Marian Tompson
AnotherLook
PO BOX 383
Evanston, IL 60204-0383
USA

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Dear Marian,

I am writing to express my concerns over recently proposed legislation in Illinois, which among other things would effectively mandate HIV testing of all infants born to mothers of unknown HIV status. On the surface, it would be hard to imagine how such a proposal could lead to anything other than benefit for these infants. However, when one takes a closer look at the possible actions that might be taken in response to this testing, they will see that this proposed legislation may well lead to unintended, but very real, negative health consequences; particularly for the very infants it seeks to protect. Before explaining why this is the case, I would like to briefly introduce myself so that you can judge my comments within the context of my qualifications to speak on this subject.

I received an MS in organic chemistry from the University of Denver in 1977, and a Ph.D. in bio/organic chemistry from the University of Colorado in 1984. Following this, I began working full-time for a small start-up biotechnology company called Applied Molecular Genetics, Inc. in Boulder, Colorado. This company eventually changed its name to Amgen, Inc., and is recognized today as the largest and most successful independent biotechnology company in the world. I worked at Amgen for over 13 years, first as a research scientist, and from 1988 on as a senior research scientist. My responsibilities at Amgen were primarily centered on the development of novel technologies to assist in therapeutic drug development, and to improve diagnostic testing methods for the detection of infectious agents associated with human disease.

In 1983, a co-worker and I designed and synthesized a modified human interferon gene that ultimately resulted in the production of a recombinant protein with novel anti-viral activity.[1] The Food and Drug Administration (FDA) approved this product (Infergen) in 1997 for use as an anti-viral drug in the treatment of Hepatitis C infections.[2] I also supervised the development of several diagnostic technologies, with a focus on detecting genetic material associated with HIV. One of these testing methodologies proved to be equal in sensitivity and specificity to a competing technology known as the Polymerase Chain Reaction (PCR), which is routinely used for the determination of what has become known as “HIV viral load” levels. I have also received several Patents covering the diagnostic technologies I developed while at Amgen.[3]

Since 1995, I have been working as an independent research scientist studying the relationship between viruses and disease with a major focus on developments in testing technologies, particularly as they relate to the diagnosis and management of HIV/AIDS. Through the course of this work I have found an ever-increasing tendency for researchers

and public health officials to recommend the use of these tests, as well as medications, for purposes other than what the FDA has approved them for. Furthermore, many of these recommendations are based only on theoretical considerations, sometimes in the complete absence of any supporting scientific data or clinical experience. And while physicians are at complete liberty to use medications as the see fit, I fear that many patients who are being subjected to interventions that have not been approve by the FDA, are not being adequately informed that this is the case. With this background, I would like to clarify how the proposed legislation in Illinois relates to all of this.

The legislation in question was introduced by Representative Mary E. Flowers on December 21, 2005, as House Bill 4306 (HB4306).[4] Specifically, this Bill proposes to amend an already existing Public Act, known as the Perinatal HIV Prevention Act (PHPA).[5] As it stands now, the PHPA requires testing of infants for antibodies to HIV within 48 hours after birth "when the HIV status of the infant's mother is unknown,"[5] unless the infant's parent or guardian has indicated "that he or she refuses to allow the newborn infant to receive HIV testing."[5]

Among other things, HB4306 would eliminate this provision for parents to refuse testing of their infant, thereby effectively mandating the testing of all infants born to mothers of unknown HIV status.[6] The original Bill also proposed to amend the PHPA with language that would require all HIV antibody positive infants to be "treated to prevent HIV infection within 24 hours after birth and until 6 weeks after birth."[4] Fortunately, this mandate for treatment was eliminated upon amendment. I say this because the United States (US) Food and Drug Administration (FDA) has never approved any drug for this purpose. Furthermore, there is no data from any clinical trial with any drug—approved or not—demonstrating that such an intervention would be of any benefit whatsoever to the infant.

