

**IN THE MATTER OF AN ARBITRATION**

BETWEEN

**Sault Area Hospital**

("SAH" or "Hospital")

and

**Ontario Hospital Association**

("OHA")

and

**Ontario Nurses' Association**

("Union" or "ONA")

**Re: 'Vaccinate or Mask' Policy**

**SOLE ARBITRATOR: James Hayes**

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Hearings on the merits were held on October 1, 2, and 9, 2014, and, in 2015, on January 26; May 11, 19- 21; June 6, 9, 22-26; July 7, 8.

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## AWARD

### Introduction

1. ONA objects to a 'Vaccinate or Mask' ("VOM") policy introduced at the Sault Area Hospital, an acute care institution (the "Policy"). The Hospital requires that healthcare workers ("HCWs") wear surgical/procedure masks each year throughout the five to six month flu season if they have not received vaccination for influenza. The grievances allege that the VOM Policy is an unreasonable exercise of management rights and a breach of employee privacy rights.

2. The backdrop to these grievances is that certain distinguished Canadian academic physicians are divided on the VOM question. It appears to be unprecedented for leading infection prevention and control academic physicians at Mount Sinai Hospital and the University Health Network to oppose each other so directly in a litigation forum, as occurred here.

3. Grievances such as these are plainly grounded in a dispute over 'best practice' public health policy determination. It seems to me self-evident that medical judgments and policy decisions relating thereto should be located, primarily, elsewhere. One would think an expert medical forum, where contrary views are welcomed and consensus sought if not achieved, would be presumptively appropriate.<sup>1</sup> All the more so because it is almost certain that there will be future material change to the scientific fact pattern currently underpinning existing VOM policies.<sup>2</sup> Aspects of the relevant medical science remain in infancy or appear to be

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<sup>1</sup> See Exhibit 66, p.14 where Dr. De Serres recommends: "a documented critique of available evidence by skilled experts who are independent of single option advocates, and with a full consideration of alternative approaches weighed against the usual policy analysis indicators (e.g. Erikson De Wals framework) is needed to ensure an optimal balance in protecting the safety and rights of both patients and HCWs"; See Exhibit 185, pp.44-45 where Dr. McGeer states her view that such a process was conducted by the Toronto Academic Health Science Network (TAHSN) between 2012 and 2014 resulting in a VOM recommendation; Dr. Gardam was extremely critical of the composition of the TAHSN Working Group: Transcript, May 21, 2015, pp.102-108

<sup>2</sup> There are ethical restrictions preventing the conduct of certain randomized controlled trials. See Exhibit 185, Report, A. McGeer, p. 26: "Assessing vaccine efficacy has also become more difficult over

incapable of formal proof, at the present time at least. The opinions of individual professionals continue to move with their understanding of the relevant evolving scientific research.<sup>3</sup> It is therefore scarcely surprising that there will be honest differences of expert opinion about the 'best' health policies and practices for a particular institution at any given point in time.

4. What is beyond doubt is that grievances of this type reach one extremity of labour relations adjudication. Whatever judicial deference may be paid to the collectively acquired expertise of labour arbitrators, labour arbitrators are not medical experts.

5. This is not to suggest that these grievances were misplaced. A trade union is typically entitled to challenge what it perceives to be an unreasonable exercise of a management right. ONA's members have a direct interest in VOM policies aimed at the conduct of their daily working lives. ONA reasonably objects to a Policy that it believes to be unwarranted. Whatever may be the limitations of a labour arbitration forum, ONA brought these grievances to the only place where it had the legal capacity to demand accountability.

6. These grievances, accordingly, raise an important issue about the appropriate engagement of a labour arbitrator with expert evidence. What approach should an arbitrator take when addressing a challenge to a policy relating to patient care, a subject matter that would normally be expected to fall within the primary domain of healthcare professionals?

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time because once vaccine is recommended for a population group, it is no longer ethical to randomize people in that group to a placebo in clinical trials. This means that vaccine efficacy must be assessed by observational trials which are susceptible to many biases, and much more difficult to interpret than randomized controlled trials". See also: Transcript, July 8, 2015 for the OHA/SAH counsel's comment at p.129

<sup>3</sup> See for example: Transcript, May 21, 2015, M. Gardam, pp. 45-55. Dr Gardam was initially in favour of a mandatory flu shot policy. At p. 47: "when I started to change my mind was when I did the paper for Lancet Infectious Diseases and I realized that all the stuff that we're spouting about how flu is transmitted is actually based on the thinnest of evidence and we need to be much more critical".

7. Where a policy directly affecting employees' conditions of work connects with the delivery of fundamental health policy—and especially where the medical/scientific underpinnings of that policy continue to evolve—what is the role of a labour arbitrator? Should an arbitrator's preference for one credible expert opinion over another, following an adversarial process, necessarily be outcome determinative?

