



STATE OF NEW YORK DEPARTMENT OF HEALTH

433 River Street, Suite 303 Troy, New York 12180-2299

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Chief of Staff

March 24, 2009

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Brian Goldweber, M.D.
c/o Barbara Ryan, Esq.
Aronson, Rappaport, Feinstein
& Deutsch, LLP
757 Third Avenue
New York, New York 10017

Leslie Eisenberg, Esq.
NYS Department of Health
Office of Professional Medical Conduct
90 Church Street
New York, New York 10007

RE: In the Matter of Brian Goldweber, M.D.

Dear Parties:

Enclosed please find the Determination and Order (No. 09-048) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

Five days after receipt of this Order, you will be required to deliver to the Board of Professional Medical Conduct your license to practice medicine together with the registration certificate. Delivery shall be by either certified mail or in person to:

Office of Professional Medical Conduct
New York State Department of Health
Hedley Park Place
433 River Street - Fourth Floor
Troy, New York 12180

If your license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, you shall submit an affidavit to that effect. If subsequently you locate the requested items, they must then be delivered to the Office of Professional Medical Conduct in the manner noted above.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), (McKinney Supp. 2007) and §230-c subdivisions 1 through 5, (McKinney Supp. 2007), "the determination of a committee on professional medical conduct may be reviewed by the Administrative Review Board for professional medical conduct." Either the licensee or the Department may seek a review of a committee determination.

Request for review of the Committee's determination by the Administrative Review Board stays penalties other than suspension or revocation until final determination by that Board. Summary orders are not stayed by Administrative Review Board reviews.

All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

James F. Horan, Esq., Administrative Law Judge
New York State Department of Health
Bureau of Adjudication
Hedley Park Place
433 River Street, Fifth Floor
Troy, New York 12180

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board. Six copies of all papers must also be sent to the attention of Mr. Horan at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

Redacted Address

James F. Horan, Acting Director
Bureau of Adjudication

JFH:djh

Enclosure

STATE OF NEW YORK: DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

COPY

IN THE MATTER
OF
BRIAN GOLDWEBER M.D.

DETERMINATION
AND
ORDER

BPMC NO. 09-48

A Notice of Hearing and Statement of Charges was served on BRIAN GOLDWEBER, M.D., on October 3, 2008, and hearings were held pursuant to N.Y. Public Health Law §230 and New York State Admin. Proc. Act §§ 301-307 and 401 on November 6, December 4, 9, and 23, 2008 at the Offices of the New York State Department of Health, 90 Church Street, New York, New York ("the Petitioner"). **Kenneth Kowald, CHAIR, Linda D. Lewis, M.D., and Robert D. Sunshine, M.D.**, duly designated members of the State Board for Professional Medical Conduct, served as the Hearing Committee in this matter. **David A. Lenihan, Esq.**, Administrative Law Judge, served as the Administrative Officer. The Petitioner appeared by **Thomas Conway, Esq.**, General Counsel, by **Leslie Eisenberg, Esq.**, Associate Counsel, New York State Department of Health, of Counsel. The Respondent appeared with counsel, **Barbara A. Ryan, Esq.**, and **Ben Flattery, Esq.** Evidence was received, including witnesses who were sworn or affirmed, and transcripts of these proceedings were made.

After consideration of the entire record, the Hearing Committee issues this Determination and Order.

PROCEDURAL HISTORY

Date of Service of Notice Of Hearing and Statement of Charges:	October 3, 2008
Answer Filed:	October 20, 2008
Pre-Hearing Conference:	September 16, 2008
Hearing Dates:	November 6, 2008 December 4, 2008 December 9, 2008 December 23, 2008
Witnesses for Petitioner:	Sharon Balter, M. D. Rachel Stricof Dr. Monica Parker, Ph.D. Dr. Edward Goldberg, M.D.
Witnesses for Respondent:	Brian Goldweber, M.D. Dr. David Lewis Dr. Abbe Carni Nurse Mimi Garcia
Deliberations Date:	February 17, 2009

STATEMENT OF THE CASE

The Respondent was charged with violating infection control practices and using the medication Propofol in an inappropriate manner. In addition, the Respondent was charged with failing to take a mandated infection control and barrier precautions course as required by the Public Health Law § 239.

A copy of the Statement of Charges is attached to this Determination and Order in Appendix I.

FINDINGS OF FACT

The following Findings of Fact were made after a review of the entire record in this matter. Numbers below in parentheses refer to transcript page numbers or exhibits, denoted by the prefixes "T." or "Ex." These citations refer to evidence found persuasive by the Hearing Committee in arriving at a particular finding. Conflicting evidence, if any, was considered and rejected in favor of the cited evidence. All Hearing Committee findings were unanimous.

1. Respondent was authorized to practice medicine in New York State in 1979 by the issuance of license number 139943 by the New York State Education Department. Respondent is a non-board certified anesthesiologist. (Tr. 419, 473, Ex. 2)

2. Since 2003, Respondent has been practicing medicine in or around New York City as an independent contractor, employed by Dr. Carni, to provide anesthesia services in private medical offices during endoscopies. (Tr. 420, 476)

3. Starting approximately in late 2003 and continuing through May of 2007, Respondent was the primary anesthesiologist in Dr. Edward Goldberg's office. Respondent also provided anesthesia services for Dr. Paulo Pacheco as well as several other gastroenterology offices in New York City. (Tr. 421, 476-478, 507, 544-545)

4. In May of 2007, Respondent voluntarily surrendered his medical license, pending the outcome of the current investigation of a Hepatitis C outbreak in New York City. (Tr. 419, 493)

5. Respondent was responsible for ordering supplies and medications relating to anesthesia, for the medical offices in which he worked. Dr. Carni paid for them. (Tr. 423, 478, 570)

6. As part of Respondent's ordinary practice, he used multi-dose vials of anesthetic: 100 cc vials of Propofol and, 50 cc vials of Lidocaine and Pentothal. Respondent did not administer all medications to all patients but he did administer Propofol to all patients and generally used 10 cc syringes. Respondent used a spike in the vial, which allowed him to remove medication from the vial with a syringe and no needle. (Tr. 66-70, 79-80, 147, 469, 479, 570; Ex. 29)

7. Respondent would place an IV in the patient's arm and withdraw medication from a vial with a syringe, inserting the anesthetic into the IV. Based on the amount of anesthetic that could fit in a 10 cc syringe and the amount of medication he documented (the amount noted in Respondent's anesthesia record is the total amount of medication given to the patient during the procedure), he frequently had to re-dose a patient. However, he did not document that fact. (Tr. 128-129, 450-453, 486-487; Ex. 29)

8. Respondent did not label the vials with the date and time that he opened them and used multi-dose vials on several patients. He stored open vials of medication, including Propofol, in the un-refrigerated closet at the office, using them on subsequent procedure days. Propofol is not to be used after 6 hours. (Tr. 164-165, 202-203, 209-210, 455, 458-459, 479-480, 517-518, 531-532; Ex. 29)

9. Respondent did not pre-fill syringes at the beginning of the procedure day. Even if he did, Propofol is to be used and discarded within 6 hours of opening. (Tr. 209-212, 301-302, 571; Ex. 22)

10. Respondent used the medication Propofol in an inappropriate manner. Propofol is indicated as a single-patient use medication even though it is sold in multi-dose

vials. The manufacturer's label indicates that Propofol should be discarded after 6 hours because it does not have adequate preservative in it to retard bacterial growth.

Respondent used multi-dose vials of Propofol on multiple patients. Respondent used the vials for periods of time exceeding 6 hours. Respondent also used the vials after storing them in the office closet overnight. (Tr. 70-73, 201, 480; Ex. 22; Ex. 23)

11. On April 12, 2007, Respondent told Dr. Balter that it was possible that he re-dosed a patient with the same syringe. At the hearing, Respondent tried to clarify this by stating that he would only do so in an emergency. Clearly, there were times when Respondent would re-dose with the same syringe, thereby creating the risk of contaminating a vial of medication. In addition, Respondent expressed surprise when he learned from Dr. Balter that there could be microscopic amounts of blood and virus flowing back through the IV and into the syringe, even if he did not see gross blood. Using a clamp on the IV would only prevent backflow onto the sheets or clothing; it would not impact the flow of virus particles from the IV into the syringe and then into the vial of medication. (Tr. 99-101, 149, 164, 297, 471-472, 517; Ex. 29)

12. New York Public Health Law § 239 requires physicians to take and complete a course in infection control and barrier precautions every four years. Respondent was aware of this requirement. Respondent completed such a course on May 1, 2002. During the investigation, in April 2007, Respondent still had not taken the course again. Respondent completed such a course after being asked to do so, on April 17, 2007. As a result, Respondent failed to comply with New York State law by completing the State mandated course in infection control practices within the required four year period. (Tr. 474; Ex. 19, 20 and 21)