Although the final House version of HB4306 falls short of mandating treatment of infants testing positive for antibodies to HIV, it does require that "the infant's parent or guardian shall be informed of the importance of obtaining timely treatment for the infant in order to prevent the newborn from becoming HIV infected."[7] The Bill also requires that the Illinois Department of Public Health (IDPH) "shall provide to health care professionals and health care facilities written information that may be used to satisfy their obligation under this Section."[7] Given that the vast majority of obstetricians have little to no clinical experience in managing, treating, or preventing HIV infection, the final version of the House Bill also proposes to establish a 24-hour Perinatal HIV Hotline to "provide to health care professionals perinatal HIV treatment information in accordance with guidelines established by the U.S. Public Health Service or other nationally-recognized experts, as determined by the Department."[7]

Even though this "HIV Hotline" and "written information" will be of great assistance in helping health care providers fulfill their obligation of informing parents of the "importance of obtaining timely treatment for the infant," I am gravely concerned that this legislation is moving forward in the complete absence of any knowledge as to what this information ultimately might be. In other words, while it appears that everyone in the

legislature is eager to mandate testing of newborns for antibodies to HIV, we do not yet know what action will be taken in response to this testing.

All of this is of greater concern when one considers: a) Whatever treatment is ultimately recommended for the newborn, it will not have been approved by the FDA; b) There is no data from any clinical trial demonstrating that any treatment (FDA approved or not) would be of any value to the infant; c) There currently are no "guidelines established by the U.S. Public Health Service or other nationally-recognized experts" that even recommend antibody testing of newborns, let alone what to do in response to a positive test result; and d) Since treatment will have to be initiated long before FDA required confirmatory testing can be completed, many infants who were never at risk in the first place will needlessly be exposed to a drug that is associated with serious potential side effects, and known to cause cancer and birth defects in animal studies.

The reason why experts, including the Centers of Disease Control (CDC),[8] do not recommend antibody tests for newborns is because infants carry their mothers antibodies, and if their mother is antibody positive, the infant will also test antibody positive "*regardless of whether they are infected*"[8] (*emphasis* mine). In fact, depending on the study, in the absence of any treatment, only about 12.9%[9] to 25%[10] of all babies born to HIV antibody positive mothers (and who would therefore themselves test positive) will ultimately acquire infection. As such, the implicit intent of testing infants for antibodies to HIV is nothing other than to covertly ascertain the antibody status of their mothers. If one really wanted to learn something about the infant's own HIV status, they would use "viral load" tests as recommended by the CDC.[11]

Even though there are no guidelines that make treatment recommendations for infants who test positive for antibodies, there are guidelines put out by the Perinatal HIV-1 Guidelines Working Group (PHWG) that make treatment recommendations for women who are already known to be HIV antibody positive. Specifically, in the case where an infant is born to a woman who is known to be HIV positive, and has received no therapy prior to delivery, the PHWG recommends: "The 6-week neonatal component of the ZDV [AZT] chemoprophylactic regimen should be discussed with the mother and offered for the newborn. ZDV [AZT] should be initiated as soon as possible after delivery, preferably within 6-12 hours."[12]

Assuming for a moment that an infant's blood can indeed be used to accurately assess the HIV status of the mother, it would seem more than reasonable to extend this treatment recommendation to infants who themselves are confirmed to be positive for antibodies (i.e., if the infant test positive, then we can assume the mother is likewise positive). However, it is important to note that this treatment is not approved by the FDA, and therefore has never been proven to be either safe, or effective. In fact, the PHWG admits that this particular recommendation is not supported by scientific evidence: "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."[12] It is for this reason that the PHWG guidelines—as well as those from all other groups—include a not too obvious footnote stating: "Information included in these guidelines may not represent

approval by the Food and drug Administration (FDA) or approved labeling for the particular product or indications in question." It would be one thing if there were no risks associated with this recommended therapy, but this is simply not the case.

