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October 24, 1994

David Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

We understand the Food and Drug Administration (FDA) has under active consideration the approval of home sample collection (HSC) kits for HIV. On behalf of the American Psychiatric Association Commission on AIDS and the American Psychological Association Committee on Psychology and AIDS, we are writing to express our strong concerns about the design and implementation of the HSC kit as proposed by Johnson and Johnson. We support the aim of increasing individual awareness of HIV sero-status which may contribute to HIV prevention, but feel an acceptable HSC kit must fully address the psychological and behavioral ramifications of this system of testing. We feel the proposed HSC system is unprecedented, untested, and therefore must be subject to the most rigorous assessment of safety.

Given the gravity of possible adverse psychological reactions to HIV testing and the lack of data concerning the safety of telephone notification of a life-threatening medical condition, we strongly urge careful pilot and post-release evaluation to assess the incidence of untoward reactions. Such reactions include severe states of anxiety and depression, increased suicidal ideation and behavior, and increased high risk behaviors for HIV transmission resulting from misinterpretation of HIV-negative test results, i.e., a false reassurance that current high risk sexual behaviors are low risk, or extreme reactions to HIV-positive status. In addition, it is possible that some consumers who test HIV-positive may re-test themselves to try to disconfirm the result rather than pursue appropriate care.

Data should therefore be collected that assesses entry into the health care system by individuals testing HIV-positive by HSC kits, so that we may better the risk-benefit ratio of this form of testing. Moreover, baseline and follow-up data should be collected to identify which individuals utilizing HSC kits may be at increased risk for psychological distress during or after the testing process.

We are also concerned that the proposed HSC system adequately anticipate psychological and behavioral complications of testing by increasing the availability of telephone counseling. These complications can and do occur at any time during the testing process, from the time of deciding to take the test to the receipt of test results. Accordingly, adequate pre- and post-test counseling must be available to consumers. Comprehensive counseling should identify individuals who need referral for additional pre-test counseling, such as consumers who are at elevated risk of serious psychological or behavioral complications of HSC kit testing and those who may be coerced into taking the test.

An adequate process of informed consent is vital to HIV testing, for both ethical and mental health reasons, and we are concerned that HSC testing kits meet present standards of informed consent. It is well documented that many individuals reading written materials such as those found in package inserts or informed consent statements do not fully comprehend the content of such documents. We feel that, at a minimum, HSC kit counselors should be available to anyone considering home testing to discuss, as objectively as possible, the risks and benefits of home testing prior to purchasing the kit. Additionally, consumers ought to be informed of alternative means of HIV testing, and whether consumers should get additional help before proceeding with HSC testing. For those who are illiterate or speak another language, these issues are exacerbated.



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We are particularly concerned that adolescents and psychologically or socially isolated individuals are at increased risk for adverse reactions. Although the HSC kit would theoretically be available only to those 18 or older, there are no safeguards in an anonymous, telephone system which prevents access by teenagers who are anxious because of a recent unprotected sexual experience. We have an overriding concern that HSC kit counselors receive adequate training and mental health professional consultative support to identify consumers who present undue risks of adverse effects upon notification of test results, and to help manage consumers who are in an acute crisis at any point of telephone contact.


Even in non-crisis situations, telephone-based referrals do not generally result in high rates of service utilization. Moreover, under what circumstances, if any, will consumers be evaluated as too unstable to receive telephone notification of HIV serostatus; e.g., intoxication or psychoses? Will HSC test kit counselors be trained to recognize consumers with psychiatric conditions (e.g., obsessive-compulsive disorder or depression) whose multiple HSC kit retesting may reflect somatic preoccupations in need of mental health assessment and treatment? Given the scope of responsibilities even well-trained counselors will assume, we are additionally concerned about psychological support for telephone counselors who are likely to experience significant distress during the course of their duties.

We believe that face-to-face HIV counseling remains the procedure of choice and that HSC kit testing should be utilized only when the former is unavailable or unacceptable to the consumer. In-person counseling allows for more adequate assessment and management of psychological responses to testing, and, most importantly, provides an unparalleled opportunity to help individuals reduce risk of HIV infection. As such, face-to-face counseling remains an essential component of HIV prevention.


Members of the American Psychiatric Association Commission on AIDS and American Psychological Committee on Psychology and AIDS are available to the FDA to discuss how HSC systems could more adequately address the prevention of both HIV infection and adverse psychological and behavioral sequelae of HIV testing. We are also prepared to consult in the further development of HSC kit systems as well as in the development of evaluation research to assess HSC kit safety and efficacy.

We appreciate your consideration of these issues. Please feel free to contact the AIDS Program Office of the American Psychiatric Association at 202.682.6104 should you need any further information.

Sincerely,


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