8. Alternatively, may this employer meet the labour relations test of reasonableness by simple proof that its VOM Policy is supported by medical opinion held by one group of leading academic physicians notwithstanding what may be the equally convincing opinion of another leading group? Put another way in labour law terms, in a *KVP*<sup>4</sup> case such as this one, is some version of *Dunsmuir*<sup>5</sup> deference owed to a credible expert opinion relied upon in good faith by an employer?

9. In approaching these questions I have borne in mind that counsel adopted one common legal position despite their disagreement about almost every other aspect of this case.

10. Both counsel stated that the resulting Award should choose between the contending scientific VOM evidence. Relying on her interpretation of *Meiorin*<sup>6</sup>, and using *Suncor*<sup>7</sup> as a recent example, ONA counsel concluded: "that's the job".<sup>8</sup> OHA/SAH counsel referred to *Dunsmuir* as a guide to the meaning of reasonableness.<sup>9</sup> However, he also submitted that in considering reasonableness: "the task is to examine...all of the scientific evidence. In fact, we say that is the

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<sup>4</sup> *KVP Co.* (1965), 16 L.A.C. 73 (Robinson)

<sup>5</sup> *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190

<sup>6</sup> *British Columbia (Public Service Employee Relations Commission)*, [1999] 3 S.C.R. 3; 1999 CanLII 652 (SCC)

<sup>7</sup> *Suncor Energy Inc. Oil Sands*, (2014), 242 L.A.C. (4<sup>th</sup>) 1 (Hodges)

<sup>8</sup> Transcript, July 7, 2015, pp. 147-149; Transcript July 8, 2015, pp.4-6

<sup>9</sup> OHA/SAH Closing Argument, para. 346

evidence that will drive your analysis”.<sup>10</sup> Counsel cited an observation made by Mr. Swan, a prominent Canadian labour arbitrator, in support:

The one point that is clear from the case law is that the decision maker must reach a legal conclusion based on the scientific evidence and other evidence presented. It is not possible to simply decide that there has been a draw between the positions presented by both sides; it is necessary, when faced with two contradictory expert opinions, to decide which of the two is more likely on the balance of probabilities to be a correct statement of the actual circumstances being evaluated.<sup>11</sup>

11. I have proceeded therefore on the basis of the parties’ joint expectation and reviewed the voluminous body of material presented by them albeit with trepidation. That will explain in part the unusual length of this Award. Nevertheless, an arbitration proceeding is not a medical colloquium. This forum remains a labour relations forum and I have sought to maintain an ultimate labour law lens.

12. In the result I conclude that counsel were correct. It is not sufficient for an employer to assert that it reasonably relied upon experts with superb curricula vitae. The calibre of the employer’s experts will always be a crucial fact for consideration but demonstration of that fact is not *ipso facto* decisive in a contested labour law matter. *Dunsmuir* principles of judicial review should not be imported to first level rights determination. More is required in my opinion. And, while caution and some measure of regard may be appropriate in a given case, arbitral timidity is not.

13. On the merits I sustain the core of the Union position. I find that the Policy was introduced at SAH for the purpose of driving up vaccination rates. I also find that the weight of scientific evidence said to support the VOM Policy on patient

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<sup>10</sup> Transcript, July 8, 2015, pp. 20, 26, 153-154; See also: OHA/SAH Closing Argument, para. 12: “The critical analysis is with respect to the scientific evidence, which the OHA and SAH submit strongly supports the Policy and compels its implementation.”

<sup>11</sup> *National Grocers* [2013] O.L.A.A. No. 354 (Swan); See: OHA/SAH Closing Argument, para. 138; See also: Transcript, July 8, 2015, p. 67 referring to Mr. Swan’s opinion: “And he makes the point that, I know recognizing as tough as it is, to reach a legal conclusion based on the scientific evidence as presented.”

safety grounds is insufficient to warrant the imposition of a mask-wearing requirement for up to six months every year. Absent adequate support for the freestanding patient safety purpose alleged, I conclude that the Policy operates to coerce influenza immunization and, thereby, undermines the collective agreement right of employees to refuse vaccination. On all of the evidence, and for the reasons canvassed at length in this Award, I conclude that the VOM Policy is unreasonable.

## **Parties**

14. ONA represents 60,000 registered nurses and allied health professionals and more than 14,000 nursing students providing care in Ontario in hospitals, long-term care facilities, clinics, and in industry, health and the community.<sup>12</sup>

15. The OHA is a member association that represents approximately 151 public hospitals in Ontario of which 135 are participating hospitals in the OHA's Central Collective Agreement with ONA.<sup>13</sup>

16. SAH provides care and services to residents in Sault Ste. Marie and the District of Algoma. SAH is an OHA member and a participating hospital. SAH and ONA are parties to a Local Collective Agreement.<sup>14</sup>

## **Grievances**

17. ONA filed an Association policy grievance on December 13, 2013. ONA members filed a group grievance on January 14, 2014. These matters are consolidated.<sup>15</sup> They grieve the VOM Influenza Management Policy implemented at the Sault Area Hospital on January 1, 2014.

