

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Monday, June 18, 2012 at 11:34:42

This form resides at
http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Protection%20of%20Public%20Health%20Generally

Office: DOHMH
Rule: Article 181-Protection
of Public Health Generally
First Name: [REDACTED]
Last Name: [REDACTED]
Street: [REDACTED]
City: Brooklyn
State: NY
ZIP: 11230
Opinion on Proposed Rule: For

Comment: I believe that most
Ultra Orthodox people are not aware of the risks involved with
Metzitzah B'Peh. At the very least, the government should inform
them of the possible risks and let parents decide for themselves
about whether they want to expose their babies to this danger.

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Monday, June 18, 2012 at 14:01:19

This form resides at
[http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agen
cy=DOHMH&rule=Article%20181-
Protection%20of%20Public%20Health%20Generally](http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Protection%20of%20Public%20Health%20Generally)

Office: DOHMH
Rule: Article 181-Protection of
Public Health Generally
First Name: [REDACTED]
Last Name: [REDACTED]
Street: [REDACTED]
City: Brooklyn
State: NY
ZIP: 11204
Email: [REDACTED]
Opinion on Proposed Rule: For

Comment: I am a practicing mohel in the
hasidic community. Although I feel that there are inherent risks to a
baby undergoing MbP, I generally do perform MbP because it is expected
of me, as a full service mohel. If there were a governmental agency
which issued guidelines for parents/mohels explaining the risks, it
would enable me to have an opportunity to explain and discuss this with
parents, thereby letting them decide whether they want to go ahead with
it or not. In addition, if I knew that other mohels stopped the
practice, by choice or by governmental pressure, it would be easier for
me to cease and desist from doing it, as I would be able to cite this
as the reason. Currently, there is no respectable way for me to refuse
to do MbP.

(3)

§ 181.21 Consent for direct oral suction as part of a circumcision.

Ben Hirsch [REDACTED]

Sent: Monday, June 25, 2012 8:47 AM

To: Resolution Comments

Ms. Bryant,

Thank you for giving the public the opportunity to opine on the above referenced amendment.

I was born and raised within the Brooklyn ultra-Orthodox community and count many learned rabbis in my immediate family (including some active in pushing for the preservation of the practice of metzitzah b'peh ("MbP")). I am the proud father of two wonderful daughters. I must admit that if I would have had a boy, I do not know whether I would have been cognizant of the exact practices inherent in direct MbP nor even whether I would have known enough to ask a *mohel* about his practices. I would likely have asked close family members for a referral to a *mohel* and unless someone raised the MbP question I would have just looked away as the ritual was performed and known nothing. Absent any tragedy, I would likely have remained in the dark even after the *bris*.

I am not ignorant of Jewish law. I spent many years studying in yeshiva and rabbinical college. Yet, absent advance notice I could likely have known little or nothing about the issue. So for my personal situation, a consent form would have served a purpose. Even during the frenzied days following the birth of a child and preparation of the *bris* I would have perused the document and studied the issue. And being somewhat independent, I would have concluded that common sense and as importantly Jewish law dictates that MbP may not be performed.

Orthodox Jewish Law:

"Between 2004 and 2011, the Department learned of 11 cases of laboratory-confirmed herpes simplex virus infection in male infants following circumcisions that were likely to have been associated with direct oral suction. Two of these infants died, and at least two others suffered brain damage."

These statistics alone prohibit any observant Jew from practicing the *minhag* (custom) of MbP. This conclusion is not subject to any interpretation but is rather black letter Jewish law. Indeed, Jewish law dictates that even if MbP was not custom but an integral component of the *bris* ritual, the health risk, as determined solely by health professionals--without any rabbinic input--requires that the practice cease. Period. Jewish law grants medical professionals absolute authority over health related issues. Simply, if a medical professional determines the existence of a health risk Jewish law takes a back seat. Jewish law dictates that the preservation of health is above all else. No rabbi has the authority to override this fundamental principle of Jewish law.

members drive their cars to respond

Case in point: Hatzolah (Orthodox volunteer EMT service) members ~~do not~~ respond to emergency calls—and transport patients to hospitals--on the Sabbath. It is a capital crime under Orthodox Jewish law to drive a car on the Sabbath. Yet, one of the most widely accepted Orthodox decisors of Jewish law in the 20th century ruled that Hatzolah members are permitted to drive their cars home from the hospital on the Sabbath after delivering the patient to the hospital. There is no preservation of life dispensation that would allow one to drive home from the hospital on the Sabbath. Regardless the ruling states that if forced to spend the remainder of the Sabbath in the hospital Hatzolah members may be reluctant to respond to calls on the Sabbath which may place lives at risk. Accordingly he ruled that they may transgress an otherwise capital crime and drive home on the Sabbath.

I bring this as an example of the intellectual gymnastics revered rabbis have engaged in to adapt Jewish law to health risk situations.

Faced with the statistics now known about the risks associated with the practice of direct MbP, Jewish law labels anyone who performs this ritual, or knowingly allows it to be practiced on their child, a criminal.

As long ago as the mid 19th century world renowned ultra-Orthodox and Hasidic rabbis ruled that the practice of MbP be banned and instead replaced with other methods of treating the circumcision wound that did not involve any direct contact between the *mohel's* mouth and the baby's penis. Not coincidentally, these rulings followed advances in medical knowledge.

While the consent form proposal will likely save some babies from disease and death and I support the proposal, it does not address the underlying problem. Sadly, certain rabbis and ultra-Orthodox and Hasidic organizations have dug in their heels and either out of ignorance or a cynical disregard for child safety in the name of “the greater good” of their retention of authority, choose to ignore the health risks and accepted Orthodox Jewish law and are placing lives at risk.

There is only one solution. The practice of MbP must be made illegal with harsh penalties for violations. To place this practice in context, remove the religious ritual component and think about how law enforcement would deal with a doctor who placed his mouth on a baby's penis, let alone after a surgical procedure.

Please do not allow logic and decency to fall by the wayside in the name of religious tolerance. There is no basis in Jewish law to allow this practice to continue. Any rabbi who says otherwise is engaging in sophistry and hoping that the political realities in New York City will prevent a serious legal challenge to the dangerous practice of direct MbP.

I assure you that few if any rabbis will risk prison in the name of sophist posturing. In the face of harsh legal penalties the practice of direct MbP will end.

Thank you for all your department is doing to protect the health and well being of children in our community. Please keep up these efforts and know that a silent majority supports what you are doing.

Sincerely,

Ben Hirsch

#4

Commentary regarding Proposed Amendment of Article 181

Dr. Yoram Unguru [Yunguru@lifebridgehealth.org]

Sent: Friday, July 06, 2012 1:03 PM
To: Resolution Comments
Cc: Julia Schillinger
Attachments: IC for Brit with Orogenit~1.docx (19 KB)

Dear Sir / Madam,

Attached is my commentary regarding the proposed amendment to Article 181 of the New York City Health Code.

Thank you.

Yoram

Yoram Unguru, MD, MS, MA
Division of Pediatric Hematology/Oncology
The Herman and Walter Samuelson Children's Hospital at Sinai
and
Berman Institute of Bioethics
Johns Hopkins University

Phone: (410) 601-6704
Fax: (410) 601-8390

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Comment on Proposed Amendment of Article 181 (Protection of Public Health Generally) of the New York City Health Code

A recent study conducted by the New York City Department of Health and Mental Hygiene (DOHMH) concluded that over an 11-year period, infants who underwent (Jewish) ritual circumcisions (*brith milah*) involving direct orogenital suction (known as *metzizah b'peh*) were at an increased risk of developing neonatal herpes simplex infection compared to infants where orogenital suction was not performed.¹ Of the 11 infected newborns, 2 died and 2 developed central nervous system infection. Similarly, over a 6-year period, 8 Israeli infants developed herpes simplex infection following ritual circumcision involving *metzizah b'peh*, with half experiencing long-term complications associated with herpes simplex infection.²

Metzizah b'peh is an ancient practice employed as part of the *brith milah* wherein the circumciser (*mohel*, plural: *mohelim*) sucks blood from the infant's penis. According to the Babylonian Talmud, the practice of *metzizah b'peh* was instituted as a means of wound care to protect the infant. However, due to its associated infectious risks including herpes simplex, many *mohelim* no longer perform direct orogenital suction. As early as the nineteenth century, in deference to medical evidence suggesting that *metzizah b'peh* placed infants' health at risk, Talmudic scholars argued that the practice should be stopped.³ With the development of alternative methods to control bleeding such as the use of sponges, pumps, and pipettes, these scholars stated that traditional direct orogenital suction was no longer obligatory. Presently, many *mohelim* indeed opt to use a glass pipette to suction the blood from the wound or alternatively use a gauze. Despite medical evidence supporting a direct link between *metzizah b'peh* and risk for infection, as well as pronouncements by both the Rabbinical Council of America and the Israeli Chief Rabbinate calling for alternative methods to *metzizah b'peh*, some traditional ultra-Orthodox Jewish *mohelim* continue to perform this practice and in doing so, risk the well-being of infants.

Evidence from studies conducted in the 1980s, suggests that many parents are not appropriately informed of the risks and benefits of circumcision.^{4,5} This apparent lack of parental appreciation for the risks and benefits of circumcision takes on particular significance for Jewish parents who may desire that *metzizah b'peh* be included as part of the ritual circumcision. Moreover, even if parents are aware of the infectious risks of *metzizah b'peh*, they may be unwilling or unable to consider alternative practices (including refusal) due to strong belief in, and loyalty to traditions, not to mention, the potential for pressure from within the Orthodox community to adhere to ancient customs like *metzizah b'peh*.

As a result of the increased risk of herpes simplex transmission associated with *metzizah b'peh*, the New York City DOHMH proposal requiring *mohelim* to obtain the written informed consent (permission) of parents⁶ prior to performing direct orogenital suction is ethically appropriate and in harmony with the American Academy of Pediatrics, Task Force on Circumcision Policy Statement.⁷ Although circumcision may be viewed as a religious practice, it is also a medical practice subject to state regulation, regardless of who performs it. Accordingly, local government has the authority to require explicit informed consent. Consistent with the *process* of informed consent, *mohelim* intending to perform direct orogenital suction would be responsible for

explaining the specific procedures included in ritual circumcision, the associated risks and benefits (including possible infection with herpes simplex virus and the consequences of infection) and possible alternatives.

Because infants (and most children) lack the ability to provide valid informed consent, this responsibility falls upon parents or legal guardians who are given wide latitude for decision-making. This is particularly true in the United States where parental decisions for minors may also consider religious, cultural, and ethnic factors. Medical decision-making for minors is primarily based on the best interests standard and unless shown otherwise, parents are assumed to have their child's best interest at heart and act accordingly.⁸

For a decision to be valid it must be both voluntary and informed. Therefore, before a parent can truly decide if *metzizah b'peh* is in their son's best interest they must be adequately informed. This places the onus on the *mohel* to provide information and a description of the procedure at hand, including benefits and risks, and to assess parental understanding of the information. Ideally, in order to assure that meaningful informed consent has been obtained, the consent process should provide parents with enough time to reflect upon their decision. Consequently, discussions should occur in advance of the actual *brith milah* and not on the day of the circumcision. Given the potential for serious harm should the infant develop herpes simplex infection, arguably, *mohelim* should prove that they are not capable of infecting infants by submitting to frequent and regular testing to document negative herpes simplex titers (as well as other transmittable diseases) and informed consent should be solicited from both parents. Importantly, ongoing discussions between representatives from both sides of the issue should continue and consideration should be given to include stakeholders from the Orthodox community in drafting the actual informed consent document. Acceptance of the informed consent document by the *mohelim* who will be using it will increase the likelihood that they will abide by the requirement to obtain parental consent prior to performing *metzizah b'peh*, keeping the practice in the open. While some *mohelim* might view the consent requirement as trivializing a sacred and long-standing religious tradition, requiring parental consent is one way to protect infants' rights.

The DOHMH amendment requiring parental consent for ritual circumcisions including *metzizah b'peh* is not an attempt to abolish the practice, which arguably would be virtually impossible. Rather, by requiring parental consent, the City of New York is seeking as much as possible to protect infants from potential harm. Although obtaining parental consent for ritual circumcision that includes *metzizah b'peh* is a necessary and appropriate step, some commentators have suggested that it is not sufficient.² Specifically, based both on Talmudic law and medical ethics, they contend that because *metzizah b'peh* increases the risk for potentially life-threatening complications associated with herpes simplex infection, it should not be performed. Although banning the practice of *metzizah b'peh* is not the scope of the proposed amendment, given the risk for a potentially devastating outcome, one wonders if it should not be.

In the United States, religious freedom is an inviolable tenet codified and protected under statute. However, there are limits to the extent of this freedom, especially when it comes to harm. Similarly, although parents are granted wide latitude for decision-making, parental authority is not absolute. Importantly, parents who are committed to their child's interests may not always make the best decision for them. Therefore, children need to be protected from the consequences of unwise decisions that jeopardize their well-being, irrespective of the decision-maker or his/her motives. When a parent's decision is not in a child's best interest, the doctrine of *parens patriae*,⁹ allows the state to intervene and to act as a "surrogate parent" for those who cannot care for or protect themselves. Likewise, when an intervention (or in the case of a necessary treatment, lack of an

intervention) places a child at risk of serious harm, parental and religious motivations take a backseat to the well-being of the child and should not be respected.¹⁰

Thus, while consent for ritual circumcision including *metzizah b'peh* is appropriate, it may not be sufficient.

This commentary was prepared by Yoram Unguru, MD, MS, MA, attending physician, Division of Pediatric Hematology/Oncology, The Herman and Walter Samuelson Children's Hospital at Sinai, and Berman Institute of Bioethics, Johns Hopkins University.

References

1. Blank S, Myers JE, Pathela P, et al. Neonatal herpes simplex virus infection following Jewish ritual circumcisions that included direct orogential suction – New York City, 2000-2011. *Morbidity and Mortality Weekly Report* 2012;61(22):405-409.
2. Gesundheit B, Grisaru-Soen G, Greenberg D, et al. Neonatal genital herpes simplex virus type 1 infection after Jewish ritual circumcision: Modern medicine and religious tradition. *Pediatrics* 2004;114:e259-e263.
3. Katz Jacob. Controversy over *Metzizah*, the unrestricted execution of the rite of circumcision. In: *Law in human hands – Case studies in Halakhic flexibility*. Jerusalem: Magnes Press, Hebrew University;1998:357-402.
4. Maisels MJ, Hayes B, Conrad S, et al. Circumcision: The effect of information on parental decision-making. *Pediatrics* 1983;71(3):453-455.
5. Herrera AJ, Cochran B, Herrera A, Wallace B. Parental information and circumcision in highly motivated couples with higher education. *Pediatrics* 1983;71(2):233-234.
6. Notice of Public Hearing: Opportunity to comment on the proposed amendment of Article 181 (Protection of Public Health Generally) of the New York City Health Code, found in Title 24 of the Rules of the City of New York.
7. Task Force on Circumcision, American Academy of Pediatrics. Circumcision policy statement. *Pediatrics* 1999;103:686-693.
8. Committee on Bioethics, American Academy of Pediatrics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics* 1995;95:314-317.
9. Juvenile Justice: History and Philosophy - The Origins Of The Juvenile Court. Available at: <http://law.jrank.org/pages/1489/Juvenile-Justice-History-Philosophy-origins-juvenile-court.html>. Accessed June 26, 2012.
10. Diekema D. Parental refusals of medical treatment: the harm principle as threshold for state intervention. *Theoretical medicine and bioethics* 2004;25(4):243-64.

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Friday, July 6, 2012 at 16:58:19

This form resides at
http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Consent%20for%20Non-Medical%20Circumcision

Office: DOHMH
Rule: Article 181-Consent for
Non-Medical Circumcision
First Name: Denise

Opinion on Proposed Rule: For

Comment: See attachment (labelled oral suctioning 07-06-12).
I will also cut-and-paste here.

This is one of the fields in which my being a doctor, a doctor working in public health, a mother, a Jewish person, and a feminist all work together to create a rather forceful, and learned, opinion.

I must say that I honestly thought that, after the last group of deaths a few years ago, this practice had been abandoned; how naïve of me!

I can't imagine going through 9 months of pregnancy, giving birth, and watching your child die so needlessly—all in the name of God.

I can't imagine a God—whether that God is thought of as an actual entity or as a construct within one's mind—who condones that. And, finally, I can't imagine that any sane woman would sign something that allows this procedure to be performed on her newborn son.

Oral suctioning after circumcision is such a horrible practice that I'm even troubled that we're allowing "consent" for it. I honestly wish it could be outlawed—or that the Ultra-Orthodox Jewish community that not only allows it but, apparently, calls for it would come to its senses. While I do not like that oral suctioning after circumcision is a legal procedure, I understand that legislation could be the first stop on the way to regulating the practice and, ultimately, replacing it.

I don't know how to get through to this community—a community that walls itself off from others geographically, in its use of

language, and through its fear of strangers and the world
"outside."
It so saddens me.

URL: [http://cityshare.nycnet/
portal/site/admin311/menuitem.d9316ceafeaaa929ade16410c6d2f9a0/?l
inkViewId=view media&hashId=CD7377F8DED59122D9826579FCBF87FA4D7F2
FC8&accessId=C430861FC20835CDE0440003BA045B3A](http://cityshare.nycnet/portal/site/admin311/menuitem.d9316ceafeaaa929ade16410c6d2f9a0/?linkViewId=view%20media&hashId=CD7377F8DED59122D9826579FCBF87FA4D7F2FC8&accessId=C430861FC20835CDE0440003BA045B3A)

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Wednesday, July 11, 2012 at 12:30:14

This form resides at
[http://www.nyc.gov/html/nycrules/html/proposed/comment form.shtm
1?agency=DOHMH&rule=Article%20181-Consent%20for%20Non-
Medical%20Circumcision](http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtm1?agency=DOHMH&rule=Article%20181-Consent%20for%20Non-Medical%20Circumcision)

Office: DOHMH

Rule: Article 181-Consent for
Non-Medical Circumcision

First Name: Denise

Opinion on Proposed Rule: For

Comment: I filed a comment last
week but I have added some more to it, after I realized I had
left off some of the issues that I was meaning to address--so
please see attached.

URL: [http://cityshare.nycnet/
portal/site/admin311/menuitem.d9316ceafeaaa929ade16410c6d2f9a0/?l
inkViewId=view media&hashId=6084551374C4568823F6279EC6D366FABEE05
CF5&accessId=C4915C985C510A3BE0440003BA045B3A](http://cityshare.nycnet/portal/site/admin311/menuitem.d9316ceafeaaa929ade16410c6d2f9a0/?linkViewId=view_media&hashId=6084551374C4568823F6279EC6D366FABEE05CF5&accessId=C4915C985C510A3BE0440003BA045B3A)

WHAT I SENT JULY 6, FOLLOWED BY MY ADDENDUM

This is one of the fields in which my being a doctor, a doctor working in public health, a mother, a Jewish person, and a feminist all work together to create a rather forceful, and learned, opinion.

I must say that I honestly thought that, after the last group of deaths a few years ago, this practice had been abandoned; how naïve of me!

I can't imagine going through 9 months of pregnancy, giving birth, and watching your child die so needlessly—all in the name of God.

I can't imagine a God—whether that God is thought of as an actual entity or as a construct within one's mind—who condones that.

And, finally, I can't imagine that any sane woman would sign something that allows this procedure to be performed on her newborn son.

Oral suctioning after circumcision is such a horrible practice that I'm even troubled that we're allowing "consent" for it. I honestly wish it could be outlawed—or that the Ultra-Orthodox Jewish community that not only allows it but, apparently, calls for it would come to its senses. While I do not like that oral suctioning after circumcision is a legal procedure, I understand that legislation could be the first stop on the way to regulating the practice and, ultimately, replacing it.

I don't know how to get through to this community—a community that walls itself off from others geographically, in its use of language, and through its fear of strangers and the world "outside."

It so saddens me.

ADDENDUM

I did not add when I filed the above, but would like to now, that the reason I included "feminist" in the first paragraph above is because the ultra-Orthodox are an extremely male-dominated sect and I feel it is very likely that mothers are pressured to allow this to be done to their sons.

By raising no objections—but still not advocating for oral suctioning—the women might currently be "agreeing" to let this be done. But they are not signing anything, which I think could change the dynamics.

I would like to (perhaps naively) believe that at the moment of signature—of recognizing she is risking her child's life—a feeling might come over some of these mothers and they might refuse to sign.

Along these lines, I believe that not only should consent be required but that it be required from BOTH PARENTS.

#6

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Sunday, July 8, 2012 at 16:39:02

This form resides at
http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Protection%20of%20Public%20Health%20Generally

Office: DOHMH
Rule: Article 181-Protection
of Public Health Generally

First Name: [REDACTED]

Last Name: [REDACTED]

[REDACTED]

Street: [REDACTED]
327

City: New York

State: New York

ZIP: 10116 [REDACTED]

Email: [REDACTED]

Opinion on Proposed Rule: For

Comment: We are all for updating
the obvious, INCLUDING for such consented circumcision. Thank
you.

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Tuesday, July 17, 2012 at 11:17:49

This form resides at
http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Consent%20for%20Non-Medical%20Circumcision

Office: DOHMH
Rule: Article 181-Consent for
Non-Medical Circumcision

First Name: John
Last Name: Lantos
Street: 2401 Gillham Road
City: Kansas City
State: MO
ZIP: 64108
Email: jlantos@cmh.edu
Opinion on Proposed Rule: Against

Comment: I am writing as a pediatrician, a bioethicist, a Jew and a certified mohel, to comment on the proposed amendment to Article 181 of the health code that would require mohelim to obtain parental informed consent before performing metzizah b'pei.

This seems to be an issue that calls for a judgment about the always tenuous and contentious border between church and state, between science and religion, between public health and ritual. It is not.

This is a situation in which parents and religious leaders are engaging in a practice that leads to the death of children. Religious freedom may allow adults to make martyrs of

themselves. It does not allow parents to make martyrs of their children.

The practice of metzitzah b'pei should be illegal. It is a practice that is quite controversial even among respected rabbinic authorities. It was initially instituted because it was thought to reduce the risk of infection after circumcision. Today, we understand that it increases the risk of infection and even of death. The Chief Rabbinate of Israel has stated that it is not essential for a ritual circumcision to be religiously recognized. It endangers children.

Note that forbidding metzitzah b'pei does not forbid or in any way limit the rights of parents to have their children circumcised or the right of mohelim to perform circumcisions. It only would require that circumcision be done in a way that is safe and does not expose children to life-threatening infections.

The requirement that any mohel obtain informed consent before performing metzitzah b'pei and that the informed consent form specifically state that this practice carries a risk of infection and death is a minimal infringement on religious freedom and perhaps an inadequate response to this medically dangerous procedure. But it is a step in the right direction. The children of New York City deserve this protection.

If the practice of metzizah b'pei is not made illegal, then there should be criminal penalties for any mohel who carries out the practice and who transmits herpes to a baby.

John D. Lantos M.D.

Professor of Pediatrics, University of Missouri - Kansas City
Director, Children's Mercy Hospital Pediatric Bioethics Center

#8

Proposed Amendment of Article 181

Philip L. Sherman [cantorsherman@gmail.com]

Sent: Friday, July 20, 2012 6:01 PM

To: Resolution Comments

To Whom It May Concern:

I have been a mohel for thirty-five years and have performed more than 20,000 ritual circumcisions. Below (in *Italics*) is a copy of the informed consent I give to the parents to sign before I perform the Brit Milah/Circumcision. This is after they have filled out my online Registration form that cannot be submitted until the parents confirm they have read the Informed Consent. I review the risks, benefits and alternatives with them orally and provide them with a written copy of the same also before the ceremony. (Also reprinted below is an article I wrote about MBP.)

Informed Consent

I have received, reviewed and understand the instructions given to me by the mohel, Cantor Philip L. Sherman. I am aware of the risks (bleeding, infection and/or damage to the penis), benefits (spiritual and physical), changes (appearance and sensitivity) and alternatives (not to circumcise). I am aware that cosmetic results will vary from child to child and cannot be guaranteed (i.e. adhesions, scar tissue, curvature, asymmetry, etc.). With this understanding, I consent to having the Brit Milah/Circumcision performed by Cantor Sherman.

I sincerely doubt that ultra-Orthodox mohels will ask/require their parents to read and sign an informed consent. I am one of the only Mohels who does this. It will also have to be available in numerous languages such as Yiddish, Hebrew, etc. Although I am not an attorney, I would think that any informed consent that includes "risks, benefits and alternatives" should cover the issue of MBP, i.e. the risk of infection. Additionally, if an ultra-Orthodox Jewish family wants to hire an ultra-Orthodox mohel who performs MBP, they knowingly want MBP as part of the ritual and are willing to take that risk.

The other major area of concern that may be causing the problem of herpes and other infections is a lack of proper aseptic technique on the part of many mohels. Proper sterilization of instruments (autoclaving), the wearing of gloves and even the routine washing of hands may not be observed.

While I commend any effort to safeguard the health of the children (and the mohels!) from illness, the reality is there may be no way to monitor or enforce the signing of an informed consent, let alone ensuring that all mohels sterilize their instruments properly, wash their hands, wear gloves, etc.

Last but not least, I would strongly recommend a thorough reexamination of the statistical data to determine if, in fact, there is a significant difference in the number of herpes cases in the ultra-Orthodox community as compared to the general population. If all of the ultra-Orthodox mohels are performing as many brisses as they are with MBP, it would seem that there should be many, many more cases of herpes than the few that have been reported over the past several years.

Respectfully submitted,

Cantor Philip L. Sherman, Mohe

www.emoil.com*****
Metzitzah B'Peh--Oral Law?

