

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TOGETHER EMPLOYEES, by Individual
Representatives, ROBERTA LANCIONE,
JOYCE MILLER, MARIA DIFRONZO,
MICHAEL SACCOCCIO, ELIZABETH
BIGGER, NATASHA DICICCO, NICHOLAS
ARNO, and RUBEN ALMEIDA

Plaintiffs,

v.

MASS GENERAL BRIGHAM
INCORPORATED,

Defendant.

Civil Action No. 1:21-cv-11686

DECLARATION OF DR. DEAN HASHIMOTO

I, Dr. Dean Hashimoto, am above the age of 18 and competent to testify. All the information in this declaration is based on my personal knowledge.

1. I am the Chief Medical Officer, Workplace Health and Wellness, at Mass General Brigham, Incorporated (“MGB”).

2. I attended medical school at the University of California, San Francisco School of Medicine. I am board certified in Occupational Medicine, a preventative medicine specialty, and have graduate degrees in public health. I also have a law degree and teach at Boston College Law School, where my scholarship focuses on health care policy and public health. I have substantial experience in developing systematic ways to evaluate medical information, including the implementation of the impartial medical examiner system in the Massachusetts Department of Industrial Accidents (DIA) and within the self-insured workers’ compensation insurance division of the Mass General Brigham. I have been the Chair of the Health Care Services Board

at the Massachusetts DIA since 1998 and oversee the development and revisions of the state medical treatment guidelines that are used for utilization review.

3. I developed and led MGB's interactive process for determining whether or not to grant medical exemptions from the vaccine requirement established by MGB's COVID-19 Vaccination Policy.

A. MGB Announced Its Vaccination Policy, Requiring That Staff Be Vaccinated against COVID-19 Unless Approved for a Religious or Medical Exemption

4. On or about August 10, 2021, MGB's President and CEO sent a notice to staff members explaining its COVID-19 Vaccination Policy (the "Vaccination Policy"). A true and accurate copy of the President's communication is at Exhibit 2. The Policy initially indicated that employees should be fully vaccinated by October 15, 2021, unless they were granted a religious or medical exemption. (Later MGB revised the Vaccination Policy to require a first dose of a two-dose series by October 15, 2021, followed by a later second dose). The deadline for employees to request an exemption was September 3, 2021. See Declaration of Dr. Michael Klompas filed contemporaneously herewith.

5. The announcement included a link to forms that employees could use to request a medical or religious exemption from the Vaccination Policy. The link to the request forms was also available on MGB's employee intranet site. Managers were also empowered to help direct employees to the forms.

B. MGB Provided a Simple Process for Employees to Request a Medical Exemption

6. In order to request a medical exemption, an employee could print a MGB form and have it completed and signed by their health care provider (HCP). A true and accurate copy

of the form (as revised following updated CDC guidance regarding pregnancy, described below in Section G of this declaration) is at Exhibit 7.

7. There were various boxes that the provider could check to indicate certain conditions indicated by the Centers for Disease Control (CDC) as potential contraindications for the COVID-19 vaccine. The MGB COVID-19 Vaccine Policy, which is posted on the MGB website, describes the medical contraindications and indications for temporary deferral of COVID-19 vaccination. See Exhibit 8. This MGB policy is based on CDC guidance, as is true for other COVID-related employee policies such as the return-to-work and testing requirements. A live link to that guidance can be accessed here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html> (last accessed 11/1/2021)

8. One box indicated: “History of severe or immediate allergic (anaphylactic) reaction to a previous dose or component of a COVID-19 vaccine.” The form noted that MGB “encourage[d] consultation with an allergy specialist.” The form asked the HCP to indicate the name of the vaccine or vaccine component to which the employee had had an anaphylactic reaction, the date that prior vaccine was received, and a description of the reaction. See Exhibit 7.

9. Another box indicated: “Temporary exemption due to administration of COVID-19 monoclonal antibodies,” and asked the HCP to identify the date of the last dose administered. See Exhibit 7.

10. Another box indicated: “Temporary exemption due to a history of multisystem inflammatory syndrome,” and asked the HCP to indicate the date of diagnosis. See Exhibit 7.