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<sup>12</sup> Exhibit 12, para.3

<sup>13</sup> Exhibit 12, para.1; Exhibit 1, Tab 1

<sup>14</sup> Exhibit 12, para.2; Exhibit 1, Tab 2

<sup>15</sup> Exhibit 12, para.6; Exhibit 3, Tab A, 1 and 2



18. The Policy requires the following among other things:

All persons carrying on activities at SAH, which includes employees, students, undergraduate and post-graduate medical trainees, physicians, volunteers and contract workers, **must receive annual influenza immunization or wear a surgical/procedure mask during the influenza season (typically from November to April)** when in a patient care/clinical area, or when engaged in work-related patient interactions in any area of the Hospital.<sup>16</sup> (bold added)

19. The Policy was applied without alteration for the remainder of the 2013-2014 flu season and throughout the following season in 2014-2015.

20. These grievances are *not* about mandatory immunization for influenza as a condition of employment. Nor do the grievances challenge the desirability of influenza vaccination for HCWs despite some witness differences as to what the scientific literature discloses concerning its short and long term efficacy.

21. During bargaining for the 2014-2016 Collective Agreement, the OHA and ONA entered into a Memorandum of Agreement (“MOA”) dated March 19, 2014. Pursuant to the MOA, the OHA and ONA agreed to my appointment to an arbitration process to resolve some of the outstanding grievances related to influenza policies and practices at various participating hospitals.<sup>17</sup> The MOA included a provision that: “Sault Area Hospital shall proceed to arbitration first after which the parties will agree to the order in which the remaining grievances proceed.”<sup>18</sup>

### **Arbitration Process**

22. These grievances took a long time to try. The Memorandum objective of securing an expeditious outcome was not met. There were the usual prehearing disputes and scheduling exigencies, the details of which are unnecessary to record.

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<sup>16</sup> Exhibit 12, para.5; Exhibit 3, Tab B, 4

<sup>17</sup> Exhibit 12, para.7; Exhibit 3, Tab A, 3

<sup>18</sup> Exhibit 3, Tab A, 3, para.4

Senior counsel conducted the case in the traditional adversarial manner. No time was wasted but neither was any stone left unturned.

23. The parties did agree to seek to achieve a Statement of Fact and Document Brief although the ultimate joint work product<sup>19</sup> was slim. Reports or will-say statements from proposed ONA experts were followed by reports from OHA expert witnesses and, finally, by ONA responses to those OHA opinions. Will-say statements for all other witnesses and copies of proposed exhibits were exchanged. Witnesses were permitted to adopt will-say statements and reports subject to the right to cross-examine. The parties retained a reporting service to ensure that complex medical testimony was taken efficiently and transcribed accurately.

24. Dr. Michael Gardam and Dr. Camille Lemieux of the University Health Network (“UHN”) in Toronto testified under subpoenae in support of the grievances. Dr. Gardam is the Medical Director, Infection Prevention and Control, UHN and an Associate Professor, Infectious Diseases, in the Faculty of Medicine at the University of Toronto. Dr. Lemieux is the Associate Director, Infection Prevention and Control, UHN and an Assistant Professor of Medicine at the University of Toronto. She is also legally trained and a member of the Law Society of Upper Canada.

25. ONA also called Dr. Lisa Brosseau, currently a Professor in the Division of Environmental and Occupational Health Sciences and Director of the Industrial Hygiene Program at the University of Illinois in Chicago, and Dr. Gaston De Serres, MD, PhD who is a medical epidemiologist with the Scientific Group on Immunization at the Institut National de Santé Publique du Québec. Dr. De Serres is also a Professor of Epidemiology at the Department of Social and Preventive Medicine at Laval University. He works primarily on vaccine preventable diseases and states

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<sup>19</sup> Exhibit 12

that he is “frequently called upon to contribute to systematic analyses to inform public policy”.<sup>20</sup>

26. The OHA and SAH countered with Dr. Allison McGeer and Dr. Bonnie Henry. Dr. McGeer is the Director of Infection Control at Mount Sinai Hospital in Toronto and a Professor of Laboratory Medicine and Pathobiology, and of the Dalla Lana School of Public Health, at the University of Toronto. Dr. Henry is the Deputy Provincial Health Officer for the Province of British Columbia.

27. This arbitration process is indebted to the contributions of these distinguished professionals. Some of the evidence provided by them is later referred to, inevitably, in sharply abbreviated form. While the professional and research interests of the experts varied to some extent, their extraordinary qualifications, the depth of their experience, and their commitment to the medical profession and public health are beyond dispute. Their evidence was presented, as one would expect, with integrity. Their professional differences of opinion reflected no lack of respect for those with whom they disagreed. Professional courtesy however did not prevent them from vigorously expressing their opposing points of view.