13. Infection control is the application of various principles and practices designed to reduce the likelihood of transmission of infectious agents. The goal is to minimize the

likelihood of infection. An infectious agent must have a way or place to survive, an opportunity or mechanism to travel from one place to another and, also, a place or way to enter another organism. Infection control is an attempt to break the chain of transmission somewhere along the line. (Tr. 229-233)

14. New York State requires that licensed health care professionals, including physicians and nurses, undergo infection control training every four years. Other personnel do not need any certification or specified training. (Tr. 233-234; Ex 19)

15. Respondent violated appropriate infection control practices in his use of multi-dose vials. Multi-dose vials are manufactured and their use is permitted by the Food and Drug Administration (FDA). The Centers for Disease Control (CDC) and the New York State Department of Health (NYS DOH) and the New York City Department of Health (NYC DOH) have been encouraging the FDA to prohibit the use of multi-dose vials because they are an opportunity for infection transmission. Although health care professionals do the best they can to use aseptic techniques and avoid introducing contaminate into a sterile vial, organisms can infiltrate a vial. Once a vial is contaminated, depending on the organism, it can proliferate or at least sustain itself in the vial for a period of time. Although the American Society of Anesthesiologists (ASA) guidelines do not prohibit the use of multi-dose vials, they state that viral particles can live in the vials for up to a full day. In addition, the ASA guidelines specifically state that Propofol is for single patient use. (Tr. 179-180, 235-236, 316-317, 331-332, 481-482; Ex. 23)

16. The proper way to use a multi-dose vial is to use aseptic techniques: one must be sure to clean the stopper before each use and, also, use a new, sterile needle and syringe each time. (Tr. 236-237)

17. Needles and syringes are labeled as sterile and single-use items. Re-using them is a violation of infection control standards. (Tr. 317-318; Ex. 23)

18. A spike system employs a mechanism - a spike -, which is placed into the rubber septum at the top of the vial, allowing access into the vial without a needle. A syringe is screwed into the spike to draw up medication. The purpose of the spike system is to protect the health care worker from a needle stick. Medication is drawn out through the syringe. However, the syringe might not contain the correct amount of medication so the health care professional may remove more medication from the vial or squeeze some medication back into the vial. The health care professional may have to do the same in order to remove air from the syringe. (Tr. 66-67, 237-240, 314; Ex. 29; Ex. 36)

19. A multi-dose vial can become contaminated when a health care worker administers the medication to a patient, into the body or, through an IV or extension tubing and then uses that same needle or syringe to re-enter the vial to obtain additional medication. The contaminate, in such a circumstance, cannot be seen with the naked eye. (Tr. 68, 240-245; Ex. 29 Fig 1, Fig 11)

20. If a spike contained a filter, it would be a bacterial filter. Such a filter could be effective at filtering out bacteria but not viruses because virus particles are so much smaller than bacteria particles. If there were a filter that could filter out viruses, the manufacturer would be proud of that fact and there would be many more on the market and in use. (Tr. 252-253, 269, 295-296)

22. Endoscopes are delicate, flexible and complex instruments used to view inside a organ or body space. The scopes have parts that enable the endoscopists to manipulate the device. There are internal channels that allow air, suction, light and instruments to pass through the long, narrow internal channels, including biopsy instruments and video optics. There are different kinds of scopes that are used in different parts of the body. (Tr. 254-256, 273; Ex. 37)

23. There are different tools - accessories - used to remove tissue specimens. Different accessories are used with different types of scopes based on their length and intended specimen. For instance, a snare is like a lasso and is used to remove a polyp. Some accessories can be used with heat to cauterize while others are used cold. In addition, some biopsy forceps are made to be re-used if sterilized in an autoclave, while others are manufactured for single use. (Tr. 256-259, 563-565; Ex. 37)

24. Reprocessing is a process of cleaning and sterilizing endoscopic equipment. It is an intricate process of manual cleaning and chemical cleansing. Initially, the scope is rinsed or cleaned with water or an enzymatic cleaner. The scope is leak tested to ensure that there are no holes in it before immersing it in water. The scope is then immersed in water and a chemical cleaner and is manually cleaned to remove gross debris that could block any subsequent exposure to the chemical germicide. The scope is then disinfected with a chemical germicide before it is rinsed, dried and, hung for storage or to be re-used. (Tr. 259-260, 266-271, 277, 306, 558-560; Ex. 24)

25. Hepatitis is a condition that involves inflammation of the liver. There can be different causes including toxins, illness or infection. The present case involves infectious hepatitis - specifically, Hepatitis B (HBV) and, Hepatitis C (HCV). These are both blood borne pathogens that are spread through blood-to-blood contact. The most common means of transmission of HBV and HCV include blood transfusions, injection, mother to child during childbirth and organ transplant. HBV can also be spread through sex; it is far less clear if HCV can be so transmitted. (Tr. 48-51; 342-343)

26. All forms of Hepatitis effect the liver -- so symptoms range from fatigue, nausea, vomiting, diarrhea to jaundice. However, not all people are symptomatic. Approximately 80% of people with HBV are symptomatic whereas only 15% of people with HCV have symptoms. This is why many people have Hepatitis but do not know and can

pass it on to others. Furthermore, most people with HBV clear the infection on their own. However, only 25% of people with HCV clear the virus. The other 75% of people with HCV remain chronically infected. Some go on to develop cancer or cirrhosis. (Tr. 52-54)

27. The incubation period for HBV is 45-180 days with a mean of 60-90 days. The incubation period for HCV is 2 weeks to 6 months with a mean of 6-9 weeks. (Tr. 55)

28. A minute amount of blood can carry enough viral particles to cause an infection. On average, people with HBV have around 10 to the eighth or ninth of viral particles circulating in their blood. On average, people with HCV have around 10 to the sixth or seventh viral particles circulating in their blood. One does not need to see any visible blood for there to be enough contamination in fluid or medication to carry an infectious agent. (Tr. 244-245, 303-304)

29. According to the current understanding by scientists, HBV can remain viable for up to seven days and, HCV can remain viable for up to one day. (Tr. 245-248, 304)

30. Hepatitis is reportable to the NYCDOH. The NYCDOH maintains a registry of infectious diseases. (Tr. 62-64)

31. The Hepatitis virus is composed of 10,000 units called nucleotides. In order for the virus to replicate, it must reproduce itself by copying these 10,000 nucleotides. Hepatitis is characterized by the fact that when it replicates itself, it is very sloppy. Within any given day, the virus will reproduce itself more than a trillion times. As a result, there is a lot of genetic variation in the virus within a given individual but even more so among different people with the same virus. (Tr. 344-346)

32. HBV and HCV are divided into subgroups. HCV has 6 subgroups or genotypes referred to by number (1-6). There is about 30-35% genetic difference in the genetic sequence of one genotype to another. Each genotype is then subdivided into another category referred to as subtype. There are 6 of them (a-f). There is about 20-25%

genetic difference between subtypes. HBV genotypes are referred to by letter (a-h). There is less known about subgroups of HBV because there is more of an epidemiologic use for this, rather than clinical. With HCV, the categories are significant because it impacts the decision to treat a patient since some genotypes and subtypes are more resistant to treatment. (Tr. 347-352)

33. Determining the genotype and subtype of a virus can be significant for epidemiologic purposes. It can offer information about how a person acquired the infection. (Tr. 353-354)

34. There are standard diagnostic blood tests to determine if a person has had an immune response to Hepatitis. If E antigen is detected, a person is considered highly infectious. (Tr. 354-357; Ex. 33)

35. There have been a number of scientific studies looking at the infectivity of infectious agents including Hepatitis and HIV. HBV is the most transmissible. Between 20-30% of people who come into contact with blood of somebody with HBV, become infected. HCV is the next most transmissible. 2-3% of people who come in contact with blood of someone infected with HCV, become infected. HIV is the least transmissible of these infectious agents. Most people with HIV are being treated which lowers the infectivity. For people who come into contact with blood of someone with HIV, like from a needle stick, .3% of people will become infected with HIV. The mode of transmission can have an effect on whether the recipient becomes infected. In other words, entry into a person's bloodstream [via IV] is more likely to cause infection than through the skin [a needle stick]. (Tr. 169, 248-250, 287-288)

36. There are only two questionable scientific articles that suggest that Hepatitis has been transmitted from person to person via endoscopes. There are many uncertainties in these articles and each concludes that anesthesia could have been the mode of

transmission of infection. The scientific literature overwhelmingly suggests that Hepatitis and HIV have been transmitted from person to person as a result of re-used syringes, dirty needles or, contaminated IV fluids. (Tr. 707, 718, 750, 763)

37. In March 2007, a patient e-mailed the New York City Department of Health and Mental Hygiene (NYCDOH) claiming that he had gotten hepatitis from a procedure he had at Dr. Goldberg's office during the summer of 2006. This patient had tested negative for hepatitis on August 7, 2006. He had an esophagogastroduodenoscopy (EGD) on August 14, 2006, a colonoscopy on September 19, 2006, and, a repeat colonoscopy on September 25, 2006. In late October 2006, he became symptomatic. His medical work-up confirmed that he had acute Hepatitis C. After interviewing the patient and learning that he had no risk factors, the NYCDOH notified Dr. Goldberg's office and arranged for a site visit to observe procedures and interview staff. The site visit was announced but occurred within a few days. (Tr. 75-78. 184; Ex. 29)