11. Finally, the form permitted the HCP to identify “Other medical reasons,” and asked the HCP to describe those reasons on the form. The form indicated “Requests with be

reviewed on a case-by-case basis. Clarification from the requesting employee and/or their physician may be requested in writing or by phone.”

12. The form instructed the HCP to submit the form to a dedicated email address.

C. The Two Clinical Panels Examining Requests for Medical Exemptions

13. MGB assembled two clinical panels to review requests for medical exemptions.

14. The first was an Occupational Health Clinical Panel, comprised of three occupational health clinical directors of the major MGB hospitals (MGH, Brigham & Women’s Hospital, Newton-Wellesley Hospital, Salem Hospital) who are nurse practitioners and registered nurses by training with substantial experience in vaccine administration and disability evaluation and management.

15. The second was an Infection Control Panel, comprised of five physicians who are experts in infection control and disease.

16. I and others worked to establish standardized processes to ensure that these two panels worked in sync with each other in examining and making consistent and thoughtful decisions about employees’ medical exemption requests.

D. MGB’s Urgent Health and Safety Priorities Provided Guidance for the Medical Exemption Review Process

17. Prior to reviewing any exemption requests, the two panels involved in the medical exemption process were advised of MGB’s urgent health and safety priorities that would guide the review process. These priorities were developed by senior leadership and health experts at MGB, a widely renowned healthcare system.

18. First, the review process needed to be prompt, given the spread of the COVID-19 Delta variant and the need to have most employees vaccinated by the deadlines set out in MGB’s Vaccination Policy. Second, the review process was to be as rigorous as possible consistent with

the law, so as to minimize the number of unvaccinated staff at MGB given the risks that unvaccinated staff presented to MGB's medically vulnerable patient population, other employees and visitors and to ensure available staff to respond to the ongoing public health crisis. Third, it would be an undue hardship for MGB to allow large numbers of employees to remain unvaccinated while interacting with MGB's medically vulnerable patient population, other employees and visitors.

19. The two panels that assessed requests for medical exemptions were aware that the pandemic, and particularly the rapid spread of the Delta variant of COVID-19, was a public health emergency, and that MGB had an urgent responsibility to help patients diagnosed with COVID-19, as well as to protect its staff, medically vulnerable population and visitors from infection. We were also aware that as a major healthcare system, the perception of safety was critical for patients, visitors and the public. Furthermore, universal vaccination of employees is necessary to preserve the integrity of the entire workforce of our healthcare system that is dedicated to providing excellent patient care, including those who contribute by remote work.

20. Under my leadership, the two panels were tasked with implementing a process for medical exemption requests that would be consistent with those urgent health and safety priorities. I was aware that the impending fall and winter seasons were particularly concerning for new waves of COVID-19 infection especially given the Delta variant. Two of the prior waves of the pandemic spread had occurred during the Fall/Winter time periods.

21. Understanding all of this context of the pandemic emergency, I took pains to create a centralized, rigorous, standardized process that would be both efficient and provide careful, individualized review.

E. The Medical Review Panels Were Tasked with Reviewing What Would Be a High Volume of Requests in an Accelerated Time Frame, to Meet the Urgent Health and Safety Priorities

22. The clinical review panels were also advised that exemption requests were to be reviewed and processed as soon as possible, with the understanding that the employees needed to receive a vaccine by October 15 under the Vaccination Policy.

23. This timeline was to ensure that any employee whose exemption was denied would have adequate time to consider vaccination, and if they decided to vaccinate, to do so under the schedule laid out in the Vaccination Policy.

F. MGB's Interactive Process with Respect to Medical Exemption Requests

24. Together with the two medical panels, we developed an interactive process with respect to medical exemption requests.

25. When medical exemption requests came in, the Occupational Health Clinical Panel reviewed the requests and involved Human Resources as appropriate in accommodation issues. Each medical exemption request was given an individualized, thoughtful, case-by-case review.

