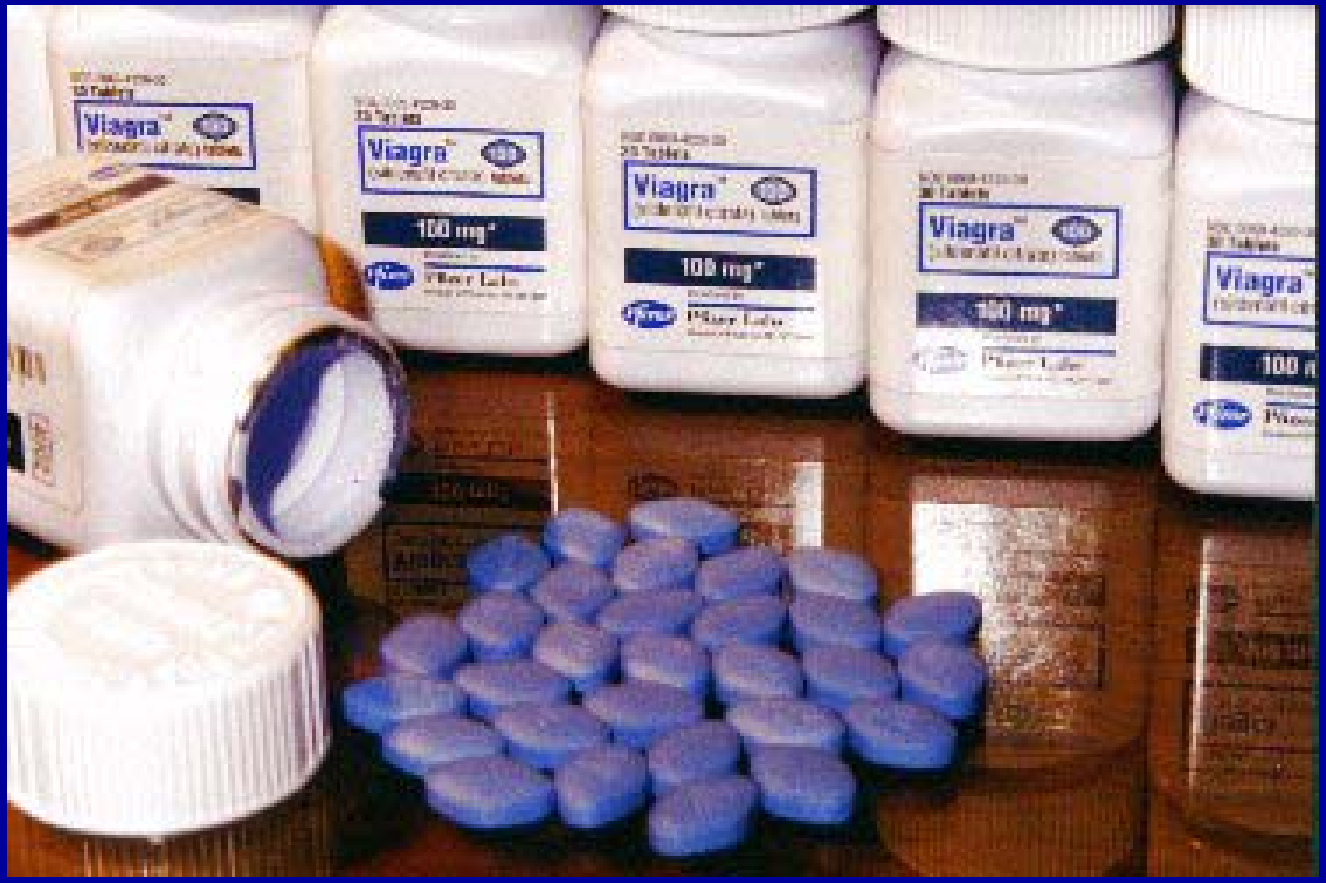
RISK/BENEFIT ANALYSIS IN BIOENHANCEMENT RESEARCH

Maxwell J. Mehlman