28. In the result the hearing transcripts ran to more than 3500 pages. There were 249 exhibits several of which constituted substantial volumes of material in themselves. Among the exhibits were over 100 academic articles, reports, and commentaries from medical and scientific journals many containing complex statistical material designed to be understood by experts and professionals in the fields of their respective inquiries.

29. Some of these scientific journal articles contained meta-analyses: summaries, reviews and/or critical commentaries concerning the relative quality of randomized controlled trials, observational and experimental studies, investigations, and related

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<sup>20</sup> Exhibit 66, Report of Dr. De Serres, p. 1

literature. The meta-analyses and literature reviews contained many conflicting evaluations and the experts who testified in this case, in turn, often differed about the conclusions they drew from those analyses and reviews.

### **Parties' Core Positions Briefly Stated<sup>21</sup>**

#### *ONA*

30. ONA maintains that the evidence supporting masks is “weak”.<sup>22</sup> Masks are of negligible use in the combat of influenza transmission by or to HCWs and patients. A VOM policy resting upon “objectively flawed” evidence for its “scientific foundation cannot be seen as a reasonable evidence based policy”.<sup>23</sup>

31. The Hospital failed to reconsider the merits of the Policy when the extent of the extreme mismatch of the influenza vaccine with the most common 2014-2015 strain of influenza became known early in that flu season.<sup>24</sup> It did not then decide to mask all employees whether or not they had been vaccinated. That failure provides a further demonstration that the Policy is inherently illogical: an illogical policy is not a reasonable policy.

32. ONA submits that: “the process followed at SAH [concerning the Policy] goes directly to its reasonableness”.<sup>25</sup> The VOM Policy was presented to the unions as a *fait accompli*. The Hospital provided no opportunity for affected health care professionals to engage in legitimate dialogue about the core of the Policy before its adoption was determined. There was internal professional opposition to VOM at the

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<sup>21</sup> Both counsel filed lengthy written legal argument. Closing submissions required two days.

<sup>22</sup> Transcript, July 7, 2015, p.109

<sup>23</sup> ONA Final Argument Overview, para.107

<sup>24</sup> ONA Final Argument Overview, paras. 144-151

<sup>25</sup> ONA Final Argument Overview, para. 191; Transcript, July 7, 2015, pp.134-135

highest levels<sup>26</sup> at the outset. The Hospital failed to consult external consultants who were on retainer to provide that very advice.<sup>27</sup>

33. These fundamental flaws, says ONA, reveal the true purpose of the Policy; that is, to drive up vaccination rates through coercive means. The motive is illegitimate. It is unpleasant to wear masks for months at a time. The compulsory wearing of an unnecessary mask is imposed as a “consequence” for an employee’s failure or refusal to accept or submit to vaccination. Such coercion undermines the individual right of employees to choose or decline to be vaccinated, a right that has been collectively bargained. Coercive intention is not reasonable intention.

34. The Policy violates employee privacy rights. A Hospital-wide posting<sup>28</sup> explains to the public that masks are required to be worn by unvaccinated employees. The mask requirement amounts to compulsory disclosure of personal medical information. *KVP* should be applied having regard to the framework set out in *Peace Country Health*<sup>29</sup>: “

There must be compelling circumstances to justify an intrusion upon an employee’s privacy. A policy is only reasonable if it is justifiable in the sense of adequate cause for infringement of the privacy right, and necessary in the sense that less intrusive rules would not suffice”.<sup>30</sup>

35. For these reasons, the Hospital’s adoption and implementation of VOM constitutes an unreasonable exercise of management rights. The Policy should be struck down on traditional *KVP* principles.

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<sup>26</sup> Opposition from both the Chief of Staff/Director of Medical Care and the Chief Nursing Executive

<sup>27</sup> ONA Final Argument Overview, para. 195

<sup>28</sup> Exhibit 3, Tab G, 48

<sup>29</sup> *Peace Country Health v. United Nurses of Alberta*, (2007), 89 C.L.A.S. 107 (Sims)

<sup>30</sup> ONA Final Argument Overview, para. 4

36. The OHA and the Hospital defend the Policy as a valid patient safety measure<sup>31</sup> supported by highly credible experts. The primary purpose of a VOM policy is source control; that is, to prevent transmission from unvaccinated HCWs to their patients when shedding influenza virus prior to symptom onset, or, in cases of asymptomatic infection.<sup>32</sup> These parties submit that: “the Policy reasonably balances the interests in protecting patient safety against the potential deadly infectious disease of influenza with ONA members’ personal autonomy and privacy”. The Policy is “consistent with SAH’s legal, contractual and ethical obligations as a public hospital”.<sup>33</sup>

37. The OHA and the Hospital submit that the process issues raised by ONA are misguided and peripheral: “The critical analysis is with respect to the scientific evidence.”<sup>34</sup> The Memorandum plainly envisages the challenge to the SAH Policy to be a lead case: “...it would be unreasonable to analyze the reasonableness of the Policy...by focusing on local evidence of development and implementation of the Policy or by focusing on evidence of the efficacy of the influenza vaccine in one influenza season”.<sup>35</sup>