According to the manufacturer of this drug, "Patients should be informed that the major toxicities of RETROVIR [AZT] are neutropenia and/or anemia. … They should be told that if toxicity develops, they may require transfusions … Patients should be informed that other adverse effects of RETROVIR [AZT] include nausea and vomiting. Patients should also be encouraged to contact their physician if they experience muscle weakness, shortness of breath, symptoms of hepatitis or pancreatitis, or any other unexpected adverse event."[13] The manufacturer also emphasizes that; "Rare occurrences of potentially fatal lactic acidosis …and severe hepatomegaly [swollen liver] with steatosis [fatty deposits] have been reported"[13] with the use of drugs like AZT; and finally: "The long term consequences of *in utero* and infant exposure to RETROVIR [AZT] are unknown."[13] Numerous other clinical side-effects associated with the use of this drug are summarized in the PDR® *Nurse's Drug Handbook*™.[14]

Mothers considering treatment of their infant may also want to know that AZT is known to cause both birth defects[13] and cancer in rodent studies.[12,13,15,16] According to the authors of one of these studies, "At 1 year of age, the offsprings of AZT-treated mice [during pregnancy] exhibited statistically significant, dose-dependent increases in tumor incidence and tumor multiplicity in the lungs, liver, and female reproductive organs."[15] Some experts argue that this is irrelevant, because available follow-up studies have not yet revealed an increased incidence of tumors in infants exposed to AZT *in utero* and after birth. However, it is important to note that AZT induced tumors "were documented only in mice sacrificed at or after the human equivalent of the second decade."[16] In other words, if these observations prove to carry over to humans, we would not expect to see tumors in exposed infants until they reach the age of 20 or older. Since this drug was not even used to treat pregnant women until 1994, we still have to wait for another several years before we will know if this is the case.

Mothers should also be informed that since AZT is designed to mimic the chemicals used to create our DNA, even short-term (4 hours) exposure in pregnant monkeys has revealed "AZT incorporation into DNA of fetal liver, lung, heart, skeletal muscle, brain, testis, and placenta."[17] Other studies have shown that this phenomenon carries over into humans, noting that "incorporation of AZT into DNA…was detected in about 70% of samples,"[18] taken from maternal and infant cord blood. The authors of this latter study also found that this phenomenon was independent of the duration of treatment, and was observed in mother/infants with as little as 10 days of AZT exposure. Justifiably, the authors conclude, "AZT-induced mutagenic events are possible in the majority of adults and infants."[18] It is more than likely that this powerful mutagenic property of AZT is the underlying cause of the tumors observed in the above-mentioned rodent studies.

Having detailed the risks associated with this drug, it is important to note that the FDA has approved AZT for use in reducing the incidence of mother-to-child-transmission (MTCT) of HIV, when administered to confirmed HIV-positive women during

pregnancy (14-34 weeks gestation), in labor (intravenously), and to the infant (syrup) for 6 weeks after birth. There is, however, a very good reason for this. Namely, there is sound data from a well-conducted clinical trial demonstrating that this intervention is indeed effective in reducing the incidence of MTCT when administered as detailed above.[19] In other words, the "potential benefit" of this intervention is well quantified, statistically significant, and in the judgment of the FDA, "outweighs the potential risks," as detailed above.

In contrast, the notion that there might be some benefit to the infant when treatment is initiated only after birth is just that, a notion.[20] Furthermore, the FDA approved regimen detailed above is intended for use only in women who are already known to be HIV positive by virtue of confirmed antibody testing. In the case at hand, however, not only will women be encouraged to accept an unproven intervention for their infants, they will be asked to do so on the basis of a preliminary "rapid" screening test in the absence any FDA required, and CDC recommended, confirmatory testing. The reason for this that confirmatory testing can take up two weeks, and according to the PHWG guidelines, infants should be treated within 6-12 hours of birth.

To make treatment recommendations on the basis of unconfirmed rapid tests can be likened to recommending chemotherapy based on the observation of a palpable tumor in the absence of a biopsy report. It would be one thing if such a recommendation were made on the basis of an oncologist's clinical experience; however, in the case at hand, the majority of obstetricians have no clinical experience dealing with HIV/AIDS. Furthermore, since the vast majority of HIV antibody positive females in the maternity ward can be expected to be without any symptoms of AIDS in the first place,[21] such clinical experience would be of little use regardless. As such, to use unconfirmed rapid test results to inform treatment decisions in this setting would appear to be completely without merit. This is particularly the case when one considers rapid tests are neither intended, nor FDA approved, for use in diagnosing infection with HIV in the first place.[22]

In spite of the fact that the practice of using rapid tests to drive treatment decisions clearly falls outside of the bounds of FDA approval, the CDC has, nonetheless, provided "guidelines" for the use of rapid tests (in the absence of confirmation) in the case of women who are in labor. Incredibly, according to these guidelines, the CDC recommends: "If the rapid HIV test result is positive, the clinician should tell the woman that she is *likely to have HIV infection* and that the baby may be exposed to HIV" (*emphasis* mine).[23] This is particularly baffling when one considers this very same document emphasizes: "An HIV test should be considered positive *only after screening and confirmatory tests are reactive*"[23] (*emphasis* mine).