Case Western Reserve University
March 31, 2005


Viagra
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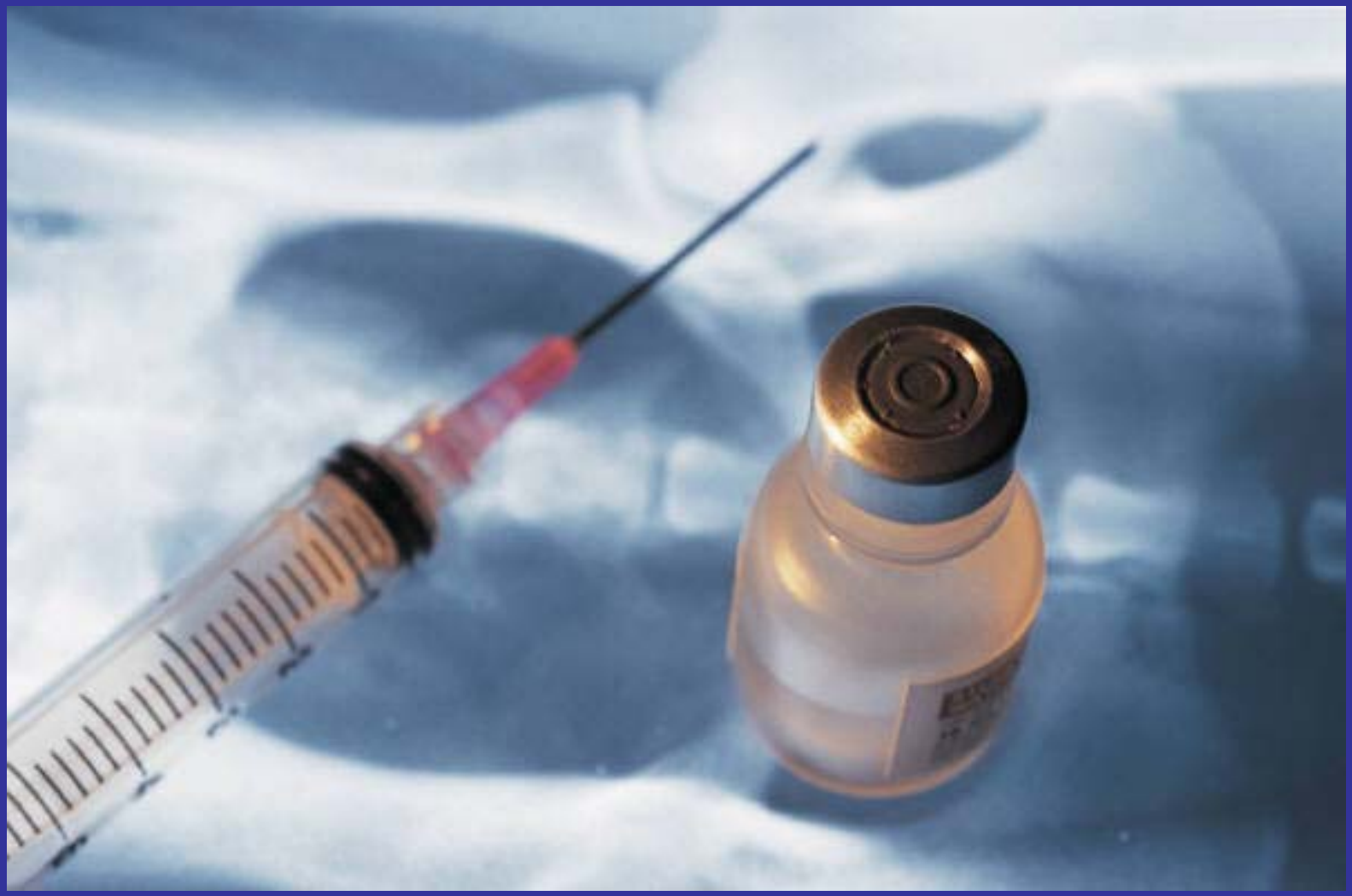
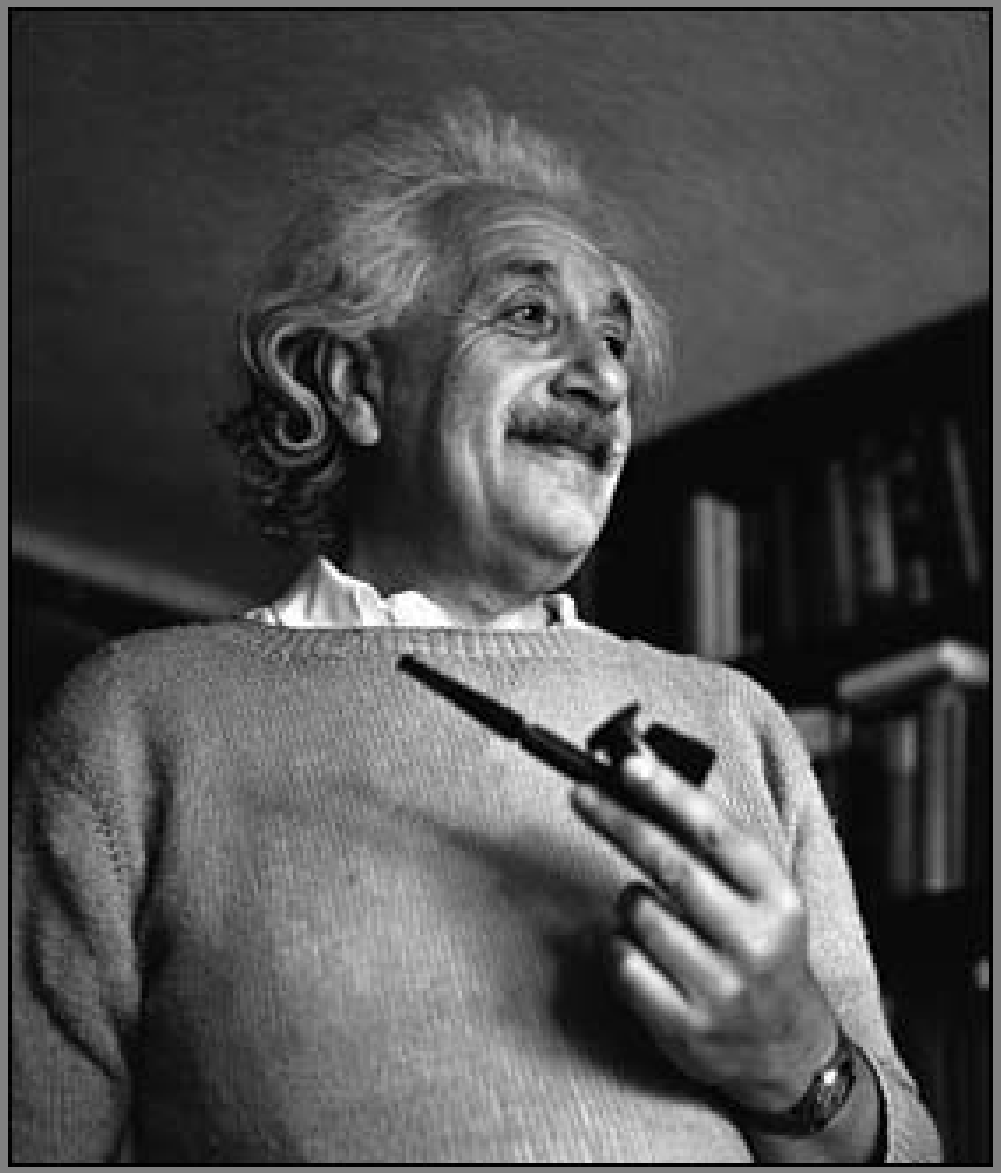
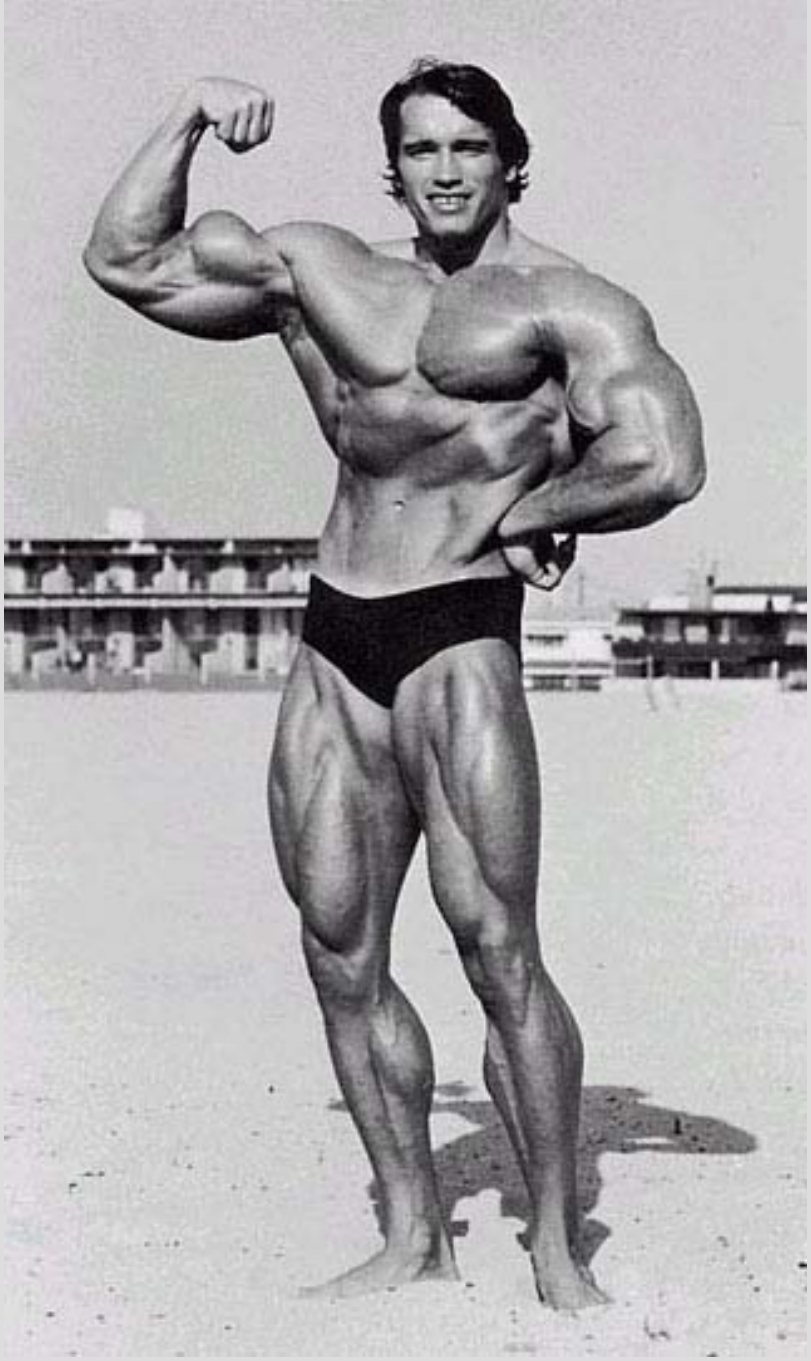