(Cantor Philip L. Sherman was trained as a mohel by Rabbi Yosef Hakohen Halperin in 1977 in Jerusalem, Israel. He is certified by the Chief Rabbinate of Israel and the Brith Milah Board of New York and has performed more than 20,000 circumcisions. Rev. Sherman is the Associate Hazan of Congregation Shearith Israel in New York City. This article appears in issue 6 of Conversations, the journal of the Institute for Jewish Ideas and Ideals.)

Recently I attended a Hassidic wedding and was seated next to one of my ultra-Orthodox co-religionists. During the course of the evening, it became known that I was a mohel. The question of *metzitzah* came up. I explained that I was a "modern" mohel and that I did not perform *metzitzah b'peh* (i.e. direct mouth-to-wound contact to perform *metzitzah*.) I used either a sterile plastic tube or a gauze pad to perform *metzitzah*. Having been in this situation before, I began to ask a few gentle, probing questions. "What if we know that a baby could possibly transmit a disease to a mohel or the reverse?" "What if the mohel and baby both appear healthy, yet there was something which could cause illness in either one of them?" The responses were typical. "If the baby is ill, we don't perform the Bris." "If the mohel is ill, we get a different mohel." "We've been doing *metzitzah b'peh* on thousands of babies, and they didn't get sick." I pressed on. "But what if it could be shown that there is the possibility that even one child could become ill or, God

forbid, die from something transmitted by the mohel?" There were two responses. "You'll never get them to give up doing metzitzah b'peh;" and "Today, there is no possibility of change," accompanied by a look which I can only describe as "It does not compute." In other words, in this gentleman's mind, these two concepts could not be reconciled. In all fairness, I should point out that this gentleman is a former Rosh Yeshiva and would qualify as a *talmid hakham*, a very learned individual. He insisted, however, that he was not a *posek*, a religious decisor.

What is *metzitzah*? What is its origin? What is its purpose? What is the controversy?

There are three steps to performing a *Berit Milah*. *Milah*, the excision of the foreskin; *periah*, the drawing back (or removal) of the secondary layer of skin, the mucosal membrane; and *metzitzah*. *Metzitzah* is the drawing of the blood from the wound following the ritual circumcision. The source is found in the *Mishnah*, Shabbat 19:2. "One performs all the necessary steps for the milah on Shabbat: One circumcises, draws back (or tears) the secondary layer of skin (the mucosal membrane, *periah*), suction, and bandages the wound with cumin powder." It was believed at that time that there was a positive health benefit to the child. The basic understanding of the Talmud is that *metzitzah* is not part of the actual *mitzvah* of *Berit Milah*. It is performed to prevent any health hazard to the child after the circumcision. In the Talmud, Shabbat 133b, Rav Papa states: "Any mohel who does not perform *metzitzah* creates a danger, and therefore should be removed from his post." The reason the mohel is removed from his post is not because he failed to perform *metzitzah*, but because he endangered the life of a child. The Talmud states very clearly: "Mal v'lo para, K'ilu shelo mal." "Someone who was circumcised but for whom *periah* was not performed, it's as if he was never circumcised." *Metzitzah* is not mentioned. Referring back to Rav Papa's statement, he said the mohel should be removed from his post. Rav Papa didn't say that the *milah* was invalid. In *Nedarim* 32a, we read that if the mohel forgot to perform *metzitzah*, the *milah* was valid. Maimonides reinforces this aspect of the Gemara by stating: "After [*milah* and *periah*], the mohel suction the area until blood flows from the far places (away from the wound). He does this so that the (health of the) child will not be endangered." The key question is: How does one perform *metzitzah*? There is no description or explanation of how *metzitzah* was performed. It is implicit that *metzitzah* was performed orally. In the *Shulhan Arukh*, *Yoreh Deah* 265:10, the Rama offers the following commentary: "We spit the blood into the earth." It seems that the mohel had sucked the blood into his mouth.

There were several incidents in Europe during the nineteenth century related to *metzitzah b'peh*. In 1837, Rabbi Eliezer Horowitz, the Chief Rabbi of Vienna, was consulted regarding a number of children who had become ill (infected) following their circumcisions. Some of the children had died. Dr. Wertheim of Vienna asked Rabbi Horowitz if instead of using oral suction to perform *metzitzah*, a *s'fog* (a sponge, or what today we would call a gauze pad) could be used to squeeze the blood from the circumcision site. Rabbi Horowitz, before rendering a final *pesak*, consulted his teacher, Rabbi Moshe Sofer, the Hatam Sofer who wrote:

Metzitzah b'peh is a requirement of a few of the *mekubalim* (the kabbalists). Therefore, as long as we can draw the blood out from the faraway places, it may be done in any way. We should rely on the experts regarding which technique is as effective as *metzitzah b'peh*... Even if the Talmud had stated that one must perform *metzitzah* with the mouth, *metzitzah* is not part of the *mitzvah* of *milah*, i.e. it is done to prevent danger to the child. According to the halakha, if one circumcises and does *periah* but neglects to perform *metzitzah*, he has completely fulfilled the *mitzvah*." (The letter of the Hatam Sofer was first printed in 1845 by Menachem Mendel Stern in the periodical *Kochvei Yitzhak*. The ruling is also quoted in Rabbi Moshe Bunim Pirutinsky's book, *Sefer haBerit*.)

The Hatam Sofer continued by saying that applying cumin powder is also listed in the *Mishnah*, yet no one argues that only cumin must be used. Since talmudic times we have found more effective ways of bandaging and achieving hemostasis. This is why there is no halakhic requirement to use cumin powder. The Hatam Sofer argued that based on the *Mishnah*, no one could say that the mouth alone had to be used to draw the blood out. (The background to these events is the religious battle between the Orthodox and the Reform movements in Germany. During this time, the Reformists were attempting to change and or abolish certain religious practices. *Milah*, or anything related to it, was high on their agenda.)

In 1888, Rabbi Samson Raphael Hirsch and Rabbi Azriel Hildesheimer, the chief rabbis of Frankfurt and Berlin respectively, publicized a halakhic ruling that *metzitzah* could be performed using a new instrument, a glass tube. It could be placed over the circumcision site and the mohel could use the tube to suction the blood with his mouth without any direct physical contact. This method seemed superior to the Hatam Sofer's suggestion of a cotton sponge. It protected the health of infant and the mohel. When I was trained as a mohel, my teacher, the former Chief Mohel of Jerusalem, Rabbi Yosef Hakohen Halperin of blessed memory, set up his instruments, which included a glass tube for *metzitzah*. He took a small wad of cotton and inserted it in the tube to prevent the blood from flowing up the tube and entering the mouth.

Rav Yosef Dov Soloveitchik reported that his father, Rav Moshe Soloveitchik, would not permit a mohel to perform *metzitzah b'peh* with direct oral contact, and that his grandfather, Rav Chaim Soloveitchik, instructed mohalim in Brisk not to do *metzitzah b'peh* with direct oral contact, either.

Another element of concern is the elevation of *metzitzah b'peh* from an ancillary step not even considered part of the *mitzvah*, to a "halakha [*Moshe miSinai*," a law transmitted by Moses on Mount Sinai. The goal is to put *metzitzah b'peh* out of reach of any change. I have spoken to several ultra-Orthodox individuals, mohels and non-mohels, who have told me that a number of their rabbis have issued rabbinic responsa indicating that if *metzitzah b'peh* is not performed, the *berit milah* is invalid!

Five years ago, there was a public controversy related to *metzitzah b'peh*. An Orthodox mohel had allegedly transmitted the herpes simplex virus to a number of infants resulting in illness and death. The New York City Department of Health ordered the mohel to stop performing *metzitzah b'peh*. The Department of Health also recommended that *metzitzah b'peh* not be performed. Needless to

say, the outcry from the ultra-religious Jewish community was great. This was a religious matter in which the Department of Health had no business getting involved! They also disputed the data connecting herpes simplex to metzitzah b'peh. Finally, there were non-religious Jews in the Department of Health who, according to the ultra-religious Jewish response, wanted to stop metzitzah b'peh and ultimately ban Berit Milah altogether.

This adverse publicity had an unintended affect in the non-religious Jewish community and in the non-Jewish world. Non-religious Jews now associated Berit Milah with illness and death, and instead of having a berit performed by a mohel, they opted to have their children circumcised in the hospital. As for the non-Jewish world, explaining metzitzah b'peh and not have it sound like child abuse was virtually impossible. This was publicity that we did not need.

The prime directive of the mohel is to safeguard the health of the child. If there is the slightest suspicion that the child is not well, we delay the berit. A mohel must also follow the strictest aseptic techniques. His instruments must be autoclaved (heat steam sterilized). Gloves must be worn, the mohel should use disposable blades and so on. I have been told by several of my Hassidic colleagues that they can't wear surgical gloves because it would be looked down upon by the people in their communities. How many times have I seen the mohel place his instruments in a stainless steel tray and pour alcohol on them to soak them prior to the milah; yet certain viruses won't be killed with alcohol alone. I even saw a mohel wearing the izmel (knife) around his neck on a chain! It wasn't until the mid- to late eighteenth century that it was discovered that washing one's hands could prevent the spread of diseases. And at the time, this concept was met with great hostility. Today, this is common knowledge and common sense. There are many ways that a mohel can spread illness to an infant, such as by using dirty or improperly cleaned instruments or not wearing gloves. And now, by performing metzitzah b'peh, we are placing the mouth, the most contaminated part of the human body, on an open wound.

Another very prominent issue related to Berit Milah is jaundice. Jaundice is a yellowish discoloration of the skin caused by increased levels of bilirubin. In the time of the Talmud (and still today), diagnoses were made by using visual methods. If the tint of baby's skin was blue or green or yellow, it indicated that the child had a particular health condition often resulting in the postponement of the berit. Today, we know that jaundice in newborns is normal. We have ways of measuring the bilirubin levels to determine if the jaundice is physiological (normal) or pathological (abnormal). Therefore, if the jaundice is normal, there is no need to postpone the berit. The baby is healthy and the berit may proceed. If a physician determines that the jaundice level is too high and recommends that the berit be delayed, the mohel must follow the directive of the physician. Conversely, the physician may opine that the berit may proceed, but the mohel may overrule the doctor on grounds and delay the berit. Again, every precaution is taken to safeguard the health of the child but we now know that jaundice is normal and should not prevent the berit from taking place. This concept is generally not accepted in the ultra-Orthodox community. If the baby is jaundiced, the berit is delayed until the jaundice clears up. Period.

In my opinion, the greatest difficulty as it relates to some in the ultra-Orthodox community is to convince them that bacteria and viruses exist, that they cannot be seen and they can cause illness or death. It is possible that a mohel (or baby) can carry a virus (herpes simplex, HIV, etc.), be asymptomatic and still transmit a disease that could result in illness or death. Both individuals appear healthy, yet one can infect and therefore, harm the other. This is clearly a matter of *sakanat nefashot*, danger to life. Knowing what we know today about the transmission of diseases, a mohel who performs metzitzah b'peh (i.e. direct oral contact) is potentially endangering his health, the health of the child, and the health of the other babies with whom the mohel will have contact that day or that week.

The other element of this discussion is that the ultra-Orthodox community does not recognize the opinions of secular individuals or government authority in relation to religious matters. Not long after the metzitzah scandal in 2005, I was a guest on a radio program pitting me, a modern mohel, against a representative of the ultra-Orthodox community. The topic was metzitzah. Certain things became very clear to me as a result of that radio program. The ultra-Orthodox community does not recognize the opinion or authority of anyone who is not part of their community. When I asked what would happen if it could be shown that a child could become ill, or God forbid, die as a result of a mohel transmitting a communicable disease, the response was that "The people in our communities don't get those diseases. Our people are holy;" and "We have been performing metzitzah b'peh on thousands of babies. How come they did not get sick?" Change, in this case, has been rendered virtually impossible.

For those who demand, insist, or require metzitzah b'peh, it can be performed orally by using a sterile glass or plastic tube. One uses the mouth, yet there is no direct contact. One may also follow the ruling of the Hatam Sofer and use a gauze pad. Metzitzah is performed and the health of the mohel and baby is protected. The custom is fulfilled.

Maimonides wrote "It is impossible to restore the lost life of a Jewish child" (Hilkhot Milah 1:18). This was written to allow the delaying of a berit on a child who is not considered healthy. Similarly, nothing done during a berit should allow the possibility that harm will come to the child, whether it is by unclean hands, improperly sterilized instruments or direct oral contact through metzitzah. Today, Rav Papa's statement might be modified to read, "Any mohel who performs metzitzah b'peh creates a danger, and therefore should be removed from his post." Knowing what we know today about the transmission of diseases, every precaution must be taken to safeguard the health of the child and the mohel.

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Analysis of the Statistics in the Documents of the DOHMH and CDC Concerning
Circumcision with MBP

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There are two documents, one of the City of New York, Department of Health and Mental Hygiene (DOHMH) and the other of the CDC, describing the statistical evidence that Metziza B'peh (MBP) is a risk factor for neonatal herpes. It is the purpose of this memorandum to summarize my evaluation of the statistical analysis that is the basis for the conclusions of these documents.

The first document is "An open letter to the Jewish community from the New York City Health Commissioner", dated December 13, 2005. It reports that in the 2-year period 2003-2004 there were three infants who developed neonatal herpes following MBP in circumcisions performed by a particular mohel. Then it was noted that on the basis of the given incidence of this disease in NYC and the number of circumcisions performed annually by a given mohel that the odds that a given mohel would be associated with three cases in a 2-year period were 1 out of 6.9 million. The unsaid implication of the latter statement was that such an association could not have happened by chance and so there was necessarily a causal relation between the MBP done by this mohel and the infection of the three babies. In particular, the letter of the DOHMH clearly meant to convey the impression that the odds were 6.9 million to 1 that MBP was the cause of the infection. The mathematical calculations used to derive these odds are faulty and the result is misleading and false.

As of 2005 the records of the DOHMH contained only this one instance of a NYC mohel ever being associated with three cases of herpes in a 2-year period. This fact, which is crucial to any analysis of the data relating herpes to MBP, was omitted by the DOHMH in its calculation. The proper odds that should have been calculated in order to take this into account are the odds that:

There was at least one mohel among those practicing MBP in NYC who had three post-circumcision herpes cases in a 2-year period over a span of a specified number of years.

The odds for this more comprehensive event are far larger than those of the event considered by the DOHMH. It will be shown that the true odds are 1 out of several hundred, and such an event could have reasonably happened by chance.

Another problem with this first document is its exaggeration of the number of cases employed in the analysis. The document states that the odds are "based on the estimated average of 30 annual cases of neonatal herpes infections in New York City." In response to my FOIL request for the work

sheets of the DOHMH, I found in them that the odds were calculated on the basis of only three annual cases, namely, those infections that were acquired after birth, and the other 27 cases were irrelevant to the calculation because the infections were acquired from the mother before or during birth. In the absence of this information about the very small number of cases, a reader of the document could have been misled about the reliability of the claim of the odds, since there is a significant difference between the reliabilities of studies based on averages of 3 and 30 cases, respectively.

Another important omission from the document is the fact that the three cases attributed to the single mohel included a set of twins. While the DOHMH counted these as two separate cases in the total of 3, the mathematical theory underlying the calculations does not permit the inclusion of both cases because they are not "statistically independent" in the sense that infection of one twin increases the probability that the infection will appear in the other one by transmission through a common caregiver or through the mother who changed the diaper and circumcision wound dressing. Consequently, for the purpose of the statistical analysis, the claim that the mohel infected 3 in a 2-year period is unsupported, and must be replaced by the claim of 2 infections in a 2-year period.

This leads to further objections to the odds of the DOHMH. In the records of the DOHMH, not only were there no other instances up to and including 2005 of any mohel in NYC having an association with 3 herpes cases in a 2-year period, but there were no other instances of any having at least 2 cases. In view of the fact that not more than 2 cases can be attributed to the mohel cited by the DOHMH, the comprehensive event whose odds should be calculated is

"There was at least one mohel among those practicing MBP in NYC who had at least two post-circumcision herpes cases in a 2-year period in a span of a specified number of years."

The DOHMH assumed in its analysis that a given mohel performs 200 circumcisions each year, and the incidence of neonatal herpes acquired after birth in NYC is 24 per million live births. The CDC report estimates that there are 4,000 circumcisions with MBP each year. It follows that the estimated number of mohelim is $4,000 / 200 = 20$. Based on these estimates, I calculated the probabilities and corresponding odds for the event defined above:

time span (years)	probability	odds
2	.00092	1 / 1,087
3	.00182	1 / 549
4	.00273	1 / 366
5	.00430	1 / 233.

Since the reporting of neonatal herpes was not mandatory in NYC before 2006, it is possible that there were unreported cases of 2 infections associated with a single mohel in a 2-year period, but the table of odds is intended merely to illustrate the possibilities over a span of at most five years. In any case these

plausible odds demonstrate that the "1 out 6.9 million odds" of the DOHMH is at best a gross exaggeration.

The second document is the CDC publication,

Neonatal Herpes Simplex Virus Infection Following Jewish Ritual Circumcisions that Included Direct Orogenital Suction - New York City, 2000-2011, June 8, 2012/61(22); 405-409.

The main point of this report is that MBP increases the risk of neonatal herpes by a factor of 3.4. In other words the chance that a baby will contract this disease is 3.4 times greater than normal if MBP is performed. While the title of the report implies that the research covers an 11-year period, its main conclusion about the factor 3.4 is based only on 5 cases in the period from April, 2006 to December, 2011.

The specific data is as follows. Of the estimated 20,493 male infants who were circumcised with MBP, there were 5 who contracted herpes. The risk is $5/20,493 = .000244$. Of the estimated 352,411 male infants (Jewish or not) who did not have MBP or even a circumcision, there were 25 who contracted herpes. The risk is $25/352,411 = .0000709$. Therefore, the "risk ratio" is $.000244 / .0000709 = 3.4$.

Since 3.4 is an only an estimate of the true risk ratio - not necessarily the true risk ratio - it is the convention is statistical analysis to report a *confidence interval* for the true value based on the estimate. The report accordingly furnishes the interval from 1.3 to 9 as a "95%" confidence interval. Its meaning is: The interval has been constructed from the data is such a way that with probability 0.95 such an interval will include the value of the true risk ratio. In other words our degree of confidence, expressed in terms of a probability, that the true risk ratio is between 1.3 and 9, is 95%. It follows, in particular, that our confidence of 95% limits us to the claim that the risk ratio is at least 1.3, or, equivalently, that the chance of herpes is increased by at least 30%.

Many, if not most, research workers are not satisfied with 95% confidence intervals and instead demand 99% confidence intervals. Consequently confidence intervals of both 95% and 99% are often reported for the same data, and the reader has the choice of using one or the other. The CDC left out the 99% confidence interval, and so I did the calculation myself, and found that the 99% confidence intervals is the interval from 0.96 to 12.04. This implies that we can be 99% confident only of the claim that the risk ratio is at least 0.96 which in turn implies that the risk ratio might be in fact equal to 1, which signifies that *the risk of herpes with MBP is the same as the risk without MBP*. This contradicts the primary claim of the CDC report that MBP is a risk factor.

It is my opinion that the statistical analysis of the DOHMH and the CDC described in these publications are faulty to the extent that they do not prove that MBP is a risk factor for neonatal herpes.



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JULY 23, 2012

BY ELECTRONIC MAIL

New York City Department of Health & Mental Hygiene
Board of Health, Office of the Secretary to the Board
2 Gotham Center, 14th Floor, Room 14-15, Box 31
Long Island City, New York 11101

Re: Consent for Non-Medical Circumcision (Health Code Article 181)

Dear Sir or Madam:

Please find attached the comments of the International Bris Association on the New York City Department of Health and Mental Hygiene's proposal to amend Health Code Article 181 to add a new provision, § 181.21, regulating ritual circumcision. As explained in the attached comments, the International Bris Association strongly opposes the proposal, believes that it violates the First Amendment to the United States Constitution in two independent respects, and accordingly urges the Department to reject it. Thank you for your consideration.

Sincerely,

Rabbi Levi Y. Heber
Director, International Bris Association

"Just as he has entered this covenant, may he enter a life of Torah, marriage and good deeds."

International Bris Association
Comments Opposing Proposed Restriction of *Metzitzah B'peh*

Ritual circumcision, including *metzitzah b'peh*, has been performed for thousands of years with a remarkable safety record.

- No case of neonatal herpes has ever been proved, through definitive DNA fingerprinting, to have resulted from transmission through *metzitzah b'peh*.
- *Mohelim* are carefully trained to ensure a sterile environment for circumcisions, including by using antiseptic mouthwash prior to performing *metzitzah b'peh*.
- Oral herpes is transmitted significantly more readily by symptomatic individuals, but no *mohel* exhibiting such symptoms would ever perform *metzitzah b'peh*.
- Data from Israel show that, despite 15,000-20,000 circumcisions annually that involve *metzitzah b'peh*, there have been only 4 confirmed cases of neonatal herpes over the past 5 years, and 2 of those involved mothers who were diagnosed with oral herpes or strongly suspected to have it. This equates to a *lower* incidence rate than for infants in New York who do *not* receive *metzitzah b'peh*.

The proposed regulation is premised on deficient scientific data, erroneous statistical assumptions, and dubious medical conclusions.

- The study upon which the regulation is premised found 5 cases of neonatal herpes allegedly associated with *metzitzah b'peh* (out of 84 total reported cases during the study period). But only 2 of those cases were "confirmed" to have involved *metzitzah b'peh*. In one of those 2 cases, symptoms did not appear until 20 days after the circumcision, even though the accepted incubation period for neonatal herpes is 2-12 days. And 2 of the 5 cases were *siblings*, which strongly suggests a common household source, rather than a link to ritual circumcision.
- Moreover, in estimating the rate of neonatal herpes among infants who underwent *metzitzah b'peh*, the study assumed that approximately 20,000 infants underwent this procedure during the study period. But other, more knowledgeable estimates have put the figure at closer to 30,000, which would dramatically reduce the relative significance of even the 5 cases found by the study.
- The far more likely cause of neonatal herpes is contact with a symptomatic family member or caregiver. Indeed, in one of the 5 cases cited by the study, it turned out that the infant's sibling was suffering from oral herpes and had shared his pacifier with the infant prior to the onset of symptoms. Unfortunately, the blind focus on *metzitzah b'peh* has distracted from these other, more likely causes.

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JULY 23, 2012

BY ELECTRONIC MAIL

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Long Island City, New York 11101

Re: Consent for Non-Medical Circumcision (Health Code Article 181)

Dear Sir or Madam:

On behalf of the International Bris Association (“IBA”), we write concerning the New York City Department of Health and Mental Hygiene’s proposal to amend Article 181 of the New York City Health Code to add a new § 181.21, which would impose new regulations restricting ritual circumcision. IBA strongly objects to the proposal, which would interject the government into a venerable religious ritual that boasts an incredible safety record, and would conscript religious actors into a misguided government effort to spread undue fear about its consequences. Indeed, for these reasons, the proposal is not just bad public policy, but it also runs afoul of both the Free Exercise Clause and the Freedom of Speech Clause of the First Amendment to the United States Constitution. Especially in light of the flawed evidence upon which the proposal is premised, the Department’s effort to impose unprecedented government restrictions upon a religious practice that has been safely performed for thousands of years would not survive the rigorous judicial scrutiny that courts would apply if the regulation were passed.

Section 181.21, by design, would target for regulation the practice known in Hebrew as *metzitzah*, one step in the ancient Jewish ritual of *bris milah*, or circumcision. The circumcision ritual is one of the most basic, most important, and most widely practiced Jewish laws; its origin is traced to the Biblical patriarch Abraham, who was divinely commanded to circumcise himself to symbolize his covenant with God. See Book of Genesis, 17:7. Following his example, the Jewish people were subsequently commanded to circumcise every male baby on the eighth day after his birth. See Book of Leviticus, 12:2. For thousands of years since, Jews around the world have adhered to this ritual requirement, including its final step—*metzitzah*—in which suction is used to draw blood from the circumcision wound. See Babylonian Talmud, Tractate Shabbat, at 133b. Traditionally, *metzitzah* was performed using direct oral suction—*metzitzah b’peh* (“MBP”)—and this method remains in widespread use in Hasidic, Orthodox, and ultra-Orthodox Jewish communities. Indeed, many prominent rabbinic authorities maintain that MBP is the *only legitimate way* to properly complete the circumcision in accordance with Jewish law.

If § 181.21 is promulgated, it would be a wholly unwarranted regulation and restriction of MBP by secular authorities. To perform this traditional ritual, the *mohel* (the individual who performs the circumcision) would first be forced to tell the parent of the child being circumcised

that MBP “exposes the infant to the risk of transmission of herpes simplex virus infection and other infectious diseases.” § 181.21(b). The parent would then be required to record in writing his or her consent to the procedure, “in a form approved or provided by the Department.” *Id.*

For reasons explained further below, this proposed regulation is unconstitutional. *First*, the regulation singularly targets for unique burdens an exclusively religious ritual, and therefore presumptively violates the Free Exercise Clause of the First Amendment. Such a regulation could be sustained only on the most compelling showing of necessity by the Department, a showing that the scant, inconclusive, and (at best) debatable data on which the regulation is premised do not begin to satisfy. *Second*, by requiring practitioners of a religious ritual to engage in specified disclosures, the regulation *compels* speech, and that is likewise incompatible with basic First Amendment principles. Requiring health warnings in the context of a religious ritual, as opposed to a commercial transaction, would be a novel and substantial offense against the First Amendment—especially because the small risks allegedly posed by MBP remain fiercely disputed by medical doctors, far afield from the type of purely factual, uncontroversial claims that courts have permitted the government to mandate in other settings.