38. Dr. Edward Goldberg is board certified in internal medicine and board eligible and previously certified in gastroenterology; he is in the process of re-certifying as required every 10 years. He has been in private practice since 1993. In 2003, he established a endoscopic suite in his office, performing diagnostic and therapeutic procedures including endoscopies, colonoscopies and biopsies. His practice is a mix of primary care, internal medicine and gastroenterology, with a large patient population who have viral infections including Hepatitis and HIV. (Tr. 536-539; Ex. 38)

39. When Dr. Goldberg set up his endoscopic suite, he purchased equipment including hardware, software, scopes and accessories from Olympus. The equipment is top of the line and includes computerized databases that the NYCDOH investigative team do not regularly see in offices visited as part of other investigations. Olympus representatives set up the equipment and initially trained the staff at Dr. Goldberg's office. Periodically,

Olympus reps continue to come to Dr. Goldberg's office to observe and train, as well as to sell other goods and deliver items, including biopsy forceps. Dr. Goldberg's database records and saves information about every procedure including demographics of the patient, the time of the procedure, the serial number of the scope used, the printed report and results of the procedure. (Tr. 540-543, 557-558, 569, 605-606; Ex. D, D1, E)

40. The NYCDOH arrived at Dr. Goldberg's office on April 12, 2007, with a team that included Sharon Balter, M.D., medical epidemiologist with the Waterborne and Enteric Disease and Hepatitis Unit of the NYCDOH, Bruce Gutelius, Epidemic Intelligence Service (EIS) officer at the NYCDOH, Rachel Stricof and Ernie Clement from the New York State Department of Health (NYSDOH) and, Catherine Dentinger from the CDC. The initial site visit of the office was within a few days of the original call to Dr. Goldberg. (Tr. 79, 87, 425, 571-573; Ex. 29)

41. At the initial site visit, the NYCDOH team interviewed staff including Dr. Goldberg and Respondent. They observed Respondent perform a mock set up of anesthesia. They also observed a colonoscopy and the entire reprocessing (cleaning) of an endoscope. The team was not permitted to observe Respondent administer anesthesia to the patients. The team also gathered documentation including patient logs that indicated the names of patients who had procedures done on the same days as the complainant. (Tr. 79-81, 147, 426-427, 574; Ex. 29)

42. The NYCDOH investigative team was able to determine very quickly that there were clusters of patients with newly reported cases of Hepatitis. They did so by comparing the patient logs from Dr. Goldberg's office with the NYCDOH database of newly reported cases of Hepatitis. They determined that these newly reported cases of Hepatitis occurred within a short period of time after the people had procedures at Dr. Goldberg's office on August 14-15, 2006. These clusters occurred on dates when patients who were

known to have Hepatitis had procedures done; these patients could have served as source patients for an outbreak. (Tr. 82; Ex. 29)

43. The investigative team was able to gather information from Dr. Goldberg's computerized database. They determined the time and order of each patient in each cluster, the type of procedure performed, the exact scope used and the type of biopsy taken, if one were, in fact, taken. (Tr. 96-97, 122-123, 133-134, 185; Ex. 29)

44. Due to the nature of Dr. Goldberg's medical practice, he frequently tested his patients for Hepatitis and HIV prior to performing endoscopic procedures. As a result, the medical records for the patients in this investigation were extremely helpful since they demonstrated which patients were Hepatitis negative prior to a procedure and which were Hepatitis positive, making them a potential source patient. A review of Dr. Goldberg's medical records indicates that, out of the patients who had procedures on August 14-15, 2006, there were 3 potential source patients. (Tr. 88-93, 124, 167-168, 204, 569; Ex. 29)

45. The NYCDOH investigative team returned to Dr. Goldberg's office, spending considerable time in this office, reviewing documents and gathering more information. They notified 51 patients who had procedures on August 14 and 15, 2006 -- and the procedure days before and after -- to come in for blood tests to determine if they were patients who had Hepatitis but who had not yet been diagnosed. Out of those 51 people, 37 were tested at Dr. Goldberg's office by his staff. The blood samples were sent to the NYCDOH Public Health Lab for processing. (Tr. 83-86, 110, 573, 575-585; Ex. 29)

46. Dr. Goldberg and his staff were also tested. No personnel at Dr. Goldberg's office had chronic Hepatitis and the patients from the clusters during the procedure days did not report any risk factors. The only apparent link between the infected patients was the fact that they had a procedure done at this medical office. (Tr. 85, 93-95; Ex. 29)

47. As a result of the site visit, the NYCDOH team had concerns about Respondent's practice. They were concerned about the use of the spike with multi-dose vials since there is the possibility of using the same syringe to re-dose a patient and then contaminating the vial. By using the same multi-dose vial on other patients, there is an increased risk of infecting other patients. In addition, the investigative team was concerned that the close proximity of the multi-dose vials to Respondent in the procedure room made it more likely that Respondent might re-dose from the multi-dose vial, using the same needle-less syringe. The team was also concerned that Respondent was using Propofol incorrectly since he was using Propofol on more than one patient when it is labeled as single-patient use. In addition, the Respondent kept and used the vials all day and sometimes overnight, even though Propofol is to be discarded after 6 hours. (Tr. 95-98, 148-149, 467-468; Ex. 29)

48. The NYCDOH team informed Respondent of their concerns - verbally and informally - within days of the initial office visit. They then notified him in writing, on May 2, 2007. This letter is part of the NYCDOH's final report. The letter includes recommendations made to Respondent which include: use single-patient vials of Propofol or discard the vial of Propofol after one use, use single use vials of other medication which should be labeled with the date opened and stored in a locked cabinet and, discard the vials per manufacturer's recommendations. The NYCDOH also recommended that Respondent complete a NYSDOH approved infection control training course, which he completed on April 17, 2007. (Tr. 95-96, 148-149, 428-434, 467-468; Ex. 29)

49. After the April 12, 2007 site visit, the NYCDOH team made recommendations to Dr. Goldberg. These recommendations were given verbally and then in writing, similar to Respondent, in a letter dated May 2, 2007. The recommendations made to Dr. Goldberg included all the same recommendations made to Respondent regarding the anesthesia, as

well as the following: re-align the procedure room to allow for specimen processing away from the clean supplies and anesthesiologist, use sterile water in the bottle used to flush the scopes, hang the caps in a dry, clean area and reprocess the cleaning brushes between uses. Dr. Goldberg testified that he implemented all recommendations immediately. (Tr. 575, 628; Ex. 29)

50. Contrary to Respondent's position, Dr. Goldberg and his staff did not change their procedures for the investigative team on April 12, 2007. Respondent claims that the staff wore protective clothing that day for the first time and that they placed the scope in a bag to be carried to the next room for reprocessing when they do not normally do so. Dr. Goldberg and Mimi Garcia both testified that they routinely wore gowns and sometimes wore masks. It was optional to wear the gown and mask since the purpose of the protective clothing is to protect themselves from material during the procedure. In addition, Ms. Garcia and Dr. Goldberg testified that it was their customary practice to carry the scope into the next room in a bag. (Tr. 435, 436, 639, 884)

51. The NYCDOH investigative team considered the possibility that the transmission of infection occurred as a result of the endoscopes or other equipment in the office. Rachel Stricof, Bureau Director of Health Care Associated Infections at the New York State DOH, was asked to observe the reprocessing to rule in or rule out the possibility that the endoscopes or other related equipment could have been the cause of transmission of Hepatitis. (Tr. 81, 159-160, 225-229, 260-262, 265; Ex. 27 and 29)

52. On April 12, 2007, Rachel Stricof, who is an epidemiologist and infection control expert, observed Dr. Goldberg perform a colonoscopy. During the procedure, Dr. Goldberg asked the assistant to obtain a stool specimen, which she did. Dr. Goldberg also asked the assistant to obtain a biopsy. The assistant brought a new, wrapped forceps to him for him to use. The biopsy was obtained and processed. Ms. Stricof observed a hefty

supply of disposable biopsy forceps wrapped in the manufacturer's packaging. Ms. Stricof also saw many used biopsy forceps properly disposed-of in the sharps container in the procedure room. At the conclusion of the colonoscopy, Ms. Stricof followed the endoscope through the entire reprocessing process. (Tr. 81, 225-229, 262, 265-266, 276, 310; Ex. 27, 35)