PROZAC
20 mg
MELATONIN U.S.A.CO.,LTD.






Botulinum
Toxin Type A
BOTOX®

ONCE-A-DAY
ARICEPT®
(donepezil HCl)
5-MG AND 10-MG TABLETS

MEDICINE TO REMEMBER™

ADvisors

Alzheimer's disease advisors share insights and information to help with day-to-day challenges and plans for the future.

- Emotional & Mental Well-Being
- Financial Planning
- Legal Matters
- Assisted Living Options

The product information provided in this site is intended only for residents of the United States.

If you're affected by Alzheimer's disease (AD), you should know that you're not alone and that treatment for the symptoms of mild to moderate AD is available. This site will help you better understand AD, how ARICEPT® (donepezil HCl) can help, community resources, and much more.

- Understanding Alzheimer's Disease
- Living With Alzheimer's
- Treating Alzheimer's With Aricept®

What's Inside — Find out about ARICEPT® (donepezil HCl), the #1 prescribed medicine for AD

It's Your Turn — Participate

Alzheimers Disease.com

Ask us a question:
Example: What is Alzheimer's?
Search

About EXELON

e-mail this page

BENEFITS OF EXELON® (rivastigmine tartrate)

EXELON is used to treat people with mild or moderate Alzheimer's disease (AD). At either stage, EXELON can help slow the rate of decline, maintain, or even sometimes improve the person's current level of function.

How EXELON Therapy Can Help

There is no known cure for AD. All people with AD get progressively worse over time no matter what medicine they take. But studies have shown that some patients with mild to moderate AD were more likely to show improvement or less likely to decline than patients given a sugar pill. In other words, EXELON may help people with AD maintain function longer than they would without treatment. **And that's the goal of**

Tools for caregivers
- Dosing Diary
- EXELON Caregiver Partnership
- Virtual Support Network
- Show All Tools
- Glossary

Like what you found? Read more:
- Seeing the Doctor
- FAQs
- EXELON Q&A

[+] FEEDBACK

Didn't find what you

About REMINYL
- How REMINYL Works
- Goals of Therapy
- Safety Information
- FAQs

About Alzheimer's Disease
Being a Caregiver
Sharing Care™ Program
Glossary

for Healthcare Professionals only

About REMINYL

REMINYL® (galantamine HBr) is available in 4-mg, 8-mg and 12-mg tablets and oral solution (4 mg/mL). REMINYL should be taken twice a day, preferably with the morning and evening meal. Patients and caregivers should be advised to ensure adequate fluid intake during treatment. It is recommended that treatment start with 4 mg (white tablets) twice a day for at least 4 weeks and then continue with 8 mg (pink tablets) twice a day for at least 4 weeks.

