

Tel: 31 20 50 40 200

Fax: 31 20 50 40 225

**October 9-13, 2004**

17th ECNP Congress, Stockholm Sweden

For information:

Organizing secretariat:

Congrex Holland

PO Box 302

1000 AH Amsterdam

The Netherlands

Tel: 31 20 50 40 200

Fax: 31 20 50 40 225