26. At the beginning of the process, the Occupational Health Clinical Panel discussed many of the requests with the Infection Control Panel. Over time, as the two panels developed a synchronized approach to particular conditions based on CDC guidance as described in Exhibit 8, there were instances where the Occupational Health Clinical Panel could make a decision on a request based on a group decision the two panels had made together as to how to handle particular categories of requests or issues within requests.

27. The two panels used a layered, nuanced approach to reviewing the requests. The panels met as often needed to discuss and process the requests, sometimes in scheduled regular meetings and sometimes more frequently to respond in a timely way to increased volume.

28. Under my direction, the Occupational Health Clinical Panel also consulted as needed with various world-renowned specialists at MGB, including specialists in Obstetrics, Allergy, and Neurology.

29. The panels followed the CDC guidance regarding medical contraindications to vaccination, which evolved over time as new data and studies emerged. A live link to that guidance can be accessed here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html> The medical contraindications to the vaccine are few and well-defined by the CDC guidance. As a result, our panel could generally make decisions based upon the original submission by the medical providers.

30. Where we had questions for the employee or his or her HCP, we would reach out to the employee or the HCP for more information. For example, the information provided was too vague, or the nature or severity of the condition was unclear, we would solicit more information in order to evaluate the request.

31. As another example, if an employee had submitted a request based on allergies from a non-allergist HCP, and the information was insufficient to enable a proper evaluation of the request, we encouraged the employee to see an allergist. In those cases, we offered that the employee could choose to see a MGB provider, or that the employee could consult his or her own provider. On a case by case basis, we permitted brief extensions of time for an employee to seek an additional medical consult where warranted.

32. The employee or his or her medical provider could provide more information at a dedicated Occupational Health e-mail mailbox.

33. Although we had set a deadline for submission of medical exemption requests, we continued to review requests that were submitted after the deadline.

G. When the CDC Changed its Guidance on Pregnancy Based on New Data, MGB Adapted Its Process to Reflect the New Guidance

34. During our medical request review process, the CDC changed its guidance, and announced an urgent health advisory to increase COVID-19 vaccination among people who were pregnant, recently pregnant (including those who are lactating), who were currently trying to become pregnant, or who might become pregnant in the future to prevent serious illness, deaths, and adverse pregnancy outcomes.

35. Hospital leadership, including me, consulted with MGB Obstetrics Chiefs about the change in CDC guidance, and together we decided that we would not grant exemptions based on pregnancy alone. (Pregnant employees could still seek exemptions based on other medical conditions that went beyond the fact of pregnancy). In those cases where an exemption had been approved solely based on pregnancy, we contacted the employee to let them know of the change. We also consulted with Human Resources and developed other temporary accommodations where feasible on a case by case basis, such as additional parental leave, given that the policy had changed based on the new guidance.

H. The Panels Made Thoughtful Considered Decisions as to Each Request

36. Ultimately, one or both panels made thoughtful, considered decisions on each request.

37. The panels also factored into their decision-making MGB's workforce and public health considerations with allowing a large number of exemptions, because to do so would impose an undue hardship given the risks that unvaccinated staff pose to MGB's medically vulnerable patient population, employees and visitors.

I. Communication of the Decision to Accept or Deny Request for Medical Exemption

38. As decisions were made, each employee who had requested an exemption received by e-mail a written decision either approving or denying the request. Each employee who received a denial was informed that the medical information provided did not demonstrate a sufficient medical reason or contraindication to support an exemption. Furthermore, the employee was informed that we would reassess the request if additional medical documentation was submitted for consideration. If the employee had any additional questions or concerns, or would like to submit further information for consideration, the employee was asked to contact the Occupational Health Services through an electronic link to the email mailbox.

39. Decisions regarding requests were made on a rolling basis to allow denied applicants as much time as possible to be vaccinated prior to the October 15 deadline. Allowances were made to ensure sufficient time including giving temporary exemptions for those consulting their doctors for more information.

J. Some Employees Reached Out to the Committee About Denial of Their Requests

40. Due to MGB's urgent timeline to achieve its health and safety priorities, MGB determined that they could not provide an appeal process for every employee whose requests were denied. MGB also determined that an appeal process would likely result in duplication, with the Committee having to review substantially the same material submitted in the first round

of the process. Instead, we invited the employee to submit additional questions or information to the Committee.