After 4 weeks of treatment with 8 mg twice a day, your doctor will evaluate the effects of REMINYL and decide if treatment should continue with 8 mg twice a day or be increased to 12 mg (orange-brown tablets) twice a day.

Who REMINYL Is For

REMINYL is a treatment for patients with mild to moderate Alzheimer's disease (AD) and may be prescribed as soon as the diagnosis is made. In fact, the earlier treatment is started, the better the effect may be. Medical studies have indicated that early treatment can result in ongoing

NEUROLOGY

THE PATIENT PAGE
Scientific breakthroughs in Neurology

Neurology 2002;59:123-125

Brief Communications

Donepezil and flight simulator performance: Effects on retention of complex skills

J. A. Yesavage, MD, M. S. Mumenthaler, PhD, J. L. Taylor, PhD, L. Friedman, PhD, R. O'Hara, PhD, J. Sheikh, MD, J. Tinklenberg, MD and P. J. Whitehouse, MD, PhD

From the Palo Alto Veterans Affairs Health Care System (Drs. Yesavage, Taylor, Sheikh, and Tinklenberg); Department of Psychiatry and Behavioral Sciences (Drs. Yesavage, Mumenthaler, Taylor, Friedman, O'Hara, Sheikh, and Tinklenberg), Stanford University School of Medicine, CA; and Departments of Neurology, Psychiatry, Neuroscience, Psychology, Nursing, Organizational Behavior, and Biomedical Ethics (Dr. Whitehouse), Case Western Reserve University, Cleveland, OH.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NIH News Release

NATIONAL INSTITUTES OF HEALTH | National Institute on Aging

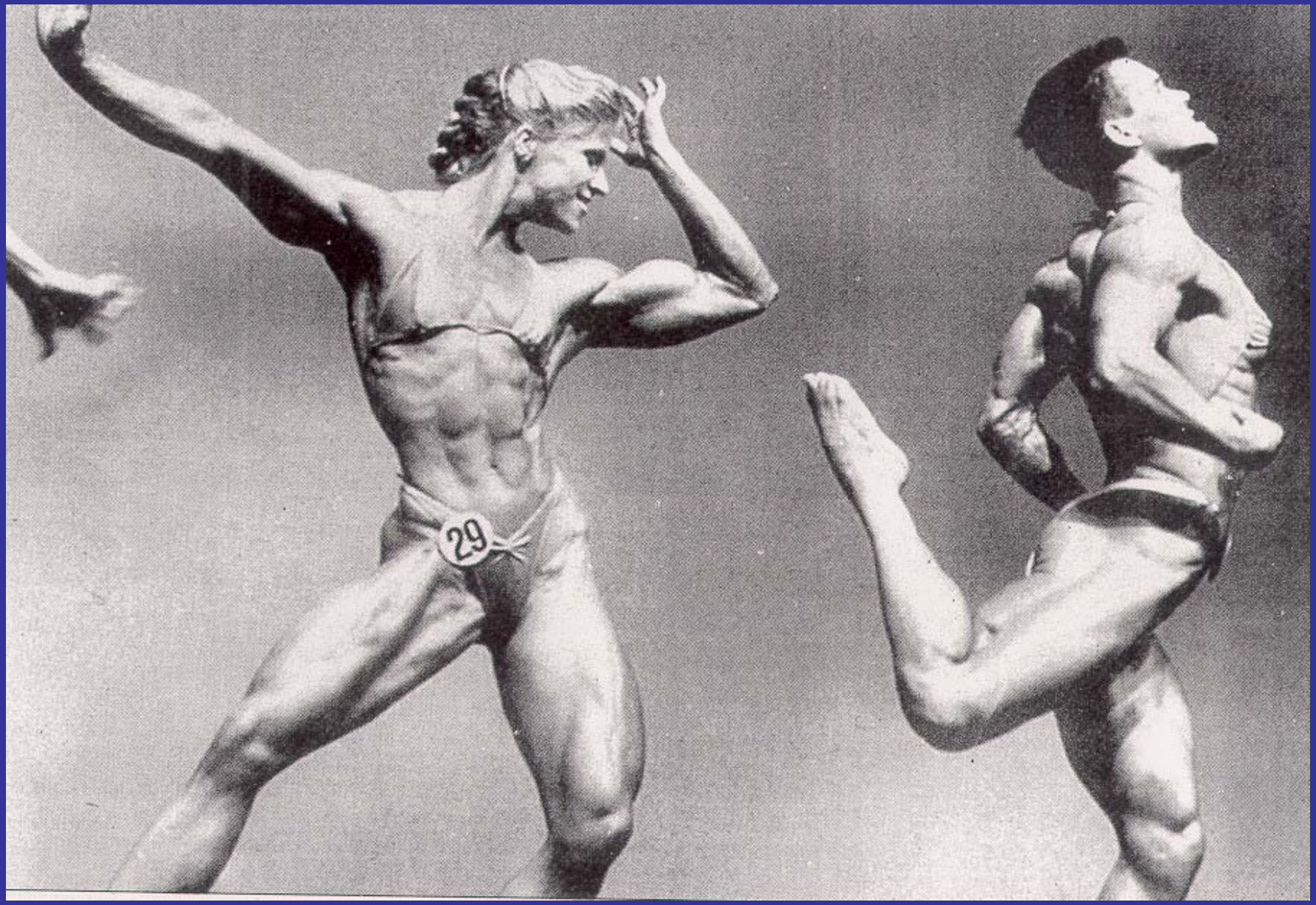
EMBARGOED FOR RELEASE
Monday, April 29, 1996