Furthermore, these CDC guidelines go on to emphasize: "The likelihood that a positive screening [i.e., rapid] test truly indicates the presence of HIV infection decreases as HIV prevalence in the tested population becomes lower."[23] Since it is well known that the prevalence of HIV among pregnant women is extremely low (estimated by the CDC to be only about 15/1000, or 0.15%),[24] the significance of this warning cannot be overlooked.

Taken in combination with the fact that rapid test are not approved for diagnosing infection with HIV in the first place, one can only conclude that the implicit intent of this CDC recommendation is to frighten women in labor and delivery to consent to therapy through the use of blatant misinformation. In contrast to this position taken by the CDC, the manufacturers of FDA approved rapid tests state that a person with a positive result should only be told that their test "*suggests*"[25] their blood "*may* contain HIV *antibodies*;"[25,26] and that the result "*must be confirmed* by another test"[25,26] (*emphasis* mine).

It is also important to note that even if an infant's blood sample were ultimately found to be positive for antibodies to HIV upon confirmatory testing, the FDA has emphasized: "The significance of antibodies [to HIV] in an asymptomatic individual is not known."[27] Manufacturers of rapid antibody tests likewise warn: "The risk of any asymptomatic person with a reactive serum or plasma developing AIDS or an AIDS-related condition is not known."[25] Manufacturers of confirmatory tests for antibodies also warn: "The clinical implications of antibodies to HIV-1 in an asymptomatic person are not known."[28] It is for this reason that some manufacturers emphasize that antibody tests "should not be used in isolation, but in conjunction with the clinical status, history, and risk factors of the individual being tested."[26] Given that we can expect the vast majority of HIV antibody positive women/infants in maternity wards to be asymptomatic (i.e., without any symptoms of HIV/AIDS),[21] it would be obtuse, if not negligent, to simply disregard these warnings.

Also of concern is that pregnancy, particularly in the case of women who have given multiple births (i.e., multiparous), is correlated with false-positive HIV antibody test results. Some contend that newer generations of tests are not prone to this problem, however, according data in the package insert of one of the recently FDA approve rapid test, 7% of multiparous females evaluated proved to test falsely positive.[29] This observation has serious implications when it comes to making treatment recommendations in maternity wards in the absence of confirmatory testing. It is further concerning that the notion of using blood from an infant as proxy for diagnosing the antibody status of their mother has never been validated using rapid tests. Furthermore, the performance characteristics (i.e., accuracy, sensitivity and specificity) of rapid tests when using blood from infants has likewise never been determined; most likely because antibody tests are not recommended for use in infants in the first place.[8]

Finally, given that it is recommended to initiate treatment "within 6-12 hours of birth,"[12] there will be an ever-increasing push to get test results back to the maternity ward as soon as possible. Fortunately—for those eager to treat newborns with experimental drugs—the FDA has "waived" two of the four currently FDA approved rapid tests,[29,30] which means that they can be used "on-site" (as opposed to formal clinical testing labs), and in the hands of persons without any training or experience in diagnostic testing. While this will enable maternity wards to inform physicians of results within the recommended 6-12 hour timeframe, it does not come without a price. Namely, according to the "untrained user studies" required by the FDA to "waive" these tests, we can expect an additional 1.0%[30] to 1.5%[29] of all negative samples to test falsely positive. At first glance, these

numbers may appear relatively small, however, as it pertains to the proposed legislation in HB4306 the consequences of this will be profound.