I. Free Exercise.

A. To protect the fundamental American value of religious liberty, the Framers of the Bill of Rights provided, in the First Amendment, that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof.” U.S. Const. Amdt. I (emphasis added). The Free Exercise Clause has long been understood to restrict action by state and local governments as well, through operation of the Fourteenth Amendment. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940).

The free exercise of religion includes, of course, both “freedom to believe and freedom to act.” *Id.* Religious liberty would mean nothing if the government could readily forbid adherents of a faith to engage in the religious acts and rituals that the faith prescribes. At the same time, religious practitioners are not constitutionally entitled to exemptions from every otherwise-applicable law that incidentally burdens religious exercise. The Supreme Court has balanced these competing concerns: While the First Amendment is not “offended” by “merely the incidental effect of a generally applicable and otherwise valid provision,” *Employment Div., Dep’t of Human Servs. of Oregon v. Smith*, 494 U.S. 872, 878 (1990), a law must satisfy the most demanding judicial inquiry when it has the “impermissible object” of targeting a religious practice, exclusively pursuing “conduct motivated by religious beliefs,” *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 524 (1993). Accordingly, the Court in *Smith* upheld a neutral, generally applicable prohibition on possession of controlled substances, even though members of a certain faith believed that the ingestion of hallucinogenic drugs was prescribed by their religion. *See Smith*, 494 U.S. at 878-82. But the Court in *Lukumi* invalidated city ordinances regulating ritual slaughter, where “almost the only conduct subject to” the ordinances was “the religious exercise” associated with the Santeria faith. *Lukumi*, 508 U.S. at 536. Such ordinances, attempting “to target” the Santeria church’s practice of ritual animal slaughter, were neither “neutral” nor “generally applicable.” *Id.* at 534, 542-43. In short, “a

court must ask whether a law's impact on religious practices is merely incidental (in which case the regulation is neutral) or intentional and targeted (in which case it is not)." *Stormans Inc. v. Selecky*, 2012 U.S. Dist. LEXIS 22370, at *43 (W.D. Wash. Feb. 22, 2012).

Even if a regulation is neutral and generally applicable, it is subject to a higher standard of judicial review if it implicates *other* constitutional rights or interests as well. See *Smith*, 494 U.S. at 881 ("The only decisions in which we have held that the First Amendment bars application of a neutral, generally applicable law to religiously motivated action have involved not the Free Exercise Clause alone, but the Free Exercise Clause in conjunction with other constitutional protections"). Thus, for example, the Supreme Court recently invalidated, on a unanimous vote, federal anti-discrimination laws as applied to the termination of a church's ministerial employee. *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 132 S. Ct. 694, 706 (2012). The Court explained that, though the employment discrimination rules were undoubtedly neutral and generally applicable, their application in the church setting also raised concerns under the First Amendment's Establishment Clause, by authorizing "government interference with an internal church decision." *Id.* at 707; see also *Smith*, 494 U.S. at 877 (reiterating that First Amendment precludes government from "lend[ing] its power to one or the other side in controversies over religious authority or dogma"). Likewise, *Smith* observed that a law that burdened religion and also implicated the "freedom of speech and of the press" would warrant more demanding judicial scrutiny. *Smith*, 494 U.S. at 881.

Laws that burden religious exercise but are not neutral and generally applicable (or that are neutral and generally applicable but also implicate other constitutional rights) are subject to a form of heightened judicial review known as strict scrutiny. See *Lukumi*, 508 U.S. at 546 ("A law burdening religious practice that is not neutral or not of general application must undergo the most rigorous of scrutiny."); see also *Smith*, 494 U.S. at 881-82. Strict scrutiny is "the most demanding test known to constitutional law." *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997). It requires the government to demonstrate a "compelling interest" justifying its regulation, and to show "that it has adopted the least restrictive means of achieving that interest." *Id.* The harms that the government seeks through its regulation to address must be "real, not merely conjectural," and the government must establish that its law "will in fact alleviate these harms in a direct and material way." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 664 (1994). Moreover, to pass strict scrutiny a law cannot be underinclusive in targeting the social ill at issue, because "a law cannot be regarded as protecting an interest 'of the highest order' ... when it leaves appreciable damage to that supposedly vital interest unprohibited." *Florida Star v. B.J.F.*, 491 U.S. 524, 541-542 (1989) (Scalia, J., concurring in part and concurring in judgment) (citation omitted). To the contrary, "[w]here government restricts only conduct protected by the First Amendment and fails to enact feasible measures to restrict other conduct producing substantial harm or alleged harm of the same sort, the interest given in justification of the restriction is not compelling." *Lukumi*, 508 U.S. at 546-47.

Given these demanding requirements, it is no surprise that "[o]nly rarely are statutes sustained in the face of strict scrutiny"; the inquiry "is strict in theory but usually fatal in fact." *Bernal v. Fainter*, 467 U.S. 216, 219 n.6 (1984) (internal quotation marks omitted). As the

Supreme Court emphasized in *Lukumi*, “[a] law that targets religious conduct for distinctive treatment or advances legitimate governmental interests only against conduct with a religious motivation will survive strict scrutiny only in rare cases.” 508 U.S. at 546.

B. The Department’s proposed regulation, § 181.21, would be subjected to strict scrutiny if challenged in court. Because it exclusively targets a religious practice for special regulation, it is not a neutral law of general applicability along the lines of the prohibition on drug possession at issue in *Smith*. Moreover, the proposed regulation raises the specter, incompatible with the Establishment Clause, of the secular government’s interference—and taking of sides—in an intra-faith doctrinal dispute over the acceptable means of performing the required *metzitzah* procedure; and also unjustifiably infringes on the freedom of speech of *mohelim* by conscripting them to deliver the Department’s disputed message.

Most importantly, § 181.21 cannot be described in any sense as a “generally applicable” law. The regulation is, by its very terms, limited to the context of “direct oral suction *as part of a circumcision*.” (emphasis added). This practice is exclusively a religious one; MBP is a Jewish ritual not practiced by anyone else. Indeed, the Department’s statement of basis and purpose for the regulation expressly explains that the proposal is designed to target the “practice known as *metzitzah b’peh*.” The Department thus effectively concedes that its regulation “refers to a religious practice without a secular meaning” and therefore “lacks facial neutrality.” *Lukumi*, 508 U.S. at 534. As in *Lukumi*, the religious ritual is “the only conduct subject to” the regulation, which was “drafted ... to achieve this result.” *Id.* at 536. Further, the Department’s deputy commissioner for disease control described the regulation as an effort to “regulat[e] how part of a religious procedure is done.” Sharon Otterman, *City Urges Requiring Consent for Jewish Rite*, N.Y. TIMES, June 12, 2012, at A23. Such “contemporaneous statements made by members of the decisionmaking body,” which were present in *Lukumi* also, confirm that the *object* of the regulation (not simply its incidental effect) is to regulate a religious practice. *Id.* at 540. Finally, there is contextual evidence that the proposal represents “an escalation of the city’s efforts to curtail the ancient Jewish procedure of *metzitzah b’peh*,” Otterman, *City Urges, supra* (emphasis added), just as the slaughter ban in *Lukumi* was, in context, understood to be an effort “to suppress Santeria religious worship,” 508 U.S. at 540. In short, § 181.21 is not a generally applicable, across-the-board regulation that happens to impose an incidental burden on Orthodox Jews, and from which those Jews seek an exemption; it is, rather, a narrow rule that exclusively and transparently targets, in operation and by design, a uniquely religious ritual. If any law is “intentional and targeted,” *Stormans*, 2012 U.S. Dist. LEXIS 22370, at *43, it is this one.

To be sure, the Department claims that its purpose in proposing § 181.21 is not to undermine Jewish ritual practice, but rather to prevent the transmission of disease. But, whether that is true or not, it does not render the regulation “generally applicable.” As Justice Scalia, the author of *Smith*, explained in *Lukumi*, it does not matter “that a legislature consists entirely of the purehearted, if the law it enacts in fact singles out a religious practice for special burdens.” 508 U.S. at 559 (Scalia, J., concurring in part and in the judgment). And § 181.21 assuredly does so.

Were there any doubt about the Department's burden of satisfying demanding judicial scrutiny of this regulation, it is resolved by the fact that § 181.21 also implicates other constitutional concerns. *First*, by attempting to regulate the process by which the *mohel* performs religious duties, § 181.21 raises Establishment Clause concerns. That Clause, according to the Supreme Court, is intended to prevent "the intrusion of either" religious or secular authorities "into the precincts of the other." *Lemon v. Kurtzman*, 403 U.S. 602, 614 (1971). But § 181.21 would inherently and necessarily require governmental supervision of the performance of religious acts, fostering the very "entanglement with religion" that the Clause aims to foreclose. *Id.* at 615; *see, e.g., Larkin v. Grendel's Den, Inc.*, 459 U.S. 116, 125 n.9 (1982) ("[A]n assumption that the Beverages Control Commission might review the decisionmaking of the churches would present serious entanglement problems."). Indeed, the regulation of MBP—especially when seen in light of the pamphlets recently published by the Department, urging parents and *mohelim* to follow the "religious authorities within the Jewish faith" that "approve different means" of complying with the *metzitzah* requirement, *see Before the Bris: How to Protect Your Baby Against Infection* (N.Y.C. Dep't of Health & Mental Hygiene 2012)—can be seen as the Department's improper attempt to choose sides in an ongoing intra-faith dispute over religious law. *See Smith*, 494 U.S. at 877 (observing that government cannot "lend its power to one or the other side in controversies over religious authority or dogma"); *cf. Commack Self-Service Kosher Meats, Inc. v. Weiss*, 294 F.3d 415 (2d Cir. 2002) (invalidating law requiring that food labeled "kosher" be prepared in accordance with Orthodox requirements, because it "[o]ok] sides in a religious matter, effectively discriminating in favor of the Orthodox Hebrew view of dietary requirements"). *Second*, as explained below, by compelling the *mohel* to issue specified health warnings about MBP, the regulation infringes the *mohel's* free speech rights under the First Amendment, *see Smith*, 494 U.S. at 881—which is, indeed, an additional and independent basis to invalidate the regulation. *See infra* at 9-15.

In sum, as a regulation that openly targets an exclusively religious practice, and simultaneously intervenes in a dispute over religious doctrine and violates the free speech rights of religious actors, there is no question that § 181.21 must be subjected to strict scrutiny. Indeed, the Department's own officials have properly conceded as much. *See Otterman, City Urges, supra* (quoting deputy commissioner for disease control as acknowledging that regulation "will be heavily scrutinized" and that Department will need to show "compelling interest").

C. On the present record, § 181.21 cannot come close to satisfying strict scrutiny, "the most demanding test known to constitutional law." *City of Boerne*, 521 U.S. at 534.

1. To be sure, the government has a compelling interest in protecting children, including from transmission of disease. But the government cannot regulate ritual circumcision in an effort to prevent the transmission of neonatal herpes unless and until it can persuasively show that the religious practice actually causes that harm. In other words, the government cannot simply assert a risk of communicable disease; rather, it must demonstrate to the court's satisfaction that the harms it seeks to address through the regulation are "real, not merely conjectural." *Turner*, 512 U.S. at 664; *see also Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (requiring government to "demonstrate that the harms it recites are real").

With respect to MBP, the Department has not done so. It would be straightforward to use a scientific testing method known as DNA fingerprinting to ascertain whether an infant with neonatal herpes was infected by a *mohel* who performed MBP. Indeed, such a process has been used by other studies of the herpes simplex virus (HSV). *Yet not a single case of HSV has ever been proved through DNA technique to have been caused by transmission through MBP.* (See Aff. of Daniel S. Berman, M.D. (“Berman Aff.”), attached as Exh. A, ¶ 19.) The reason is simple: *Mohelim* are trained to use effective sterilization techniques, including rinsing with antiseptic mouthwash before performing MBP. (See Affidavit of Rabbi Levi Y. Heber (“Heber Aff.”), attached as Exh. B, ¶¶ 4, 8.) Such methods have been proven to eliminate, for a sufficient period of time, any traces of HSV from the saliva of even *symptomatic* carriers of the disease, see, e.g., Meiller *et al.*, *Efficacy of Listerine Antiseptic in reducing viral contamination of saliva*, 32 J. OF CLINICAL PERIODONTOLOGY 341-46 (2005), and thus surely would suffice for *mohelim*, who would at worst be *asymptomatic* (see Heber Aff., ¶ 8) and thus far less likely to transmit it in any event (see Berman Aff., ¶ 18).

Rather than relying on DNA fingerprinting that could definitively link MBP to the transmission of HSV in a particular case, the Department relies instead on its alleged discovery of “11 cases of laboratory-confirmed herpes simplex virus infection in male infants following circumcisions that were likely to have been associated with direct oral suction.” These cases are analyzed in a recent report published by the Centers for Disease Control and Prevention (CDC) in its Morbidity and Mortality Weekly Report, entitled *Herpes Simplex Virus Infection Following Jewish Ritual Circumcisions that included Direct Orogenital Suction – New York City, 2000–2011*, which concludes that the risk of neonatal herpes is 3.4 times higher for infants who have undergone MBP relative to those who have not. The data, estimates, assumptions, and conclusions of that report, however, are deeply flawed, as elaborated in detail in the affidavit of Dr. Daniel S. Berman, an infectious disease specialist who has carefully studied the issue.

The report’s approach is to compare, based on the number of reported cases of HSV-1 (the type of HSV at issue), its rate of incidence among male infants who did *not* undergo MBP to the rate among those who did. The report, however, makes material errors at each stage.

First, in calculating the baseline, expected rate of incidence to be 7.1 cases of HSV-1 per 100,000 births, the report relies upon the number of cases of HSV-1 reported to the Department from 2006 through 2011. That calculation produces the *diagnosis* rate, however, not the rate of *actual incidence*. A case of HSV-1 would only have been reported if the medical examiner suspected, and then tested for, HSV-1; as a result, some cases likely were missed—a point conceded in another study published just last year in the journal *Sexually Transmitted Diseases*. (See Berman Aff., ¶ 14 & Exh. 1, at 6.) Although the CDC report also relied on reported cases to determine the rate of incidence among infants suspected to have undergone MBP, there is reason to believe that diagnosis in that situation would be *more likely*—because of the heightened awareness over the last five years to the possible transmission of HSV through MBP. Although the CDC report could have accounted for this likely bias by taking into account the number of diagnostic tests ordered for male infants suspected to have had MBP, compared to the number of tests ordered for male infants who were not, the report does not do so. (See Berman Aff., ¶ 14.)

Second, the report then calculated the number of projected cases of HSV-1 among male infants who underwent MBP during the five-year period of study. To do so, the report estimated the total number of infants in that category at 20,943, based on statistics from a national census of Jewish day schools and assumptions about the number of Jewish infants who undergo MBP. Both the estimate and the assumptions are highly questionable. A new population study by the UJA Federation of New York reports high birthrates among Orthodox and ultra-Orthodox families in New York City over the last few years. Moreover, the CDC report's estimates of the percentage of Jewish male infants who receive MBP also appear too low, as it includes only 50% of the yeshiva population and *nobody* outside the ultra-Orthodox community. A position paper published by the Interministerial Oversight Committee of *Mohelim* of the Israeli Chief Rabbinate and Ministry of Health estimates the total number of MBP circumcisions in New York City over the period at issue to be approximately 30,000—about 50% higher than estimated by the CDC. For both reasons, the CDC report's estimate of the cases of MBP—and thus of the number of expected cases of HSV-1 among that group—is far too low. (See Berman Aff., ¶ 15.)

Third, the report treats five cases, over the five-year period, as associated with MBP, and uses those cases to establish the actual incidence rate of HSV-1 among male infants who undergo MBP. But there are several problems with this computation. For one, only *two* of those cases were “confirmed” to have involved MBP at all; the other three are listed as only “probable” cases of MBP. (See Berman Aff., ¶ 12.) There is also reason to doubt, in light of further investigation conducted by Dr. Berman, the accuracy of even the “confirmed” cases. (See Berman Aff., ¶ 12.) Moreover, one of the two confirmed cases—*i.e.*, half of the sample of confirmed cases of HSV associated with MBP—involved an *untyped* form of HSV, not HSV-1. It therefore should not be counted at all. (See Berman Aff., ¶ 12.) Additionally, two of the five cases involve *siblings*, one infected in 2008 and the other in 2011. Especially in light of the paucity of other cases—these siblings make up two of the three reported cases of HSV following MBP during the four years between 2008 and 2011—that suggests that these cases of HSV were not independently linked to MBP. Far more likely, the siblings both contracted the disease from a common household source, or one contracted it from the other. (See Berman Aff., ¶ 13.) Finally, the CDC report indicates that, in one of the five cases, the infant began to exhibit symptoms of herpes only *twenty days* after the circumcision took place—but it is well established in the medical literature that the incubation period for herpes infection is 2-12 days. See R. Distel et al., *Primary Genital Herpes Simplex Infection Associated with Jewish Ritual Circumcision*, ISRAEL MED. ASS'N J. 5:893, 894 (2003); L. Rubin & P. Lanzkowsky, *Cutaneous Neonatal Herpes Infection Associated with Ritual Circumcision*, 19 PEDIATRIC INFECTIOUS DIS. J. 3:266, 267 (2000).

In short, the Department's CDC report adopts a baseline incidence rate that is too low; projects a level of incidence based on unduly low assumptions of the number of cases of MBP; and then reports a level of actual incidence that is overstated in several ways. And, despite those flaws, the report concludes that there were only three or four additional cases of HSV among infants who had MBP than one would otherwise expect (five, instead of 1.46). Because those numbers are so small—of questionable significance even were they not premised on tainted data and assumptions—*any* errors in the calculations (let alone all of the errors described above) could dramatically alter the report's conclusions, and eliminate entirely the alleged increased risk

of MBP. (See Berman Aff., ¶¶ 10-11.) In light of these methodological flaws, it is Dr. Berman's professional belief that the evidence does not support the theory that MBP has resulted in transmission of HSV-1. (See Berman Aff., ¶¶ 3, 22-23.)

Skepticism about the CDC report is further bolstered by figures supplied by the Director of the Medical Ethics Unit at Shaare Zedek Medical Center in Jerusalem, which indicate that despite an estimated 15,000-20,000 MBP circumcisions in Israel *annually*, there have been only seven suspected cases of neonatal herpes over the past five years—only four of which were confirmed to be HSV-1, and two of which involved mothers who were diagnosed with herpes or strongly suspected to have it. Those figures suggest an incidence rate of HSV-1 following MBP that is well *below* the CDC report's projected rates. (See Berman Aff., ¶ 20 & Exh. 2.)

If the Department intends to take the unprecedented step of regulating a venerable religious ritual that has been safely performed for thousands of years and never definitively linked to transmission of any disease, the Constitution requires better evidence than this.

2. Even assuming that the Department were able to prove some *de minimis* risk that MBP can, in extremely rare cases, result in transmission of HSV-1, strict scrutiny demands that the Department regulate the risks of HSV-1 transmission neutrally and even-handedly. As the Supreme Court stated in *Lukumi*: "Where government restricts only conduct protected by the First Amendment and fails to enact feasible measures to restrict other conduct producing substantial harm or alleged harm of the same sort, the interest given in justification of the restriction is not compelling." *Lukumi*, 508 U.S. at 546-47. In other words, a regulation that exclusively restricts a religious practice must not be *underinclusive*; if the harm that the regulation purports to address arises in other circumstances, the government must address those other circumstances as well—it cannot proceed only against the religious practice.

Here, however, § 181.21—at best—does just that. Even the CDC report estimates the risk of HSV-1 transmission associated with MBP at something below 2 additional cases per 10,000 births. That is, by all measures, an extremely low risk, far below the risk posed by contact between newborns and individuals who exhibit *symptoms* of HSV-1 such as cold sores. (See Berman Aff., ¶ 18.) In fact, there is compelling evidence that (at least) one of the five cases identified by the CDC report as an MBP-associated case of neonatal herpes actually involved transmission from a symptomatic sibling, who shared his pacifier with the infant shortly before the latter fell ill. See Debbie Maimon, *Behind the Campaign Against Metzitzah B'peh*, YATED NE'EMAN, July 13, 2012. Yet the Department ignored that evidence, *see id.*, and has taken *no* action with respect to this far more serious risk. Instead, the *only* type of contact with infants that the Department has chosen to regulate is the exclusively religious practice of MBP.¹

Even on the Department's theory, only five of the 84 cases of HSV reported over the past five years could even *possibly* be linked to MBP. Yet that small minority of cases has been the sole focus of the Department's regulatory attention, leaving entirely unaddressed the *other* risks

¹ Nor has the Department attempted to regulate or require informed consent for common behaviors, such as certain sexual practices, that routinely result in the transmission of herpes and other infectious diseases in adults.

of herpes transmission, which account for well over 90% of reported cases. This represents not only fatal underinclusiveness on the part of § 181.21, but also a serious abdication by the Department of its responsibility to promote the public health.

Section 181.21's single-minded focus on MBP, ignoring other non-ritual practices that may pose an even more substantial risk of transmitting disease, offends the Free Exercise Clause and cannot be sustained under strict scrutiny. The regulation's "facial underinclusiveness" in addressing the transmission of HSV "raises serious doubts about whether [the Department] is, in fact, serving, with this [regulation], the significant interests" that it claims to be concerned with. *Florida Star*, 491 U.S. at 540. It suggests, perhaps, that the Department is concerned with the *de minimis* risks that are only *arguably* associated with MBP only because it sees less value in that religious ritual than it sees in non-religious practices that pose the same or greater risks. But that is precisely the type of illicit, albeit subtle, "animus toward religion" that the First Amendment's Religion Clauses are designed to prohibit. *Locke v. Davey*, 540 U.S. 712, 725 (2004).

In sum, if the Department is going to undertake "the extraordinary measure" of burdening ritual circumcision with new regulations purportedly to prevent transmission of disease, "it must demonstrate its commitment to advancing this interest by applying its prohibition evenhandedly," to religious and non-religious individuals alike. *Florida Star*, 491 U.S. at 540. On this score, too, § 181.21 fails the demanding requisites of strict judicial scrutiny.

II. Freedom of Speech

A. The First Amendment protects, of course, not just religion but also speech: "Congress shall make no law ... abridging the freedom of speech." U.S. Const. Amdt. I. And, as the Supreme Court has long held, the freedom to speak includes the freedom *not* to speak. "Since *all* speech inherently involves choices of what to say and what to leave unsaid,' one important manifestation of the principle of free speech is that one who chooses to speak may also decide 'what not to say.'" *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995). (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 11 (1986) (plurality opinion)). Thus, the Supreme Court's "leading First Amendment precedents have established the principle that freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006). The government may not, held the Court in a seminal opinion by Justice Jackson, "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943); *see also Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (holding that freedom of speech includes "the right to refrain from speaking at all").

It is indisputably irrelevant, for purposes of the First Amendment, that the message the government wants the individual to repeat may be factually true. The constitutional principle "that the speaker has the right to tailor the speech, applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Hurley*, 515 U.S. at 573. Thus, in *McIntyre v. Ohio Elections Commission*, 514 U.S. 334 (1995),

the Court invalidated a state law that required anyone distributing campaign literature to include on it the name of the person or entity responsible for the literature, even though such a disclosure would obviously have been factually accurate. *See id.* at 357. Likewise, the Court in *Riley v. National Federation of the Blind of North Carolina*, 487 U.S. 781 (1988), struck down as an impermissible compulsion to speak a law that “require[d] professional fundraisers to disclose to potential donors the gross percentage of revenues retained in prior charitable solicitations,” even though that information was true and relevant. *Id.* at 784; *see also id.* at 796–97.

Like laws that discriminate against religious practices, laws that compel speech are subject to highest level of judicial scrutiny. “Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech,” and such a regulation therefore qualifies as a “content-based regulation of speech.” *Riley*, 487 U.S. at 795. And such content-based restrictions are “subject to exacting First Amendment scrutiny.” *Id.* at 798. It is therefore “well-established that a regulation compelling noncommercial speech is subject to strict scrutiny and must be narrowly tailored to serve a compelling governmental interest.” *Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor and City Council of Baltimore*, 2012 U.S. App. LEXIS 13157, at *19 (4th Cir. June 27, 2012). The First Amendment directs that “government not dictate the content of speech absent compelling necessity, and then, only by means precisely tailored.” *Riley*, 487 U.S. at 800. Compelled speech is thus permissible only when there is a compelling interest; where the regulation is carefully tailored to advance that interest; and where there are no less-restrictive means by which the government’s interest could be met.

B. The proposed regulation, § 181.21, mandates that the *mohel* inform the parent of the child to be circumcised that “direct oral suction exposes the infant to the risk of transmission of herpes simplex virus infection and other infectious diseases.” § 181.21(b). This mandated disclosure is a quintessential example of compelled speech; the regulation requires the *mohel* to make a statement that he does not wish to make. It therefore squarely infringes upon the *mohel*’s constitutional right, under the First Amendment, “to tailor” and “shape” his own speech. *Hurley*, 515 U.S. at 573-74. This is true even though the message that the Department seeks to compel the *mohelim* to transmit “could encourage or discourage the listener from” choosing to proceed with MBP; it remains the case that “a law compelling its disclosure would clearly and substantially burden the protected speech.” *Riley*, 487 U.S. at 798. By “[m]andating speech” that the *mohel* “would not otherwise make,” the Department’s regulation “necessarily alters the content of the speech.” *Id.* at 795. Section 181.21 is therefore a content-based regulation of speech, and thus cannot survive unless it satisfies the rigorous demands of strict scrutiny.