38. Citing *Dunsmuir* and other authorities concerning the standard of judicial review, the OHA and Hospital also submit that arbitral focus should be “to determine whether the Policy falls within a range of acceptable and rational solutions; it is not to assess whether the same policy would have been implemented by ONA”, or, “whether SAH exhausted all possible alternatives”.<sup>36</sup>

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<sup>31</sup> OHA/SAH Closing Argument, para.379 citing *Public Hospitals Act—Hospital Management*, RRO 1990, Reg. 965, s.4

<sup>32</sup> Exhibit 185, Report, A. McGeer, p. 36; Transcript, June 24, 2015, A. McGeer, p. 154; Transcript, June 25, 2015, A. McGeer, p. 32

<sup>33</sup> OHA/SAH Closing Argument, para. 15

<sup>34</sup> OHA/SAH Closing Argument, para. 12

<sup>35</sup> OHA/SAH Closing Argument, para. 11

<sup>36</sup> OHA/SAH Closing Argument, paras. 353, 345

## Relevant Provisions of Collective Agreement

39. The Central Collective Agreement and the Local Collective Agreement together constitute the collective agreement for each of the participating hospitals, including SAH (the “Collective Agreement”). The present Collective Agreement has a term of April 1, 2014 to March 31, 2016 and the previous Collective Agreement had the term of April 1, 2011 to March 31, 2014.<sup>37</sup>

40. The ONA/SAH Local Agreement contains the following management rights clause:

B-1 The Association recognizes that the management of the Hospital and the direction of the working force are fixed exclusively in the Hospital and shall remain fully, with the Hospital except as limited by a provision of this Agreement. Without restricting the generality of the foregoing, the Association acknowledges that it is the exclusive function of the Hospital to:

....

(e) discuss with the Association, make, enforce and alter from time to time reasonable rules and regulations to be observed by the nurses, provided that such rules and regulations shall not be inconsistent with the provisions of this Agreement.<sup>38</sup>

41. The ONA Central Agreement includes the following provisions:

Article 1.02: It is recognized that nurses wish to work with the Hospital to secure the best possible nursing care and health protection for patients. Appropriate committees have been created under this Agreement to work towards this objective.

Article 6.05(a): It is a mutual interest of the parties to promote health and safety in workplaces and to prevent and reduce the occurrence of workplace injuries and occupational diseases. The parties agree that health and safety is of the utmost importance and agree to promote health and safety and wellness throughout the organization.

Article 6.05 (e) (vi): The Union agrees to endeavor to obtain the full cooperation of its membership in the observation of all safety rules and practices.

Article 18.07: The parties agree that influenza vaccination may be beneficial for patients and nurses. Upon a recommendation pertaining to a facility or a

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<sup>37</sup> Exhibit 12, para.4

<sup>38</sup> Exhibit 1, Tab 2, Appendix 5, Article B-1

specifically designated area(s) thereof from the Medical Officer of Health or in compliance with applicable provincial legislation, the following rules will apply:

- a) Nurses shall, subject to the following, be required to be vaccinated for influenza.
- b) Omitted
- c) Hospitals recognize that nurses have the right to refuse any required vaccination.
- d) If a nurse refuses to take the vaccine required under this provision, she may be placed on an unpaid leave of absence during an influenza outbreak in the hospital...
- e) If a nurse refuses to take the vaccine because it is medically contraindicated, and where a medical certificate is provided to this effect, she or he will be reassigned during the outbreak period
- f) Omitted
- g) Omitted
- h) This clause shall be interpreted in a manner consistent with the *Ontario Human Rights Code*.<sup>39</sup>

## Diebolt Award

42. The specific VOM issue here in dispute has been addressed by a Canadian labour arbitrator once before. See: *Health Employers Assn. of British Columbia* (2013), 237 L.A.C. (4<sup>th</sup>) 1 (Diebolt) ["Diebolt Award"].

43. That Award records that the issue was heavily contested by an impressive group of expert witnesses, supported by a large body of documentary material. Dr. McGeer and Dr. Henry gave evidence in that earlier proceeding on behalf of the employers.

44. In the result, Arbitrator Diebolt sustained the challenged policy as "a valid exercise of the Employer's management rights" and dismissed all of the other objections that were raised. That VOM policy does not materially differ from the Policy disputed in the instant grievances. It appears that the arbitrator's general preference of the evidence of Dr. McGeer and Dr. Henry was a decisive factor in reaching the conclusion that he did.<sup>40</sup>

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<sup>39</sup> Exhibit 1, Tab 1

<sup>40</sup> See Diebolt Award, para. 185: "given the areas of expertise of McGeer and Henry their evidence on the transmission issues have special relevance".