53. On April 12, 2007, Ms. Stricof observed the reprocessing process in Dr. Goldberg's office which began with Dr. Goldberg suctioning enzymatic cleaner through the scope and washing off the outside of the scope. Dr. Goldberg placed the scope into a large bag for the assistant to carry to the next room. The assistant, Abbie Morse, who was wearing a gown, gloves, mask and eye shield, rinsed off the scope and leak tested it. She then filled a sink with water and enzymatic detergent and manually cleaned and washed the scope. The assistant used brushes to clean the channels of the scope. The brush was pushed through the channels until they came out clean. The assistant then placed the scope inside an automated reprocessor, filled with a liquid germicide, Rapicide, so the scope could be bathed for a specific amount of time at a specific temperature, 39-40 degrees Celsius, automated by the machine. The last phase of the reprocessor includes forced air through the channels, which helps them dry. Once the machine completes its cycle and beeps, the scope was removed, dried, the channels are wiped with alcohol to speed the drying process. The scope was then hung in the closet to dry further or to be used again for another procedure. (Tr. 266-271, 306; Ex. 24)

54. Gluderaldehyde is a high level disinfectant or a chemical sterilant, depending on the time used. Rapicide, a gluderaldehyde product, can be effective at room temperature, but the higher the temperature, the less time the chemical needs. Rapicide can achieve high level disinfection within 5 minutes at 35 degrees. Dr. Goldberg's

automated reprocessor was set at 39-40 degrees and runs for 20 minutes. Gluderaldehyde eradicates Hepatitis easily. (Tr. 270-271, 285, 308, 312, 314, 324, 864)

55. Ms. Stricof concluded that the reprocessing in this medical office was excellent. She only had a few minor recommendations; none of which would be associated with the transmission of a blood borne pathogen. In fact, out of 15-20 investigations that she has been involved in, she has never concluded that there were no infection control violations and she has never concluded that the reprocessing was excellent. Ms. Stricof made her observations and conclusions completely blind to other factors in the investigation. (Tr. 273, 275, 277-279, 318, 329)

56. The investigative team also considered the possibility that the transmission occurred as a result of the biopsy forceps. However, they ruled this out for two reasons: Dr. Goldberg used disposable biopsy forceps and he used different types of forceps for different types of biopsies. Furthermore, not all patients had biopsies and, among the patients who had biopsies, they did not all have the same type of biopsy requiring different types of forceps. The investigative team also observed disposable biopsy forceps in and around the office and they saw them disposed of in the garbage. Moreover, the reprocessing was deemed to be excellent. This would eradicate contamination that could occur as a result of a forceps moving through an endoscope. (Tr. 130-133; Ex. 29 and 35)

57. Contrary to Respondent's position, Dr. Goldberg did not re-use disposable forceps. There is no evidence - other than Respondent and Dr. Carni's testimony - that the forceps were in short supply or re-used. Respondent stated that he had the impression that Dr. Goldberg re used forceps. In fact, during cross-examination, when I asked Respondent if he recalls ever seeing Dr. Goldberg re-use a forceps on a different patient, he said no. Dr. Carni testified about a specific time he claims to have seen Dr. Goldberg re-use forceps. All other witnesses - including Rachel Stricof, Dr. Goldberg and Ms. Garcia

testified that the forceps were delivered to the office, either as ordered or as a promotional gift, they were stored in the closet, on the shelves in the procedure room or wherever they could be placed. Ms. Stricof testified that she saw them in the manufacturer's packaging, in the closet and on the shelves and she saw used forceps in the garbage receptacle. Dr. Goldberg testified that he used disposable forceps and never re-used them. Ms. Garcia testified that Dr. Goldberg never re-used forceps. Ms. Garcia further testified that she never reprocessed the forceps and that the office never ran out of the forceps. She testified that if she were ever asked by Dr. Goldberg to take a used forceps out of the garbage for him to re-use - as alleged by Dr. Carni - she would not do so. (Tr. 437-438, 491; Ex. 29)

58. Once the Public Health Lab confirmed the patients with positive test results, the blood samples were sent to the Wadsworth Center for additional testing. Wadsworth performed tests to determine the genotype and subgroup of Hepatitis to see if there was any viral relationship among the people with Hepatitis. Once Wadsworth determined relatedness among the various groups of patients, they performed molecular testing of the NS5B region of the virus to further analyze the level of relatedness among these groups. (Tr: 103-104; Ex. 29)

59. After the team received preliminary results from Wadsworth indicating the relatedness of the virus among the patients in Dr. Goldberg's office, they were confident that there was a serious outbreak. They then expanded their investigation to include all of Dr. Goldberg's patients. They checked his patient list with the New York City (NYC) registry. However, based on the epidemiologic data from this investigation, the team believed that the most likely cause of transmission was Respondent's use of multi-dose vials of Propofol. As a result, they expanded the investigation to include other offices where Respondent worked as well. They checked the patient lists from the other offices

where Respondent provided anesthesia with the NYC registry. They sent letters to patients from these 10 medical offices, notifying them that they should be tested for Hepatitis and HIV. The team received some reports of patients who tested positive for Hepatitis. One such result was from a patient who had an endoscopic procedure in Dr. Pacheco's office where Respondent provided the anesthesia. (Tr. 110-118, 448; Ex. 29)

60. The newly diagnosed patient from Dr. Pacheco's office had a colonoscopy but no biopsy, on June 3, 2005, shortly after a person who also had a colonoscopy, who was known to have chronic Hepatitis C. Respondent provided the anesthesia, which included Propofol. The newly infected person had a negative Hepatitis test 10 days after this procedure - almost at the end of the incubation period. Molecular testing was done on these two people and demonstrated a very high relatedness between the viruses, making it very likely that she was infected by the source patient. (Tr. 117-119, 121-122; Ex. 29)

61. This newly infected patient did have the same type of procedure as the source patient. Dr. Pacheco did not have the same computerized system as Dr. Goldberg so it is not known if the same scope was used. However, she did not have a biopsy so the transmission could not have occurred as a result of contamination from the biopsy forceps. Ernie Clement, an infection control expert from the NYSDOH, was present at the site visit of this office on September 20, 2007. This site visit was also announced. Like Ms. Stricof in Dr. Goldberg's office, Mr. Clement was asked to observe the reprocessing process in this office to rule in or rule out the endoscopes as a possible source of transmission of infection. Mr. Clement found no deviations from infection control standards and concluded that the reprocessing in this office was very good. Again, the only common link was that these patients received anesthesia from Respondent. Specifically, Propofol, from a multi-dose vial. (Tr. 119-121, 156, 184; Ex. 29)

62. Once the investigative team found this second office with a provable cluster, they stopped their investigation. They did not look into all the other offices Respondent worked at and they did not pursue other possible clusters. (Tr. 213; Ex. 29)

63. New York State requires physicians to complete a course in infection control practices every four years. Respondent had taken this course previously on May 1, 2002. During the April 12, 2007 site visit, the investigative team asked Respondent whether Respondent had taken the course within the requisite time frame - he had not. Respondent did not provide any explanation for his lapse. He simply took the course on April 17, 2007 and submitted his new certificate to Dr. Balter. Respondent practiced medicine without completing the required course on infection control within the time period set forth in the New York Public Health Law. (Tr. 134 136, 207, 457; Ex. 19, 20, 21 and 29)

64. Dr. Balter has been involved in hundreds of outbreak investigations and approximately 20 of these involved Hepatitis. In many of the investigations they cannot say how the outbreak occurred. However, this is the fourth investigation in which Dr. Balter concluded that the outbreak was likely caused by the anesthesia. In this particular investigation, there was the perfect constellation of circumstances. There were infectious patients, undergoing procedures, requiring anesthesia. Although it was not his routine practice, it was possible that Respondent re-dosed with the same syringe. He must have done so here. The subsequent patients were known to be Hepatitis negative at the time of the procedure and, there were patients who tested positive after the procedures, who submitted blood samples for molecular testing. Some of those blood samples were adequate for the lab to obtain virus and complete molecular testing. (Tr. 47-49, 151, 173-176; Ex. 29)

65. Monica Parker is a molecular geneticist and the chief of the Laboratory of Blood Borne Diseases at the Wadsworth Center, a center within the Office of Public Health

at the NYS DOH. One of her many responsibilities includes outbreak investigation support. Since 2004, she has participated in 7 outbreak investigations. Six of these investigations related to Hepatitis and one involved HIV. (Tr. 333-338; Ex 30)

66. Molecular or genetic testing (the terms are often used interchangeably) is a way of looking at the presence of an organism inside someone's body. The testing can be qualitative to see whether or not you detect an organism in the body. The testing can be quantitative to determine how much of an organism is in the body, such as a viral load test. Another form of testing is viral genotyping to look at the genetic material of the organism. (Tr. 339-340)

67. Epidemiologic investigations use molecular testing to confirm their data regarding relatedness of viruses. However, in order to perform molecular testing, you need a specimen. If a person has cleared the virus, either on their own or as a result of treatment, there may be an insufficient amount of virus in the blood to perform molecular analysis. (Tr. 104-105, 382)