Public Information Office
(301) 496-1752

New Findings Suggest How Caloric Restriction May Prolong Healthy Life

Researchers at the National Institute on Aging's (NIA) Gerontology Research Center (GRC) have shown for the first time that reducing calorie intake by 30 percent lowers body temperature in monkeys. This lowered body temperature is a result of a lowered metabolic rate due to limited food intake. The next step for NIA researchers is to look for a relationship between reduced metabolic rate and changes in longevity. The temperature finding in monkeys is similar to findings in rats and mice who lived longer when they were placed on calorie restricted diets. The results in monkeys appear in the April 30,1996 Proceedings of the National Academy of Sciences (PNAS).

The NIA study of nearly 200 rhesus and squirrel monkeys began in 1987. Scientists based their investigations on knowledge gleaned from 60 years of research in rodents and other small animal species that showed reduced calorie intake can extend lifespan, maintain vitality, and delay or reduce the incidence of age-associated disease. Until recently, no one had studied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An intervention is not an enhancement if --

- The individual was significantly below population norms for the characteristic.
- The individual remains within population norms after the intervention.
- The intervention was intended to combat disease or dysfunction.

Before a person can consent to participate in research --

- The investigator(s) must design the study to **maximize benefits and minimize risks.**
- For NIH-supported research, the research institution must assure NIH that it will discharge its responsibilities for **protecting the rights and welfare of human subjects** of research conducted at or sponsored by the institution.
- NIH must assure itself of the adequacy of the proposed **protection for humans**, animals, or the environment to the extent they may be adversely affected by the project proposed in the application.
- **The IRB must determine that "the risks to subjects are reasonable in relation to anticipated benefits"** (46 cfr §46.111(a)(2)).
- No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective **informed consent** of the subject or the subject's legally authorized representative.

"G]enetic interventions to enhance traits should be considered permissible only in severely restricted situations."