45. Counsel for the OHA/Hospital submits that the Diebolt Award was “a thorough and reasoned decision supported by a substantial body of expert evidence and jurisprudence”. Citing numerous authorities including *Irving Pulp & Paper Ltd*<sup>41</sup> he submits that: “principles of certainty, consistency and predictability apply to ensure that adjudicators give appropriate consideration and weight to past decisions”.<sup>42</sup> Counsel also referred to *University Health Network (CM-34)* where Arbitrator Surdykowski stated that: “Of course there is a first case on every issue, but even here an arbitrator will generally follow even a first reasoned decision on an issue unless he is convinced that it is wrong.”<sup>43</sup>

46. I have paid close attention to the Diebolt Award. However, none of the ONA witnesses heard in this matter testified before Arbitrator Diebolt. As previously mentioned, the Union in the instant case called witnesses with expertise in epidemiology as well as infection control. While union witnesses before Arbitrator Diebolt had some training in epidemiology, their primary interests lay elsewhere as he noted.<sup>44</sup> The Diebolt Award does not disclose that the experts in that case were pressed in detail with each of the scientific and medical investigations, studies, and literature upon which their opinions were based as both counsel did here comprehensively with skill and determination.

47. Research and related commentary in the field has not stood still. In such a situation the precedential value of previous decisions will be more limited than the more typical second, third, or umpteenth view of a standard collective agreement provision. This is even more so where the statutory regimes governing the first and subsequent arbitrations differ, as is the case with the Diebolt Award and the present matter.

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<sup>41</sup> 2013 SCC 34

<sup>42</sup> OHA/SAH Closing Argument, para. 299

<sup>43</sup> (2013) 115 C.L.A.S. 216, para. 48

<sup>44</sup> Diebolt Award, paras. 183-185

## VOM Policy at SAH

48. As previously stated, ONA takes the position that the Policy was presented to Hospital employees as a ‘done deal’ with no room to consider the merits of a VOM policy. It says that this lack of process demonstrates that the Policy was never about the validity of a mask-wearing component and all about imposing a negative incentive upon employees to opt for what amounts to, for many of them, involuntary vaccination. The Union states that lack of process goes to the unreasonableness of the Policy.

49. On the other hand the OHA/SAH maintains that focus on local SAH evidence is a distraction. What these grievances require is an examination of the scientific evidence underpinning an evidence-based, patient safety VOM policy that has been introduced at many other Ontario hospitals.

50. Given the position taken by ONA on this issue, I find it preferable to outline what occurred at SAH at the outset of this Award.

### *The CEO's initial decision*

51. Ron Gagnon<sup>45</sup>, the Chief Executive Officer of SAH, testified by will-say Statement. He said that earlier disturbing critical incidents at the Hospital “shaped his beliefs and actions, and those of SAH, with regard to safety”. He and his Senior Management Team (“SMT”) were concerned about the low rates of influenza immunization at SAH for its employees, physicians, and volunteers. Mr. Gagnon stated that the Hospital’s Human Resources Group was engaged to develop a policy.

52. Minutes of an SMT meeting held on January 30, 2013 record the following discussion:

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<sup>45</sup> Exhibit 246

R. Gagnon—recent report indicates that we are at 42% compliance on flu shot immunization (employees 46%, physicians 41%, volunteers 23%). **Need to determine the most aggressive stance that we can take, which will stand the test of arbitration, to either mandate staff to comply, or impose consequences (ie. masks that they would be charged for).** Also need to review IPAC best practices. (bold added)<sup>46</sup>

53. A Briefing Note prepared for the SMT meeting on February 6, 2013 supported a motion to approve “a new policy to be enforced in the fall of 2013 requiring all employees, physicians and volunteers that are involved in direct patient care to be immunized or wear a mask”. *Inter alia*, reference was made to such a policy having been implemented at Health Sciences North in Sudbury.<sup>47</sup>

54. Minutes of the February 6, 2013 SMT meeting record the following:

HR was asked to come up with most aggressive stance we could take regarding immunization of staff for influenza. HR recommendation to create a team to determine if and where we need a policy(s) and develop action plans related to those policies. Agreement that having a patient representative on the committee would be optimal. Recommended that immunization goal for 13/14 flu season should be 100%.<sup>48</sup>

55. Chris Johns, Manager, Human Resources and Corporate Safety, was asked in February 2013 by his Director “to make the policy more robust, to increase immunization rates, to protect the patients, and to look at the idea of a group plan implementation.”<sup>49</sup> Mr. Johns is not a regulated health professional and has no infection control background. He was not then aware that the Hospital had infection control consultants on retainer.