With this background, I would like to illustrate how all of this might pertain specifically to the state of Illinois. For this purpose, I will rely on estimates from the CDC at the national level, with the assumption that Illinois might be representative of national statistics. In year 2000, the Office of the Inspector General (OIG) for the Department of Health an Human Services commissioned the CDC to provide national estimates of: 1) the overall prevalence of HIV in pregnant women; 2) the uptake of HIV antibody testing in pregnant women (i.e., the proportion of women tested in the prenatal period, during labor, and after delivery); 3) the proportion of infants infected with HIV as a result of MTCT according to when treatment is initiated; and 4) estimates of how improvements in delivery of therapeutic and clinical intervention might further lower the number of children infected.

According to the results of this study, which were published in April of 2002,[24] the CDC estimates that 6% of all births in the US are to women of unknown HIV status at time of delivery (i.e., 94% are tested prior to delivery). Given that there are currently about 181,000 annual births in Illinois,[31] this means we can expect about 10,860 of these births to be from mothers of unknown HIV status at the time of delivery (i.e., 6% of 181,000). Given that the CDC further estimates about 0.15% of all pregnant women are HIV positive at the time of delivery, this means we can expect about 16 of these women who haven't been tested before delivery, to be HIV positive (i.e., 0.15% of 10,860). Based on an overall transmission rate of 13%-25% for infants born to mothers who have received no treatment, we can estimate that 2-4 of the infants born to these 16 women will ultimately become infected. It is these 16 women and their newborns that stand to theoretically benefit from the mandatory testing proposed by HB4306.

Ignoring for a moment that there is no data from any clinical trial proving that anything can be done to reduce the transmission rate in these 16 HIV-exposed infants, let's assume that such an intervention might reduce the probability of infection by as much as 50%. If all of these mothers agreed to treatment, then the net effect would be to avert 1-2 infant infections annually. As such, it would be difficult to imagine how anyone of sound-mind could argue against this propose intervention. It is important to emphasize, however, that this benefit is only theoretical, and it is also based on the assumption that 100% of mothers with infants who score positive on rapid tests will consent to treatment; and the likelihood of this happening is highly dependent on what information they and their physicians are given prior to making this decision.

If these women and their physicians are told the truth about the recommended intervention, it is likely that very few would agree to the treatment. In other words, what mother would agree to subject their newborn to a treatment that: a) is not approved by the FDA; b) has never been proven to be of any benefit; and c) is known to be associated with severe side-effects, and to cause cancer and birth defects in animal studies? If the mother is further informed that the test used to covertly assess her HIV status may well prove to be falsely positive on confirmatory testing, and is not approved by the FDA for

diagnosing infection with HIV in the first place, the chances of getting her consent to treat may well dwindle further yet. The net effect of this is that as consent to treat dwindles, so does the theoretical benefit. For example, if only 50% of mothers consent, then we might expect to avert only a single, and if only 25% of mothers were to consent, we would be looking at only a 50% chance of sparing a single infant from infection.

If, on the other hand, the IDPH and the staff at the Perinatal HIV Hotline choose not to disclose the information detailed in this document, and perhaps even tell mothers with infants testing positive on rapid tests that they are "likely to have HIV infection," consent for treatment might be quite good. The downside of this, however, is that as the proportion of mothers who agree to treatment goes up, so does the number of newborns that will needlessly be exposed to the risks associated with this treatment as a result of false-positive rapid tests. As such, it is important to try and estimate the number of false-positives we might expect as a result of the mandatory testing proposed by HB4306.

First, it is important to understand that in order to find the above-mentioned 16 HIV-positive mothers of "unknown HIV status," we have to screen all 10,860 infants born to mothers of "unknown HIV status" at the time of delivery. While it is quite likely that such an exercise will successfully identify all 16 women who are truly antibody positive, many more samples can be expected to score positive as a result of false-positive test results. For example, if we apply the 1.0%-1.5% (average 1.25%) false-positive rate observed in the manufactures' "untrained user studies" to the 10,860 infants to be screened, we can estimate that an additional 136 truly HIV-negative samples to also score positive (i.e., 1.25% of 10,860). In other words, of the 152 women (i.e., 16 true positives, and 136 false positives) who might be told that they are "likely infected," confirmatory testing will ultimately reveal that the vast majority (136, or 90%) are not.

