

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

CENTRAL RABBINICAL CONGRESS OF:
THE USA & CANADA, *et al.*,

Case No. 12-Civ.-7590

Plaintiffs,

Judge Naomi Reice Buchwald

vs.

NEW YORK CITY DEPARTMENT OF
HEALTH & MENTAL HYGIENE, *et al.*,

Defendants.

SUPPLEMENTAL AFFIDAVIT OF DR. DANIEL S. BERMAN, M.D.

1. I submit this supplemental affidavit in response to the affidavits and declarations offered in this case by Dr. Farley (“Farley Decl.”), Dr. Wald (“Wald Aff.”), Dr. Kimberlin (“Kimberlin Aff.”), Dr. Stanberry (“Stanberry Aff.”), Dr. Whitley (“Whitley Aff.”), and Dr. Zenilman (“Zenilman Aff.”).

2. In contending that MBP causes—and has caused—transmission of HSV-1, these experts rely on seven categories of circumstantial evidence. They do so because no DNA evidence exists linking any case of neonatal HSV to MBP. Indeed, the Department of Health and Mental Hygiene has refused to sign onto the protocol for DNA testing that the State of New York established together with neonatal experts and the Orthodox Jewish community. (*See* Aff. of Robert Simins (“Simins Aff.”), ¶¶ 8-18.)

3. The experts’ reliance on each of these seven categories of circumstantial evidence is flawed, as explained below. In my professional opinion, the evidence does not show that MBP *has ever* resulted in transmission of HSV-1.

Category 1: Biological “Plausibility” of Transmission

4. Many of the defendants’ experts argue that the alleged link between MBP and HSV is supported by the “biological plausibility” of transmission through orogenital contact. (Stanberry Aff., ¶ 7; Wald Aff. ¶¶ 10-12; Zenilman Aff. ¶¶ 19-29 .) However, just because transmission is *plausible* does not mean that it *actually occurs*. In fact, there are many examples of biological plausibility where causation has not been established.

5. For example, the hepatitis-C virus has been isolated in breast milk, and there is strong biological plausibility that the virus can be transmitted through breastfeeding. But this has never been proved to occur. As a result, there are no recommendations from the Centers for Disease Control or any Health Department for hepatitis-C infected mothers to avoid breastfeeding.

6. Another example involves the transmission of HIV through saliva. While HIV has been isolated in saliva, creating strong biological plausibility of transmission, such transmission has never been proved to occur, and it is assumed that the disease is not so transmitted.

7. More directly, Dr. Farley explains in his affidavit that “the human mouth is filled with micro-organisms, including bacteria and viruses.” (Farley Decl., ¶ 7.) Bacteria, in particular, are *always* present in the mouth (unlike the HSV-1 virus, which at most is only intermittently shed into saliva). Transmission of bacterial infection through MBP is therefore strongly biologically plausible. Likewise, Dr. Zenilman observes that “direct exposure to an open wound poses a potential risk of transmitting other blood-borne pathogens, including viral hepatitis, HIV, and even upper respiratory pathogens such as enteroviruses.” (Zenilman Aff., ¶ 29.) Yet nobody has reported an increased incidence of bacterial infection, viral hepatitis, HIV, or enteroviruses following MBP.¹

8. Why would transmission not occur despite biological plausibility? It could be a function of the briefness of the contact during MBP, which is usually limited to one second. Or it may be a function of the precautions that *mohelim* take before performing MBP, including rinsing with an antiseptic, which in the case of Listerine has been shown to kill HSV in saliva. (Dr. Farley complains that these precautions have not been proved “to reduce herpes transmission via direct oral suction” (Farley Decl., ¶ 56), but it would be impossible to prove reduction in a risk that itself has never been proved.)

