

Is Mandatory Testing of Newborns for HIV in the United States a Good Idea?

Rodney Richards, PhD is a bio/organic chemist who worked for many years for Amgen, the world's largest biotechnology company. Richards worked specifically in the area of HIV test development. In the following letter Richards questions the wisdom of Illinois legislation HB4306 that would mandate an HIV test for infants when the HIV status of the mother is unknown without the parents or guardian having any right to refuse the test. The bill also recommends, but does not mandate, that all HIV-positive infants be treated with AZT (Zidovudine; Retrovir) from within 24 hours after birth until 6 weeks. Richards points out that such treatments for "HIV-exposed" infants will not have been approved by the FDA, that there is no clinical evidence for its value and that there are no published guidelines for this kind of treatment. The first big problem is that the antibodies detected shortly after birth are from the mother, so this conveniently assesses the HIV status of mothers who refuse testing. It is widely agreed that this testing does not indicate HIV infection in an infant. The Perinatal HIV-1 Guidelines Working Group which also recommends such treatment also admits that "Definitive clinical trial data in humans are not available to address whether ZDV administered only during the neonatal period would reduce the risk of perinatal transmission." This means that many infants who will later turn out to be HIV-negative will still be exposed to AZT. Richards points out that this therapy is extremely toxic, with side effects including anemia so severe that transfusions are required, nausea and vomiting, muscle weakness, liver and pancreas damage. He quotes manufacturer documentation stating that the long term effects of this treatment are unknown. This is part of an effort to make sure that all HIV-positive mothers are exposed to AZT during pregnancy. Richards is concerned that science showing an association with birth defects and cancer are being ignored. Richards is concerned that these effects stem from AZT's emulation of one of the four building blocks. Interference with DNA synthesis can cause these problems and many others besides. One of the components of this system is the reliance on so-called "rapid" tests, to diagnose all pregnant women just before birth. This introduces more over-medication because many women will be false-positive on a rapid test, their infants will be medicated, and only later will other tests reveal that the mother was antibody-negative. Richards addresses the problem of "Positive Predictive Value", a seeming conundrum that even a highly accurate test will be highly inaccurate when used in a very low risk group. A 99% accurate test can still easily provide 90% false positive results due to this acknowledged weakness of screening. More false positive results, and excess treatment, will be derived from the known fact that women who have had a previous child are at risk for a false positive HIV test. Again, even if this is discovered later by confirmatory tests, their children will have been exposed to AZT for some time. Richards estimates, based on public statistics, that this intervention could at best save one or two infants every year from HIV infection in Illinois, yet would unnecessarily expose more than a hundred infants every year to AZT. The use of rapid tests will also expose many women to several weeks of fear when they are told that they might be HIV-positive, only to be told later that this was "just" a false-positive rapid test. Public health initiatives should result in more public good than harm, but in Dr. Rodney Richard's opinion this is not one of those initiatives.

The position paper *Is Mandatory Testing of Newborns for HIV in the United States a Good Idea?* is available to download in English and French on our Position Papers page on the AnotherLook website <www.AnotherLook.org>