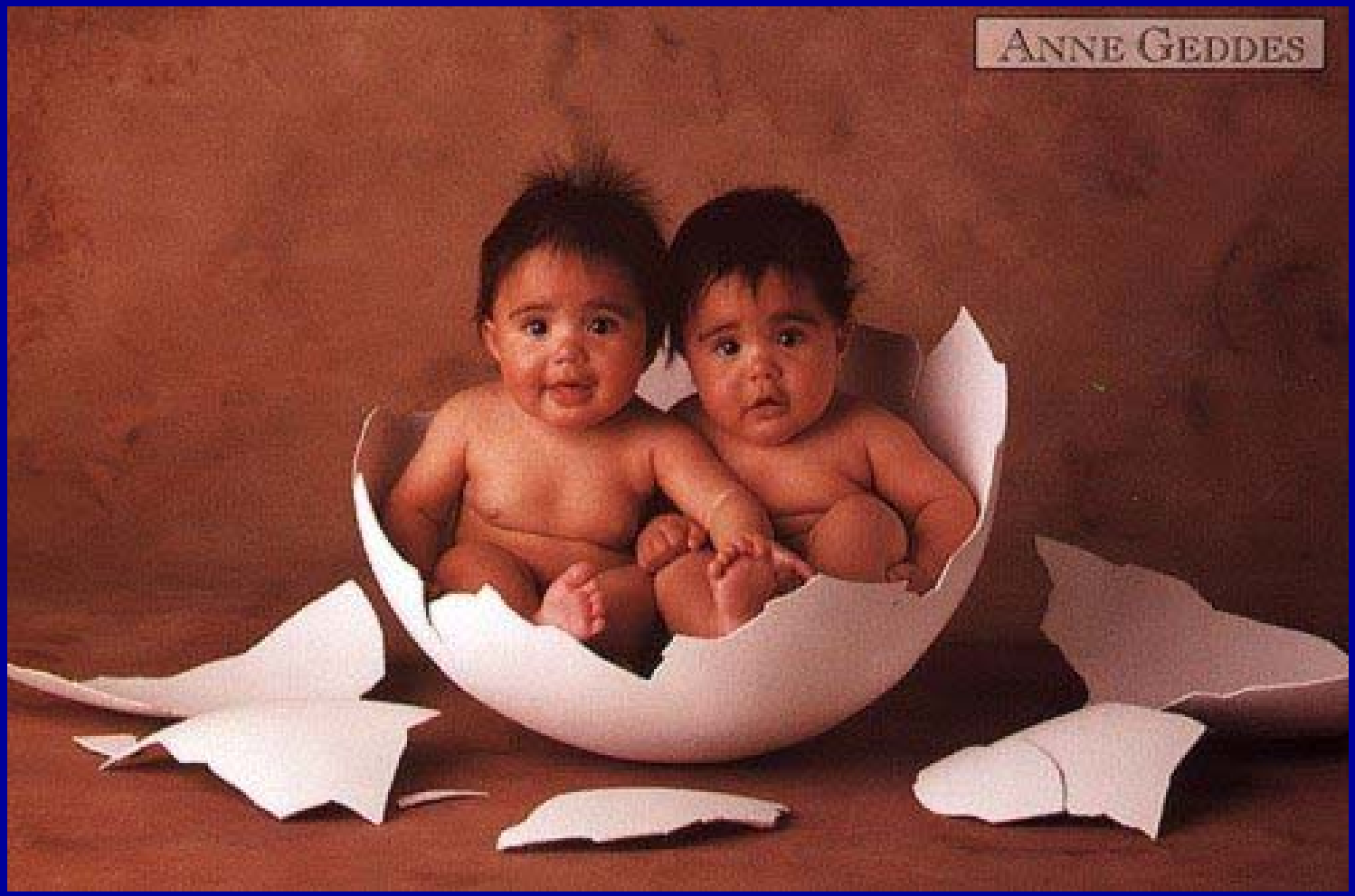
- "clear and meaningful benefit";
- "no trade-off with other characteristics or traits";
- "equal access ... irrespective of income or other socioeconomic characteristics."

AMA COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (Arch. Fam. Med. 3:633 (1994))

How should enhancement benefits be measured and compared with the risks to subjects?

- What is a clinically significant enhancement endpoint?
- How comfortable are we in offsetting health risks with subjectively measured and valued enhancement benefits?


WIZARD OF ID | BRANT PARKER & JOHNNY HART
I TOOK TWO MEMORY PILLS BY MISTAKE!
SO WHAT?
4-13
I'M REMEMBERING THINGS I WAS TRYING TO FORGET
PARKER