Category 2: Incubation Periods

9. The defendants’ experts emphasize that the hypothesis of transmission through MBP is strengthened by the fact that the reported cases fall within the expected incubation period for such transmission. (See, e.g., Kimberlin Aff., ¶ 6; Wald Aff., ¶ 13; Zenilman Aff., ¶ 24; Farley Decl., ¶¶ 15, 59.) But a closer look at the individual reported cases shows that this is not true. Of the 11 reported cases, at least four actually fall *outside* the expected incubation period had MBP been the source of the disease. The relevant details of the individual cases can be found in the tables on pages 3 and 5 of the Department’s report, which is attached as Exhibit K to the Farley Declaration.

10. The most recent (2012) edition of the classic textbook, *Principles and Practices of Pediatric Infection Diseases*, in Chapter 204, which addresses HSV, states that the incubation period for HSV depends on the category of infection: the skin, eyes, and mouth (“SEM”) category “typically manifests during the first two weeks of life”; for the central nervous system (“CNS”) category, “typically, fever and lethargy appear

¹ Dr. Farley cites some very old reports claiming transmission of syphilis and tuberculosis through MBP. (Farley Decl., ¶ 18.) But no cases of either disease following MBP have been reported since 1946, and it is difficult to evaluate the accuracy of such old studies, especially when the authors demonstrated strong anti-Semitic sentiment (describing Jews as “a low and ignorant class of people,” who are “careless, uncleanly, and even filthy”). In any event, such transmission would not prove in any way the transmission of herpes virus, which is the only infectious agent that has been considered even as a *possibility* of being transmitted in this way for the past 66 years.

between two and three weeks of life”; and, in the case of disseminated virus, symptoms usually appear between days 5 and 10 of life. Since most infections are acquired at birth, this suggests an incubation period of up to 14 days for SEM infections, of 14-21 days for CNS infections, and of 5-10 days for disseminated infections.

11. Case number 6 from the Department’s report was a CNS case, and the infant presented with the disease just seven days after the circumcision. Based on the incubation period for CNS disease (14-21 days), it is therefore unlikely that MBP was the source of the infection.

12. Case number 7 was a SEM case, which typically presents within two weeks of exposure. But this infant did not present until 20 days after the circumcision, again making MBP an unlikely source of the infection.

13. Case number 8 was a CNS case, and so the expected incubation period would be more than two weeks after exposure. But this infant presented with the CNS infection just one week after circumcision—and 15 days after birth—which does not support the theory of exposure through MBP, but rather is consistent with transmission at the time of the birth.

14. Case number 11 was a disseminated case, and so the expected incubation period was between 5 and 10 days. But this infant presented 11 days following the circumcision, which is consistent not with transmission through MBP but rather with transmission through household contacts after the circumcision.

15. Thus, using the incubation periods provided by the classic textbook in the field, four of the 11 reported cases occurred at times inconsistent with the theory of transmission through MBP. In the remaining seven cases, the timing was consistent with transmission not just through MBP but also through a variety of different contacts over a 1- or 2-week period.

16. In Dr. Farley’s declaration, he offers a different set of incubation periods, which contradict the textbook. In particular, Dr. Farley states that SEM and CNS cases usually present at 10-12 days after exposure, with disseminated cases presenting later, at 16-19 days after exposure. (Farley Decl., ¶ 15.) Using these incubation periods, only *two* of the 11 reported cases fall within the expected incubation period had transmission occurred through MBP. In particular, *none* of the three disseminated cases (cases 3, 4, and 11) presented anywhere close to 16 days after circumcision—although two of the three did present 16 days after *birth*, suggesting that the infection was acquired then. And, of the remaining cases, only cases 2 and 9 presented within the 10-12 days window following circumcision that Dr. Farley claims would have been expected.

17. The timing of the presentation of the infections in the 11 reported cases therefore does not corroborate—and, in fact, undermines—the Department’s theory that MBP was the source of the virus in these cases.

Category 3: Location of Lesions

18. Many of the defendants' experts point to the location of the lesions in the reported cases as additional evidence that the disease was transmitted through MBP. In particular, the experts note that lesions were present on the genitals or in areas that are served by the same nerves ("dermatomally related") as the genitals. (*See, e.g.*, Kimberlin Aff., ¶ 6; Wald Aff., ¶¶ 11–12; Zenilman Aff., ¶ 24; Farley Decl., ¶¶ 11, 59.)