68. Monica Parker was initially contacted by the NYCDOH investigative team to determine the scope of her lab's capacity to assist in the investigation of the Hepatitis outbreak related to Respondent. She was not provided any epidemiologic data. They decided that the NYC Public Health Lab would do the initial diagnostic screening tests to determine who had Hepatitis. Then, Wadsworth would perform genotyping and subtyping. Wadsworth would also perform molecular testing to try to determine how the virus was transmitted. Molecular testing for the HBV specimens would have to be done at the CDC, since Wadsworth did not have the capacity to do molecular testing for HBV. The CDC would also re-do the analysis done by Wadsworth and perform a more specific analysis on the HCV specimens. (Tr. 103-104, 357-360; Ex 29 pg. 9-11)

69. The scientists at Wadsworth started their molecular analysis by replicating a specific target region of the genome referred to as the NS5B region. This region is relatively stable and it tolerates some variation. The NS5B region provides enough information to be able to subtype a virus. After Wadsworth was able to genotype the specimens, they used the NS5B region to subtype the specimens to begin analyzing how closely related the viruses were. (Tr. 361-365; Ex. 29 pg. 9-11)

70. The staff at Wadsworth made copies of about 300 nucleotides of the original DNA and then they used primers (A, C, G and T) to establish a sequence - an order of these primers that is unique to this specific virus. They then use a computer to compare that sequence to other sequences in a database -- to determine how closely related the sequences are to one another or to other specimens. The computer runs a program and generates the results in a phylogenetic tree which shows the level of relatedness among all samples that were compared. In the NS5B region, sequences from specimens from different people with the same genotype and subtype could be 90 - 95% identical. This means that they are not particularly related to each other. When you see more than 95% identity between specimen sequences, it means that the viruses are more closely related to each other than you would expect in the general population. This means that these people could have a common source of infection. (Tr. 366-370, 374-376, 379-380; Ex. 29)

71. You would not expect to see a very high score, like 99%, in two randomly selected people with the same genotype and subtype. When the analysis results are around 95%, further analysis is required. In these instances, analysis of the HVR-1 region could be helpful to determine the level of relatedness among different viruses. (Tr. 374-376)

72. Molecular analysis of the HVR-1 region (hyper variable 1 region) was done at the CDC. This region is a far more unstable region, tolerating a great deal of variation. This region can provide additional analysis that helps demonstrate the level of relatedness of different viruses. The scientists at the CDC performed the same type of computer testing on the NS5B region of the HCV specimens in this case, confirming the results generated by the staff at Wadsworth. The CDC then performed more labor intensive analysis on the HVR-1 region and they generated phylogenetic trees demonstrating the degree of relatedness among the viruses that they analyzed. (Tr. 365-366, 377-379; Ex. 29 pg 9-11)

73. Since the HVR-1 region is much more variable, you do not expect as high an identity level between individuals with a common source of infection. A number in the low 90s in that region is very significant because unrelated viruses are in the 75-80% range. (Tr. 380)

74. Bootstrapping is a way of determining how reliable the molecular analysis results are. To do a boot strapping test, the computer takes the same sequences that have been analyzed and randomly sorts them into different positions, creating new sequences. The computer then analyzes those randomly created sequences and compares them 1,000 times. If the sequences are not very related to each other, the results are a very low score. If the sequences are closely related to one another, the score will be higher. (Tr. 372-374, 406)

75. The scientists in the lab did not have epidemiologic data from the investigation. The lab results were performed in an unbiased setting. They produced data and forwarded it to the epidemiologists. In fact, the staff at Wadsworth was able to identify the source patients and the newly infected patients. It is this combination of information -

epidemiologic data and molecular results - that strongly suggest the conclusions in this case. (Tr. 107, 369, 405, 407; Ex. 29)

76. Patient A/Patient 4-3 was a patient of Dr. Paulo Pacheco. She was known to have Hepatitis C 1a. On June 3, 2005, at about 9:00 am, she underwent a colonoscopy and had a polypectomy. Respondent administered anesthesia to Patient A which included 150 mg of Propofol. (Ex. 3 pg. 9, 20, 38, 51, 60; Ex. 29 Fig 14 and pg 32-35; Ex. 32)

77. Patient A is a source patient for the outbreak in this case. Respondent would have had to re-dose Patient A because 150 mg of Propofol would not fit into one 10 cc syringe. (Ex. 3 pg. 9, 20, 38, 51, 60; Ex. 29 Fig 14 and pg 32-35; Ex. 32)

78. Patient B/Patient 4-4 was a patient in the office of Dr. Paulo Pacheco. On June 3, 2005, at about 9:30 am, she underwent a colonoscopy. No biopsy was performed. Respondent administered anesthesia to Patient B, including 160 mg of Propofol. The medical record includes a serology showing that Patient B was Hepatitis negative on June 13, 2005 (10 days after the procedure). (Ex. 4 pg. 11, 34; Ex. 4a; Ex. 29 and 32)

79. Patient B learned that she was Hepatitis positive after receiving notification from the NYC DOH. (Ex. 4 pg. 19)

80. Wadsworth Center received specimens for Patients A and B (patients 4-3 and 4-4) sometime after the other specimens. Both had been determined to have HCV 1a. Molecular analysis was performed and the results indicate that the virus in Patient A and B were 98% identical. The CDC confirmed the level of relatedness of these viruses at the NS5B region and performed further analysis at the HVR-1 region. These results indicate that the viruses are very, very highly related which suggests that they have a common source of infection or, that one transmitted the infection to the other. (Tr. 118-119, 394-395; Ex. 29 pg. 32-35 and Ex. 31)

81. HCV 1a was transmitted from Patient A (4-3) to Patient B (4-4) on June 3, 2005, by Respondent administering Propofol with a multi-dose vial. (Tr. 119)

82. Patient C/Patient 1-3 was a patient of Dr. Goldberg. He was known to have Hepatitis C 1b. On August 14, 2006, at about 1:30 PM, he underwent a colonoscopy using colonoscope number 230-4193 and loaner 1. He had a sigmoid colon biopsy. Respondent administered anesthesia to Patient C including 190 mg of Propofol. (Ex. 5 pg. 237, 278, 335; Ex. 29 Fig 7 and pg. 15-28; Ex. 32)

83. 83. Patient C was a source patient. Respondent would have had to re-dose him since 190 mg of Propofol would not fit into one 10 cc syringe. (Ex. 5 pg. 237, 278, 335; Ex. 29 Fig 7 and pg. 15-28; Ex. 32)

84. Patient D/Patient 1-5 was a patient of Dr. Goldberg. On August 8, 2006, he was known to be Hepatitis negative. On August 14, 2006, at about 2:30 PM, he underwent an esophagogastroduodenoscopy (EGD) with endoscope number 230-6163 and had biopsy of the antrum and duodenum. Respondent administered anesthesia to Patient D including 180 mg of Propofol. (Ex. 6 pg. 8, 16, 39; Ex. 29 Fig 7; Ex. 32)

85. Patient D learned that he was Hepatitis positive as a result of the NYC DOH serology testing that was done in April 2007 (Ex. 6).

86. Patient E/Patient 1-6 was a patient of Dr. Goldberg. He was known to be Hepatitis negative in 1998. On August 14, 2006, at about 2:45 PM, he underwent a EGD with endoscope number 230-6164 and had a biopsy of the EG junction. Respondent administered anesthesia to Patient E including 140 mg of Propofol. (Ex. 7 pg. 7, 62, 73; Ex. 29 Fig. 7; Ex. 32)

87. Patient E learned he was Hepatitis positive as a result of the NYC DOH serology testing done in April 2007. (Ex. 7)

88. Patient F/Patient 1-7 was a patient of Dr. Goldberg. He was known to be Hepatitis negative on August 7, 2006. On August 14, 2006, at about 3:00 PM, he underwent a EGD with endoscope number 230-6163. He had a biopsy of the stomach and antrum. Respondent administered anesthesia to Patient F including 140 mg of Propofol. (Ex. 8 pg. 9, 15, 29; Ex. 29 Fig 7; Ex. 32)

89. Patient F learned he was Hepatitis positive in October 2006 when he became symptomatic. (Ex. 8)

90. Patient G/Patient 1-4 was a patient of Dr. Goldberg. He was known to be Hepatitis negative on August 3, 2006. On August 14, 2006, at about 2:00 PM, he underwent a colonoscopy with colonoscope number 291-4749. He had a snare polypectomy. Respondent administered anesthesia to patient G including 210 mg of Propofol. (Ex. 9 pg. 9, 56, 101; Ex. 29; Ex. 32)