If we assume for a moment that all of these mothers agree to treat their infants, then the cost of theoretically averting 1-2 annual infant infections (i.e., as a result of treating the 16 truly HIV-exposed infants) would be to needlessly expose all 136 infants with false-positive test results to the risks associated with this treatment. If only 25% of mothers were to agree to treatment, then the cost of having a 50% chance of averting a single infection would be to needlessly expose 34 infants. In other words, in order to save one infant, at least 68 others must be needlessly put at risk. And finally, regardless of how many mothers choose to consent, all 136 of the women with false-positive test results may well be told that they are "likely to have HIV infection." While the CDC recommendations acknowledge: "The seriousness of the psychological effect of such a result is self-evident,"[23] the manufacture of a confirmatory antibody test puts it more succinctly: "the psychosocial and medical implications of a [false] positive antibody test may be devastating."[32]

It should be emphasized that the above exercise pre-supposes that all maternity wards will use "waived" tests in order to improve turnaround time. In reality, many hospitals have in-house clinical laboratories staffed with qualified personnel, and the false-positive rate in these settings can be expected to be much lower. On the other hand, the above exercise doesn't even take into consideration the 7% false-positive rate observed in

multiparous females, as mentioned above. In other words, even if this particular test were used in a clinical laboratory with experienced personnel, we might expect many more false-positives than detailed above. According to a recent CDC *National Vital Statistics Report,*[33] 60% of all births in the US are to multiparous females. Applying these numbers to the 10,860 infants to be screened each year in Illinois, we might expect 456 false-positive test results as a consequence of this factor alone.[34] One study funded by the CDC has encouragingly suggested that false positive rapid test results may be reduced substantially if the test is repeated in duplicate on all initially positive samples;[35] at least when testing blood form mothers directly. Whether or not this benefit might be observed in the case where mothers are tested using blood from their infants as proxy is unknown.

On the positive side, since the blood from all infants scoring preliminarily positive on rapid tests will be subjected to confirmatory testing, many of the mothers who were erroneously told they are "likely to have HIV infection," will only have to carry this psychological burden for a week or two (i.e., until confirmatory tests prove them to be negative). However, many of these wrongly diagnosed women will have to wait much longer than this before learning they are not infected. The reason for this is that many persons with false positive screening tests (e.g., rapid tests) will test "indeterminate" on follow-up testing, and these results can only be resolved as truly negative by repeat testing on samples taken 1-3 months into the future.[36] According to the package insert of one FDA approved confirmatory test, more than half of all persons with false positive screening tests in low risk populations (e.g., blood donors or pregnant women) can be expected to fall into this category.[32]

In the same regard, many infants who were needlessly treated on the basis of false positive rapid tests will likewise only be exposed to the risks associated with this drug for a week or two. However, those with indeterminate confirmatory test results will likely be treated for the entire 6 weeks period. Regardless, based on the above-mentioned studies that demonstrated wide-spread "AZT-induced mutagenic events"[18] in the tissues of monkey fetuses after only 4 hours of exposure,[17] and in the cord blood of human infants after as little as 10 days of exposure;[18] none of this should be of any comfort to mothers who gave their consent to treat on the basis of a false-positive rapid test result.

It is also worth mentioning that since all HIV antibody positive mothers will be encouraged to refrain from breastfeeding, infants with false-positive rapid tests—as well as their mothers—will needlessly be denied both the physiological and psychological benefits of early breast feeding, in some cases for several months (i.e., mothers with indeterminate test results will likewise be encouraged to refrain from breastfeeding until it is certain that they are negative). This is particularly tragic when one considers the mothers of these children will also be carrying the psychological burden of pondering the death sentence that was given to them shortly after giving birth. Knowing that their newborn infants may likewise meet the same demise, can only serve to increase this burden beyond anything that can be imagined. Furthermore, given that false positive rapid tests are more likely to occur in multiparous females, most of these women will also have to ponder the fact that there is a 25% chance their other children will die from AIDS

as well. The fathers of these newborns will likewise have to ponder the fact that they are also “likely” infected, at least until their test results might reveal otherwise.