19. Since all of these infants had been circumcised, it is not surprising—or probative—that lesions presented on the genitals. As the 2012 edition of *Principles and Practices of Pediatric Infectious Diseases* states, "skin lesions tend to appear at sites of trauma, such as the site of attachment of fetal scalp electrodes, the bulb syringe trauma site on palatal mucosa, the margin of the eyes, or at a circumcision site." (Page 1031.)

20. Moreover, since we are dealing with a population that has had a fresh circumcision, this would be a likely site of infection from *any* source, including members of the infant's household. For example, someone changing the baby's diaper or dressing the circumcision wound could introduce the virus to the site. Indeed, in one of the 11 cases there is powerful evidence that this is precisely what occurred. *See infra* ¶ 29. (*Accord* Zenilman Aff., ¶ 21 ("[T]he freshly-circumcised penis is an open portal for the introduction of any harmful microbes present at the wound, including HSV if the circumcision site is exposed to infected secretions.")) So, even if the location of the lesions were indicative of the location of infection, that does not favor the Department's hypothesis (infection through MBP) over alternative hypotheses (such as infection from a caregiver or family member).

21. These points also distinguish the collection of cases discussed by Dr. Wald based on her practice in Seattle. (Wald Aff., ¶ 11.) Those cases, unlike the 11 reported cases in the MMWR study, were not limited to male, recently circumcised infants. So it is not surprising that genital lesions were less common among those cases.

22. Tellingly, the Department's report does not say where the *initial* lesions presented for any of the 11 cases, and it reports that at least three of the cases involved lesions in a wide variety of areas. (*See* Farley Decl., Exh. K, at 2 (describing twins with "lesions on their abdomen, buttocks, and perineum" and a 2003 case involving vesicles "on the penis, perineum, buttocks, back, and foot").) And, in the case of the September 2011 baby, the mother of the infant has stated that the first lesion appeared on the *foot*. (*See* Aff. of Robert Simins, ¶ 21.) Yet, as Dr. Wald points out, it is precisely the "early lesions" that "often indicate the site of inoculation." (Wald Aff., ¶ 12.) Subsequent lesions are not as probative, because, as Dr. Farley notes, "[i]f infection disseminates in the blood, herpes blisters may appear on other, more distant places on the body." (Farley Decl., ¶ 12.)

23. To the extent that the defendants' experts argue that lesions on the foot or abdomen are probative of transmission through MBP because these are dermatomally related to the genitals (that is, served by the same nerve), that is false. As shown by the

illustration provided by Dr. Farley (Farley Decl., Exh. D), the sole of the foot contains dermatomes L5 and S1; the abdomen has thoracic dermatomes. None of these areas is served by either S2 or S3, which feed the penis and scrotum respectively.

24. Furthermore, while the Department's report claims that genital lesions were present in all of the five cases within the study period, I have been able to examine the medical file for only one of these five—and it does not support the Department's assertion. In the case of the September 2011 infant (case number 11), there were multiple examinations by physicians, none of whom identified a lesion on the penis or scrotum or other areas of the skin that are "dermatomally-related." This raises questions about whether genital lesions were actually present in the other cases.

25. Contrary to Dr. Zenilman's assertion, I do not reject "the existence and role of dermatomes in herpetic infection." (Zenilman Aff., ¶ 24.) But I see no evidence that the distribution of lesions in the reported cases proves that MBP was the source of the infections.

Category 4: Exclusion of Other Routes of Transmission

26. Some of the Department's experts also claim that transmission through MBP was likely the cause of the 11 reported cases because other possible routes for the transmission of the disease were excluded. (*See, e.g.*, Farley Decl., ¶ 25; Stanberry Aff., 15-16; Kimberlin Aff., ¶ 6; Zenilman Aff., ¶ 33.) Hardly so.