For the same reasons given above in connection with the Free Exercise Clause, § 181.21 does not and cannot satisfy strict scrutiny in the free-speech context either. *First*, and most importantly, the factual record is too arguable and too speculative, as Dr. Berman’s detailed affidavit demonstrates. The science on this issue is not anywhere close to definitive—and the government cannot compel speech based on speculation about unproven and miniscule risks. *Second*, the regulation is woefully underinclusive, requiring health warnings to be given by *mohelim* prior to performing MBP—but not prior to the riskier contacts between infants and *symptomatic* individuals, or other, non-religious oral-genital contacts. Such underinclusiveness

“raises serious doubts about whether the government is in fact pursuing the interest it invokes, rather than disfavoring a particular speaker or viewpoint”—here, the view that MBP is safe. *Brown v. Entm't Merchants Ass'n*, 131 S. Ct. 2729, 2740 (2011).

In addition, the free-speech context offers an additional reason why § 181.21 fails strict scrutiny: The Department cannot demonstrate that compelling speech by *mohelim* is the least-restrictive means of educating the public about what (in its view) are the risks of MBP. See *Sable Comm'cns of Cal., Inc. v. FCC*, 492 U.S. 115, 126 (1989) (holding that strict scrutiny requires government to use “least restrictive means to further the articulated interest”); *Reno v. Am. Civil Liberties Union*, 521 U.S. 844 (1997) (requiring government to bear “especially heavy burden ... to explain why a less restrictive provision would not be as effective”). Where the government itself could publicize its message, compelled speech is not the least-restrictive means of educating the public. Thus, in *Riley*, the Court noted that the goals of the disclosure rule could be served equally well if the State “itself publish[ed] the detailed financial disclosure forms it requires professional fundraisers to file.” *Riley*, 487 U.S. at 800. The same, of course, is true here. If the Department wants to educate parents about the alleged risks of MBP, it need not conscript an army of *mohelim*. Instead, it could publish pamphlets and distribute them in the affected communities. Indeed, the Department *has already begun to do just that*. See *Before the Bris: How to Protect Your Baby Against Infection* (N.Y.C. Dep't of Health & Mental Hygiene 2012). The Department's independent efforts to spread its message about MBP further illustrates that § 181.21's compelled speech is neither necessary nor narrowly tailored.

C. The Department could attempt to justify the compelled speech mandated by § 181.21 by characterizing it as a health or safety warning, akin to those commonly found on consumer products, or those given by licensed professionals like doctors in the course of practicing their regulated professions. In the context of commercial advertising, the government may require the disclosure of “purely factual and uncontroversial information,” *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985), in order to “dissipate the possibility of consumer confusion or deception,” *In re R.M.J.*, 455 U.S. 191, 201 (1982). Similarly, licensed professionals are, “as part of the practice of medicine, subject to reasonable licensing and regulation by the State,” including compelled disclosure necessary for informed consent. *Planned Parenthood of Se. Pa. v. Casey*, 500 U.S. 833, 884 (1992). But this doctrine cannot sustain § 181.21, for two reasons.

1. *First*, these doctrines are categorically inapplicable here, because § 181.21 regulates a *religious practice*, not a *commercial transaction*. The former is entitled to far greater First Amendment protection than the latter, and the courts have so recognized.

Zauderer permits the government to mandate “purely factual and uncontroversial” disclosures, but only in the limited context of “commercial advertising,” where “the interests at stake in this case are not of the same order.” *Zauderer*, 471 U.S. at 651. “Although the State may at times ‘prescribe what shall be orthodox in commercial advertising’ by requiring the dissemination of ‘purely factual and uncontroversial information,’ outside that context it may not compel affirmance of a belief with which the speaker disagrees.” *Hurley*, 515 U.S. at 573

(citations omitted). Indeed, the government is forbidden to “prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion.” *Barnette*, 319 U.S. at 642. Likewise, licensed professionals like doctors, who practice for pay in a heavily regulated environment, are subject to “licensing and regulation by the State,” which could embrace regulations requiring certain speech. *Casey*, 500 U.S. at 884. But that is a narrow exception in a unique context—practice of a professional vocation—where regulation is the norm and First Amendment interests are especially low. See generally Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. Ill. L. Rev. 939 (2007).

The performance of a ritual circumcision is obviously not a commercial transaction subject to reduced constitutional protection. Commercial speech is that which “proposes a commercial transaction,” *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989), and thus relates “solely to the economic interests of the speaker and its audience,” *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 561 (1980). Ritual circumcision is, of course, a religious act; it is motivated—for both the parents and the *mohel*—by spiritual belief and religious dictate, not by economic motivations. Indeed, the Code of Jewish Law requires *mohelim* to perform circumcisions without regard to payment. See *The Code of Jewish Law, Yoreh De’ah*, at 260:1 & 261:1. And most *mohelim* typically perform circumcisions without asking for any economic benefit in return. (See Heber Aff., ¶ 2.)

The Fourth Circuit’s recent decision in *Greater Baltimore Center* is highly instructive. There, the City of Baltimore sought to require pregnancy counseling centers to post signs indicating that they do not provide abortion services. The court ruled that this compulsion to speak was subject to strict scrutiny, and was not subject to the reduced *Zauderer* test because the speech in question was not commercial in nature. The plaintiff pregnancy center, which opposed abortion, was providing “free” services, and was motivated by “religious and political belief,” not by the profit motive. 2012 U.S. App. LEXIS 13157, at *23. The same is true here.

A contrary result, the Fourth Circuit explained, would mean that “any house of worship offering their congregants sacramental wine, communion wafers, prayer beads, or other objects with commercial value, would find their accompanying speech subject to diminished constitutional protection”—a plainly absurd result. *Id.* at *24. Section 181.21 raises the specter of similarly absurd regulations: Could the Department force priests to issue health warnings and obtain informed consent waivers prior to delivering communion, on the theory that communal sharing of a single cup (the typical Catholic practice) presents a risk of transmission of disease? Could the Department require imams leading services in mosques to warn congregants, before directing them to bow in prayer, that the result could be long-term back pain? Despite these risks—which undoubtedly exist—regulations of that sort surely could not survive, and that is because the Constitution prevents the government to compel speech in these religious contexts.

The *Greater Baltimore Center* decision also speaks to the inapplicability of the special exception for compelled speech by licensed professionals. The court there explained that, while doctors may be compelled to provide certain information to their patients, that is because such regulations are “imposed incidental to the broader governmental regulation of a profession and

[are] justified by this larger context.” *Id.* at *24-*25. “In contrast,” the court explained, the plaintiff pregnancy center “do[es] not practice medicine” and is “not staffed by licensed professionals,” making this narrow doctrinal exception inapposite. *Id.* at *25. Again, the same is true here. *Mohelim* are not—and, indeed, could not, given the First Amendment’s Religion Clauses—ever be subject to the type of all-encompassing, comprehensive regulatory and licensing regimes that govern the medical profession. See *Aguilar v. Felton*, 473 U.S. 402, 413 (1985) (“[P]ervasive monitoring by public authorities ... infringes precisely those Establishment Clause values at the root of the prohibition of excessive entanglement.”). Ultimately, it is no surprise that religious officials performing religious duties would have more robust First Amendment rights than professionals selling services under government oversight.

2. In any event, even if ritual circumcision could be categorized as a mere commercial transaction or performance of a professional duty subject to reduced constitutional protection, § 181.21 fails even on that lesser standard. Even in those contexts, the government is entitled to mandate only the disclosure of “purely factual and uncontroversial” information, such as the undisputed toxicity of poisonous chemicals. Yet the disclosures that the proposed regulation would require *mohelim* to provide are far from “uncontroversial.” They are, to the contrary, hotly debated on both scientific and theological grounds—and, in at least one respect, *completely* without factual basis. On no view of the First Amendment may the government compel speech that the speaker reasonably believes to be factually false.

Under *Zauderer*, the government may require commercial disclosures, but only of “purely factual and uncontroversial” information. 471 U.S. at 651. Thus, for example, Vermont was constitutionally permitted to require manufacturers of products that contain mercury to label those products to so indicate. See *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001). There was no dispute, of course, that the products actually contained mercury. Likewise, the New York City Board of Health could permissibly require restaurants to post accurate caloric information about the items on their menus, given that the restaurants did not dispute the substance of the compelled disclosure. See *N.Y. State Restaurant Ass’n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009).

By contrast, however, Illinois could not force the manufacturers of sexually explicit video games to label their products as appropriate for ages 18 and up, because that was a “highly controversial message,” not an undisputed one. *Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006). Similarly, Vermont violated the First Amendment by requiring dairy producers to specially label products derived from cows treated with synthetic growth hormones, because the State could not satisfy its burden to show “a reasonable concern for human health or safety” as a result of the hormone. *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996). And, most recently, a federal court in California held that San Francisco could not constitutionally compel cellular phone providers to make certain disclosures to customers, because they misleadingly left an “overall impression ... that cell phones are dangerous,” even though “cell phones have not been proven dangerous”—though their radio frequency emissions were labeled “possibly” carcinogenic by the World Health Organization. *CTIA-The Wireless Ass’n v. City & Cnty. of San Francisco*, 827 F. Supp. 2d 1054, 1062-63 (N.D. Cal. 2011).

Uncontroversial factual accuracy is thus a *sine qua non* of any mandated commercial disclosure. It is also, of course, a condition on any mandated disclosures in the professional context. See Post, *Informed Consent to Abortion*, *supra*, at 978-79 (“[C]onstitutional questions should also arise if the state corrupts physician speech by requiring doctors to transmit misleading information in the context of informed consent.”). In this respect, the Department’s proposed regulation founders badly.

First, the regulation compels *mohelim* to tell parents that MBP “exposes the infant to the risk of ... other infectious diseases,” in addition to HSV-1. § 181.21(b). Yet the Department cites *no evidence at all* that MBP has resulted in transmission of any infectious disease apart from HSV-1. And, as Dr. Berman attests, the modern medical literature is devoid of reports of any other such infections—such as HIV, viral hepatitis, or bacterial infection, for example—being transmitted through MBP. (See Berman Aff., ¶ 21.) The regulation thus compels a disclosure that, far from being “purely factual and uncontroversial,” is without any factual basis.

Second, the warnings about transmission of HSV-1 are premised on a study that, as shown above, *see supra* at 6-8, rests on numerous dubious findings and erroneous assumptions. Dr. Berman, having reviewed the study and other data, has reached the conclusion that the evidence does not support the theory that MBP has resulted in transmission of HSV-1. (See Berman Aff., ¶¶ 3, 23.) Other data, such as the figures supplied about the incidence of HSV-1 in Israel, further call into question the accuracy of the regulation’s claim that MBP exposes infants to the risk of neonatal herpes. This is therefore not a case where the speaker concedes that the government’s message is accurate, but simply wishes to avoid saying so. Rather, like the labels in *Blagojevich*, § 181.21 imposes a duty to spread a view that is “highly controversial” in the medical and religious communities. See 469 F.3d at 652. Many *mohelim* do not agree with the substance of the compelled disclosure, and they have at least a reasonable basis for their view. The regulation thus conflicts with the basic First Amendment principle that government “may not compel affirmance of a belief with which the speaker disagrees.” *Hurley*, 515 U.S. at 573.

Indeed, the regulation—far from serving the purpose of “dissipat[ing]” any possible “consumer confusion or deception,” *In re R.M.J.*, 455 U.S. at 201—actually creates confusion and is potentially misleading itself, even if the CDC report is entirely accurate. For one thing, the disclosure says nothing about safety precautions that *mohelim* routinely take in performing MBP, and their significance in terms of any risk that may exist of transmission of HSV-1. For another, the disclosure does not *quantify* the risk in any way, leaving parents potentially uncertain of the actual dangers that the Department believes are posed by MBP relative to other behaviors. Much like the cellular phone disclosures invalidated in *CTIA*, § 181.21 creates an “overall impression” that MBP is dangerous, but the truth is far more subtle and complex. *CTIA*, 827 F. Supp. 2d at 1062. The Constitution simply does not permit the Department to conscript *mohelim* to deliver the Department’s controversial, objectionable, and misleading message.

Judaism puts the highest premium on the protection of human life, and the IBA of course shares the Department's goal of ensuring the safety and health of the newborn male children who undergo circumcision. But the sparse and flawed data simply do not support the Department's theory that MBP poses a health danger, especially in light of its safe practice over the course of thousands of years as part of the ancient circumcision ritual. On such a thin and deficient factual record, the Constitution does not allow the Department to target for unique burdens a longstanding religious practice, or to compel *mohelim* to spread a dubious medical theory with which they disagree on both scientific and theological grounds. The IBA therefore strongly urges the Department to reject the proposed § 181.21. Thank you for your consideration.

Prepared for the IBA by its counsel:

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Exhibit A

Affidavit of Dr. Daniel S. Berman, M.D.

Qualifications and Overview

1. I am a medical doctor specializing in infectious disease. I graduated from New York University School of Medicine in 1982, completed a Residency in Internal Medicine in 1985 at the New York University Medical Center, and then completed a Fellowship in Infectious Diseases at the New York University Medical Center in 1987. I am Board-certified in Internal Medicine and Infectious Diseases. I have been in private practice since 1987. I have been the Chief of Infectious Diseases at the New York Westchester Square Hospital Medical Center since 1989. I am also on the attending staff as an Infectious-Diseases specialist at the Montefiore Medical Center. Among other things, I have cared for patients with Herpes simplex infection.

2. I have carefully reviewed the recent report, published on June 8, 2012, by the Centers for Disease Control and Prevention (CDC) in its Morbidity and Mortality Weekly Report (MMWR), which attempts to prove based on an investigation conducted by New York City's Department of Health and Mental Hygiene (DOHMH) that neonatal Herpes simplex infection (HSV-1) can be transmitted through orogenital suction, in Hebrew called *metzitzah b'peh* (MBP), performed as part of Jewish ritual circumcision. I have examined and studied, in light of my knowledge and experience in this area, the findings recorded by this report, as well as the conclusions drawn from them. I have also independently investigated some of the individual cases that form the basis for the report.

3. In my professional opinion, there are serious flaws in the CDC report's methodology and analysis, raising doubts about the validity of the data and the strength of the conclusions reached by the researchers. Based on my review, the data do not support the conclusion that MBP increases the risk of neonatal Herpes simplex infection. In short, I see *no evidence* for the transmission of HSV-1 through ritual circumcision.

The CDC Report and Its Findings

4. The CDC report focuses on a total of 11 cases of neonatal Herpes simplex infection that occurred in the past 11 years. This included a period from 2000 until April 2006, during which time reporting of neonatal Herpes simplex infection to the DOHMH was not required, and a second period, from April 2006 through December 2011, during which time reporting was mandatory.

5. During the period of mandatory reporting, there were a total of 84 cases of laboratory-confirmed neonatal Herpes simplex infection in New York City (within 60 days of birth). There are two types of Herpes simplex infection; HSV-1 is generally associated with oral herpes, commonly known as cold sores or fever blisters; whereas HSV-2 is associated with genital infection. Of the 84 cases during the mandatory reporting period, 45 were in males (HSV-1:22; HSV-2:15; and untyped HSV:8) and 39 in females (HSV-1:15; HSV-2:18; and untyped HSV:6). The report does not state how many total cases of neonatal Herpes simplex infection there were during the first period.

6. The report states that, during the first period, there were five cases of neonatal HSV-1 infection in those who either "probably" or were "confirmed" to have had MBP, and one case of untyped HSV neonatal infection. Of these six cases, in four of them the children were "confirmed" to have had MBP, and in two it was "probable." In the second period, there were four cases of HSV-1 neonatal infection and one untyped case in children either "probably" or "confirmed" to have had MBP. Only two of those five cases (including the untyped case) were "confirmed" to have involved MBP; the other three were only "probable." Together, these are the report's 11 cases.

7. The investigators estimated that the number of boys born in New York City who did not have MBP performed during the 5 1/2-year period of mandatory reporting of neonatal Herpes simplex infection was 352,411. As there were 25 reported cases of neonatal HSV-1 infection in this group, the rate of neonatal HSV-1 infection was 7.1 per 100,000. The investigators further estimated that the number of boys born during this time who were likely to have had MBP was 20,493. Accordingly, they inferred that the total number of HSV-1 cases arising from that subgroup should have been 1.46. The report claims that there were five cases in this group. As five is 3.4 times greater than 1.46, the investigators concluded that "infant males who underwent circumcision with confirmed or probable direct orogenital suction had an estimated risk 3.4 times greater than the risk for 1 or untyped HSV infection among males who were unlikely to have had direct orogenital suction." Another way of expressing this is that there should have been 1.46 cases among the ones who underwent MBP. Since we cannot have a fraction of a case, this means there should have been one or two cases. Over the 5 1/2 year period, there were three or four "extra" cases found among the estimated 20,000 who had MBP.

8. The investigators theorized that HSV-1 can be transmitted from the mouths of *mohelim* (circumcisers) to babies during MBP, even in the absence of any sores in the mouth of the mohel, through a process of asymptomatic "viral shedding."

Flaws in the CDC Report

9. I have great concerns about the validity of the findings included in the CDC report. Both the evaluation of the purported 11 cases, and the assumptions underlying the extrapolations from those cases, appear to be flawed. The report's methodology and conclusions likewise appear to be deficient in critical respects.

10. At the outset, it must be recognized that the investigators' conclusion rests on the observation that there were only three or four "extra" cases from among the over 20,000 estimated to have had MBP over a period of over five years. This is a very small number. Indeed, a report published just last year in the *Journal of Sexually Transmitted Diseases* based on nearly the same data, warned that "[t]he relatively limited number of case limits our ability to make definitive statistical comparison among our cases and ... makes certain statistical analyses unstable." (Exh. 1, at 6.)

11. Moreover, because of the small sample size, any change to either the number of actual cases involving MBP, the number of actual cases *not* involving MBP, or

the estimated total number of children to have undergone MBP, could drastically affect the report's ultimate conclusion. All of these, however, are quite dubious.

12. *First*, during the mandatory reporting period used to establish the relative risk figure of 3.4, only *two* of the five alleged cases were "confirmed" to have involved MBP, while the other three cases were only "probable." This alone raises doubts about the accuracy of the data. Without 100% certainty as to the performance of MBP, no meaningful conclusions can be reached. Furthermore, the report indicates that it treated a case as "confirmed" to have involved MBP if the parents so reported. But I personally am aware of one case from the earlier period that was listed as "confirmed" even though the *mohel* stated on many occasions that he *did not* perform MBP, and even passed two polygraph tests regarding this statement. This raises uncertainty about even the cases reported to have involved "confirmed" MBP. Moreover, one of the two "confirmed" cases involved *untyped* HSV, not HSV-1. An untyped case should not be considered at all in the analysis. All of this translates into the fact that only one "confirmed" case of MBP was connected to HSV-1 during the five years of mandatory reporting used by the investigators as their key evidence—entirely in line with the investigators' projected number of one or two cases.

13. *Second*, the figure of five cases is additionally problematic because there is no evidence that each of these cases was *independently* linked to MBP—and, in fact, there is reason to believe otherwise. In particular, two of the five cases were siblings, one in 2008 and the second in 2011. Given that, during the four-year period between 2008 and 2011, there was only one other case reported in all of New York City, it is much more plausible to conclude that these siblings were infected by a common household source, or from one brother to the next, rather than by the *mohel*. Why would there be no other reported cases from this *mohel* or any other *mohel* in New York City from 2008 until 2011, aside from these two brothers (and one other case in 2008)? If only one of the siblings was infected by the *mohel* (and the other infected from his brother), the number of cases would drop to four; if both siblings were infected from a common household source, the number would drop to three—relative to a baseline expectation, according to the researchers, of one or two cases.

14. *Third*, the report calculated its projected rate of infection based on the total number of reported cases of HSV during the period from 2006 through 2011. The rate of diagnosis, however, is not the same as the rate of actual incidence of infection. To make a diagnosis of HSV-1, the treating physician must first consider the possibility of such a diagnosis and then do the appropriate diagnostic studies. It is likely that HSV-1 would be more likely to be suspected, and therefore tested for, in a boy suspected to have had MBP than in one who was not, even with an identical clinical presentation, because of a heightened awareness of the possibility of transmission through MBP. In other words, for a boy who was not suspected to have had MBP, it is quite possible that cases were missed, as the diagnosis was never considered. If so, the projected number of cases in the MBP sub-group would be higher than the figure of 1.46 used by the researchers. One way to analyze this possibility would be to account for the number of diagnostic tests that were performed to search for HSV-1 in boys suspected to have had MBP, versus in those

who were not—but the CDC report does not include such an analysis.

15. *Fourth*, the report's relative risk figure was premised, and very dependent, upon its estimate of the number of boys upon whom MBP was performed during the five years in question. The report estimated that number at 20,943, based on statistics from a national census of Jewish day schools. However, a new population study presented by the UJA-Federation of New York, *Jewish Community Study of New York: 2011*, reports that there has been an explosion of births of Orthodox Jewish children in New York City in the past few years, such that 74% of Jewish children born in New York City are Orthodox. These new statistics would substantially change the estimated number of boys who had MBP, and changes to that estimate would significantly impact the projected rate of infection and thus the relative risk figure.

16. Although the study bases its relative risk figure only on data from the mandatory reporting period, it also draws support for its conclusions from six cases reported during the prior study period. There are serious flaws in the evaluation of those six cases as well. Only five were shown to be HSV-1, whereas the sixth was untyped. As with the sample used to compute the relative risk figure, only four of the six cases from this earlier period were "confirmed" to have had MBP, while the two other cases were listed as "probable." And, as mentioned above, as to one of these four "confirmed" cases, the *mohel* has stated that he did not perform MBP, and was supported by two different polygraph tests. Furthermore, of the six cases, two were twins, and it has been medically proven that if one baby acquires the infection, it can easily be transmitted to the second baby through a caretaker or through direct contact, if no special precautions are taken. There is no indication that such precautions were taken in the case of these twins. The *mohel* who performed MBP on these twins—the same *mohel* who has stated that he did *not* perform MBP in one of the other four "confirmed" cases—was one of the busiest and most experienced *mohelim* in the New York area, and had performed many thousands of circumcisions prior to these babies, without any case of HSV-1.

17. I also have concerns regarding the accuracy of the charge that MBP was the cause of the infection in the reported cases. The report considers the distribution of the lesions in dermatomes associated with the genital area (region of the skin that is fed by a specific nerve) as evidence of transmission through MBP. However, in the case of the twins, the report also describes lesions on the abdomen, buttocks, and perineum, including the genitals. This is a very wide area that includes many dermatomes. In the third case associated with the same *mohel*, lesions were described on the penis, perineum, buttocks, back, and foot. This is an even wider area of distribution. Medically speaking, it is very difficult to draw conclusions as to the source of the infection when such a large area is affected.

18. In addition, it is well established in medical literature—and confirmed through DNA testing—that Herpes virus has been transmitted to infants through household contacts. Indeed, transmission from a symptomatic individual is far more likely to occur than transmission from an asymptomatic individual, like a *mohel*. Yet the investigators failed to consider the possibility of household contacts as potential sources

of infection in any of the cases. The report does discuss excluding healthcare workers as potential causes, but makes no mention of the exclusion of the more proven possibility of household contacts. Strict infection control is used to prevent transmission in the hospital setting, while such infection-control policies are not in effect in most homes, where the baby is just as susceptible from a biological standpoint to contract Herpes simplex infection. Furthermore, many Orthodox children live in homes with many siblings and crowded conditions, which would make transmission of HSV-1 from household contacts even more possible.

19. Finally, the gold standard for demonstration of transmission of HSV is DNA fingerprinting, which could (if the investigators' conclusions were correct) connect the infection to the *mohel* definitively. This has been done in other studies demonstrating HSV infection. But there has been not one single case in history, let alone the 11 cases in question, where DNA fingerprinting has proved transmission through MBP.

20. My concerns about the CDC report's findings and conclusions are corroborated by figures supplied to me by Dr. Avraham Steinberg, the Director of the Medical Ethics Unit at the Shaare Zedek Medical Center in Jerusalem. (See Exh. 2.) Dr. Steinberg estimates that MBP is performed 15,000-20,000 times per year in Israel; yet there have been only seven suspected cases of neonatal herpes over the last five years. Those figures suggest an incidence rate of HSV-1 following MBP that is far lower than the rate estimated by the CDC report. Moreover, of the seven suspected cases that Dr. Steinberg reports, only four were actually confirmed to be cases of HSV. And, of those four, fully half involved mothers who either were diagnosed with, or suspected to have, herpes themselves—making it very likely that they, not the *mohelim*, transmitted the infection in those cases.

21. To the extent that the report alludes to an inherent risk of transmission through MBP of "other pathogens," it supplies absolutely no data at all to support such a conclusion. MBP has been performed for thousands of years with a remarkable safety record. I am unaware of any reports, since 1946, of any infections transmitted through MBP except for these new reports of Herpes simplex infection under discussion. HIV, viral hepatitis (A, B, or C), and bacterial infection have, to my knowledge, never been described in association with MBP.

Conclusions

22. My professional opinion is that the data relied upon by the CDC report to establish its observed number of cases, and the data and estimates relied upon to establish the projected number of cases, are deeply flawed, casting serious doubt on the validity of the report's findings.

23. In sum, I see no evidence for the transmission of HSV-1 through ritual circumcision. The evidence in the CDC report simply is not sufficient to prove any cause-and-effect relationship between MBP and HSV-1 infection.

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 20 day of July, 2012, at Bronx, New York.

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

STATE OF NEW YORK
COUNTY OF Bronx

Subscribed and sworn before me this 20 day of July 2012.

Charlene R. Brown
Notary Public

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

My commission expires on: 7/31/2013

Exhibit 1

Population-Based Surveillance for Neonatal Herpes in New York City, April 2006–September 2010

Shoshanna Handel, MPH,*† Ellen J. Klingler, MPH,† Kate Washburn, MPH,†
Susan Blank, MD, MPH,†‡ and Julia A. Schillinger, MD, MSc†‡

Background: Population-based data for neonatal herpes simplex virus (HSV) infection are needed to describe disease burden and to develop and evaluate prevention strategies.