In summary, although well intended, the potential benefits that might result from the proposed legislation in HB4306 are entirely theoretical, and at least as of now, have not even been detailed. In strong contrast, the potential harms that could arise as a result of this legislation are very real, particularly for the very infants this legislation seeks to protect. As detailed above, this legislation may well lead to the needless exposure of perhaps a hundred or more infants each year to a chemical with well-known serious side effects; and which has been shown to mutate human DNA and cause cancer in animal studies. All of these infants will likewise needlessly be denied the psychological and physiological benefits of breastfeeding for at least a week or two, and in many cases for several months.

Although the mothers of these infants with false-positive test results will not be exposed to the risks of this treatment, they will needlessly be subjected to unimaginable psychological stress as a result of erroneously being told that they are likely infected with a deadly virus; all within hours of one of the most glorious events in their lives. Hopefully the joy of ultimately finding out that they are negative will mitigate at least some of the psychological damage caused to these women as a result of their false diagnosis.

In conclusion, the goal of public health initiatives should be to promote actions that can be expected to result in more good than harm. In the case at hand, however, there are no known benefits to treating infants born to HIV positive mothers. In other words, the “good” of such an intervention is unknown, and any harm in excess of “unknown” should therefore be considered sufficient to disqualify this intervention as being of any value to public or individual health. In other words, even if the mandatory testing proposed by HB4306 led to the unwarranted treatment of a single infant, or the needless psychological stress of a single mother, it would not be justified. Knowledge of the fact that the mandatory testing proposed by this Bill may well lead to tens, if not hundreds of such tragic cases each year, will hopefully serve as a wake-up call to the legislators’ in Illinois to shelf this proposal as soon as possible.

Sincerely,

Rodney M. Richards

Endnotes:

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[5] Public Act 93-0566
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[7] HB4306 amended.
[8] CDC. *Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women*. MMWR 2001; 50(No. RR-19): [inclusive page numbers].
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[11] The so-called viral load tests refer to tests that seek to detect a small fragment of the genetic code for HIV through the use of nucleic acid amplification technologies. Although the FDA required package inserts for all of these test explicitly warn that they are not intended for use in diagnosing infection with HIV, the CDC has nonetheless recommended their use for this purpose in the case of infants (see endnote 8).
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[13] GlaxoSmithKline. Package insert for RETROVIR® (Zidovudine). Available at http://us.gsk.com/products/assets/us_retrovir.pdf
[14] The following is taken from the 2001 edition of the PDR® Nurse's Drug Handbook™: Zidovudine (Azidothymidine, AZT). **Side Effects**: *Hematological*: Anemia (severe), granulocytopenia. *Body as a whole*: Headache, asthenia, fever, diaphoresis, malaise, body odor, chills, edema of the lip, flu-like syndrome, hyperalgesia, abdominal/chest/back pain, lymphadenopathy. *Gastro Intestinal*: Nausea, GI pain, diarrhea, anorexia, vomiting, dyspepsia, constipation, dysphagia, edema of the tongue, eructation, flatulence, bleeding gums, mouth ulcers, ***rectal hemorrhage***. *Central Nervous System*: Somnolence, dizziness, paresthesia, insomnia, anxiety, confusion, emotional lability, depression, nervousness, vertigo, loss of mental acuity. *Cardiovascular*: Vasodialation, syncope, vasculitis (rare). *Musculoskeletal*: Myalgia, myopathy, myositis, arthralgia, tremor, twitch, muscle spasm. *Respiratory*: Dyspnea, cough, epistaxis, rhinitis, pharyngitis, sinusitis, hoarseness. *Dermatologic*: Rash, pruritus, urticaria, acne, pigmentation changes of the skin and nails. *Urinary*: Dysuria, polyuria, urinary hesitancy or frequency. *Other*: Amblyopia, hearing loss, photophobia, ***severe hepatomegaly with steatosis***, lactic acidosis, changes in taste perception, hepatitis, pancreatitis, hypersensitivity reactions, including *anaphylaxis*, hyperbilirubinemia (rare), ***seizures***.
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[20] Some have argued that there may be a benefit to such treatment based on the results of an epidemiological study conducted in New York (Wade NA, et al. *N Engl J Med* 1998; **339**:1409-14), which suggested substantially lower transmission rates among children who in the course of routine practice received AZT shortly after birth as compared to those who received no treatment whatsoever. However, while the results of such studies may reveal correlations, they cannot be used to declare causal links between factors, and it is for this reason that the FDA will not accept data from such studies in support of product approval. It is also for this reason that the authors of this study explicitly state their results, "*suggest* that there are reductions in the rates of perinatal transmission of HIV even with the use of abbreviated regimens that are begun … in the first 48 hours of life" (*emphasis* mine). Investigators from the CDC have commented on this data suggesting that the treatment difference in this study may well be due to artificially high transmission rates in untreated children as opposed to beneficially low transmission rates in those who were treated (Fiscus, SA and Schoenbach VJ. *N Engl J Med* 1999; **340**: 1040-43). A similar study conducted on infants in North Carolina (Fiscus SA, et al. *Pediatr Infect Dis J* 2002; **21**: 664-8) uncovered no evidence suggesting a possible benefit to children treated after birth. In fact, for infants who were treated in the first 48 hours of life in this study, the overall transmission rate was found to be 42.9%, which is notably higher than what would be expected in the absence of any treatment whatsoever. Taken in isolation, the results of this study suggest that treatment might actually increase the number of infants that will become infected.