27. Although the Department's report claims that "transmission from the mother or health-care workers was largely excluded" (Farley Decl., Exh. K, at 4), the extent of the Department's investigation to exclude household contacts was to ask if members of the household had a history of oral herpes or any signs or symptoms of oral herpes during the time that they cared for the baby. (*See* Farley Decl., ¶ 31 (noting that, in the case of the infected twins, the mother, grandmother, and nurse had "no history of oral herpes" or "reported symptoms of oral herpes during the time they were caring for the infants").) To be sure, transmission is more likely from symptomatic carriers of HSV than from those who are asymptomatic.² But the entire theory of transmission through MBP is based on the possibility of asymptomatic transmission. Just as it is possible that HSV could be transmitted from an asymptomatic *mohel*, it could be transmitted from an asymptomatic family member or caregiver. So how could the Department "exclude" the chance of transmission through family members just because they were asymptomatic, only to pin the blame on *mohelim* who were *also* asymptomatic? Put another way, one cannot reasonably conclude from the fact that family members were asymptomatic for herpes that the disease must have been transmitted by a *mohel* who was asymptomatic. To truly exclude household contacts as a source, antibody testing of the family members and caregivers should have been performed.

² Asymptomatic carriers of the disease are capable of transmitting it, but are less likely to do so because they are less likely to be shedding the virus than those displaying symptoms. Contrary to Dr. Zenilman's suggestion (Zenilman Aff. ¶ 14), I never disputed the risk of transmission via asymptomatic shedding.

28. Moreover, in at least two of the reported cases, we know that there *was* evidence supporting transmission through family members. In particular, in the case of the infant that died in September 2011 (case number 11), the infant's sibling had a history of recurrent oral herpes, which the mother disclosed to the Department; this sibling had visited the newborn baby when the latter was three days old and they had even shared a pacifier. Those facts provide very powerful evidence of transmission from the sibling.

29. Dr. Farley, responding to the possibility of infection through the sibling, says that this is "unlikely" because "it is difficult to imagine a scenario where a very young child would have had contact with the genitals of his newborn baby brother." (Farley Decl., ¶ 45.) But, as the defendants' experts recognize, HSV can be transmitted through saliva coming into contact with a mucous membrane, such as the infant's mouth. (Wald Aff., ¶ 6; Zenilman Aff., ¶ 11.) Dr. Farley appears to be assuming that the virus must have entered through the genital area because of the subsequent appearance of genital lesions. As already explained, however, (i) the mother of this infant reported that the first lesion appeared on the infant's foot; (ii) none of the physicians recorded lesions on the infant's genitals; and (iii) this infant presented with disseminated HSV, and (as Dr. Farley concedes) when the virus is disseminated, lesions often appear at sites distant from and unrelated to the site of infection. (*See supra* ¶¶ 22, 24.)³

30. Similarly, the Department did not report that in another of the cases (case number 6), the infant's mother had a history of oral lesions, including when she changed the infant's circumcision dressing. This mother had a habit of biting the finger that she would then use to apply ointment to the bandage used to dress the circumcision wound. (*See Simins Aff.*, ¶ 22.) Again, this is extremely suggestive of transmission through household contacts, but the Department attempts to conceal and ignore it.

31. The defendants' experts also attempt to explain why transmission from the mother—which is how neonatal herpes is "usually" acquired (Wald Aff., ¶ 8)—is not likely in the 11 reported cases. Dr. Stanberry points out, for example, that if the mother were infected with HSV, the infant would have received antibodies "protecting it from the virus." (Stanberry Aff., ¶ 16.) Dr. Farley similarly states that "it would be highly unusual for a mother to be the source of infection acquired after delivery because the babies of mothers with HSV-1 infection are protected against infection by the transfer of maternal antibody across the placenta." (Farley Decl., ¶ 30.)