41. Some employees who were displeased with the denial of their requests wrote to the Occupational Health mailbox to express their disappointment with the decision or seeking to provide additional information. The panels reviewed those additional communications to determine if they contained any new medical information sufficient to support the exemption.

42. However, because the surge in cases from the Delta variant in the summer and fall of 2021 was (and is) stressing the health care system and this was an emergency, MGB's ability to engage in this interactive process on these issues was not limitless.

K. Decisions on Individual Plaintiffs' Requests for Exemptions

Maria DiFronzo

43. On or about August 11, 2021, DiFronzo submitted a medical exemption request form stating that she was pregnant and indicating that her estimated delivery date is March 4, 2022. A true and accurate copy of the DiFronzo Medical Exemption Request is at Exhibit 9.

44. On or about August 24, 2021, MGB sent her a denial. A true and accurate copy of the DiFronzo Medical Exemption Denial is at Exhibit 10. Her denial email referenced the CDC guidance on pregnancy.

Roberta Lancione

45. On or about September 2, 2021, Lancione submitted a medical exemption request form stating that she previously experienced an angioedema following receipt of the influenza vaccine and that she was currently being treated for chronic lymphocytic leukemia with Venetoclax. A true and accurate copy of the Lancione Medical Exemption Request is at Exhibit 11.

46. On or about September 9, 2021, MGB sent her a denial. A true and accurate copy of the Lancione Medical Exemption Denial is at Exhibit 12. Neither of her conditions were included in the CDC contraindications and she did not submit any additional information in response to the denial letter.

Joyce Miller

47. On or about August 17, 2021, Miller submitted the attached medical exemption request form stating that she would experience “severe mental anguish / anxiety (if required to get experimental vaccine.” [sic]. A true and accurate copy of the Miller Medical Exemption Request is at Exhibit 13.

48. All medical exemption requests based upon mental health concerns were reviewed by Occupation Health Panel and were either reviewed by or based on guidance from the Infection Control Panel.

49. On or about September 9, 2021, MGB sent her a denial. A true and accurate copy of the Miller Medical Exemption Denial is at Exhibit 14.

Michael Saccoccio

50. On or about August 19, 2021, Saccoccio submitted the attached medical exemption form stating that the reasons for his request were: “Anxiety, PTSD.” A true and accurate copy of the Saccoccio Medical Exemption Request is at Exhibit 15.

51. On or about September 9, 2021, MGB sent him a denial. A true and accurate copy of the Saccoccio Medical Exemption Denial is at Exhibit 16. He was advised that the medical information that he provided did not demonstrate a sufficient medical reason or contraindication to receiving the vaccine.

52. Saccoccio supplemented his submission on or about September 13, 2021 with information from his medical provider and ask that MGB reconsider its denial. A true and accurate copy of the Saccoccio Supplemental Documentation is at Exhibit 17.

53. Saccoccio supplemented his reconsideration request further on or about September 17, 2021 with additional information from his medical provider. A true and accurate copy of the Saccoccio Additional Supplemental Documentation is at Exhibit 18.

54. On or about September 24, 2021, MGB confirmed its denial of Saccoccio's request, having taken the supplemental submissions into account. A true and accurate copy of the Confirmation of Saccoccio Medical Exemption Denial is at Exhibit 19. His request was reviewed by the Occupation Health Panel and the Infection Control Panel, and both panels recommended that his request be denied.

L. Any Unvaccinated Employee Can Return to Work Upon Vaccination

55. Any of the named Plaintiffs in this matter—or any MGB employee currently on unpaid leave due to non-compliance with the MGB Vaccination Policy—is eligible to return to work as soon as he or she is compliant with the Vaccination Policy.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. Executed this 30 day of October, 2021.

Dean Hashimoto

Dr. Dean Hashimoto

CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2021, a copy of the foregoing document was filed electronically through the Court's electronic filing system ("ECF system") and that counsel for Plaintiffs is a registered user of the ECF system. Notice of this filing will be sent by operation of the Court's ECF system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's ECF system.

/s/ Katherine A. Perrelli

Katherine A. Perrelli