56. The policy was first given to Occupational Health which deals with employee safety, not patient safety.<sup>50</sup> In February 2013 Mr. Johns asked Occupational Health Nurse Carolle Manzo “to do some research as to instituting a policy of getting influenza vaccination or wearing a mask for the season in patient care areas”.<sup>51</sup>

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<sup>46</sup> Exhibit 3, Tab D, 15

<sup>47</sup> Exhibit 3, Tab D, 16

<sup>48</sup> Exhibit 3, Tab E, 21

<sup>49</sup> Transcript, June 29, 2015, C. Johns, p. 66

<sup>50</sup> Transcript, June 29, 2015, C. Johns, p. 67; Transcript, June 9, 2015, C. Manzo, p. 83; Transcript, June 9, 2015, C. Manzo, pp. 53-56

<sup>51</sup> Transcript, June 9, 2015, C. Manzo, p. 20

Neither the normal process for policy development for occupational health, or for infection control matters, was followed.<sup>52</sup>

57. Ms. Manzo assumed that “the decision had been made that the policy would be a vaccinate or mask policy” when she and Mr. Johns were charged with drafting a policy in February 2013.<sup>53</sup>

*Preparation of the draft policy*

58. Ms. Manzo compiled literature and various policy statements and spoke with an occupational health colleague at Health Sciences North in Sudbury where a VOM policy had been instituted.<sup>54</sup> A first draft of a VOM policy was prepared based on Health Sciences North.<sup>55</sup> She was not asked to look into the human rights aspect of the policy.<sup>56</sup> She did not review the existing Hospital policy concerning Infection Prevention and Control (“IPAC”).<sup>57</sup> She did not present or give to anyone copies of the research that she conducted.<sup>58</sup> Ms. Manzo prepared the VOM draft policy based on her understanding that influenza is transmitted by large droplets and aerosol generating procedures only.<sup>59</sup> No one asked her to look at the efficacy or effectiveness of the surgical masks for influenza.<sup>60</sup> She did not ask for assistance with respect to obtaining an expert opinion as to masks or the transmission of influenza.<sup>61</sup>

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<sup>52</sup> Transcript, October 2, 2014, N. Marcello, p. 17; Transcript, June 29, 2015, C. Johns, pp. 73-74; Transcript, June 9, 2015, C. Manzo, p. 120, 170

<sup>53</sup> Transcript, June 9, 2015, C. Manzo, p. 68; See also pp. 81-2

<sup>54</sup> Transcript, June 9, 2015, C. Manzo, p. 21ff, p. 26; Exhibit 128A and B

<sup>55</sup> Transcript, June 9, 2015, C. Manzo, p. 28-29

<sup>56</sup> Transcript, June 9, 2015, C. Manzo, p. 70

<sup>57</sup> Exhibit 2; Transcript, June 9, 2015, C. Manzo, p. 58

<sup>58</sup> Transcript, June 9, 2015, C. Manzo, p. 104

<sup>59</sup> Transcript, June 9, 2015, C. Manzo, p. 106; Dr. Henry explained an aerosol medical generating procedure as “things we do to patients in the hospital that can produce these very small particles of aerosol”, Transcript, June 22, 2015, p. 225

<sup>60</sup> Transcript, June 9, 2015, C. Manzo, p. 109

<sup>61</sup> Transcript, June 9, 2015, C. Manzo, p. 204

59. The SAH By-Laws provide for a standing committee called the IPAC Committee whose purpose is “to foster the prevention of infection, especially nosocomial infections in the hospital and patient safety”.<sup>62</sup> The Committee was not asked to look into the issue of either transmission of influenza or whether the wearing of a mask would impact such transmission.<sup>63</sup> Nor did Mr. Johns conduct any research or look at any such evidence.<sup>64</sup>

60. On June 9, 2013 Mr. Johns sent an e-mail to the heads of all SAH bargaining agents including Glenda Hubley, President of ONA Local 46. The e-mail<sup>65</sup> included the following and indicated that a VOM policy would be in place:

Sault Area Hospital is committed to maintaining a healthy and safety workplace. One step towards achieving this goal is the creation and implementation of an employee influenza management policy...

....

The major change to be put in place this year is that employees who have not received the influenza vaccine will be required to wear a surgical mask in patient care areas for the duration of the influenza season. Later today, the Occupational Health Nurse will be reaching out to employees throughout the hospital, from various areas and levels (including the JHSC) requesting their representation on a committee to prepare and implement an influenza management policy at Sault Area Hospital. The goal for finalizing the policy and deal with logistic issues is the end of August. This will enable time for disseminating the information to all staff well before the 2013-2014 influenza season starts.<sup>66</sup>

61. Ms. Hubley responded to the e-mail on the same date advising that: “The Union reserves the right to grieve. Please be advised that any ONA member sitting on this committee is not a representative of the ONA and does not represent the ONA’s view point or opinions on the matter.”<sup>67</sup>

62. Responsibility for the Policy was transferred from Human Resources (Occupational Health) to IPAC in September 2013.<sup>68</sup> The SAH By-Laws provide for

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<sup>62</sup> Transcript, June 9, 2015, C. Manzo, p. 17; Transcript, October 2, 2014, N. Marcello, p. 13

<sup>63</sup> Transcript, June 29, 2015, C. Johns, p. 76

<sup>64</sup> Transcript, June 29, 2015, C. Johns, p. 78, p. 128

<sup>65</sup> Exhibit 3, Tab F, 26

<sup>66</sup> Transcript, June 9, 2015, C. Manzo, p. 119

<sup>67</sup> Exhibit 3, Tab F, 26

<sup>68</sup> Transcript, October 2, 2014, N. Marcello, p. 44, p. 75; Transcript, June 29, 2015, C. Johns, pp. 29, 74; Transcript, June 9, 2015, C. Manzo, p. 38

such a standing committee.<sup>69</sup> An Influenza Planning Committee had been struck earlier. Occupational Health deals with employee safety while IPAC deals with patient safety.