Methods: From April 2006 to September 2010, routine population-based surveillance was conducted using mandated provider and laboratory reports of neonatal HSV diagnoses and test results for New York City resident infants aged ≤ 60 days. Case investigations, including provider interviews and review of infant and maternal medical charts and vital records, were performed. Hospital discharge data were analyzed and compared with surveillance data findings.

Results: Between April 2006 and September 2010, New York City neonatal HSV surveillance detected 76 cases, for an average incidence of 13.3/100,000 (1/7519) live births. Median annual incidence of neonatal HSV estimated from administrative data for 1997 to 2008 was 11.8/100,000. Among surveillance cases, 90.8% (69/76) were laboratory confirmed. Among these, 40.6% (28/69) were HSV-1; 39.1% (27/69) were HSV-2; and 20.3% (14/69) were untyped. The overall case-fatality rate was 17.1% (13/76). Five cases were detected among infants aged >42 days. In all, 80% (20/25) of the case-infants delivered by cesarean section were known to have obstetric interventions that could have increased risk of neonatal HSV transmission to the infant before delivery. Over half (68%, or 52/76) of all cases lacked timely or ideal diagnostics or treatment.

Conclusions: Administrative data may be an adequate and relatively inexpensive source for assessing neonatal HSV burden, although they lack the detail and timeliness of surveillance. Prevention strategies should address HSV-1. Incubation periods might be longer than ex-

pected for neonatal HSV. Cesarean delivery might not be protective if preceded by invasive procedures. Provider education is needed to raise awareness of neonatal HSV and to assure appropriate testing and treatment.

Infection with herpes simplex virus type-1 (HSV-1) or type-2 (HSV-2) during the neonatal period, or neonatal herpes (neonatal HSV), causes severe morbidity and high mortality rates even when treated.^{1,2} The majority of infections (85%) are acquired perinatally, although postnatal (10%) and congenital (5%) infections do occur.³ There is evidence that an increasing proportion of adult genital HSV infections are attributable to HSV-1^{4,5}; however, approaches for preventing neonatal HSV are limited and focused on HSV-2.^{1,2,6}

Experts have advocated for making neonatal HSV a nationally notifiable disease; however, neonatal herpes is currently only reportable in a few jurisdictions in the United States (US).^{7–10} Estimates of national incidence from other countries range from 1.15/100,000 to 8/100,000 live births.^{11–16} Incidence estimates from different parts of the United States are higher, ranging from 8.4/100,000¹⁷ to 69/100,000 live births¹⁸; this range includes estimates that are not population based, as well as a nationally representative incidence estimate gleaned from a database of pediatric hospital admissions.^{18,19,20} Given variability in the prevalence of genital herpes across geographic regions of the United States,⁵ variation in incidence of neonatal HSV is expected. Variations are also likely caused by differences in methods used to measure neonatal HSV disease burden. We present findings from a population-based surveillance system for neonatal HSV for the first time in the United States, and compare these findings with analyses of administrative data for the same population.

MATERIALS AND METHODS

In late March 2006, neonatal HSV infection became a reportable disease in New York City (NYC).²¹ Clinical laboratories were required to report positive results for HSV on specimens from infants aged ≤ 60 days who were residents of NYC, and healthcare providers were required to report diagnoses of neonatal HSV infection for the same age group, regardless of whether laboratory results confirmed infection. Certificates of birth, death, and spontaneous termination of pregnancy (fetal death before delivery) were obtained from the NYC Bureau of Vital Statistics for all cases. To identify cases not reported by a provider or laboratory report, a retrospective search of vital records was performed at regular intervals.

The NYC Department of Health and Mental Hygiene investigated reported cases using a standard form. Investigations included confirmation of laboratory testing, telephone interviews with providers involved with each case, review of infant medical records, and maternal labor and delivery records. Interviews with parents were conducted only where

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The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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postnatal infection was considered probable. Data collected regarding infant patients included demographics; gestational age; birth weight; circumcision status and date (males only); whether ill at birth; presence and anatomical distribution of lesions; comorbidities; HSV test and its results; acyclovir treatment; cerebrospinal fluid (CSF) and liver function tests and their results; and dates of: first symptom, first seeking medical attention, hospital admission and discharge, specimen collection, diagnosis, and treatment initiation and completion. Data collected regarding infant patients' mothers included demographics, gravidity and parity, history of HSV infection, prenatal HSV serologic testing status, antiviral medication during pregnancy, and presence of genital herpes lesions at delivery. Data collected regarding delivery of infant patients included presentation (vertex or breech), mode of delivery (vaginal or cesarean section), interval between rupture of membranes and delivery, and artificial rupture of membranes or any invasive obstetric procedures.

We defined a confirmed case of neonatal HSV infection as one occurring in an infant aged ≤ 60 days who tested positive for HSV by culture, direct immunofluorescence assay or other antigen detection test, or polymerase chain reaction. The upper limit for the age range was 60 days to test our hypothesis that some perinatally transmitted cases may not appear until shortly after the neonatal period. We defined a probable case of neonatal HSV as one occurring in an infant aged ≤ 60 days with no laboratory confirmation of HSV infection, but who had each of the following: (1) a diagnosis of HSV, (2) treatment with acyclovir for ≥ 7 days, (3) illness clinically compatible with neonatal HSV, and (4) no alternative diagnosis. In NYC, postnatal HSV-1 infections have occurred after ritual Jewish circumcision practices in which the ritual circumciser (*mohel*) uses his mouth to suck blood away from the incision on the newly circumcised penis.²² Infection after ritual circumcision was defined as a confirmed case of HSV-1 or untyped HSV, or a probable case, in a male infant who had been circumcised outside of a hospital, with date of illness onset occurring after circumcision; if the date of illness onset was missing, then the date of first specimen collection for HSV testing was used.

Incidence was calculated for infants aged ≤ 60 days and for infants aged ≤ 42 days using the number of cases reported during 4.5 years as the numerator. In the denominator, we added three-quarters the number of live births in 2006 plus the number of live births for 2007 to 2009 plus three-quarters the number of live births in 2009 to estimate the number for January to September 2010. Maternal age and race/ethnicity-specific incidence were calculated using maternal age and race/ethnicity data obtained from birth certificates. To obtain a denominator for these incidence calculations, we used a similar method as described earlier and the number of live births by age and race/ethnicity from 2008 to estimate the numbers for 2009 and 2010, since more current data were not available. Case-fatality rates were calculated overall and by viral type.

Pearson chi-square testing was performed by using SAS 9.1 (SAS Institute, Inc., Cary, NC) to identify statistically significant differences in distribution of characteristics among cases with regard to viral type, fatality, infant sex, clinical manifestation, presence of lesions and fever, delivery mode, maternal race, and age at presentation.

We classified cases as follows: skin, eye, or mucous membranes (SEM) infections were those in which herpetic lesions were present or SEM specimens tested positive for HSV with no evidence of central nervous system (CNS), disseminated, or congenital infection. CNS infections were those that were CSF-positive for HSV with no evidence of disseminated

or congenital infection. Disseminated infections were those in which there was no evidence of congenital infection, and both aspartate aminotransferase and alanine aminotransferase levels were elevated.²³ Congenital infections were those with signs of HSV-related illness or those from which HSV-positive specimens were collected within 24 hours of birth, or those with stigmata of congenital infection (e.g., microcephaly, microphthalmia, or retinal scarring) noted at birth.

We measured delays in seeking care, diagnosis, and treatment, as well as instances of inappropriate medical treatment. We defined a delay in seeking medical care as >1 day between date of first symptom and date medical care was first sought, a delay in diagnosis as >1 day between date medical care was first sought and date of diagnosis or first specimen collection for HSV testing, and a delay in treatment as >1 day between herpes diagnosis or first specimen collection and beginning treatment with acyclovir. Cases were classified as adequately evaluated if lumbar puncture and liver-function testing were recorded as performed. Inappropriate treatment was defined as administration of less than the recommended course of acyclovir (60 mg/kg/d of intravenous acyclovir for 14 days for SEM cases and 21 days for CNS and disseminated cases); we considered 21 days appropriate therapy for congenital neonatal HSV.²⁴

To explain how HSV might have been transmitted despite the protective effect of cesarean delivery, we recorded obstetric factors that might have increased risk for disease transmission before the cesarean delivery. An interval of >4 hours between rupture of membranes and delivery was considered to pose a risk for HSV transmission,²⁵ as were artificial rupture of membranes, vacuum extraction, and use of fetal scalp electrodes, intrauterine pressure catheters, or forceps.

We used hospital discharge data to measure number of cases of neonatal HSV diagnosed among infants with an NYC zip code of residence who had been discharged from a New York State hospital during January 1997 to December 2008 and who were aged ≤ 60 days at time of admission, and included any hospital discharges listing an International Classification of Diseases (ICD) Version 9 (ICD-9) code for herpes (codes 054.0–054.9) as the principal, primary, or other diagnosis code. A unique identifier was created by concatenating the encrypted date of birth, sex, and the zip code of the patient's residence to identify infants with more than one hospital discharge listing a herpes ICD-9 code, and only the first such admission was counted. Annual incidence was calculated using annual neonatal HSV hospital discharges as the numerator and annual number of live births in NYC as the denominator.

RESULTS

During the first 4.5 years (April 2006–September 2010) of neonatal HSV surveillance in NYC, 75 reported cases met our case definitions. One additional case was identified by death certificate search, providing 76 cases for analysis. Overall incidence of neonatal HSV was 13.3/100,000 live births or 1/7519 live births; among infants aged ≤ 42 days, incidence was 12.4/100,000 live births or 1/8065 live births. Among 72/76 (94.7%) cases with information regarding maternal age at delivery, median maternal age was 25 years (range, 16–43 years). Age-specific incidence was highest among infants born to women aged <20 years (47.4/100,000 live births or 1/2110) and declined thereafter (Table 1). Infants born to black non-Hispanic mothers were 1.5 times as likely to be infected with HSV as those born to white non-Hispanic or Hispanic mothers. Black non-Hispanic mothers had the youngest median age at

TABLE 1. Distribution of Cases by Maternal Age and Race/Ethnicity

Maternal Age (yr)	All Race/ Ethnicities			Black Non-Hispanic		Hispanic		White Non-Hispanic		Asian		Other/ Unknown	
	n	Incidence	%	n	Incidence	n	Incidence	n	Incidence	n	Incidence	n	Incidence
All ages (<i>P</i> < 0.0001)	76	13.3	100.0	23	18.0	24	13.2	18	10.4	4	4.9	7	259.3
<20	18	47.4	23.7	10	79.8	2	9.3	2	72.7	0	0.0	4	2,191.8
20-24	21	18.3	27.6	6	19.4	7	14.4	5	21.5	1	8.6	2	353.1
25-29	15	10.1	19.7	4	12.1	5	10.0	3	7.8	2	7.6	1	135.6
30-34	10	6.7	13.2	0	0.0	5	13.5	5	8.7	0	0.0	0	0.0
>34	12	10.1	15.8	3	12.8	5	19.9	3	5.8	1	5.8	0	0.0

delivery (20 years, as compared with 27.5 years for white non-Hispanic and 26 years for Hispanic mothers).

Among the 76 cases, 69 (90.8%) were confirmed and 7 (9.2%) were probable; all had laboratory testing performed. Among the 69 confirmed cases, 28 (40.5%) patients were infected with HSV-1; 27 (39.1%) with HSV-2; and 14 (20.3%) had positive laboratory results that were not type specific. No statistically significant differences between HSV-1 and HSV-2 cases were identified with regard to sex, fatality, clinical manifestation, presence of lesions or fever, delivery mode, or maternal race. In all, 43 (56.6%) of the cases were boys. Of the 13 deaths, 8 (61.5%) were among girls; 9 (69.2%) occurred within the first 2 weeks of life (Table 2). Although not statistically significant, the fatality rates differed by HSV type (21.4% among HSV-1 cases and 18.5% among HSV-2 cases). Most of the cases (56.5%) were SEM; 23.2% were disseminated, 17.4% were CNS infections, and 2.9% were congenital infections. Lesions were present among 41 (60.3%) of the 68 cases for which lesion data were available. Fever was present among 19 (31.1%) of the 61 cases for which data were available. Among the 61 cases with known fever and lesion data, 19.7% had neither fever nor lesions (Table 3). In all, 27 (69.2%) SEM

cases had lesions noted, compared with 5 (41.7%) CNS cases, 7 (43.8%) disseminated cases, and both (100%) of the congenital cases.

Four (9.3%) of the 43 male patients met the definition for infection after ritual Jewish circumcision. All 4 case patients had lesions on the penis or the scrotum (2 on the penis only, 1 on the scrotum only, and 1 on both the penis and the scrotum); 3 of the 4 case-patients were laboratory-confirmed HSV-1 cases. The interval between circumcision and illness onset ranged 2 to 12 days (median, 3.5 days). One of the case-patients had CNS infection, the remaining 3 had SEM disease.

Of all cases, 56 (73.7%) were diagnosed at age ≤14 days; 12 (15.8%) at age 14 to 30 days; 3 (3.9%) at age 31 to 42 days; and 5 (6.6%) at age 43 to 60 days. Case-patients diagnosed at age ≤14 days had a higher fatality rate than those diagnosed at age ≥15 days (21.4% vs. 5%; *P* = 0.094). Of the 5 cases diagnosed among infants >42 days, 2 were HSV-1 (delivered by cesarean section); 2 were HSV-2 (one vaginally, and the other with unknown mode of delivery); and 1 was a probable case (cesarean section). Among the 57 case mothers for whom we had data, 11 (19.3%) had a known history of HSV, and 5/52 (9.6%) of those for whom data were available

TABLE 2. Characteristics of Fatalities

Sex	HSV Type	Syndrome	Mode of Delivery	Obstetric Risk Factors	Maternal History of HSV	Age at Diagnosis (in Days)	Age at Death (in Days)	HSV Indicated on Death Certificate
Male	1	Disseminated	Cesarean	Yes ^{a*}	Unknown	7	12	No
Female	1	SEM	Vaginal	Unknown	Unknown	N/A	0	No
Female	1	Disseminated	Vaginal	Yes [†]	No	8	5	Yes [‡]
Female	1	Disseminated	Cesarean	Yes ^{†§}	Unknown	8	14	Yes [‡]
Male	2	Disseminated	Cesarean	Unknown	Unknown	11	11	Yes [‡]
Male	2	Disseminated	Cesarean	Yes [†]	No	6	12	No
Male	2	Disseminated	Cesarean	Yes [†]	No	5	8	Unknown
Male	1	SEM	Cesarean	No	No	14	20	Unknown
Female	Unknown	Congenital	Cesarean	Yes [§]	No	0	3	Unknown
Female	Unknown	Disseminated	Cesarean	No	No	10	23	Yes [‡]
Female	1	Disseminated	Vaginal	Yes [§]	No	8	11	Unknown
Female	2	Disseminated	Cesarean	Yes ^{†¶}	No	12	15	Unknown
Female	2	Disseminated	Vaginal	Yes ^{†***}	No	16	29	Unknown

*Internal monitor.
[†]Prolonged rupture of membranes.
[‡]Underlying cause.
[§]Artificial rupture of membranes.
[¶]Immediate cause.
^{**}Intrauterine pressure catheter.
^{***}Vacuum extraction.

TABLE 3. Characteristics of Case Infants and Their Births, by Viral Type

	All Cases		Confirmed Cases						P (HSV-1 vs. HSV-2)	Probable Cases	
			Untyped		HSV-1		HSV-2				
	N	%*	n	%*	n	%*	n	%*	n	%*	
Total	76	100%	14		28		27			7	
Deaths (case-fatality rate)	13	17.1	2	14.3	6	21.4	5	18.5	0.787	0	0
Sex (n = 76)											
Male	43	56.6	8	57.1	16	57.1	13	48.1	0.504	6	85.7
Female	33	43.4	6	42.9	12	42.9	14	51.9		1	14.3
Mean/median age at diagnosis, in days (n = 76)	12.5/9.5		7.9/8.0		13.8/9.5		13.6/11.0		0.957	11.9/7.0	
Clinical manifestation (n = 69)			13		27		23			6	
SEM	39	56.5	9	69.2	17	63.0	8	34.8	0.135	5	83.3
CNS	12	17.4	1	7.7	3	11.1	7	30.4		1	16.7
Disseminated	16	23.2	2	15.4	7	25.9	7	30.4		0	0
Congenital	2	2.9	1	7.7	0	0	1	4.4		0	0
Lesions present (a case can have lesions in multiple sites) (n = 68)			13		27		22			6	
Yes—head	20	29.4	2	15.4	8	29.6	7	31.8	0.951	3	50.0
Yes—trunk	13	19.1	3	23.1	4	14.8	4	18.2	0.804	2	33.3
Yes—genitals/buttocks	13	19.1	6	38.5	4	14.8	1	4.5	0.219	3	50.0
Yes—extremities	17	25.0	4	30.8	7	25.9	6	27.3	0.073	0	0
None	27	39.7	3	23.1	15	55.6	9	40.9	0.308	0	0
Fever present (n = 61)			13		25		18			5	
Yes	19	31.1	2	15.4	8	32.0	9	50.0	0.234	0	0
No	42	68.9	11	84.6	17	68.0	9	50.0		5	100.0
Delivery mode (n = 72)			13		28		24			7	
Vaginal	45	62.5	10	76.9	17	60.7	14	58.3	0.862	4	57.1
Cesarean	27	37.5	3	23.1	11	39.3	10	41.7		3	42.9
Obstetric risk factor ¹ (n = 63)			13		25		19			6	
Yes	52	82.5	11	84.6	22	88.0	13	68.4	0.111	6	100.0
No	11	17.5	2	15.4	3	12.0	6	31.6		0	0
Maternal genital lesions at delivery (n = 52)			12		19		16			5	
Yes	5	9.6	1	8.3	2	10.5	1	6.3	0.653	1	20.0
No	47	90.4	11	91.7	17	89.5	15	93.7		4	80.0

*Column percentages.

¹Obstetric risk factors include the following: rupture of membrane >4 h preceding delivery, artificial rupture of membrane, and invasive monitoring or procedures.

HSV indicates herpes simplex virus; SEM, skin, eye, and mucous membrane infection; CNS, central nervous system infection.

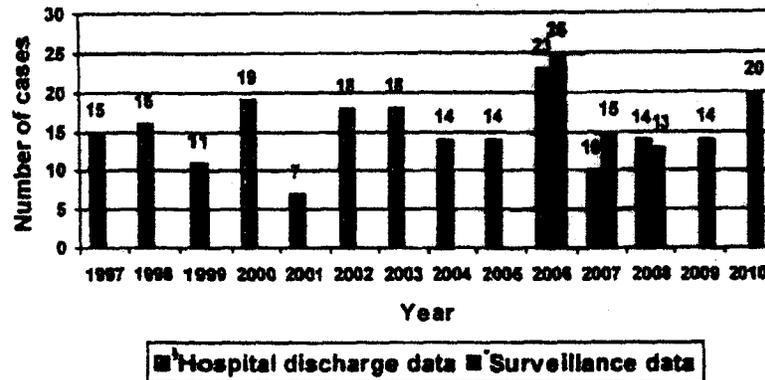
had lesions at delivery. None of the 8 cases diagnosed after 30 days of age were born to a mother with a known history of HSV or acyclovir use during pregnancy.

We found a delay in seeking care for 12/59 (20.3%) cases (median: 2 days; range: 2–10 days), a delay in diagnosis for 26/66 (39.4%) cases (median: 4.5 days; range: 2–21 days), and a delay in initiating acyclovir treatment for 18/61 (29.5%) cases (median: 3 days; range: 2–18 days). Overall, 38/54 (70.4%) cases with complete information with which to judge delays had one or more delays. Of the 38 cases where there were delays, 12 (31.6%) had fever, 27 (71.1%) had lesions, and 4 (10.5%) had neither fever nor lesions. Of 66 liveborn infants with complete information regarding lumbar puncture, 57 (86.4%) received lumbar puncture with

HSV testing. Of 63 infants, 50 (79.4%) with available information had liver-function tests performed. Only 19 (51.4%) of the 37 patients for whom we had data related to treatment had received an appropriate acyclovir regimen; all of these had received an adequate evaluation. Over half (68%, or 52/76) of all cases lacked timely or ideal diagnostics or treatment.

Length of hospitalization was calculated for 61/76 (80.3%) cases; median was 15 days and varied with clinical manifestation—disseminated cases, median was 11 days (range, 2–39); SEM cases, median was 15 days (range, 0–86 days); and CNS cases, median was 22 days (range, 10–46). The 2 congenital cases were hospitalized for a median of 40.5 days (range, 3–78).

Figure 1. NYC resident neonatal herpes cases identified using an administrative data set of discharges from New York State (including New York City) hospitals during 1997–2008, compared to those reported to New York City through routine public health surveillance during 2006–2010. *Hospital discharge data for 2009 and 2010 are not yet available. **For 2006, and for 2010, the total number of cases was estimated by annualizing 9 months of reported cases.



Where mode of delivery was known, 37.5% (27/72) of the infants were delivered by cesarean section. Among the 25 cases delivered by cesarean for whom we had data related to obstetric risks for HSV transmission, 20 (80.0%) had at least one such risk. (17 had >4 hours between rupture of membranes and delivery, 10 had artificial rupture of membranes, 5 had invasive instrumentation including vacuum extraction, fetal scalp electrodes, intrauterine pressure catheters, or forceps.) Only 2 of the cesarean deliveries were performed because of a perceived risk of HSV transmission. In both cases, the mother had a known history of genital HSV, and active genital lesions were noted at delivery. Among 45 cases delivered vaginally, 31 (68.9%) had at least one known obstetric risk for neonatal HSV transmission. (20 had >4 hours between rupture of membranes and delivery; 16 had artificial rupture of membranes; 12 had invasive instrumentation including vacuum extraction, fetal scalp electrodes, intrauterine pressure catheters, or forceps.)

Administrative Data Findings

During the 12-year interval from 1997 through 2008, a total of 179 infants were discharged with an ICD-9 code for herpes after an admission at age ≤ 60 days; 84/179 (46.9%) were male. Only 20/179 (11.2%) infants had been admitted at age >42 days. Median duration of admission was 14 days. During 1997 to 2008, annual incidence of neonatal HSV ranged from 5.6/100,000 live births (in 2001) to 18.3/100,000 live births (in 2006); median annual incidence was 11.8/100,000 live births. For infants aged ≤ 42 days, incidence ranged from 4.8/100,000 live births (in 2001) to 15.1/100,000 live births (in 2006); median incidence was 11.0/100,000 live births (Fig. 1).

DISCUSSION

We present the first population-based surveillance findings for neonatal HSV in the United States, as well as a comparison with findings from an administrative data set for the same population. Both methods yielded similar incidence rates, and were within the range of previously reported estimates. Our findings provide insight into neonatal HSV epidemiology. Laboratory-confirmed cases were diagnosed well after the first 30 days of life, and these included HSV-2 infections, suggesting a longer-than-expected incubation period. Our findings also reveal a substantial proportion of cases attributable to HSV-1.

The similarity in incidence estimates gleaned from NYC surveillance, and administrative data indicate that the latter may provide a reasonable means of measuring HSV disease burden in jurisdictions without resources to implement neonatal HSV

surveillance. However, administrative data are often untimely and therefore do not allow for a public health response to epidemiologic findings. In addition, administrative data can be difficult to deduplicate, rely on ICD-9 codes that are not specific to neonatal HSV, and often lack detailed clinical and laboratory information, thereby limiting accuracy and utility.

Disparities in risk for neonatal HSV by maternal age and race/ethnicity were apparent in our findings. Younger mothers might be less likely to be infected with HSV at the start of a pregnancy and at increased risk for acquiring HSV during pregnancy. Moreover, because genital HSV-2 infections are particularly prevalent among black non-Hispanic New York residents,²⁶ they might be more likely than women of other races/ethnicities to be exposed to HSV.

Our findings differed in several ways from those reported by other North American investigators. We found a lower proportion of CNS cases (17.4%, as compared to 30%) and a higher proportion of SEM cases (56.5%, as compared to 45%) than previously reported.³ The former was surprising, especially because highly sensitive nucleic-acid amplification tests are increasingly being used to test CSF specimens.^{27,28} and the majority of our cases (76.0%) had CSF testing. However, our findings on distribution of cases by clinical manifestation was similar to what was found in Canadian surveillance.¹¹ Our findings on prevalence of fever (31.1%) was also similar to what has been previously reported.²⁹ We also found a higher case-fatality rate among disseminated cases (62.5%) than previously reported (29%), but no fatalities among CNS cases, in contrast to previous reports of fatality rates of 4% to 15%^{2,29} among CNS cases. These findings may be explained, at least in part, by our use of a definition for disseminated disease which selects for only very severe disease and by the increasing use of highly sensitive tests (polymerase chain reaction) to test CSF, which may classify as CNS disease cases who might have been considered SEM in the past.

Over one-third of the reported case-patients had been delivered by cesarean section, suggesting that the protective effect of cesarean delivery can be undermined when other obstetric risk factors for transmission have already occurred. Because a majority of neonatal HSV cases were among infants born under circumstances that would not prompt provider suspicion of risk for HSV infection, opportunities for intervention are limited. Prenatal screening of pregnant women and their sex partners could enable providers to counsel seronegative women with seropositive partners about abstinence or safer sex during pregnancy,¹⁷ or to recommend acyclovir suppressive treatment during the third trimester to HSV-positive women,^{30–32} but

both of these strategies are unproven, expensive, and carry risks (of undue strain on the woman's relationship and possible toxicity to the infant,¹ respectively).