[21] The reason why the majority of women in maternity wards can be expected to be without symptoms of AIDS is that a) the vast majority are not HIV positive in the first place, and b) since it takes on average about ten years from the time a person tests positive for antibodies to HIV to manifest symptoms of AIDS, only a small fraction of even the HIV positive women in maternity wards can be expected to have symptoms at any given time.

[22] Screening tests such as rapid tests seek to detect *antibodies* to HIV in order to *aid* in the diagnosis of *infection* with HIV. However, because these tests are designed to be very sensitive, they are known to produce many false positive results, particularly in low risk groups such as blood donors and pregnant women. For this reason, the manufacturers of all of these test, along with the FDA and CDC, recommend that all samples that test positive on screening tests be subjected to supplemental testing before telling a patient they are positive for *antibodies* to HIV. According to CDC recommendations, persons with *antibodies* to HIV should be considered *infected* with HIV. The manufacturers of these tests, however, make no such claim. On the contrary, most of them emphasize that the significance of *antibodies* to HIV in healthy persons, even if confirmed, is *unknown*.

[23] CDC. *Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status: A Practical Guide and Model Protocol.* January 20, 2004.

[24] Department of Health and Human Services: Office of Inspector General. *Reducing Obstetrician Barriers to Offering HIV testing.* April 2002 (OEI-05-01-00260).

[25] Bio-Rad. Multispot HIV-1/HIV-2 Rapid Test: Subject Information Notice.

[26] Medmira. Reveal™ Rapid HIV-1 Antibody Test: Subject Information Brochure.

[27] Suzan Cruzan. FDA News Release April 30, 1987; P87-11.

[28] Cambridge Biotech Corp., Rockville MD. Package Insert for HIV-1 Western Blot. US License No. 1063. June 2, 1998.

[29] OraSure Technologies, Inc. Package insert for OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test.

[30] Trinity biotech. Package insert for Uni-Gold™ Recombigen® HIV test.

[31] According to the Illinois Department of Public Health, there were 180,665 births in Illinois for year 2004.

[32] Epitope, Inc., Beaverton, OR. Package Insert for HIV-1 Western Blot Kit. US License No. 1133, March 20, 1991. Epitope, Inc., Beaverton, OR. Package Insert for OraSure[R] HIV-1 Western Blot Kit. US License No. 1133, January 10, 1996.

[33] CDC. Births: Preliminary Data for 2003. *National Vital Statistics Reports* November 23, 2004; Vol. 53, No. 9.

[34] 10,860 x 0.6 x 0.07 = 456.

[35] Bulterys M, et al. Rapid HIV-1 testing during labor. *JAMA* 2004; **292**: 219-23.

[36] An indeterminate supplemental test result may represent an incomplete antibody response in persons who have been recently exposed to HIV. Since it may take 1-3 months to develop a full antibody response in such cases, the only way to rule out infection is to repeat the test on a sample taken at that time. If the follow-up sample also tests indeterminate or negative, the patient can then be told they are not infected.