32. To be sure, most infants born to seropositive mothers are sufficiently protected by the antibodies received *in utero* from the mother to avoid infection. But transmission from mothers during birth is nevertheless the most common method of transmission, as Dr. Wald concedes. The antibodies, in other words, are not always

³ Dr. Zenilman, addressing the same issue, says that HSV is not transmitted through "household items." (Zenilman Aff., ¶ 33.) I never claimed that the virus was transmitted through "items"; rather, I pointed out that herpes can be transmitted through household *contacts*, such as with caregivers or family members. To the extent that Dr. Zenilman is suggesting that HSV could not be transmitted through the shared use of a pacifier, it is not clear why that would be so. Surely Dr. Zenilman would recommend against allowing a symptomatic child to share his pacifier with a newborn infant.

enough. That is why “the American College of Obstetrics and Gynecology recommends that cesarean section delivery be performed if a pregnant woman has any signs of genital herpes at time of delivery”—notwithstanding the theoretical protection afforded by the maternal antibodies. (Farley Decl., ¶ 13.)

33. With respect to the infected twins, Dr. Farley states that even though the mother tested positive for herpes antibodies, she was an unlikely source of the infection because “the twins were born by cesarean section and cesarean delivery strongly protects against the acquisition of neonatal herpes infection.” (Farley Decl., ¶ 28.) Once again, however, while caesarean delivery reduces the risk of transmission, it does not eliminate it: The virus can be transmitted congenitally, prior to delivery, as Dr. Farley himself notes. (Farley Decl., ¶ 13.) Indeed, 9 of the 13 fatalities from neonatal herpes in New York City reported by a 2011 study that Dr. Farley cites involved infants who were born by caesarean section. (See Farley Decl., Exh. G, at 3 tbl. 2.)

34. In short, transmission from an asymptomatic *moherl* is no more likely than transmission through an asymptomatic family member or mother, which possibility has not been ruled out, and is far less likely than transmission through a *symptomatic* family member, which are known to have existed in at least some of the reported cases.

Category 5: Susceptibility to Infection

35. Much of the “evidence” cited by the Department’s experts actually just underscores that the infants who underwent circumcision were susceptible to HSV, which could have been transmitted even by an asymptomatic individual. That is quite true, but does not support the hypothesis of transmission through MBP as opposed to household contacts or other routes of transmission. It therefore does not provide any additional evidence supporting the Department’s theory of transmission through MBP.

36. For example, many of the Department’s experts repeat that infants undergoing circumcision face a higher risk of HSV transmission, because the wound is a possible entry point for the virus. (See, e.g., Stanberry Aff., ¶ 10; Zenilman Aff., ¶ 21; Farley Decl., ¶ 11; Wald Aff., ¶ 10.) That is true—but it explains why these infants were particularly susceptible to herpes from *any* source, not just MBP. (As discussed, this also shows why some of the infants may have exhibited genital lesions, regardless of the source of the infection. See *supra* ¶¶ 19-20.)

37. Dr. Wald points out that infants in the Orthodox community are less likely to have received maternal antibodies against HSV-1, because fewer Orthodox mothers are seropositive for the disease. (Wald Aff., ¶ 19.) Again, however, to the extent that this is true, it shows only that these infants were particularly susceptible to HSV-1, not that MBP was the source of the infection.

38. Many of the experts point out that HSV can be shed by an asymptomatic person, who can transmit the disease to others. (See, e.g., Kimberlin Aff., ¶ 4.) Indeed, Dr. Farley says that asymptomatic transmission is how HSV infections “have become so

common in the general population.” (Farley Decl., ¶ 10.) Once again, while this explains how an asymptomatic *mohel* could in theory transmit HSV, it equally explains how even an asymptomatic family member or caregiver could do so. As Dr. Farley notes, asymptomatic transmission has caused HSV infection to become common in the general population, because most people are unaware that they might be shedding the virus and unaware of the possibility of transmission. No precautions are routinely taken to prevent such transmission, at least outside of a hospital environment. Yet the Department somehow draws from this the unwarranted inference that the *mohel* must have been the source of the virus.

