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OPINION

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ETHICS ON RESEARCH AND CARE EN OPINION ON THE RECRUITMENT OF VOLUNTEERS FOR VACCINE TRIALS USING ADVERTISEMENTS PLACED IN THE PRESS

In correspondence dated November 27, 1991, Professor Jean-Paul Lévy, director of ANRS, sought the National AIDS Council's Opinion as to the legitimacy of recruiting healthy volunteers for vaccine trials using press advertisements and poster campaigns. The National AIDS Council resolved to consider this issue at its plenary session of December 3, 1991, while deciding to postpone substantive examination of it until further information had been obtained. To that end, at its plenary session of December 18, 1991 the Council heard evidence from Doctor Elizabeth Rouveix, a doctor at Ambroise-Paré hospital and the clinician in charge of the ANRS vaccine trial programme, and Doctor Françoise Linard, a psychiatrist at Rothschild and Claude-Bernard hospitals.

After having considered the matter at its plenary session in January 13, 1992, the National AIDS Council based its Opinion on arguments relating firstly to the specific characteristics of the ANRS project, and secondly to the use of press advertisements.

1. THE SPECIFIC CHARACTERISTICS OF THE ANRS PROJECT

1.1.The issue submitted by the ANRS relates exclusively to phase I trials. The objective of this phase is to measure the degree to which a substance is harmful or harmless (unlike phase II trials, which constitute the first attempt to assess its effectiveness, and phase III, comparison with a reference product or to the absence of any product, and phase IV, in which any unforeseen effects of the substance are monitored over the long term). This type of trial can certainly lead to psychological and social consequences for healthy volunteers taking part, and is not exempt from the risks common to all biomedical tests. However, the protein injections planned by the ANRS protocols cannot in any event be a source of risks of viral character.

They are therefore compliant with Article L. 209-14 of the Code of Public Health, which specifies that "biomedical research of no direct individual benefit must not entail serious foreseeable risk for the health of those taking part". It is however imperative that healthy volunteers should be protected against possible confusion between vaccine-related HIV-positive status and HIV-positive status due to viral infection.

1.2 The trials that ANRS wishes to conduct are not tests of treatments intended for HIV-infected individuals. They are vaccine trials whose purpose, as specified by Professor Levy in the letter in which he lays the matter before the NAC, is to test "possible future vaccine components" which would have a preventive effect against HIV. In other words, as indicated in the ANRS information document on the "problems posed by an AIDS vaccine" (December 1991), they are not vaccine trials in the strict sense, but no more than experiments whose aim is firstly to demonstrate the harmlessness of preparations which it is hoped can be used later in vaccines; and, secondly, to examine whether those same preparations are capable of stimulating responses from the immune system, HIV-neutralizing antibodies in particular. It is only in a later phase, once numerous theoretical and practical problems have been solved, that we will probably go on to trials aimed at verifying the effectiveness of a vaccine."

1.3 The usual methods for recruiting volunteers for these trials do not seem appropriate for the ANRS project. Normally, biomedical tests are of two types : some, described as tests of direct individual benefit, relate to research for which a direct benefit is expected for those involved (sufferers or individuals at risk in a disease prevention context) and such tests are never remunerated. The second type, described as tests without direct individual benefit, are carried out with the participation of healthy volunteers receiving payment.

In the present case, the ANRS considers it necessary to start out by building a broadly based network of healthy unpaid volunteers with whom it would be possible to test future protocols. The motivation of those volunteers was considered essential in what is a more burdensome procedure than usual, since the biological and clinical follow-up is planned to last between 15 and 18 months, much longer than is usual for phase I trials.

For this reason, it appeared imperative, if the protocol was to be conducted in a proper scientific manner, to take care not to recruit individuals especially exposed to the risk of viral infection. This conclusion led the ANRS to decide to avoid using the usual sources of healthy volunteers and, because of the significant size of the planned recruitment (initially, 60 subjects, and later more than one hundred), to make use of a public appeal.

2. THE PUBLIC APPEAL

2.1 Public appeals are not a problem as such, in the context of an epidemic which is itself a public event of which the entire population needs to be aware. This approach may indeed succeed in attracting sufficient numbers of motivated applicants to build the network of volunteers desired by ANRS. While it does raise the question of what criteria should be applied to include or reject individual volunteers, this major issue has been considered by those responsible for the protocol, as was highlighted by the evidence heard by the National AIDS Council from Doctors Rouveix and Linard.

2.2 Nevertheless, this approach does raise various issues to which the National AIDS Council wishes to draw attention.

2.2.1 The most serious was illustrated by the untimely media announcement made on November 27, 1991, despite the fact that Professor Levy had hardly finished submitting the issue of the appropriateness of the project for consideration by the National AIDS Council. This initiative, which was widely reported in the press, convinced many HIV-positive individuals and AIDS sufferers that the development and distribution of an anti-AIDS vaccine was virtually complete, whereas research in the area was in fact in its infancy. This was clumsy public relations and poor media message control, despite the fact that the choice of the press as a channel to inform the general public of the ANRS project required a special effort at explanation on the part of its promoters.

2.2.2 In this connection, it would be appropriate, firstly, to reflect upon the choice of the media to be used as an information channel, in particular the preference for specialist medical journals, and, secondly, to advise that the term "vaccine" should be used with care. It would also seem to be necessary to emphasize the differences between patient treatment trials and vaccine component trials.

Under such conditions, taking due account of the specific characteristics of the ANRS project and emphasizing the need for a clear public relations policy, the National AIDS Council considers that a public appeal by the ANRS in the media is legitimate in principle, in order to recruit healthy volunteers for phase I vaccine trials.