

Italian agency questioned about first astronaut

Munich. Only weeks after the Italian government accused its space agency (ASI) of misappropriating research funds (see *Nature* 357, 351; 1992), the agency is being asked to defend its choice of the country's first astronaut.

Two weeks ago, Antonio Parlato, member of parliament for Naples, asked for a formal parliamentary investigation into the selection of Franco Malerba to fly on a joint mission with the United States to be launched later this month. Parlato alleges that Malerba did not qualify for selection because he was not scientifically qualified and he did not live and work in Italy. The mission, known as TSS, involves a satellite tethered to the space shuttle Columbus that will test the feasibility of obtaining power from space for a future space station.

In 1977, five candidates were chosen by Italy to fly with the first European space lab mission in 1983. None of them was chosen, but Guerriero contacted them again in 1983 when the National Aeronautics and Space Administration (NASA) offered Italy a slot on the TSS mission. The applicants were told that they must move to Rome and work on short-term contracts related to the mission. Three of them did so: Cristiano Cosmovici, Andrea Lorenzoni and Franco Rossitto.

The TSS was to be launched in 1990 and ASI began its selection process in February 1989. But the next month ASI readvertised on the grounds that the original candidates might no longer be medically fit. Fifteen new candidates were recruited and Umberto Guidoni, a plasma physicist at the Institute for Space Physics in Frascati, was selected as Malerba's backup.

Of the original candidates, Lorenzoni was eliminated by the scientific committee, and Cosmovici and Rossitto were ordered to undergo medical testing by the Italian air force, which declared both unfit. ASI's recommendation of Malerba was accepted by NASA's panel of experts, and he began his training in July 1989.

Malerba was working in Nice, France, in the sales department of the US-based Digital Equipment Company at the time of his selection and training. He did not receive a contract with ASI until November 1990. As such his appointment did not meet the requirement that the astronaut should be an experienced plasma physicist nor, according to Parlato, NASA regulations on employment. But Stephen Ballard of NASA says that "a relationship with a sponsoring organization is established when someone is nominated and they show up. Malerba's case is not exceptional."

Alison Abbott

Group asks NIH to stop growth hormone trials

Washington. A scientific watchdog group has petitioned the US National Institutes of Health (NIH) to halt a ten-year trial of human growth hormone in healthy children who are small in stature. Claiming that the experiment violates both the letter and the spirit of federal regulations controlling experiments on children, Jeremy Rifkin, president of the Washington-based Foundation on Economic Trends, says he will sue NIH if the trials are not ended.

US regulations state that federally funded trials involving children must either present no more than a minimal risk to the children or offer them the prospect of direct benefit. Exceptions are made for research likely to yield useful information about the children's condition.

NIH is conducting two trials, one in short children with normal levels of the growth hormone and a second involving children with Turner's Syndrome, a genetic disease that causes adults to be well under five feet tall. The syndrome affects only females.

In the case of the Turner's Syndrome trial, Rifkin opposes the use of a placebo-controlled group on the grounds that the trial (which involves ten years of weekly injections, regular X-rays and nude photography) is traumatic for the children. He points out that half of the 80 girls in the trial will eventually discover that they were actually members of the control group and had been denied a therapy that is effective only when begun early in childhood. Such use of children as "guinea pigs", Rifkin complains, is "exploitative and abusive".

He is even more upset by experiments involving children who are short but not deficient in the growth hormone. He cites studies that suggest human growth hormone therapy can produce side effects ranging from facial disfigurement to leukaemia and thyroid problems. Because being short is not a medically recognized disease or affliction, Rifkin says, the trials violate US regulations.

Many researchers have already made the same arguments and Rifkin's petition — filed on 22 June by his foundation and the Physicians Committee for Responsible Medicine — touches on an issue of considerable debate within the scientific community.

Several university Institutional Review Boards (IRBs) approved the Turner's Syndrome protocol in 1988, and some of those institutions now belong to the clinical network of institutions participating in the NIH trials. But several other IRBs, including that at the University of Nebraska,

rejected the protocol. Ernest Prentice, the assistant dean for research at the University of Nebraska Medical Center and the vice chairman of the Nebraska IRB, says "we felt that [the trial] was not only unethical, it was also not in compliance with the federal regulations".

Concerned that the regulations may be open to interpretation, "we did a great deal of research into the thinking that went into the regulations and their intent", Prentice says. "In this particular case it was pretty clear cut — there was just no adequate justification given" for going ahead with the trial.

The Nebraska group published an article arguing against the experiment in the January/February 1989 issue of *IRB*. Another group, from the University of Chicago, has argued (see *Journal of the American Medical Association* 261, 7; 1989) that short stature does not fit the usual definition of a 'disease' and that human growth hormone therapy for children not deficient in the hormone is of questionable benefit.

NIH officials believe that the two trials are necessary and appropriate. Arthur Levine, scientific director of the National Institute of Child Health and Human Development, says that some studies have shown that simply visiting a growth clinic and receiving a placebo makes some children grow. If so, he says, that would satisfy the federal regulations that such trials must offer a potential benefit to those in the control groups.

The Nebraska IRB rejects that claim, and points out that diabetic children are injected regularly and are not statistically taller than their cohort. (Levine disputes its logic, saying that diabetes itself affects height and could mask the growth-stimulating effects of injections.)

More important, Levine argues, is the fact that some doctors are already giving human growth hormone to healthy but short children. "Since it's going to be used, we have an obligation to learn if it is effective for the long term", he says. "Scientifically, we feel we're on solid ground."

Levine believes that such a research project satisfies the exemption in the regulations for trials that "present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children".

Rifkin's group has vowed to continue its opposition to the trials if NIH does not back down. "We've been fighting this for two years and we've exhausted our [administrative] remedies. We're ready to sue", he says, perhaps within a month.

Christopher Anderson