91. Patient G learned he was Hepatitis positive in February 2007. (Ex. 9)

92. The Wadsworth Center tested blood specimens for Patients C, D, E, F and G. These people had HCV genotype 1 subtype b. The viral load for Patient G was too low to test but the genetic sequences of the other people in this cluster were compared to each other. The percentage identity for Patients D, E and F was greater than 99% (essentially identical sequences). It is extremely unusual for different people to have sequences that are essentially identical to each other. The bootstrap score for these three people is 92. To have a boot strap score over 90 is very significant. These molecular results indicate that these three people had a common source of infection and that they became infected close in time to each other. In addition, the identity between these three patients and the source patient --Patient C-- is more than 98%. The difference in the level of identity of the newly infected patients and the source patient is most likely because the source patient had chronic Hepatitis for many years, allowing for years of variability to evolve in the virus in his

blood, as compared to the three who were recently infected. In addition, the CDC confirmed Wadsworth's results and also performed additional analysis of the HVR-1 region of the virus. These results demonstrate a very high likelihood that the three newly infected people were infected by the same source. (Tr. 107-108, 381-391; Ex. 29 pg. 15-29; Ex. 31)

93. Patient G was known to have been infected with HCV 1b. However, his viral load was too low to enable Wadsworth Center to perform further molecular analysis. Patient G had a colonoscopy 30 minutes after the source patient and 30 minutes before the other confirmed patients. Although there is no molecular testing to confirm that his virus is related to the source patient in this cluster –Patient C -- the epidemiologic data makes it likely that he fits into this cluster. (Tr. 388; Ex. 29)

94. HCV 1b was transmitted from Patient C to Patient D, Patient E, Patient F and Patient G on August 14, 2006, by Respondent administering Propofol with a multi-dose vial. The actual names of these enumerated patients are presented in the record at Exhibit 32. (Tr. 386-388)

95. Patient H/Patient 1-16 was a patient of Dr. Goldberg. He was known to have Hepatitis C 1a. On August 15, 2006, at about 9:30 am, he underwent a colonoscopy using colonoscope number 230-4193. He had a snare polypectomy. Respondent administered anesthesia to Patient H including 260 mg of Propofol. (Ex. 10 pg. 18, 43; Ex. 29 Fig 8; Ex. 32)

96. Patient H was a source patient. Respondent would have had to re-dose Patient H since 260 mg of Propofol would not fit into one 10 cc syringe. . (Ex. 10 pg. 18, 43; Ex. 29 Fig 8; Ex. 32)

97. Patient I/Patient 1-17 was a patient of Dr. Goldberg. She was known to be Hepatitis negative. On August 15, 2006, at about 10:00 am, she had a colonoscopy using colonoscope number 291-4749. She had a sigmoid colon biopsy. Respondent

administered anesthesia to Patient I including 190 mg of Propofol. (Ex. 11 pg. 64, 99-100; Ex. 29 Fig 8; Ex. 32)

98. Patient I/1-17 learned that she was Hepatitis positive in December 2006. Patient I became infected with both HCV and HBV. (Ex. 11; Ex. 29 Fig 8)

99. Patient J/Patient 1-20 was a patient of Dr. Goldberg. On August 15, 2006, at about 11:15 am, she had a colonoscopy with colonoscope number 230-4193 and, she had a snare polypectomy. Respondent administered anesthesia to Patient J including 180 mg of Propofol. (Ex. 12 pg. 14, 50, 93-95; Ex. 29 Fig 8; Ex. 32)

100. Patient J learned that she had HCV 1a in April 2007. (Ex. 12)

101. The medical record for Patient H/1-16 indicates that he was known to have chronic Hepatitis C 1a. Patient H refused to provide a blood specimen for the investigation. Patient I/1-17 was treated by Dr. Goldberg for HBV and HCV and as a result, the viral load in her specimen was too low to undergo molecular testing. The lab was able to perform molecular testing on the specimen from Patient J/1-20 but there were no others to compare it to. As a result, confirmatory molecular testing for this HCV 1a cluster is not available. (Tr. 105-106, 392- 393; Ex 10, Ex. 29 and 32)

102. Patients I and J had colonoscopies within two hours of Patient H who was known to have chronic HCV. The scope used on the source patient was not used on Patient I but was used on Patient J. They did not all have the same type of biopsies. Respondent administered Propofol to all of these patients and, based on the amount of Propofol administered to Patient H (260 mg), Respondent would have had to re-dose, more than one time. Patient I learned that she was Hepatitis positive within months of the procedure and Patient J learned as a result of the investigations blood testing. Both had HCV 1a. Based on the epidemiologic data, although there is no molecular testing to

demonstrate relatedness among these viruses, it is likely that Hepatitis was transmitted by Respondent, from Patient H to Patients I and J via anesthesia. (Ex. 10, 11, 12 and 29)

103. Patient K/Patient 1-10 was a patient of Dr. Goldberg. He was known to have Hepatitis B. In fact, in May 2006, his viral load was very high and he was E antigen positive, making him highly contagious. On August 14, 2006, at about 4:00 PM, he underwent a colonoscopy using colonoscope number 230-4193. He had a sigmoid colon biopsy. Respondent administered anesthesia to Patient K including 210 mg of Propofol. (Tr. Pg. 139; Ex. 13 pg. 17, 20, 46, 60; Ex. 29 Fig 10; Ex. 32)

104. Patient K was a HBV source patient. Respondent would have had to re-dose him since 210 mg of Propofol would not fit into one 10 cc syringe. (Tr. Pg. 139; Ex. 13 pg. 17, 20, 46, 60; Ex. 29 Fig 10; Ex. 32)

105. Patient L/Patient 1-11 was a patient of Dr. Goldberg. On August 14, 2006, at about 4:30 PM, she had a upper EGD using endoscope number 230-6163. She had a biopsy of the Antrum and duodenum. Respondent administered anesthesia including 140 mg of Propofol. (Ex. 14 pg. 19, 23; Ex. 29 Fig 10; Ex. 32)

106. She learned she had HBV as a result of the investigation serology testing. (Ex. 14 pg. 4)

107. Patient M/Patient 1-12 was a patient of Dr. Goldberg. On August 15, 2006, at about 7:45 am, he had a colonoscopy using colonoscope number 230-4193. He had a snare polypectomy. Respondent administered anesthesia including 260 mg of Propofol. (Ex. 15 pg. 3, 15-16, 19; Ex. 29 Fig 10; Ex. 32)

108. Patient M learned he had HBV as a result of the investigation serology testing. (Ex. 15 pg. 15)

109. Patient N/Patient 1-17 was a patient of Dr. Goldberg. On August 15, 2006, at about 10:00 am, she had a colonoscopy using colonoscope number 291-4749. She had a sigmoid colon biopsy. Respondent administered anesthesia including 190 mg of Propofol. (Ex. 11 pg. 9, 99-100; Ex. 29 Fig 10; Ex. 32)

110. Patient N learned she had HBV in December 2006 and then it was confirmed as part of the investigation serology testing. (Ex. 11 pg. 38, 45, 154)

111. Patient O/Patient 1-18 was a patient of Dr. Goldberg. On August 15, 2006, at about 10:40 am, he had a sigmoidoscopy using scope number 230-4107. He had no biopsy. Respondent administered anesthesia including 90 mg of Propofol. (Ex. 16 pg. 32, 52; Ex. 29 Fig 10; Ex. 32)

112. Patient O learned he had HBV in January 2007 when he became symptomatic and then it was confirmed as part of the investigation serology testing. (Ex. 16 pg. 43, 55)

113. Patient P/Patient 1-14 was a patient of Dr. Goldberg. On August 15, 2006, at about 8:50 am, he had a colonoscopy using colonoscope number loaner 1. He had a snare polypectomy. Respondent administered anesthesia including 210 mg of Propofol. (Ex. 17 pg. 9-11, 19; Ex. 29 Fig 10; Ex. 32)

114. Patient P learned he had HBV as a result of the investigation serology testing. (Ex. 17 pg. 22)

115. Patient Q/Patient 1-25 was a patient of Dr. Goldberg. She was known to be Hepatitis negative in May 2006. On August 15, 2006, at about 1:00 PM, she had an upper EGD using endoscope number 230-6164. She had a biopsy of the stomach and Antrum. Respondent administered anesthesia including 160 mg of Propofol. (Ex. 18 pg. 16, 23, 32-33; Ex. 29 Fig 10; Ex. 32)

116. Patient Q learned she had HBV as a result of the investigation serology testing. (Ex. 18 pg. 10)

117. All specimens with HBV were sent to the CDC for additional molecular testing. The CDC was not able to amplify the DNA for any of the HBV samples (except the source patient) because the others had cleared the infection. As a result, there is no molecular test results regarding the genetic relatedness of the viruses. However, the statistical odds of 6 people who all had procedures done on the same day after a person with highly contagious HBV, who didn't have risk factors, becoming newly infected with HBV is so low that the likelihood of an outbreak occurring here is great. (Tr. 106, 176, 393; Ex. 29)

118. Respondent transmitted HBV from Patient K to Patients L, M, N, O, P, and Q by administering Propofol with multi-dose vials that he left in the office closet on August 14, 2006, and that he continued using on August 15, 2006. (Tr. 393- 396)

119. Doctor David Lewis of Atlanta, Georgia, testified on behalf of Respondent, indicating that improper scope re-processing is a major factor to consider in an investigation such as the one in this case (T. 656-689).