Postpartum infections could be reduced by educating parents and caregivers about ways to avoid transmitting infection. Unfortunately, it is difficult to modify the practice of ritual Jewish circumcision with oral suction because of the religious value attached to it by certain sects.⁵³ A vaccine for HSV would be the best prevention strategy, but the HSV vaccine in Phase III trials has recently proven ineffective.⁶ To prevent the majority of neonatal HSV cases, a vaccine would have to be effective against both HSV types and be administered before sexual debut.

Opportunities to intervene in the progression of disease were missed, evidenced by delays in diagnosis for over 1/3 of cases and delays in initiating antiviral treatment in nearly 1/3 of cases. A majority (89.5%) of those cases where delays in care seeking, diagnosis, and/or treatment were present had fever or lesions, which may support the case for increased caregiver and provider education. Nonspecific presentation, like the 19.7% of cases we found with neither fever nor lesions, does make diagnosis of neonatal HSV difficult, so pediatric providers should be encouraged to consider neonatal HSV in the differential diagnosis of ill infants, to perform SEM testing, lumbar puncture, and liver function tests, and to initiate intravenous acyclovir treatment immediately when neonatal HSV is suspected.

Our study has several limitations. It is likely that neonatal HSV cases were underreported and those reported might be biased toward more severe disease. The relatively limited number of cases limits our ability to make definitive statistical comparisons among our cases and to those reported in other case series and makes certain statistical analyses unstable. Due to missing information on some cases, there may be some misclassification of disease syndrome; however, that is most likely to have resulted in an overestimate of SEM cases. We lack data concerning lumbar punctures performed at the end of treatment; therefore, we were unable to assess whether follow-up treatment was performed when needed. Length of hospitalization for neonatal HSV might have been overestimated because it includes hospitalization for non-HSV illness, and might appear misleadingly short for disseminated cases, which are more likely to result in death. The number of congenital cases might have been overestimated because we may have included infants' ill at birth with conditions other than neonatal HSV who were colonized with HSV, which might have cleared without treatment. Finally, some of our findings may not be generalizable outside of NYC. For example, the incidence is affected by the prevalence of genital HSV in the population, which varies. However, some of our findings (e.g., delays in diagnosis, treatment, and seeking care, and case fatality rates) are likely to be generalizable.

CONCLUSION

Administrative data may provide an adequate and inexpensive means to assess local neonatal HSV burden, although such data lack the detail and timeliness of surveillance data. We believe routine surveillance for neonatal herpes is of value; our data provide new insights, give a baseline incidence from which to evaluate the impact of future prevention efforts, and point to the need for parental and provider education regarding neonatal HSV. Challenges remain for reducing incidence of neonatal HSV, as all current prevention strategies are limited.

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Exhibit 2

Shaare Zedek Medical Center, Jerusalem



המרכז הרפואי שערי צדק, ירושלים (ע"ר)

Affiliated with the Hebrew University School of Medicine, Jerusalem

מסונף לביה"ס לרפואה של האוניברסיטה העברית בירושלים

Prof. Avraham Steinberg, MD
Director, Medical Ethics Unit

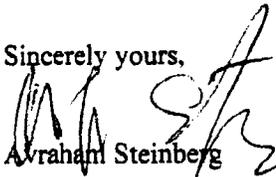
July 11, 2012

Dear Dr. Berman,

In response to your question concerning MBP and neonatal Herpes in Israel I can provide you with the following information:

1. Number of MPB: There is no registry of this practice. Our estimate is that there are 15,000-20,000 cases annually.
2. Number of neonatal Herpes associated with MBP: There is no registry in Israel of neonatal Herpes. We know of 7 suspected cases in the past 5 years. In 3 the PCR was negative, so that most probably the rash was not herpes; in one case the mother was diagnosed with active herpes; and in another one the mother had a rash very suspicious of herpes. In no case was there a scientific proof that the mohel was the source of the infection.

Sincerely yours,



Avraham Steinberg

Exhibit B

Affidavit of Rabbi Levi Y. Heber

1. I am an ordained Rabbi and a *mohel* certified by the American Board of Ritual Circumcision. I have been performing the *bris milah*—ritual circumcision—for over eighteen years, prior to which I went through an extensive training period. Among other things, I direct and oversee the operations of the International Bris Association, a non-profit organization committed to promoting the sacred observance of the *bris milah* ritual, and providing education and information about this practice. The International Bris Association also helps to locate and coordinate *mohelim* for those who are in need of a *mohel*'s services.

2. My motivation in performing the *bris milah* ceremony is to faithfully comply with the requirements of Jewish law, to respect and execute the sacred covenant between G-d and the Jewish People, solemnized by the patriarch Abraham thousands of years ago. Accordingly, I—like most *mohelim*—perform the *bris* without demanding any payment in exchange.

3. The opinions below are based on my extensive experience as a *mohel*, and the many discussions and communications with other *mohelim* that I have had in my capacity as the director of the International Bris Association, including at numerous conferences, training sessions, and seminars.

4. Every *mohel* is trained with both medical knowledge and knowledge of Jewish law, or *halakha*, so that he can safely and properly perform the *bris milah*. A *mohel* is trained to carefully observe the child's health prior to performing the *bris*; to ensure proper care and a sterile environment during the *bris*; and to provide proper and appropriate care for the infant after the *bris* is performed. In my experience, the requirements of Jewish law in this area are actually *more demanding* than standard medical procedures, and many medical professionals would therefore recommend a *mohel* over a physician to perform a circumcision.

5. By way of example, a *mohel* will—as a matter of caution—delay the *bris* past the required time (eight days after birth) if a child is exhibiting signs of jaundice. By contrast, standard medical procedure does not call for screening for jaundice as a prerequisite for performing circumcision, and physicians will in many cases declare an infant ready for circumcision even where a trained *mohel* would delay the procedure.

6. One of the critical components of the *bris milah* is the *metzitzah* stage. This involves orally drawing blood from the wound and surrounding areas. *Metzitzah* is an essential stage of the *bris*, required by Jewish law, and a *mohel* who does not follow the proper procedures in this regard is—as a matter of Jewish law—disqualified from service as a *mohel*.

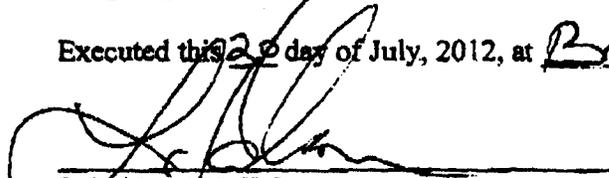
7. With respect to *metzitzah*, the *mohel* is extensively trained to ensure that he performs the procedure both in accordance with Jewish law and without exposing either the child or the *mohel* to any physical harm.

8. For example, in my experience, a *mohel* will absolutely not perform a *bris* if he is experiencing any cold sores. Further, in my experience, *mohelim* rinse their mouths with antiseptic mouthwash immediately before performing *metzitzah*, in order to ensure sterility for the procedure. In my experience, these precautions are more than sufficient to assure the safety of *metzitzah*, which is performed tens of thousands of times every year without incident.

9. *Mohelim* worldwide have been performing the *bris milah* for over 3700 years, with excellent results—unmatched by any other medical procedure.

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.

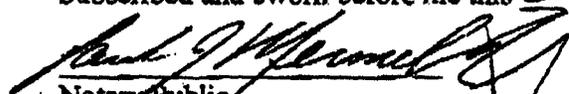
Executed this 20 day of July, 2012, at Brooklyn, New York.



Rabbi Levi Y. Heber

STATE OF NEW YORK
COUNTY OF Kings

Subscribed and sworn before me this 20 day of July 2012.



Notary Public

My commission expires on: 02/18/2015

SIGNED AND SWORN BEFORE ME
ON 7-20-12
PAUL J. MERMELSTEIN
NOTARY PUBLIC, State of New York
No. 01ME 4784146
Qualified in Kings County, Commission Expires Feb. 18, 2015

#11

Comment on the Proposed Amendment of Article 181 (Protection of Public Health Generally

Margaret Moon [mmoon4@jhmi.edu]

Sent: Monday, July 23, 2012 1:47 PM

To: Resolution Comments

Cc: Julia Schillinger

Thank you for this opportunity to comment on the proposal to require written informed consent from parents or legal guardians of infant boys undergoing ritual circumcision with direct oro-genital contact.

I am a pediatrician and bioethicist at the Johns Hopkins University, School of Medicine and the Berman Institute of Bioethics at the Johns Hopkins University.

Informed consent is a process by which we affirm and manifest our ethical duty to respect our patients as human beings with the capacity to make choices about their own well being. Informed consent is not about the signature on a piece of paper, it is about a relationship between two moral agents, both responsible for their own choices and actions. The goal of informed consent is to offer the patient a chance to make a voluntary choice about the benefits of a procedure, given the risks and the alternative options. The process of informed consent should offer the patient the type of information that a "reasonable person" would want to have in order to make a rational and voluntary choice. There is no voluntary choice without the information.

Informed consent is an active process. Its moral purpose cannot be achieved in the absence of an open discussion between the practitioner and the patient. Like all aspects of health care, informed consent may be interpreted within the constraints of a particular culture, but its meaning does not change. The duty to support a patient in making a voluntary choices about their own well being is not relative. Cultural differences may affect the manner in which informed consent is sought, but not its imperative.

The specific situation addressed by the proposed amendment is interesting in that it brings the practitioner/patient relationship into a different but parallel environment. With regard to the practice of circumcision, the relationship of a mohel to the parents of the infant boy is not different, in any morally relevant way, from that of a doctor in the newborn nursery. While all other aspects of the ritual circumcision may be simply religious in nature, the instant the mohel takes an knife to the penis of newborn, all differences fall away and the moral duties are equivalent.

The emergence of incontrovertible evidence that herpes simplex virus was transmitted from a mohel to several newborn male babies has created a new category of information that reasonable parents planning a ritual circumcision procedure would want to have before making their choice about circumcision. The risk is identifiable, the potential for a very bad outcome is significant and measurable and, most importantly, that risk can be avoided if the parents so choose. The active practice of meaningful informed consent in this setting is necessary to support parents in fulfilling their duty of love and care. We cannot ask parents to

protect their children and at the same time refuse to give them the tools to do so.

The idea that the parents of a newborn male would be asked to yield both their moral right to make an informed and voluntary decision about the wellbeing of their child and their duty to protect that child from preventable harm seems bizarre and wholly unnatural.

I fully support the proposed amendment to Article 181.

Margaret R. Moon MD MPH
Assistant Professor of Pediatrics
Division of General Pediatrics and Adolescent Medicine
Core Faculty
Johns Hopkins Berman Institute of Bioethics

200 N. Wolfe St.,
Room 2060
Baltimore MD 21287
410 614 3865

From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Monday, July 23, 2012 at 14:40:35

This form resides at
http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Protection%20of%20Public%20Health%20Generally

Office: DOHMH
Rule: Article 181-Protection
of Public Health Generally

Opinion on Proposed Rule: Against

Comment: This activity should be considered criminal. There is no reason on earth that this should be permitted. I strongly agree with prohibiting this act.



Agudath
Israel
of America
אגודת ישראל באמריקה

July 23, 2012

New York City Department of Health & Mental Hygiene
Board of Health, Office of the Secretary to the Board
2 Gotham Center, 14th Floor
Long Island City, NY 11101

Greetings:

Agudath Israel of America, founded in 1922, is a national Orthodox Jewish organization headquartered here in New York City. Among our other activities, we advocate for the interests of our constituents and for religious liberty interests in general.

We wish to comment on the Department of Health's proposal to require written consent from parents for *metzitzah b'peh*, oral suction, a practice that for many Jews is part of *bris milah*, Jewish ritual circumcision.

We should state at the outset that there are differing views within the Orthodox Jewish community regarding *metzitzah b'peh*. There are those rabbinic authorities who believe that it is required as part of a *bris milah*, and there are those who believe that there are legitimate alternatives to direct oral suctioning. In those communities that regard *metzitzah b'peh* as essential, there is simply no way that *bris milah* can be performed without direct oral suction. For them, any government regulation of *metzitzah b'peh* impinges on an essential religious practice, and thus raises the highest level of constitutional concerns. The fact that some Orthodox Jews view *metzitzah b'peh* differently is not legally relevant; as the Supreme Court stated in *Thomas v. Review Board*, 450 U.S. 707, 716 (1981), "it is not within the judicial function and judicial competence to inquire whether the petitioner or his fellow worker more correctly perceived the commands of their common faith. Courts are not the arbiters of scriptural interpretation."

Agudath Israel shares the legal and medical concerns raised by the International Bris Association and the Central Rabbinical Congress to the proposal, as set forth in their submissions to the Department. We see no need at this time to provide the Department with yet another legal brief discussing whether the Department's proposal is medically justified in light of the evidence, or any additional arguments as to why the proposal raises serious constitutional concerns. However, we wish to take this occasion to offer a perspective that the Department might find useful before it attempts to adopt and implement the proposed regulation.

As we see it, there are two ways that the Department can attempt to secure its objective of trying to prevent infants from contracting infection from *metzitzah b'peh*.

The Department can take unilateral action, without consulting with the affected community and without attempting to explore any alternatives to direct government regulation. That is the path that the Department appears to have chosen. The result is the fostering of the perception in the community that the Department is heavy-handed, set on direct confrontation, and potentially interested in perhaps banning *metzitzah b'peh* and regulating other aspects of *bris milah* as well. Should the Department choose to continue in this direction, the result will clearly be litigation and more confrontation. In the end, whether the Department's regulation survives will be decided by a judge. And even should the Department prevail, the resulting perception in the Orthodox Jewish community will be an extremely negative one, a perception that the Department is not interested in working with the community but simply in imposing regulations on a time-honored religious practice. We submit, respectfully, that this is not the best way to ensure the health and safety of children.

We would like to suggest that there is another path. That is the path of consultation and cooperation. It is the path that the New York State Department of Health chose in 2006, when the issue of *metzitzah b'peh* was most recently considered. Instead of unilaterally promulgating regulations, the State Health Department chose to work together with our community. Meetings were held with doctors and rabbis from throughout the Orthodox Jewish community, at which serious discussions took place as to how to best protect children from infection while at the same time respecting those who believed that *metzitzah b'peh* is an essential part of *bris milah*. The result was the adoption of a very detailed "circumcision protocol regarding the prevention of neonatal herpes transmission" that was accepted and signed by then-Commissioner Novello and other top state health officials, and by many prominent rabbis representing the spectrum of the Orthodox Jewish community.

Those protocols are attached as part of our testimony. They require that parents be informed about the risks of neonatal herpes and be informed of the warning signs of this infection. They require very specific sanitary procedures to be performed by a *mohel* both prior to and subsequent to the performance of *metzitzah b'peh*. And they require extensive follow-up testing of the infant and the *mohel* and others in cases where herpes has been discovered.

We submit that these protocols are a good example of what can be achieved when a government health department seeks to work with a community rather than simply act alone and promulgate regulations affecting a religious practice. Perhaps the 2006 protocols need to be updated. But clearly the protocols should provide the Department with good evidence that ours is a community that is capable of working together with government to address the health concerns raised by the religious practice of *metzitzah b'peh*.

New York City Department of Health & Mental Hygiene
July 23, 2012
Page 3

We therefore respectfully urge the Department to refrain from enacting the proposed amendment to Article 181 at this time, but instead move forward, as the State Health Department did in 2006, to work together with responsible rabbis and community leaders to help develop and implement the types of protocols that will effectively prevent any risk to health while at the same time respecting and preserving the religious and constitutional rights of members of our community for whom *metzitzah b'peh* is an essential religious practice.

Many thanks for your consideration of our views.

Sincerely,



Rabbi David Zwiebel
Executive Vice President

DZ/aa

#13a



State of New York
Department of Health
Corning Tower, Empire State Plaza
Albany, New York 12237

ANTONIA C. NOVELLO, M.D., M.P.H., Dr. P.H.
Commissioner

Phone: (518) 474-2011
Fax: (518) 474-5450

May 8, 2006

Dear Rabbis:

I want to thank all of you for coming to Albany over the past few months to discuss our mutual interest in finding an acceptable solution to the issues surrounding metzizah b'peh and their perceived complications.

The meetings have been extremely helpful to me in understanding the importance of metzizah b'peh to the continuity of Jewish ritual practice, how the procedure is performed, and how we might allow the practice of metzizah b'peh to continue while still meeting the Department of Health's responsibility to protect the public health. I want to reiterate that the welfare of the children of your community is our common goal and that it is not our intent to prohibit metzizah b'peh after-circumcision; rather our intent is to suggest measures that would reduce the risk of harm, if there is any, for future circumcisions where metzizah b'peh is the customary procedure and the possibility of an infected mohel may not be ruled out. I know that successful solutions can and will be based on our mutual trust and cooperation.

I have received your letter dated April 10, 2006. In this letter the members of the rabbinical council acknowledge that much progress has been made; and both parties, the Department of Health (DOH) staff and the Rabbinical Council, continuously have demonstrated a spirit of cooperation which has been instrumental in helping us deal with this sensitive public health issue.

As you have pointed out, we have accomplished much, and we need to be grateful for this progress. At this time, the DOH is in the process of proposing to the Public Health Council of New York State two health initiatives in connection with neonatal care:

1. Designation of herpes infection in infants aged 60 days or younger (neonatal herpes) as a communicable disease, reportable to local health department and then to the State.
2. Endorsing the Department of Health's new statewide standard of care: a) All newborns who undergo a medical or surgical procedure after birth, should be seen by a trained health care professional within 3-10 days after the procedure, or immediately if any complications develop.

Both of these health initiatives will be presented for final implementation at the next New York State Public Health Council meeting on May 12, 2006.

Finally, I am enclosing for your evaluation: 1) circumcision protocol to prevent neonatal herpes transmission; and, 2) herpes simplex virus in the newborn information page.

This last one after your evaluation and comments will need to be distributed to mothers of male newborns in the congregation.

Again, I want to thank you for addressing these challenging issues in the spirit of finding a solution that meets both the religious covenant and our obligation as a health department to protect public health. I look forward to your response to these new proposals and to further discussion with you when we next meet.

Shalom,

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner of Health

- cc: 1) Circumcision protocol to prevent neonatal herpes transmission
2) Herpes simplex virus in the newborn information page
3) Designation of Communicable Disease Regulation

Circumcision

DOH STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

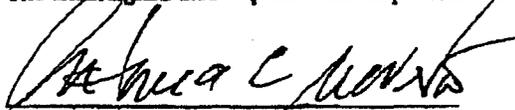
Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

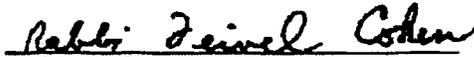
The undersigned, ANTONIA C. NOVELLO, M.D., M.P.H., Dr.P.H., as Commissioner of the New York State Department of Health, and the undersigned RABBIS, as representatives of their respective congregations, hereby agree that the attached Circumcision Protocol Regarding the Prevention of Neonatal Herpes Transmission sets forth:

- (1) their mutual understanding of the facts stated therein and the best practices for neonatal care of infants who are to undergo circumcision with metzizah b'peh;
- (2) their mutual expectation that the RABBIS will inform members of their congregations about this issue on an ongoing basis;
- (3) in the event that the New York State Department of Health learns of the infection of an infant with Herpes Simplex Virus which occurred on or after April 28, 2006 within a compatible incubation period following metzizah b'peh,
 - (A) the actions to be taken by the New York State Department of Health in the investigation of the infection,
 - (B) the actions to be taken by the mohel and any other person in question, and
 - (C) the support and cooperation expected of the undersigned RABBIS.

The undersigned also express their respect for the efforts everyone has made to reach this understanding.


 Antonia C. Novello, M.D., M.P.H., Dr.P.H.
 New York State Commissioner of Health

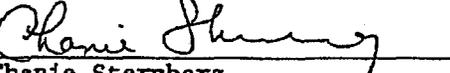
6/9/06
Date


 Rabbi Feivel Cohen

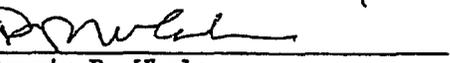
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 Robert Simins

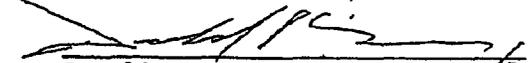
June 12 06
Date


 Chanie Sterenberg

6/12/06
Date


 Dennis P. Whalen

6.12.06
Date


 Donald P. Berens

6/12/06
Date


 Perry Smith

June 13, 2006
Date

Rabbi Yitzchok Isaac Eichenstein 6/12/06
 Rabbi Yitzchok Isaac Eichenstein Date

Rabbi Mendel Silber _____
 Rabbi Mendel Silber Date

Rabbi Hillel Weinberger JUNE 12/06
 Rabbi Hillel Weinberger Date

Rabbi Yitzchok Glick 6/12/06
 Rabbi Yitzchok Glick Date

Rabbi Abraham Blum 6/12/06
 Rabbi Abraham Blum Date

Rabbi Hillel David June 12 '06
 Rabbi Hillel David Date

Rabbi Moshe Steinmetz 6-12-06
 Rabbi Moshe Steinmetz Date

Rabbi Israel Eisenberg JUN. 12, 06
 Rabbi Israel Eisenberg Date

Rabbi Aaron Goldmunzer JUN. 12, 06
 Rabbi Aaron Goldmunzer Date

Rabbi Yitzchok Sternberg Jun 12/06
 Rabbi Yitzchok Sternberg Date

Rabbi Yonasan Menczer 6-12-06
 Rabbi Yonasan Menczer Date

-3-

Yechiel Goldberg 6-12-06
 Rabbi Yechiel Goldberg Date

David Niederman 6/12-06
 Rabbi David Niederman Date

Kalman Halberstam JUN/12/06
 Rabbi Kalman Halberstam Date

Moshe Weiss 6-12-06
 Rabbi Moshe Menachem Weiss Date

Mordchai Brill _____
 Rabbi Mordchai Brill Date

Joel Zicherman _____
 Rabbi Yoel Zicherman Date

Isreal Rubin 6-12-06
 Rabbi Isreal Rubin Date

Yossi Rubin 6-12-06
 Rabbi Yossi Rubin Date

Alfred Diamant 6/12/06
 Rabbi Alfred Diamant Date

 Rabbi Martin Orbach Date

Philip Zimmerman 6-12-06
 Rabbi Philip Zimmerman Date

David Weiss 6/12/06
 Rabbi David Weiss Date

Shia Rubin 6-12-06
 Rabbi Shia Rubin Date

Aron Silbertstein June 12 '06
 Rabbi Aron Silbertstein Date

Sholma Leib Weinberger June 12/06
 Rabbi Sholma Leib Weinberger Date

Simcha Stroli 6-12-06
 Rabbi Simcha Stroli Date

Shloma Blum _____
 Rabbi Shloma Blum Date

Joshua Fischer June 12 06
 Rabbi Joshua Fischer Date



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

DESIGNATION OF COMMUNICABLE DISEASE

WHEREAS, herpes infection in infants aged 60 days or younger, henceforth referred to as neonatal herpes, is a serious disease associated with neurologic devastation of the infant, and neonatal death; and

WHEREAS, neonatal herpes infection can be transmitted from an infected mother to the fetus congenitally, or to the neonate perinatally at delivery; and

WHEREAS, neonates can also acquire the virus postnatally; and

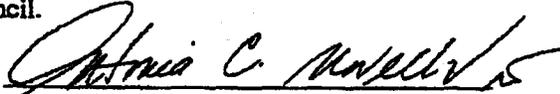
WHEREAS, neonatal herpes is one of the most common of all congenital and perinatal infections in the United States, infecting approximately 1/1,500 to 1/3,200 live births each year; and

WHEREAS, early detection of cases of neonatal herpes may prevent disseminated disease and death by early institution of antiviral therapy; and

WHEREAS, transmission may be prevented through proper identification and treatment of infected mothers and Cesarean delivery of infants born to infected mothers; and

WHEREAS, New York State data is needed to accurately measure the incidence of this disease, and identify missed opportunities for prevention;

NOW THEREFORE, pursuant to the authority vested in me by 10 NYCRR Section 2.1(a), I have determined that neonatal herpes infection is communicable, and a significant threat to the public health, and hereby designate neonatal herpes as a communicable disease under 10 NYCRR Section 2.1. This designation shall remain in effect until May 12, 2006, the next scheduled meeting of the Public Health Council.


Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner of Health

Date: April 28 / 2006

Circumcision Protocol Regarding the Prevention of Neonatal Herpes Transmission

- I. Since congregants may have heard about the issue pertaining to metzizah b'peh and circumcision, Rabbis should actively inform members of their congregations about this issue on an ongoing basis. The following information will need to be provided.
 - A. Herpes Simplex Virus (HSV) is known to cause rare, but very severe infections in newborns.
 - B. HSV is also known to spread to newborns during delivery by actively infected mothers.
 - C. Any pregnant women with a history of, or signs or symptoms suggestive of, herpes lesions around the birth canal, must inform their obstetricians of this fact. It is standard of care at present for infants to be delivered surgically by caesarean section from mothers suspected of having an active HSV infection around her birth canal.
 - D. While 23% of American women are chronically infected with HSV-2, most adults (~70%) are chronically infected with the other type of HSV (HSV-1) that is primarily associated with infection of the mouth, eyes and hands. Because HSV-1 is known to be shed in saliva even while the person has no lesions or experiences no other signs or symptoms of active infection, there is a theory in some medical literature that, although extremely rare, the practice of metzizah b'peh could be a route of transmission for HSV-1.
 - E. Parents, then, should be fully informed by the Rabbis regarding this.
 - F. When the infants are at home, parents and caregivers should wash their hands thoroughly with soap and water before cleaning the circumcision site.
 - G. Parents should watch for, and bring to the attention of their physician/nurse, any signs such as low grade fever, infection at the circumcision site, skin rash, or one or more blisters or blebs that may develop during the first 2 weeks after circumcision. This is crucial for the early diagnosis and treatment of HSV-1 infection. NYSDOH has provided educational materials (attached) regarding HSV infection in the newborn to be distributed to the congregation.