ANNE GEDDES

Olympics

After failing drug test, Muehlegg, Lazutina tossed from Games

Monday, February 25, 2002

By Larry Siddons, The Associated Press

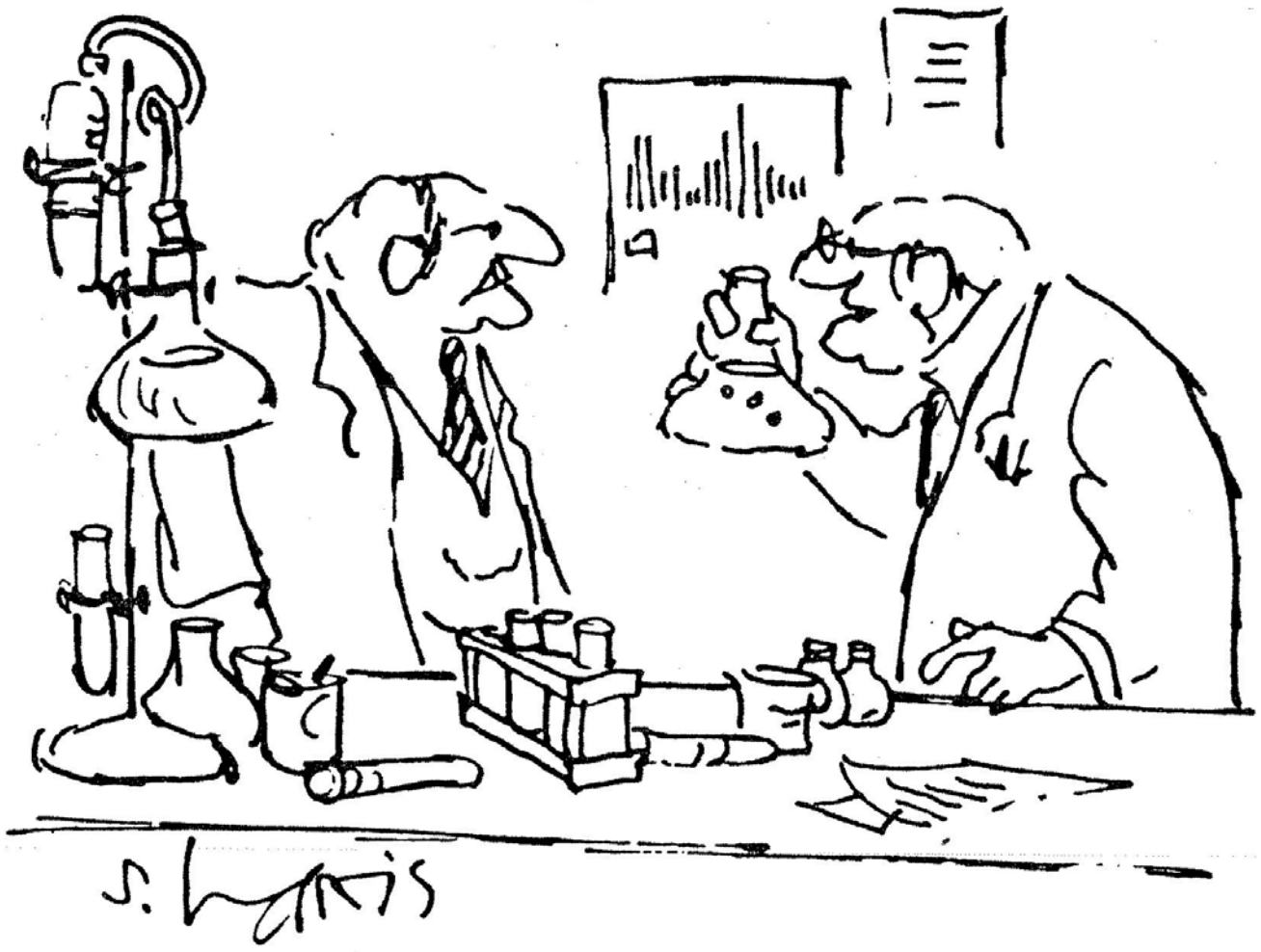
SALT LAKE CITY -- Vowing to stay one step ahead of athletes, Olympic officials stripped gold medals from two cross-country skiers yesterday for using a drug so new it's not yet on the banned list.

Cross-country skiers Larissa Lazutina of Russia and Johann Muehlegg of Spain forfeited their most recent medals after testing positive for a performance-enhancing drug intended to help kidney patients avoid anemia.

A third cross-country skier, Olga Danilova of Russia, also tested positive for the same drug, darbepoetin, which boosts the production of red blood cells that carry oxygen to muscles.

All three athletes were tossed out of the Winter Olympics on the final day of competition.

SPEED BUMP by DAVE COVERLY



"It may very well bring about immortality,
but it will take forever to test it."