120. Doctor Lewis is a microbiologist with an expertise in hepatitis infection surveillance involving colonoscopy and endoscopy (T. 656 *et seq*). Dr. Lewis opined that the infections in this case could have been transmitted through improperly cleaned scopes or the re-use of contaminated biopsy forceps (T. 673-674), or through the re-use of a contaminated cleaning brush, which is used to clean the scopes (T. 686-711). Biofilms also could possibly contribute to contamination (See T. 711). The panel did not accept the conclusions of Doctor Lewis.

CONCLUSIONS OF LAW

Based on the above noted Findings of Fact, the panel concluded, unanimously, that the Factual Allegations, set forth in the Statement of Charges (Appendix 1), were proven by a clear preponderance of the evidence. The Hearing Committee, by unanimous vote, **SUSTAINED** factual allegations A and B, and **SUSTAINED** each of the five specifications, unanimously. The rationale for the Hearing Committee's conclusions is set forth in the Discussion below.

Respondent is charged with five specifications alleging professional misconduct within the meaning of the Education Law §6530. This statute sets forth numerous forms of conduct, which constitute professional misconduct, but does not provide definitions of the various types of misconduct. The definitions utilized herein are set forth a memorandum prepared by the General Counsel for the Department of Health. This document, entitled "Definitions of Professional Misconduct Under the New York Education Law," sets forth suggested definitions for gross negligence, negligence, gross incompetence, and incompetence.

The following definitions were utilized by the Hearing Committee during its deliberations:

Gross Negligence is negligence that is egregious, i.e., negligence involving a serious or significant deviation from acceptable medical standards that creates the risk of potentially grave consequence to the patient. Post v. New York State Department of Health, 245 A.D. 2d 985, 986 (3rd Dept. 1997); Minielly v. Commissioner of Health, 222 A.D. 2d 750, 751-752 (3rd Dept. 1995). Gross negligence may consist of a single act of negligence of egregious proportions, or multiple acts of negligence that cumulatively amount to egregious conduct, Rho v. Ambach, 74 N.Y. 2d 318, 322 (1991). A finding of gross

negligence does not require a showing that a physician was conscious of impending dangerous consequences of his or her conduct.

Negligence is the failure to exercise the care that would be exercised by a reasonably prudent licensee under the circumstances.

Incompetence is a lack of the skill or knowledge necessary to practice the profession.

Gross Incompetence is an unmitigated lack of the skill or knowledge necessary to perform an act undertaken by the licensee in the practice of medicine.

Using the above-referenced definitions as a framework for its deliberations, the Hearing Committee made the following conclusions of law pursuant to the factual findings listed above. All conclusions resulted from a unanimous vote of the Hearing Committee.

VOTE OF THE HEARING COMMITTEE

FIRST SPECIFICATION

GROSS NEGLIGENCE

Respondent was charged with committing professional misconduct as defined in N.Y. Education Law § 6530(4) by practicing the profession of medicine with gross negligence on a particular occasion.

Based on a preponderance of the evidence, the Hearing Committee concludes, unanimously, that the Respondent committed professional misconduct by violating § 6530 (4) of the N.Y. Educ. Law by violating infection control practices and using the medication Propofol in an inappropriate manner.

The Committee therefore concludes, unanimously, that the First Specification was **SUSTAINED.**

Vote: SUSTAINED (3-0)

SECOND SPECIFICATION

NEGLIGENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Education Law § 6530(3) by Practicing the profession of medicine with negligence on more than one occasion by violating infection control practices and using the medication Propofol in an inappropriate manner.

The Committee therefore concludes, unanimously, that the Second Specification was **SUSTAINED.**

Vote: SUSTAINED (3-0)

THIRD SPECIFICATION

GROSS INCOMPETENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Education Law § 6530(6) by Practicing the profession of medicine with gross incompetence by violating infection control practices and using the medication Propofol in an inappropriate manner.

The Committee therefore concludes, unanimously, that the Third Specification was **SUSTAINED.**

Vote: SUSTAINED (3-0)

FOURTH Specification

INCOMPETENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Education Law § 6530(5) by Practicing the profession of medicine with incompetence on more than one occasion by violating infection control practices and using the medication Propofol in an inappropriate manner on more than one occasion.

The Committee therefore concludes, unanimously, that the Fourth Specification was **SUSTAINED.**

Vote: SUSTAINED (3-0)

FIFTH SPECIFICATION

FAILURE TO COMPLY WITH PROVISIONS GOVERNING PRACTICE OF MEDICINE

Respondent is charged with committing professional misconduct as defined in N.Y. Education Law § 6530(16) by willfully or grossly negligently failing to comply with substantial provisions of federal, state, or local laws, rules, or regulations governing the practice of medicine in that he failed to take a mandated infection control and barrier precautions course as required by the Public Health Law § 239.

The Committee therefore concludes, unanimously, that the Fifth Specification was **SUSTAINED.**

Vote: SUSTAINED (3-0)

DISCUSSION

The Hearing Committee carefully reviewed the Exhibits admitted into evidence, the transcripts of the four (4) Hearing days, the Department's Proposed Findings of Fact, Conclusions of Law, and Sanction as well as the Respondent's Proposed Findings of Fact and Conclusions of Law. During the course of its deliberations on these charges, the Hearing Committee considered the following instructions from the ALJ:

1. The Committee's determination is limited to the Allegations and Charges set forth in the Statement of Charges. (Appendix I)
2. The burden of proof in this proceeding rests on the Department. The Department must establish by a fair preponderance of the evidence that the allegations

made are true. Credible evidence means the testimony or exhibits found worthy to be believed. Preponderance of the evidence means that the allegations presented are more likely than not to have occurred (more likely true than not true). The evidence that supports the claim must appeal to the Hearing Committee as more nearly representing what took place than the evidence opposed to its claim.

3. The specifications of misconduct must be supported by the sustained or believed allegations by a preponderance of the evidence. The Hearing Committee understands that the Department must establish each and every element of the charges by a preponderance of the evidence and, as to the veracity of the opposing witnesses, it is for the Hearing Committee to pass on the credibility of the witnesses and to base its inference on what it accepts as the truth.

4. Where a witness's credibility is at issue, the Committee may properly credit one portion of the witness' testimony and, at the same time, reject another. The Hearing Committee understands that, as the trier of fact, they may accept so much of a witness' testimony as is deemed true and disregard what they find and determine to be false. In the alternative, the Hearing Committee may determine that if the testimony of a witness on a material issue is willfully false and given with an intention to deceive, then the Hearing Committee may disregard all of the witness' testimony.

5. The Hearing Committee followed ordinary English usage and vernacular for all other terms and allegations. The Hearing Committee was aware of its duty to keep an open mind regarding the allegations and testimony. With regard to the testimony presented, the Hearing Committee evaluated all the witnesses for possible bias or motive. The witnesses were also assessed according to their training, experience, credentials, demeanor, and credibility. The Hearing Committee considered whether the testimony

presented by each witness was supported or contradicted by other independent objective evidence.

The Hearing Committee first considered the credibility of the various witnesses, and thus the weight to be accorded their testimony. The Department presented several witnesses all of which the panel found credible and persuasive. The expert witnesses of the Department, Doctors Balter and Parker, along with Epidemiologist Stricof, presented a cogent and persuasive scientific case that, in the estimation of the panel, clearly established, by a preponderance of the evidence, that Respondent, through his negligent use of Propofol, was the cause of the outbreak of Hepatitis in New York City that occasioned this case.

The panel gave great weight to the fact that a patient from Dr. Pacheco's office had a colonoscopy but no biopsy. It was argued by Respondent that a possible cause of the outbreak was the use of dirty biopsy forceps. This argument was found not to be persuasive. The record shows that this particular patient from Dr. Pacheco's office, who contracted Hepatitis had a procedure – but no biopsy – shortly after a person who also had a colonoscopy, who was known to have chronic Hepatitis C. It was therefore not the biopsy that was the problem. The key connection between this patient and the one who had chronic Hepatitis C was the anesthesia. It was clear that the problem came from the Respondent who provided the anesthesia, which included Propofol. As set forth in the Findings of Fact above, it was established that this newly infected person had a negative Hepatitis test 10 days after this procedure - almost at the end of the incubation period. The persuasive evidence of the Department's Expert witnesses demonstrated that Molecular testing was done on these two people and it presented a very high relatedness between the viruses, making it very likely that the she was infected by the source patient. The

panel found it highly significant that this newly infected patient did have the same type of procedure as the source patient. Dr. Pacheco did not have the same computerized system as Dr. Goldberg so it is not known if the same scope was used. However, she did **not** have a biopsy so the transmission could not have occurred as a result of contamination from the biopsy forceps, as was argued by the Respondent's attorney and Expert witness.