II. The following precautions are to be taken every time circumcision with metzizah b'peh is performed, whether by a mohel, by another participant, or by a combination of them:

A. Both participants must do the following:

1. Wash hands thoroughly immediately before the circumcision. Remove rings, watches, and bracelets before beginning hand washing.
2. Remove any debris from underneath fingernails using a nail cleaner under running water.

B. The mohel performing the circumcision must do the following:

1. Using either an antimicrobial soap or an alcohol-based hand scrub, scrub hands for the length of time recommended by the manufacturer, usually 2-6 minutes. If using an alcohol-based hand scrub, pre-wash hands with a non-antimicrobial soap and dry hands completely, then use the alcohol-based product as recommended and again allow hands to dry thoroughly before performing the circumcision (Reference 1).
2. After circumcision, cover the circumcision area with antibiotic ointment and sterile gauze.
3. Alert the mother and/or father to watch for fever, rash, blisters or inflammation around the genital area and then report immediately to physician/nurse regarding these findings.

C. The person performing metzizah b'peh must do the following:

1. Wipe around the outside of the mouth thoroughly, including the labial folds at the corners, with a sterile alcohol wipe, and then discard in a safe place.
2. Wash hands with soap and hot water for 2-6 minutes.
3. Within 5 minutes before metzizah b'peh, rinse mouth thoroughly with a mouthwash containing greater than 25% alcohol (for example, Listerine®) and hold the rinse in mouth for 30 seconds or more before discarding it (Reference 2).

May 9, 2006

2

III. A. If an infant becomes infected with HSV on or after April 28, 2006 within a compatible incubation period following metzizah b'peh, the NYSDOH will conduct an investigation without prejudging the cause. Such an investigation would include but not be limited to interviewing, reviewing medical records of, and testing the mohel in question and all pertinent caregivers. The mohel in question must stop metzizah b'peh (up to 45 days) until the NYSDOH investigation is completed.

B. So long as each local health department in whose jurisdiction such public health investigation is proceeding agrees to be bound by, without addition to or modification of, any and all provisions of this Circumcision Protocol, community Rabbis are expected to lend their support and cooperation in the event of any such public health investigation.

IV. The investigation described in Section III above will include the following laboratory testing:

A. The lesion(s) on the baby will be swabbed and tested for HSV by conventional virus culture.

B. If the culture result on the baby is positive, the virus will be typed to determine whether it is type 1 or type 2 HSV.

C. The primary caregivers (up to four) and the mohel will be serologically tested (Western Blot) for evidence of herpes virus infection. If found to be infected, further serologic testing will be done to identify the virus type: HSV-1 or HSV-2.

1. If the serologic test (Western Blot) on the mohel is negative or is a different type (HSV-1 or 2) from the type found in the newborn, the mohel will be ruled out as the source of herpes infection in the newborn. He may resume practice of metzizah b'peh following the precautions described in Section II, above.

2. If, on the contrary, the mohel's virus type matches the virus type of the newborn (type 1 or type 2), then the mohel, and any other care givers whose virus type also matches the newborn's virus type will undergo viral culturing to attempt to recover the virus. The sample for viral culture will be obtained by daily mouth swabs. Since viral shedding can occur between 9 and 15 days per month, recovery of the virus may take as long as a month of swabbing. When HSV is isolated, it will undergo further testing by restriction fragment length polymorphism (RFLP). RFLP will be arranged by the NYSDOH and the sample will be sent to a world-renowned laboratory capable of state-of-the-art RFLP testing and analysis, satisfactory to the NYSDOH. RFLP testing

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will take an additional time period of up to two weeks. All RFLP testing will be conducted in a blinded fashion such that the testing laboratory does not know the identity of the subjects' specimens.

D. The following actions will be taken, based on the RFLP results:

1. If the herpes viral DNA of the newborn and the mohel are identical, as determined by RFLP (the best scientific method available), then the mohel is implicated as the source of herpes infection in the infant.

This mohel will therefore be banned for life from performing metzizah b'peh in the State of New York.

2. After RFLP:

- A. If the mohel and newborn have a different HSV viral DNA subtype, then the mohel is determined not to be the source of the infant's infection. He may resume performing metzizah b'peh, adhering to precautions set forth in Section 2, above.

- B. In the event, however, that it is a caregiver who has an identical HSV viral DNA subtype as the newborn, and that caregiver is a hospital employee, the hospital will be informed by the NYSDOH and directed to develop a plan to prevent further infections. In this circumstance, the mohel may resume performing metzizah b'peh, adhering to precautions set forth in Section 2, above.

- C. In the event it is a parent or a family member who has an identical HSV viral DNA subtype as the newborn, then the parents or family member will be informed by NYSDOH, given educational materials on HSV and advised to consult his or her physician regarding steps to take to prevent transmission to a newborn in the future. In this circumstance, the mohel may resume performing metzizah b'peh, adhering to precautions set forth in Section 2, above.

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3. In the event that the mohel cannot be ruled out as the source of infection in the newborn because 1) herpes virus has not yet been recovered for RFLP subtyping and 2) no other caregiver is shown to have herpes virus identical to the newborn's virus, then, under these circumstances for the mohel to continue the practice of metzizah b'peh, he has to take one of the following options (the choice of which one shall be at his discretion):

- A. Continue abstaining from practicing metzizah b'peh until such time, if any, as the virus is recovered from the mohel or any other person, through additional swabbing and results are obtained after testing by RFLP. If such results are obtained, then the appropriate actions will be taken as set forth in this Section IV, Subsection D, paragraphs 1 or 2; or
- B. When the mohel will participate frequently in circumcision with metzizah b'peh, take one 500 mg valacyclovir tablet orally every day of his life (Reference 3); or
- C. When the mohel will participate only occasionally in circumcision with metzizah b'peh, take one 500 mg valacyclovir tablet orally every day for three days before circumcision.

The NYSDOH reserves the right to do mouth swabs for herpes culture on mohels choosing to go on valacyclovir to confirm that they are herpes culture negative.

References.

- (1) Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care settings. MMWR 2002/51 (RR16); 32-33.
- (2) Meiller TF et al: Efficacy of Listerine® Antiseptic in reducing viral contamination of saliva. J Clin Periodontol 2005; 32: 341-346.
- (3) There is no information regarding the effects of antiviral prophylaxis on HSV-1 shedding or transmission. However, antiviral prophylaxis has been shown to decrease clinical attacks of oral HSV-1 and to decrease HSV-2 shedding. [Sacks SL et al: HSV shedding. Antiviral Research 63S1 (2004) S19-S26]

HERPES SIMPLEX VIRUS IN THE NEWBORN

What is Herpes Simplex Virus?

Herpes Simplex Virus (HSV) is a virus that usually causes skin infections. There are two types of HSV: HSV type 1 usually causes small blisters on the mouth, eye, or lips (cold sores) and HSV type 2 usually affects the genital area. HSV infection in newborn babies can be very severe and can even cause death. This is because newborns' immune systems are not fully developed.

Who gets HSV and how is it spread?

- About 70% of all adults in the U.S. are infected with HSV-1 and may shed virus in their saliva at any time during their lifetime, even if they don't have symptoms like sores in the mouth or cold sores.
- Anyone can get either type of HSV. HSV-1 infection usually occurs in childhood, before age 5, from close contact with someone shedding HSV-1, often with cold sores.
- Most HSV infections in newborns are caused by HSV-2 that the infant catches from the mother's birth canal.
- Newborns can sometimes get HSV-1 from close contact with someone who is shedding HSV-1 virus in their saliva or has an active HSV-1 outbreak (cold sores).

What are the symptoms of HSV infection?

- Most people with HSV-1 can shed it in their saliva with no symptoms, or they may have a cold sore: a small fluid filled skin blister which breaks open, crusts over, and disappears in about 21 days.
- Infected newborns may have mild symptoms at first, such as low grade fever (100.4 degrees F., or more, rectally), poor feeding, or one or more small skin blisters. This can happen 2-12 days after HSV exposure. If any of these occur, notify your doctor immediately.
- Newborns can become very sick quickly with high fever and seizures, and may become lethargic (floppy).
- HSV infection in newborns can be very severe and can even cause death.

What is the treatment for HSV?

- Cold sores in children and adults don't need to be treated. Creams with anti-HSV medicine can treat cold sore symptoms, if necessary.
- Newborns with HSV require hospitalization for intravenous antiviral medication for 21 days. Even with this treatment, some newborns can suffer death or brain damage from HSV infection.

How can you prevent your newborn from getting HSV?

- If you are pregnant and have a history or signs and symptoms of genital HSV-2 infection, tell your doctor as soon as possible. A C-section delivery is recommended if a mother has an HSV-2 outbreak near the time of birth.
- Everyone should wash their hands before touching the newborn.
- Do not kiss your baby or let others kiss your baby if you or they have cold sores on the mouth or lips.

Care instructions (Recommendations for parents and caregivers):

- Wash hands thoroughly with soap and water before touching the newborn.
- Contact your doctor immediately if there are any signs of HSV infection. These include low grade fever (100.4 degrees F., or more, rectally), poor feeding, irritability, and skin rash in the form of pimples or blisters, seizures or other similar symptoms that may develop within three weeks following birth.
- All newborns should be seen by their healthcare provider between the first and third week of life.

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July 23, 2012

New York City Department of Health and Mental Hygiene
Board of Health
Office of the Secretary to the Board
Attention: Rena Bryant
2 Gotham Center, 14th Floor, Room 14-15, Box 31
Long Island City, NY 11101-4132

Re: Proposed Amendment to New York City Health Code, Article 181.

Dear Ms. Bryant:

These comments are submitted on behalf of the Central Rabbinical Congress of the U.S.A. and Canada ("CRC") in opposition to the proposed amendments to Article 181 of the New York City Health Code. The CRC is a rabbinical organization of approximately 350 rabbis representing congregations and religious schools serving over 150,000 Orthodox Jews. The CRC, among other activities, provides guidance on issues for Orthodox Jews and acts to protect and preserve Jewish religious practices.

I. INTRODUCTION

The proposed rule seeks, for the first time in the United States, to insert the government directly into a private religious ritual. The proposed regulation will require specific acts of the religious persons performing a religious circumcision (a *bris*), and force those persons (the *mohelim*) to provide a government-drafted document that is inconsistent with their religious beliefs to Jewish parents who desire a particular type of *bris* for their infant sons. The *mohel* will be prohibited from performing the ceremony if the parents refuse to sign the consent form for their own religious reasons, thus positioning the government as a barrier to the completion of one of the most sacred covenants of the Jewish faith.

The regulation only applies to *mohelim* who practice the *metzitzah b'peh* (MBP) form of the ritual circumcision. It does not seek to ban the practice, but to force the government's view into the midst of the particular religious practice and custom. As drafted, and as likely to be applied, the proposed rule fails all applicable tests as to its legality.

Independent of the direct conflict with religious practices and millennium-long custom, it fails to meet the requirement for the adoption of any rule or regulation as it is contrary to law and is arbitrary and capricious. The Department, relying on flawed epidemiology, has not shown a scientifically reliable connection between MBP and the transmission of infectious diseases to infants and resulting harm. Even if the Department believes there is sufficient evidence of such a causal connection, it has not shown why existing methods of general public education and available sterilization techniques are insufficient so as to warrant the direct intrusion into a sacred rite. The rule is also legally deficient since it is not accompanied by the language that will be required in the consent form, thereby depriving the public and the religious community of an opportunity to comment and object to language that, being developed solely with secular interests in mind, is likely to be very offensive to the Orthodox Jewish community, thereby antagonizing the very group of people targeted by this rule.

Obviously, consideration of the legality of this rule cannot be separated from the fundamental constitutional questions and the violations of federal and state constitutional provisions that prevent the government from interfering with the free exercise of religion. Rather than a neutral law of general applicability that has only incidental impact upon religious practices, this rule intentionally targets and only applies to a specific religious practice, *metzitzah b'peh*. Given its purpose, this rule is subject to rigorous constitutional scrutiny, in which the government must demonstrate a compelling state interest and prove that it has chosen the least restrictive means of satisfying that compelling interest. The rule fails on both points.

II. THE RULE IS ARBITRARY AND CAPRICIOUS AND IN VIOLATION OF LAW

A. The Rule Lacks a Rational Basis

The Notice of Intent published for the rule refers to the threat of transmission of infectious diseases, particularly herpes simplex viruses, from an infected *mohel* to the open wound of a circumcised child. The Notice also claims that the Department has knowledge of 11 cases between 2004 and 2011 where infants were infected with herpes simplex viruses "following circumcisions that were likely to have been associated with direct oral suction." The Notice states that two infants died and two suffered brain damage. The Notice also states that "some" of the parents of those children claimed they had no knowledge that the *mohel* would use MBP and that other parents, of uninfected children, also were unaware of the practice before the ritual.

We have requested, pursuant to the Freedom of Information Law, copies of the documents supporting the statements in the Notice of Intent and those have not yet been provided. As presented, the statements in the Notice supposedly supporting the need for the rule are very vague and conclusory and do not, on their own, support the need for the new rule. Per our request, the Department has extended the comment period, without providing a specific date, to allow us to comment after review of the requested documents. Therefore, CRC reserves its right to supplement or modify its comments after an opportunity to review the record.

These comments will not provide a detailed refutation of the allegations in the Notice, but we refer to the numerous comments and studies being submitted under separate cover which question the conclusion that MBP presents a significant public health risk. Set forth below are examples of some of the inherent irrationality of the justification for the rule.

The Department contends there were 11 cases of viral herpes infections of infants and presumes that there was a direct causal connection between those cases and MBP. While the Notice states that the cases occurred between 2004 and 2011, it is our understanding the Centers for Disease Control study that is one of the bases for the rule, in turn refers to data from New York City. And contrary to the statement in the Notice, those 11 cases occurred between 2000 and 2011, not the year 2004. The effect of the error in the Notice is to present a greater frequency of infection occurring over a shorter period of time. In fact the frequency was far less. In addition, we believe that DOH is underestimating the number of MBPs that occur on an annual basis, further inflating the potential risk.

In contrast to the equivocal language used by DOH to indicate causation and risk supposedly inherent to MBPs, we are not aware of any epidemiological evidence that directly connects those cases to *mohelim* who were carriers of the virus. Nor is that figure given any context as to the total number of *brissim*¹ that were performed during that period and how many of those were conducted using MBP. The Department has not discussed whether there are records of infection in infants who were circumcised without MBP either in a synagogue, home or hospital setting. Overall, there is an absence of perspective in the justification for the rule. The reliance upon questionable epidemiological statistics raises serious questions as to the scientific justification for the rule; a reliance that must be subject to judicial review.

Most significant is the complete lack of acknowledgment or assessment of the longstanding DOH public health campaign. We have been informed that since 2006, DOH has been distributing pamphlets throughout New York City hospitals advising parents of newborns about MBP and the potential risks that the City suggests are associated with the practice. Those pamphlets were significantly revised in May of this year. While DOH may have broad legal authority in the realm of public education, the CRC finds the current edition of the DOH pamphlet strikingly offensive as it presents flawed scientific information and serves to denigrate and dissuade observant Jews from engaging in an important religious practice. Nevertheless, DOH has not provided any information regarding whether it has studied the efficacy of that program and how the supposed rates of infection may have changed since the inception of the pamphlet education program or increased efforts by the religious community to educate *mohelim* regarding proper sterile practices. Nor has DOH disclosed its analysis supporting its conclusion that signed consent forms are a necessary measure that will reduce the rate of infection. As argued below, DOH wholly ignores an evaluation of the effectiveness of its existing public outreach campaign and the sanitary practices promoted by the Jewish community. Prior to interfering with religious beliefs, the DOH must first evaluate existing public health measures and make findings as to why those measures are inadequate.

CRC's questioning of the basis for the rule is not intended to minimize the tragedy of the deaths and serious injuries suffered by the infants. The loss of a child, an infant, is a terrible tragedy. CRC, its member rabbis and organizations provide guidance on the proper manner to

¹ "Brissim" is the plural of "bris."

conduct the sanctity of circumcision to protect the health of the child. The CRC supports providing information to the Orthodox community on the importance of and proper practice of *metzitzah b'peh* and has always provided guidance on proper sterile techniques to prevent infection, including the use of antiseptic mouthwash by the *mohel* prior to MBP. Those measures demonstrably eliminate all but the remotest alleged risks.

But all theoretical risk cannot be eliminated. Babies can contract infections in hospitals during a circumcision because mistakes happen and because disease transmission can occur via multiple pathways. Lacking far more evidence of a significant connection of MBP to infant infections and a demonstration that adherence to the religious sanitary rules are insufficient to protect public health, there is insufficient justification for the rule. DOH's record fails to provide a rational basis for either the need or structure of the rule.

B. The Regulation is Improperly Vague

1. No Model Consent Form

The regulation requires that *mohelim* use a parental consent form "approved or provided by the Department,"² yet a model form or required language has not been published with the Notice of Intent. Since the whole purpose of the regulation is to require a signed consent, it is imperative that the language be provided at this time and prior to promulgation of the regulation. Failure to provide an opportunity to comment on the core of the regulation is a denial of due process and a violation of the City Administrative Procedure Act.³

Based upon our initial review of the DOH's regulations, we have only identified one other instance where DOH regulations stipulate a DOH-approved consent form. That involves instances of voluntary sterilization by licensed medical practitioners.⁴ A review of that form provides a clear example of the strong advocacy language that is often employed in consent forms where the myriad possible complications from a procedure are explained in stark detail. It is reasonable to presume that DOH will require similarly stark language that may raise concerns regarding accuracy and tone, along with the very real possibility of direct intrusion into or contravention of religious beliefs. Therefore, as a matter of fundamental due process to be able to comment on proposed regulations, the model language must be provided. Failure to do so also intrudes upon the constitutionally protected right to the free exercise of religion and is another fatal flaw that is discussed below.

2. No Provision for Implementation

² Proposed New York City Health Code § 181.21(b).

³ Under New York City Charter § 1043 (b), agencies must publish the "full text of the proposed rule" in order that the public may review it for comment. In this case, an essential and central component of the rule—the parental consent form itself—is not provided. Thus, it is impossible for the public to fully review the complete regulation and provide substantive comments, thwarting the intent of the City Administrative Procedure Act's public participation components. For those who would be required to distribute and sign this form, such an omission denies them the opportunity to fully understand and participate in a process that will directly affect their lives and their religious practices.

⁴ New York City Administrative Code § 17-405(3). A copy of the form can be found at http://www.health.ny.gov/health_care/medicaid/publications/docs/ldss/ldss-3134.pdf

While the CRC cannot accept a regulation unsupported by a rational basis and that intrudes on a sacred religious practice, it must be noted that even if adopted, the regulation lacks any provision for how it will be implemented and when it will take effect. Since a *mohel* may only use a DOH-approved form, and none is provided with the regulation, there is no indication of how a *mohel* could get a form approved and how long it would take. Since many *brisim* occur on a daily basis, and under Jewish law the *bris* must occur on the eighth day after birth,⁵ no guidance is provided as to how a *mohel* could avoid the potential criminal penalty while still performing his religious duties. The failure to address this fundamental question highlights the lack of care paid to this proposed regulation and demonstrates that it is more of a reaction to inflammatory press coverage and not an example of a neutral health regulation designed to protect public health.

C. The Proposed Rule Exceeds DOH's Jurisdiction

While it is recognized that DOH's authority to protect public health is broad, it is not unlimited. DOH's regulation must not only be rational, but also constitutional and consistent with legislative intent and regulatory practice as to the manner of its implementation. In this instance, the rule marks an unprecedented intrusion into a sphere of life heretofore completely devoid of government intrusion. As noted in Point III, below, the regulation is clearly an unconstitutional interference with the free exercise clause of the First Amendment, but even without consideration of the direct impact on religion, it represents unwarranted intrusion into private relationships and activities.

1. Creation of a New Regulated Class

Existing DOH regulations generally fall into four categories: (1) regulations all individuals/property owners must follow, (2) regulations which apply to licensed/certified professionals, (3) regulations which apply to licensed establishments or facilities, such as restaurants, hospitals, tattoo parlors, etc., and (4) regulations which apply to regulated individuals whose position opens them up to regulation, such as landlords, employers, etc. The latter three categories of regulation involve professions or transactions which are traditionally regulated, and those engaged in those professions/transactions would expect to be subject to at least some regulation.

The MBP informed consent mandate does not fall into any of these categories. Unlike doctors or surgeons, *mohelim* are not required to hold any license or certification in order to perform the *bris*.⁶ The MBP does not take place in any licensed establishment or facility; in fact, it traditionally takes place in a synagogue or private home. Further, *mohelim*, or religious leaders in general, do not hold a position which traditionally subjects them to governmental regulation. This regulation would create a new category of regulated persons; a subset of Jewish Orthodox *mohelim*—who would not otherwise have any reasonable expectation that their religious practices would be subject to governmental regulation—would be the only individuals occupying that category.

⁵ Unless delayed for health reasons.

⁶ In fact, government licensing or direct regulation of religious leaders would be unconstitutional.

By creating a new regulated class, this regulation would allow the City to insert itself into a religious practice in an unprecedented manner. We can find no other religious ceremony that has been subjected to such direct regulation by the City of New York. In fact, New York City has explicitly exempted religious practices or ceremonies from many regulations.⁷ For example, a provision of the Fire Code prohibits the maintenance or use of open flames inside large public gathering centers, but an exemption is carved out for use of open flames for ceremonial or religious purposes.⁸ The use of amplified sound devices is not allowed in the City without a permit, with the exception of the use of sound devices by a church or synagogue "in connection with religious rites or ceremonies."⁹ The City regulates pools and bathing establishments, but wholly exempts from regulation "pools used only for religious purposes" such as ritual immersion.¹⁰ Each of these regulations was promulgated out of concern for public health and safety, yet the City recognized and honored its obligation to avoid burdening religion by exempting religious rites and ceremonies from the broad sweep of its laws. We are deeply disturbed that similar respect was not afforded to the Orthodox Jewish community in this case.

2. The DOH is Attempting to Compel Private Speech by Unregulated Individuals Privately Engaging in an Unregulated Activity.

The DOH has significant and expansive authority to regulate activities rationally related to public health.¹¹ Religious and constitutional questions aside, if the Department had reliable and uncontested scientific evidence that a secular practice posed a threat to the public health, the City could impose restrictions on how residents engaged in that practice; for example, requiring the use of protective measures or imposing restrictions on who could engage in the practice. The City also retains the authority to distribute information, or to compel licensed health care professionals to distribute information, regarding public health.¹² But that is not the case here.

This rule does not regulate *the practice itself* so much as it regulates *the information* that must be passed between the parties, privately, during a ceremony that takes place in a synagogue or private home. The MBP is a practice that is perfectly legal and hitherto unregulated by the DOH or any other local, state or federal authority. Yet the Department is now attempting to command that a *mohel* distribute information with which he does not agree, and mandates that parents sign a consent form, before engaging in this legal, unregulated activity. We have reviewed the Department's regulations and can find no basis in the City Charter, the City Health Code, or any other regulations which indicate that the Department may compel otherwise unregulated persons to distribute information on the City's behalf. There is no evidence the DOH has the authority to mandate that an otherwise unregulated person must obtain informed consent before engaging in an otherwise unregulated activity. Nowhere in the Charter does it appear to say that the DOH has the authority to regulate what information passes between private unregulated parties within the privacy of a residence or place of worship. Moreover, we can find no basis in law which allows the City to compel unregulated persons to engage in speech which is contrary to their beliefs.

⁷ New York City Administrative Code § 308.3.7 (1.1).

⁸ New York City Administrative Code § 308.3.7 (1.1).

⁹ New York City Rules, Title 38 § 8-06 and New York City Administrative Code § 10-108(i).

¹⁰ New York City Rules, Title 24 § 165.01 (b)(3) and New York City Administrative Code § 3109.2.

¹¹ New York City Charter § 556(a).

¹² New York City Charter § 556(d).

The City here attempts to impose an informed consent requirement on otherwise unregulated individuals, engaged in a private, unregulated practice. The requirement would allow the DOH to reach into a place of worship or private home and compel an individual to engage in Department-sanctioned speech. While the Department's authority is extremely expansive, this stretches the bounds of any reasonable interpretation of that authority.

3. The Regulation Would Establish a Dangerous Precedent

This attempt to regulate private speech would create a dangerous precedent, starting the slide down the proverbial "slippery slope" by permitting government interference in private matters generally and religious practices specifically. If DOH is permitted to require that otherwise unregulated individuals pass certain information to others and obtain their consent before engaging in otherwise unregulated activities, a vast array of potentially new and intrusive regulations could be imposed on private behavior. Any unregulated activity which carries a possible health risk could require a similar informed consent process, for example, engaging in sexual intercourse with a person who may be infected with an STD; consumption of alcohol by a woman who may be pregnant; the sale of cigarettes to the parents of young children; or serving large quantities of soda or high fructose corn syrup to children at a picnic.

This also opens up the possibility that DOH may impose additional restrictions on MBP, that there may be additional regulation of the *bris* generally, or that other religious ceremonies could be subject to regulation. While the Department has said they do not plan to ban MBP, upholding this regulation would open the door to giving the DOH the power not only to impose other restrictions, but to interfere in any other religious practices which may have a potential impact on health. Could DOH require that a Roman Catholic priest obtain signed consent forms before communicants sip from the communal cup during celebration of the Eucharist, due to the potential risk of spreading infections by sharing the cup? Certainly dozens of such practices, across a wide spectrum of religions, could then be open to DOH interference and secular judgment.