Category 6: Clustering of Cases Around Particular *Mohelim* and Families

39. Some of the Department’s experts claim that the clustering of cases involving a single *mohel* and/or a single family bolsters the thesis that the virus was transmitted through MBP. (See, e.g., Zenilman Aff., ¶¶ 26-27; Farley Decl., ¶¶ 42-43, 60.) That is not a reasonable inference to draw. If anything, this clustering corroborates the contrary hypothesis, that common household contacts were the source of these infections.

40. Dr. Zenilman, for example, concludes from the fact that two of the five reported cases during the study period involved brothers circumcised by the same *mohel* that the virus must have been transmitted by that *mohel*. (Zenilman Aff., ¶ 33.) But I believe it is far more logical to infer that the two brothers acquired the infection from a common household source, or that the second brother acquired it from the first. It is very improbable that this *mohel*, who presumably performed hundreds of circumcisions each year, infected *only* two brothers *from the same family*, three years apart.

41. To use an example, if two brothers who attend the same school were to both contract food poisoning, one might suspect the school cafeteria as the source of the infection. But, if no other students at the school were affected, it would be more logical to infer that the brothers were infected at their *home*. The same is true here. Given that nobody *except* brothers contracted HSV after circumcision by this particular *mohel*, it makes more sense to view these cases as a cluster around this particular *family*, not as a cluster around this particular *mohel*.

42. Similarly, Dr. Farley infers causation from the fact that three infants acquired HSV after MBP performed by a single *mohel*, Mohel A. (Farley Decl., ¶ 27.) But this *mohel* has denied performing MBP on the third of these infants, and even passed a lie detector test to that effect. (See Simins Aff., ¶ 20.) The remaining two infants, on whom the *mohel* acknowledged performing MBP, were *twins* who were circumcised at the same time. Again, therefore, the far more logical and likely inference is that the twins acquired the infection from their mother (who tested positive for HSV antibodies), from another household contact, or one from the other—a possibility well-documented in the medical literature.

Category 7: Statistical Analysis

43. The Department's experts also repeat the finding of the Department's MMWR study that there is a statistically significant association between MBP and HSV infection. (See, e.g., Kimberlin Aff., ¶ 8; Wald Aff., ¶ 14; Gelman Aff., ¶¶ 4-26; Farley Decl. ¶¶ 46-53.) Notably, none of these experts conducted their own studies on this topic; they rely exclusively on the Department's report.

44. Statistical analysis is not my area of expertise, but I note that, in addition to the critiques made by Dr. Breuer and Dr. Federgruen of the Department's analysis and assumptions, the Department's report treats the incidence rate of HSV in the general population as equivalent to the *reported* rate among that population. However, there is a strong likelihood of screening bias here, because the index of suspicion for the diagnosis of neonatal herpes is so much higher—given the attention and controversy surrounding MBP—for an Orthodox Jewish boy than for any other infant. Indeed, the Department directed health-care providers to "maintain a high index of suspicion for herpes infection" following MBP. (Farley Decl., Exh. T, at 3.)

45. By contrast, although Dr. Farley claims that "the number of cases reported in the medical literature must be considered a minimal estimate of the actual occurrence of neonatal herpes following ritual circumcision with direct oral suction because ... it is likely that some cases of neonatal herpes following ritual circumcision were not recognized as being related to direct oral suction" (Farley Decl., ¶ 23), the facts do not bear out that claim. In the approximately six years before HSV became reportable, six cases of HSV following MBP were reported. In the approximately six years after, five cases were reported. This demonstrates that neonatal herpes associated with MBP has not been "underreported," as the Department long claimed.

I declare under penalty of perjury under the laws of the State of New York that the foregoing is true and correct to the best of my knowledge.

Executed this 30 day of November, 2012, at Bronx, New York.

Daniel S. Berman, M.D.
Daniel S. Berman, M.D.

STATE OF NEW YORK
COUNTY OF Bronx

Subscribed and sworn before me this 30 day of November, 2012.

Charlene R. Brown
Notary Public

My commission expires on: 7/31/2013

CHARLENE R. BROWN
NOTARY PUBLIC, STATE OF NEW YORK
No. 03-4648048
Qualified in Bronx County
Term Expires 7/31/2013