It is noted that Ernie Clement, a infection control expert from the NYSDOH, was present at the site visit of this office on September 20, 2007. This site visit was also announced. Like Ms. Stricof in Dr. Goldberg's office, Mr. Clement was asked to observe the reprocessing process in this office to rule in or rule out the endoscopes as a possible source of transmission of infection. Mr. Clement found no deviations from infection control standards and concluded that the reprocessing in this office was very good. Again, the only common link was that these patients received anesthesia from Respondent. Specifically, Propofol, from a multi-dose vial. (Tr. 119-121, 156, 184; Ex. 29)

The panel found that there was insufficient evidence to support the premise that Dr. Goldberg routinely *re-used* single-use, disposable biopsy forceps, as the Respondent contended. The City DOH Report states that, during the investigation, Respondent reported that biopsy forceps were re-used at Dr. Goldberg's office, however this was dismissed as *there was no documentation to support or refute this, only statements from staff.* (Exhibit 29, p.37; T-526 l. 14-20).

It is noted that Dr. Carni testified that he witnessed Dr. Edward Goldberg re-use a disposable biopsy forceps, which he discarded and *then retrieved from the waste can* to re-use on the same patient, since the office had no more biopsy forceps available (See T. 791 L. 15 through 793 L. 17). The Respondent has argued that this testimony supports the inference that biopsy practices at this location may have been a cause of the transmission

of blood borne pathogens. The Hearing committee did not believe this testimony of Dr. Carni and found it to be false and self-serving.

Instead the panel believed the testimony of Doctor Goldberg and Nurse Garcia. Dr. Goldberg testified that he used disposable forceps and never re-used them. Ms. Garcia testified that Dr. Goldberg never re-used forceps. Ms. Garcia further testified that she never reprocessed the forceps and that the office never ran out of the forceps. She testified that if she were ever asked by Dr. Goldberg to take a used forceps out of the garbage for him to re-use - as alleged by Dr. Carni - she would not do so. (Tr. 437-438, 491; Ex. 29)

The thrust of the Respondent's argument was that the Hepatitis outbreak could have been caused by a reuse of the biopsy forceps. According to the Respondent, the testimony about infection control practices at the East 60th Street practice location did not instill confidence that such practices could be ruled out as a source of hepatitis transmission.

It was contended by the Respondent and his expert witness that there are other competent inferences to be drawn about the cause of the hepatitis transmission in this case and therefore the burden of proof has not been met to sustain the charges against respondent. The panel determined that this is not the case. The panel concluded that it was established and shown that the biopsy forceps were not the cause of this outbreak because some patients contracted Hepatitis who did not have biopsies. They had other procedures and thus their Hepatitis cannot be blamed on dirty forceps as none was used.

On the subject of Propofol usage, the Respondent contended that there was no evidence in the form of testimony or otherwise, to support the allegation that Respondent used the Propofol medication in an inappropriate manner. The panel found that this was not the case and that Respondent's use of Propofol was highly inappropriate.

The record shows that the Respondent used multi-dose vials of anesthetic including 100 cc vials of Propofol. It was shown that Respondent administered Propofol to all patients and generally used 10 cc syringes and that he used a spike in the vial, which allowed him to remove medication from the vial with a syringe and no needle. The panel believed the testimony that Respondent would place an IV in the patient's arm and withdraw medication from a vial with a syringe, inserting the anesthetic into the IV. It was clearly established from the medical records that the Respondent frequently had to re-dose patients and that he did not document that fact.

Furthermore, the storage of Propofol was shown to be inappropriate as he stored open vials of Propofol in the un-refrigerated closet at the office and used these previously opened vials on subsequent procedure days. Propofol is not to be used after 6 hours. Thus it was clearly established that the Respondent used the medication Propofol in an inappropriate manner since it is indicated as a single-patient use medication even though it is sold in multi-dose vials. The manufacturer's label indicates that Propofol should be discarded after 6 hours because it does not have adequate preservative in it to retard bacterial growth. Respondent used multi-dose vials of Propofol on multiple patients. Respondent used the vials for periods of time exceeding 6 hours. Respondent also used the vials after storing them in the office closet overnight. The panel accepted the testimony of the experts that this misuse was the prime cause of the Hepatitis outbreak that occasioned this case.

As to the failure to take the infection control course, it was clearly established that, from May of 2002 through April of 2007, Respondent practiced medicine without repeating the State mandated infection control and barrier precautions course as required by the New York Public Health Law § 239. There was no dispute about the fact that the Respondent took the requisite infection control course in 2002 and, although due to take it again in

2006, did not do so. However he did take the course in 2007 -- shortly after it was brought to his attention that he had not repeated the course as required and, thus, the course completion occurred eleven months late, well after the outbreak in this case.

HEARING COMMITTEE DETERMINATION AS TO PENALTY

The Hearing Committee, pursuant to the Findings of Fact and Conclusions of Law set forth above, after due deliberation, unanimously determined that the first and second charges and specifications raised against Respondent were sustained.

The Committee has a responsibility to protect the patients of the State. The issue before this Committee is to choose a penalty that offers the best protection to the people of the State. The Committee finds that the Respondent has committed sufficiently egregious misconduct that is worthy of the revocation of his medical license.

The Committee concluded that the only way to ensure the safety of the public is to revoke Respondent's medical license. Anything other than that sanction would risk a recurrence of this behavior. The public should not bear that risk.

The Committee also concluded that the Respondent's conduct in this matter has violated the public trust by his failing to take the mandated infection control and barrier precautions course as required by law. It is noted also that this Respondent has had two prior disciplinary actions brought against him. These were settled by Consent Agreements in 1999 and 2002. The Hearing Officer kept these from the purview of the Committee until after they had sustained the charges herein, lest their fact-finding be prejudiced. These Consent Agreements are in the present record as ALJ Exhibits # 1 and # 2. These prior proceedings further support the penalty determination to Revoke the Respondent's License.

ORDER

IT IS HEREBY ORDERED THAT:

1. The First through Fifth Specifications of professional misconduct, as set forth in the Statement of Charges, are **SUSTAINED;**
2. The Respondent's license to practice medicine is hereby **REVOKED;**
3. This Determination and Order shall be effective upon service on the Respondent. Service shall be either by certified mail upon Respondent at Respondent's last known address and such service shall be effective upon receipt or seven days after mailing by certified mail, whichever is earlier, or by personal service and such service shall be effective upon receipt.

DATED: Port Washington, New York

Mark 20, 2009

Redacted Signature

Kenneth Kowald, CHAIR,

Linda D. Lewis, M.D.

Robert D. Sunshine, M.D.

TO:

Leslie Eisenberg
Associate Counsel
New York State Department of Health
Office of Professional Medical Conduct
90 Church Street
New York, N.Y. 10007

Barbara Ryan, Esq.
Aaronson, Rappaport, Feinstein & Deutsch, LLP.
Attorney for Dr. Goldweber
757 Third Avenue
New York, N.Y. 10017

APPENDIX I

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER
OF
BRIAN A. GOLDWEBER, M.D.

STATEMENT
OF
CHARGES

Brian A. Goldweber, M.D., the Respondent, was authorized to practice medicine in New York State on or about October 5, 1979, by the issuance of license number 139943 by the New York State Education Department.

FACTUAL ALLEGATIONS

- A. On one occasion on June 3, 2005 at 38 East 57th Street, New York, N.Y. 10022 (Patient A-B) and on three other occasions on August 14-15, 2006 at 121 East 60th Street, New York, N.Y. 10022 (Patients C-Q):
1. Respondent violated appropriate infection control practices.
 2. Respondent used the medication Propofol in an inappropriate manner.
- B. From in or about May 1, 2002 through April 17, 2007, Respondent practiced medicine without repeating the State mandated infection control and barrier precautions course as required by the New York Public Health Law Section 239.



SPECIFICATION OF CHARGES

FIRST SPECIFICATION

GROSS NEGLIGENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(4) by practicing the profession of medicine with gross negligence on a particular occasion as alleged in the facts of the following:

1. Paragraph A and its subparagraphs.

SECOND SPECIFICATION

NEGLIGENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(3) by practicing the profession of medicine with negligence on more than one occasion as alleged in the facts of two or more of the following:

2. Paragraph A and its subparagraphs.

THIRD SPECIFICATION

GROSS INCOMPETENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(6) by practicing the profession of medicine with gross incompetence as alleged in the facts of the following:

3. Paragraph A and its subparagraphs.

FOURTH SPECIFICATION

INCOMPETENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(5) by practicing the profession of medicine with incompetence on more than one occasion as alleged in the facts of two or more of the following:

4. Paragraph A and its subparagraphs.

FIFTH SPECIFICATION

FAILURE TO COMPLY WITH PROVISIONS

GOVERNING PRACTICE OF MEDICINE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(16) by wilfully or grossly negligently failing to comply with substantial provisions of federal, state, or local laws, rules, or regulations governing the practice of medicine as alleged in the facts of:

5. Paragraph B.

DATE: October 5, 2008
New York, New York

Redacted Signature

~~Roy Nemerson~~
Deputy Counsel
Bureau of Professional Medical Conduct