III. THE PROPOSED RULE IS UNCONSTITUTIONAL

The proposed rule presents a clear violation of the Free Exercise Clause of both the United States and New York Constitutions,¹³ as it is a "non-neutral regulation" that unlawfully interferes with a protected religious practice. Subject to judicial review, a court would therefore apply a "strict scrutiny" standard of review to analyze the provision, and would find that even if the government's interests in enacting the regulation were compelling, the proposed regulation was not drawn in the narrowest terms necessary to accomplish those interests (*see Church of the Lukumi Babalu Aye, Inc. v City of Hialeah*, 508 US 520, 546 [1993]).

¹³ "The Free Exercise Clause of the First Amendment, which applies to the states by virtue of the Fourteenth Amendment (*see Cantwell v. Connecticut*, 310 U.S. 296, 303 [1940]), guarantees that government shall make no law 'prohibiting the free exercise' of religion [US Const. amend. 1]. New York's Bill of Rights provides: 'The free exercise and enjoyment of religious profession and worship, without discrimination or preference, shall forever be allowed in this state to all humankind; . . . but the liberty of conscience hereby secured shall not be so construed as to excuse acts of licentiousness, or justify practices inconsistent with the peace or safety of this state' (N.Y. Const., art. I, § 3)" (*Catholic Charities of Diocese of Albany v Serio*, 28 AD3d 115, 121-22 [3d Dept 2006] *aff'd*, 7 NY3d 510 [2006]).

Recent New York jurisprudence¹⁴ dictates how regulations such as § 181.21 are to be evaluated when opposed by members of religious orders alleging infringement on religious liberty; the controlling authority demonstrates that a strict scrutiny analysis¹⁵ of the regulation must result in its withdrawal or inevitable nullification by the courts.

A. The Proposed Rule Imposes an Unreasonable Interference on a Religious Practice

As noted above, the CRC believes that the proposed regulation is invalid because it lacks a rational basis. Alternatively, the Orthodox community is entitled to an exemption from the application of the rule on religious grounds.¹⁶ To be successful in either claim, the Court of Appeals has established that “the party claiming an exemption bears the burden of showing that the challenged legislation, as applied to that party, is an unreasonable interference with religious freedom” (7 NY3d at 510).

It is manifestly evident that the objections to the rule trigger the strict scrutiny test. As noted above, there are significant questions regarding the evidence supporting the rule and its rational basis. We have noted the lack of supporting data and comparison with overall infection rates and the failure to consider the effectiveness of existing sterile practices. The public has been denied the opportunity to comment on the text of the consent form. Those serious, if not fatal flaws must be measured against the ritual with which the rule is designed to interfere. The *bris* is a vitally important religious ceremony in the Orthodox Jewish tradition; criticism or negative portrayals of this sacred practice, based on preliminary scientific findings that the community questions, listed on a document that the community has yet to review, is unreasonable. The act of issuing the consent form to parents disrupts a ceremony that has existed in a stable form for millennia. Moreover, the CRC fears that the consent form could imply that the *mohelim* criticize or are apprehensive about the practice—a message that is contrary to the ceremony’s symbolism. This regulation amounts to a state intrusion into an ancient and consecrated ritual that should be devoid of such interference.

Concededly, merely showing that the state has imposed obstacles to this particular religious practice is insufficient to trigger the strict scrutiny analysis that would exempt religious practitioners from § 181.21, or nullify it entirely. Even where a law has the incidental effect of burdening a particular religious practice, a law that is neutral and of general applicability need not be justified by a compelling governmental interest (*Catholic Charities of Diocese of Albany v Serio*, 28 AD3d 115, 122 [3d Dept 2006] *affd*, 7 NY3d 510 [2006], citing *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 531 [1993]). “Only a law that does not meet the

¹⁴ See generally *Catholic Charities of Diocese of Albany v Serio* (7 NY3d 510 [2006]).

¹⁵ “A law burdening religious practice that is not neutral or not of general application must undergo the most rigorous of scrutiny” (*Church of the Lukumi Babalu Aye, Inc. v City of Hialeah*, 508 US 520, 546 [1993]).

¹⁶ See *Wisconsin v Yoder*, 406 US 205, 235[1972], in which the Supreme Court exempted Amish respondents from adhering to a compulsory education law, and stated:

“Aided by a history of three centuries as an identifiable religious sect and a long history as a successful and self-sufficient segment of American society, the Amish in this case have convincingly demonstrated the sincerity of their religious beliefs, the interrelationship of belief with their mode of life, the vital role that belief and daily conduct play in the continued survival of Old Order Amish communities and their religious organization, and the hazards presented by the State’s enforcement of a statute generally valid as to others.”

interrelated requirements of neutrality and general applicability will be subject to strict scrutiny” (28 AD3d at 115).

Therefore, to determine whether a strict scrutiny analysis governs the review of this law, there must also be a determination that § 181.21 is not a regulation generally applicable to the public. That point is self-evident.

B. The Proposed Regulation is Not a “Neutral Law”

In *Catholic Charities*, the New York Court of Appeals quoted the U.S. Supreme Court to explain that “the right of free exercise does not relieve an individual of the obligation to comply with a ‘valid and neutral law of general applicability on the ground that the law proscribes . . . conduct that his religion prescribes’ . . . [W]here a prohibition on the exercise of religion ‘is not the object . . . but merely the incidental effect of a generally applicable and otherwise valid provision, the First Amendment has not been offended” (7 NY3d 510, 521 [2006], citing *Empl. Div., Dept. of Human Resources of Oregon v Smith*, 494 US 872 [1990]).

The second question in an analysis of the DOH regulation, then, is whether the rule can be described as a “neutral law of general applicability.” By the very language of the regulation, this law is clearly not a generally applicable one.

The U.S. Supreme Court held in *Church of the Lukumi Babalu Aye, Inc. v City of Hialeah* (508 US 520 [1993]) that “a ‘neutral law . . . is one that does not ‘target [religious] beliefs as such’ or have as its ‘object . . . to infringe upon or restrict practices because of religious motivation’” (7 NY3d at 521). In this instance, DOH explicitly states in the “Statement of Basis and Purpose” supporting proposed regulation § 181.21, the provision is designed to regulate the practice of *metzitzah b'peh*, which the DOH describes as “direct oral suction.” By invoking the Hebrew name, the DOH makes clear that the chief object behind (and only practical application) of the law is to restrict a specific religious practice.

Although the text of the regulation omits any reference to the practice by its Hebrew terminology, the phrase “direct oral suction” undeniably refers to the religious communities which exclusively practice the technique.¹⁷ There is no “general applicability” to this regulation; by definition, it does not apply to the licensed (secular) surgeons whose administration of a circumcision does not require *metzitzah b'peh*. The only instance in which this regulation would be applicable are ones in which the practices of discernible religious communities are implicated. Unlike in *Catholic Charities*, religious beliefs *are* the target of the proposed regulation at issue here; both in effect and in the explicitly stated rationale supporting the promulgation of this regulation, the law’s object is clearly to interfere with the exercise of a specific religious practice exclusive to a few distinct religious communities (see 7 NY3d at 522).

C. Because the Rule Unreasonably Interferes With Religious Practice and is Not Generally Applicable, the Strict Scrutiny Standard of Review Applies

¹⁷ In fact, “oral suction” is a direct English translation of the Hebrew *metzitzah b'peh*.

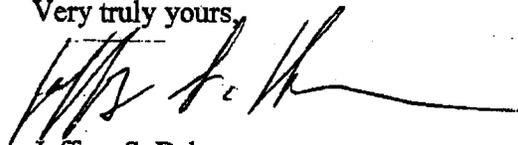
The U.S. Supreme Court holds that laws burdening religion which are "not neutral or not of general application" are subject to the most rigorous level of scrutiny applied by the courts (*Church of the Lukumi Babalu Aye, Inc. v City of Hialeah*, 508 US 520, 546 [1993]; see also *Tenafly Eruv Ass'n, Inc. v Borough of Tenafly*, 309 F3d 144, 165 [3d Cir 2002] ruling that if a law "is not neutral—i.e., if it discriminates against religiously motivated conduct—or is not generally applicable—i.e., if it proscribes particular conduct only or primarily when religiously motivated—strict scrutiny applies). First Amendment jurisprudence commands that non-neutral laws burdening religion must advance governmental interests "of the highest order" and must be narrowly tailored to achieve those interests (*Church of the Lukumi Babalu Aye*, 508 US at 546; *Tenafly Eruv Ass'n*, 309 F3d at 165). In this case, even assuming the City's interests are compelling, the DOH was not sufficiently narrow in its tailoring of the regulation. On its own, this lack of narrow tailoring is enough to invalidate this regulation on First Amendment grounds.

In pursuing enactment of this regulation, DOH is straying well beyond what is necessary to accomplish its stated goal of alerting the public to the *alleged* health risks of direct oral suction. Indeed, DOH is already engaged in a campaign to disseminate literature to the public pertaining to the alleged health risks of this practice, yet it has not examined the adequacy of that effort. Nor has it considered the sterile procedures for *metzitzah b'peh*. It therefore has no basis for implementing a new measure that so dramatically imposes on the Orthodox Jewish community's religious rites. To force *mohelim* to act in compliance with a regulation that is scientifically questionable and unnecessarily heavy-handed is an unlawful burden on this community's constitutionally protected religious freedom.

A law that targets religious conduct for distinctive treatment or advances legitimate governmental interests only against conduct with a religious motivation will survive strict scrutiny only in rare cases (*Church of the Lukumi Babalu Aye, Inc. v City of Hialeah*, 508 US 520, 546 [1993]). This is not one of those rare cases. DOH simply has not demonstrated that its interests are sufficiently compelling to require regulation of a religious practice that affects a small and distinct population, where the science fails to demonstrate a conclusive link to significant health risks, and that existing measures for sterile procedures are insufficient to achieve the government's goal.

In light of the clear unconstitutionality of the regulation, DOH should take the prudent step of withdrawing the regulation and working with the community to refine an accurate and religiously sensitive public education effort.

Very truly yours,



Jeffrey S. Baker
Dean S. Sommer

#149

התאחדות הרבנים דארצות הברית וקנדה

CENTRAL RABBINICAL CONGRESS OF THE U.S.A. AND CANADA

85 Division Avenue • Brooklyn, NY 11211 • Tel. (718) 384-6765 • Fax: (718) 486-5574

7"55

July 23, 2012

Via E-mail and Regular Mail

New York City Department of Health and Mental Hygiene
Board of Health
Office of the Secretary to the Board
Attention: Rena Bryant
2 Gotham Center, 14th Floor, Room 14-15, Box 31
Long Island City, NY 11101-4132

Dear Ms. Bryant:

We are writing to express our strong opposition to the proposed amendments to Article 181 of the New York City Health Code which would require a *mohel* to obtain a signed consent from a baby's parents, before applying *metzitzah b'peh* during a *bris*. The intrusion by the City, into one of the Jewish faith's most sacred acts, is profoundly disturbing. We urge the Department not to adopt this rule.

The Central Rabbinical Congress of the U.S.A. and Canada ("CRC") is a rabbinical organization of approximately 350 rabbis representing congregations and religious schools serving over 150,000 Orthodox Jews. We work to protect and preserve Jewish religious traditions that have been practiced for thousands of years. In order to protect those practices, the CRC has retained the law firm of Young/Sommer LLC to review the legality of the proposed regulation. Their enclosed letter discusses the fatal legal flaws in the regulation.

The regulation should not be adopted not only because of the legal problems. It should not be adopted because of the significant flaws in the underlying science that supposedly supports the rule. Those flaws have been extensively documented in other comments being submitted to the Department. Of equal, if not greater importance is that it should be rejected because it is contrary to one of the fundamental principles upon which this country was founded – the freedom to practice one's religion without government interference.

Our community of Orthodox and Hasidic Jews primarily emigrated to this country after the horror of the Holocaust, when almost all of European Jewish life was destroyed. The survivors came here to reestablish their families and institutions in a country that protected religious freedom, where they would no longer be subject to state sanctioned oppression.. This country provided a haven from that oppression and we have grown and prospered in this wonderful land of freedom.

As Jews, particularly the Ultra-Orthodox, we cherish that freedom even as we understand that our religious practices may seem unusual to the secular world. We recognize that our way of life can lead to misunderstanding, confusion and sometimes fear, which we try to minimize whenever possible without compromising our core beliefs.

Where there is a lack of understanding of our practices, there can be sensationalized reports inflamed by the media. Last year's death of an infant from HSV-1 was prematurely attributed to transmission from *metzitzah b'peh*, despite a lack of evidence of a connection with the *mohel*. Evidence now indicates the infection came from the baby's older brother who had open HSV-1 cold sores. Those facts have not been publicized in the media, because that form of transmission is far less sensational than blaming it on *metzitzah b'peh*.

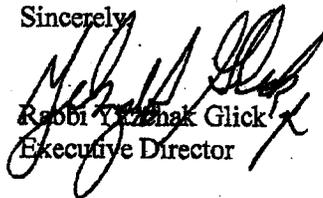
Metzitzah b'peh as part of a *bris* is the most ancient and fundamental ritual in the Jewish faith marking Abraham's covenant with G-d. Therefore the CRC promotes this practice. It also provides guidance to *mohelim* on the proper and sanitary measures that should be taken during the *bris*. Included in those instructions is the use of antiseptic mouthwash that has been demonstrated to kill virtually all HSV-1.

We also oppose this restriction on medical grounds. If the DOH's desire to adopt this regulation is driven by a legitimate public health concern and not an animus toward a particular religious practice, then this regulation is a particularly inefficient means of addressing the issue. Instead of denigrating a religious practice, the DOH should be more broadly educating parents about the risks to infants from HSV-1 and the relative ease by which they may be infected, including contamination from symptomatic family members. Obviously the risks extend far beyond the Jewish community.

We cannot always explain our practices and beliefs to the modern secular world. Nor do we feel an obligation to do so. We trust in the Department to stand up to what verges on hysteria and recognize that legitimate public health education can be undertaken to protect all infants in New York City from HSV-1, and not focus on intruding on our religious rites. In fact, in recent weeks we have worked with the Department so it is aware of the sanitary practices of the *mohelim*, and so that the Department can develop public education materials that are factually accurate and respectful of our faith. We look forward to continuing those efforts.

Thank you for consideration of our comments.

Sincerely,



Rabbi Yitzhak Glick
Executive Director

Cc: Commissioner Farley

#15

chief Rabbis

Levi Heber [levi@hlevi.com]

Sent: Monday, July 23, 2012 4:54 PM

To: Resolution Comments

Attachments: MBP Israel Rabbis.pdf (124 KB)

Rabbi Levi Y. Heber

International Bris Association

Levi@circumcision.net

www.circumcision.net

917-539-8700

1.888.MOHEL44

ברית מילה

בהלכה

ACCORDING TO THE DECREES OF THE HIGHEST
RABBINICAL AUTHORITIES OF OUR GENERATION

BRIS MILAH

MUST BE PERFORMED BY METZITZA B'PEH (MBP)
WITHOUT ANY DEVIATION



CHIEF RABBI OF ISRAEL

יוסף שלי אלישיב
ירושלים

מ"טו תמוז תש"ח

הו"ר ר' יוסף אלישיב.
דברי תפילה וזמור המזמור שכתב א"צ אישון
ואין הדם קובל על כל המעשים המעשי
ב"פ. וכל מעלותיו. ל. מ. א. א.

אשר טעמו חזק על ידי הנהגת
אשר חזק וכל מי שחזק
יפתי א"צ א"צ א"צ א"צ
זו היא תורה זו תורה
תורה, זה המעשה הזה
ע"פ ה. א. א. א. א. א.
היה זה המעשה הזה
יפתי א"צ א"צ א"צ א"צ
ואשר חזק וכל מי שחזק
אשר חזק וכל מי שחזק

[TRANSLATION FROM HEBREW]

Yona Metzger
 Chief Rabbi of Israel
 President of the Chief Rabbinic Council

By the help of Heaven, 4th Av, 5772
 23 July, 2012
 [...]

CALL TO THE PUBLIC

The commandment of circumcision is among the most important in the Torah, and thirteen covenants were made [by G-d with the Jewish people] concerning it. It is the foundation of the bond between the Jew and his Creator, and ever since the Torah was given until today, the Jewish people have given their lives for it, throughout the generations, to fulfill it in accordance with all its details and fine points according to Torah law.

It is well-known to the public the great obligation to observe meticulously all details of the Torah laws concerning circumcision according to their Halachic requirement, without any change from Jewish tradition as practiced for the past thousands of years. This includes the actual circumcision [removing the foreskin], *peri'ah* [revealing the *glans*], and *metzitzah* – that one should not change the manner in which they have been practiced following the standard practice since time immemorial.

Obviously, one should take all steps necessary to ensure sterilization of the entire circumcision process in all its stages, as we have instituted here in the Holy Land, that everyone authorized by the Chief Rabbinate of Israel to circumcise receives full training in how to perform the circumcision process in such a way that it cause no possibility of any danger to the circumciser or to the one circumcised. Here is not the place to list these rules. But when circumcision is performed according to the proper guidelines, it has no aspect that is harmful, Heaven forfend.

To our regret, recently we have heard various calls of organizations and even non-Jewish governments and courts around the world that have dared to find fault, Heaven forfend, in the Torah's commandments and to forbid fulfillment of the covenant of circumcision according to its Halachic requirement as we have been commanded to do it by the Creator of the universe.

I call upon every [Jew] whose ancestors stood at Mount Sinai not to listen to those speaking such calumnies and to fulfill our G-d's commandment which, we have been promised, will never be forgotten by the Jewish people, as our Sages, of blessed memory, have said (Talmud, *Shabbat* 130a):

“We have learned: Rabbi Shimon, son of Elazar, said, ‘Every commandment that the Jewish people have endangered their lives for it at a time of governmental persecution – such as [the prohibition of] idolatry, and circumcision – is still observed by them.’”

The courageous self-sacrifice of our ancestors over thousands of years to observe this commandment even in a time of persecution has resulted in our being promised that this commandment will continue to be fulfilled by us. Therefore we should not fear or be afraid of those standing against us to prevent us from fulfilling this precious commandment in all its details and fine points, for we have been promised that their evil scheme will never succeed.

Therefore, I hereby call from the depth of my heart to everyone able to help and assist in putting a stop to these evil schemes to do whatever they can for the sake of this great and precious commandment, and may the merit of this commandment protect all who assist in this, and may the blessed G-d fulfill all the desires of their hearts for good and blessing throughout their lives, Amen, so may be His will.

[official stamp] Writing and signing this in honor of the Torah,

[signature]

Yona Metzger
Chief Rabbi of Israel

Yona Metzger
Chief Rabbi of Israel
President of The Chief Rabbinate Council



יונה מצגר
הרב הראשי לישראל
רئيس מועצה הרבנות הראשית

בס"ד, ד' אב, תשע"ב
23 יולי, 2012
כל- 821 עב

קול קורא

הנה מצות מילה היא מן המצוות החמורות שבתורה, אשר נכרתו עליה י"ג בריתות, והיא יסוד הקשר בין היהודי לבין בוראו, ומאז מתן תורה עד היום מסרו ישראל נפשם עליה בכל הדורות, לקיימה כדינה בכל פרטיה ודקדוקיה.

נודע בשערים, גודל החיוב להקפיד על קיום כל פרטי דיני המילה כהלכתם, ללא שינוי ממסורת ישראל הנהוגה מזה אלפי שנים. דבר זה כולל את המילה, חפריעה והמציצה, שאין לשנות מסדר עשייתן כפי שהיה נהוג מקדמת דנא.

כמובן, יש לנקוט את כל הפעולות הנדרשות על מנת להבטיח סטריליזציה של כל תהליך המילה על כל שלביו, כפי שהנהגנו כאן בארץ הקודש, שכל המוסמכים למול מטעם הרבנות הראשית לישראל מקבלים הדרכה מלאה כיצד לבצע את תהליך המילה באופן שלא יגיע ממנו ספק סכנה למוהל או לנימול, ולא כאן המקום לפרט כללים אלו. אולם כאשר נעשית המילה באופן מבוקר ומפוקח, אין בה שום צד נזק חייו.

לצערנו, בזמן האחרון אנו שומעים קולות שונים, של ארנונים ואף ממשלות ובתי משפט נכבדים ברחבי העולם, אשר מלאים ליבם להטיל דופי במצוות התורה חייו, ולאסור על קיום ברית המילה כהלכתה אשר נצטוונו עליה מפי בורא העולם.

חנני קורא לכל מי שעמך רגלי אבותיו על הר סיני, שלא ישמע לקול מלעזים, ויקיים כדון את מצוות אלו קינו, אשר מובטחים אנו כי לא תשכח מפי עם ישראל לעולם, כמו שאמרו חז"ל במסכת שבת (קל, א):
"יתנא, רבי שמעון בן אלעזר אומר: כל מצוה שמסרו ישראל עצמן עליהם למיתה בשעת גזרת המלכות, כגון עבודת כוכבים ומילה - עדיין היא מוחזקת בידי".

מסירות הנפש של אבותינו לפני אלפי שנים לקיים מצוה זו אף בשעת הנזירה, גרמה לכך שאנו מובטחים שתקיים מצוה זו בידינו. לכן אין לנו לירא ולפחד מהעומדים כנגדנו לבטל אותנו ממצוה יקרה זו על כל פרטיה ודקדוקיה, שכן מובטחים אנו כי מזימתם לא תצלח.

לפיכך אני קורא בזה בקריאה מעומקא דליבא לכל מי שכידו לעזור ולסייע בביטול מזימות אלו, לעשות כל אשר ביכולתו למען מצוה גדולה ויקרה זו, וזכות המצוה תגן על כל המסייעים בה, וימלא חי' יתברך כל משאלות ליבם לטובה ולברכה כל הימים, אמן כן יהי רצון.

הכו"ח ביקרא דאורייתא,
יונה מצגר
הרב הראשי לישראל



From: ()
Subject: DOHMH - Comment on Proposed Rule

Below is the result of your feedback form. It was submitted by
() on Tuesday, July 24, 2012 at 17:44:28

This form resides at

http://www.nyc.gov/html/nycrules/html/proposed/comment_form.shtml?agency=DOHMH&rule=Article%20181-Protection%20of%20Public%20Health%20Generally

Office: DOHMH

Rule: Article 181-Protection of Public Health Generally

Opinion on Proposed Rule: Against

Comment: 38 million children play sports in the us 1 out of ten get injured
shoudt this get regulated before ?
there is no clear cut evidence that metzitzah bpeh has a sugnigent health risk niether the nyc
department of health nor other federal state or local goverment has the authority to regalate a
religuis practice

אגודת הרבנים דארצות הברית וקנדה
THE UNION OF ORTHODOX RABBIS
OF THE UNITED STATES AND CANADA
226 EAST BROADWAY
NEW YORK, N.Y. 10002

212-694-6337
212-694-6338

בי"ה

לכל בני ישראל בכל מקום שהם

נדע בשערים חשיבותה של מצות מילה, שעליה נאמר "גדולה מצוה זו משאר המצוות", ועליה נברכו שלש עשרה בריתות, וזו היא המצוה שנכנסו בני ישראל לברית קדוש עם הקב"ה.

מיום היות ישראל לעם מסרו נפשם כדי לקיים המצוה בשלימותה ובחידוה, ע"י הקפדה בתכלית על שלשת חלקי המצוה: מילה, פריעה ומציצה, כפי שנמסק בשולחן ערוך, וכפי שנהוג בישראל למעלה משלוש אלפים שנה.

מזיות ולאחרונה קמו שוב ממשלות ברחבי העולם, ומחשבתם הזדונית היא לבטלה כליל חז"ל או לשנות מכפי שנהגו אבותינו, על כן באנו בדברינו אלה להגיד את דעתנו, דעת תורה הקדושה, דאין לשום אדם או ממשל הכח או חרשות לבטל ח"י או לשנות מצוה מן התורה, ובפרט במצוות מילה.

פגים אנו בזה לכל בני ישראל בכל מקום שהם לעמוד בתוקף על משמרת הקדוש, להתחזק במצוה זו לעשותה כראוי ולחזק ידי המתעסקים לבטל מחשבת זדון.

וכבר אמרו חז"ל דבכחות מצות מילה נטאלו אבותינו ממצרים ובזכותה הם עתידין ליטול ולשומעים יונעים ותבא עליהם ברכת טוב,

וע"ז באנו עה"ה ראש חודש מנחם אב ה'תשע"ב



אריה ליב רלבינג
הרב אריה ליב רלבינג
בשם בדין אגודת הרבנים

#18

From:

Sent: Monday, July 23, 2012 6:02 PM

To: Julia Schillinger

Subject: Re: Comment on the Proposed Amendment of Article 181 (Protection of Public Health Generally)

I write in strong support of the amendment requiring consent for ritual circumcision where direct oral suction of the genital wound may be performed. I believe that if the practice cannot be stopped entirely, then informed consent where both parents knowingly understand the risks of direct oral suction is the best way address intractable and preventable public health issue going forward.

For the rule to achieve its intended purpose of true informed consent among all parents whose infant(s) undergo direct oral-genital suction during ritual circumcision, it should ne required that such informed consent be documented and filed with the DOHMH and that Mohels retain copies of the signed informed consent forms.

Specifically, the new rule should be implemented so that a Mohel must file a copy of all signed informed consent forms with the DOHMH within 24 hours of circumcision with direct oral suction, and the mohel must retain copies of informed consents for every circumcision where oral suction was performed for a period of 3 years. Such copies must be made available on request from the health department.

The filing and retaining of documentation of informed consent will provide the health department with necessary information for surveillance and disease control activities, reduce potential for fraud around the informed consent process, and result in better monitoring and enforcement of the informed consent process. This in turn will better ensure that accurate information about health risks of direct oral suction following circumcision is getting to the people who need it: the parents. Implementation of the new rule without the ability to at least monitor the extent to which informed consent is actually taking place would make very little sense in my view, and would likely risk the new rule not achieving its intended purpose of protecting infants.