*Professional concerns about VOM*

63. Minutes of the July 11, 2013 IPAC Committee Meeting include the following references to Dr. Heather O'Brien. Dr. O'Brien was and remains the Chief of Medical Staff and Director of Medical Care at the Hospital:

Dr. O'Brien asked if direction for the requested change [the VOM policy] was received from Senior Management...**Dr. O'Brien indicated that she declined to participate on the influenza committee as she does not agree or support the policy change...Dr. O'Brien sought confirmation on the intent of the influenza committee. She noted that if the intent is to prevent the spread of the influenza virus then everyone should wear a mask; if the intent is to persuade everyone get (sic) the vaccine then the policy is reasonable. If you really don't want to pass the flu around everyone should wear a mask considering the vaccine is only 65% effective.**<sup>70</sup> (bold added)

64. The first meeting of the Influenza Planning Committee was held on July 18, 2013.<sup>71</sup>

65. A further meeting of the Influenza Planning Committee was held on July 29, 2013 but there were no additional meetings of that Committee in August, September, or October. There was no discussion about the following items: mask effectiveness, vaccine effectiveness, privacy issues, stickers, eye protection, surgical or procedural masks as opposed to respirators. No expert opinion was sought concerning masks.<sup>72</sup>

66. Mr. Johns and Ms. Manzo prepared a Briefing Note dated September 13, 2013 for the SMT "to update them on the progress of the Influenza Planning Committee, the policy that was developed during that committee. Also, the mask situation, the

<sup>69</sup> Exhibit 4, Tab D, Article 21.1 at p. 47

<sup>70</sup> Exhibit 4, Tab 7; See also: Transcript, June 9, 2015, C. Manzo, pp. 92-94, 96

<sup>71</sup> Transcript, June 29, 2015, C. Johns, p.25

<sup>72</sup> Transcript, June 9, 2015, C. Manzo, pp. 122-124

cost that would be involved in implementing the policy”.<sup>73</sup> The Briefing Note included the following:

In early 2013, a concern was raised at SMT hot topics regarding the immunization rate of employees, volunteers and physicians and subsequent risk to patients.

In response to this discussion, Human Resources was asked to investigate, identify and recommend the most aggressive approach that could be taken to progress towards 100% compliance with influenza immunization

....

In addition, bargaining agents were invited to participate on the work team, as well as given notice of the impending policy change. In response to this each bargaining agent responded stating they were not willing to participate as they did not agree with the direction and they reserved the right to grieve.<sup>74</sup>

67. SAH has a Consulting Services Agreement with UHN. Dr. Lemieux and Dr. Gardam are the UHN physicians responsible for providing “infection prevention and control consultation services to SAH”. The appended Schedule to that Agreement includes but is not limited to the following “IPAC consultation on an as needed basis”:

Advise upon policy development or policy revision (does not include development or writing of policies)

Provide expert advice to Infection Prevention and Control at SAH on specific infection control issues

Advise upon Occupational Health issues as these relate to infectious diseases [influenza immunization is specifically referenced]<sup>75</sup>

68. Dr. Lemieux and Dr. Gardam were not consulted by the Hospital concerning its VOM Policy<sup>76</sup> although infection control practitioners at SAH typically do so “especially in a situation of developing a new policy that hasn’t historically been within the manual”.<sup>77</sup>

69. On October 7, 2013 Natalie Marcello, who was the IPAC team lead at the time<sup>78</sup>, advised Dr. Lemieux by e-mail<sup>79</sup> about the new VOM policy and received the following response less than two hours later:

<sup>73</sup> Transcript, June 9, 2015, C. Manzo, p.37

<sup>74</sup> Exhibit 3, Tab E, 22

<sup>75</sup> Exhibit 4, Tab 14

<sup>76</sup> Exhibit 20, para.6

<sup>77</sup> Transcript, October 2, 2014, N. Marcello, p. 15

<sup>78</sup> Transcript, October 2, 2014, p. 12

<sup>79</sup> Exhibit 4, tab 11

I'm dismayed that the hospital has decided to go this route. It is very punitive and there is no literature substantiating that it does anything to minimize influenza transmission. But big jurisdictions like NY state are going to this.

I would agree that the main 'benefit' of this is to drive immunization rates up (so an indirect benefit), given that few people would want to wear a mask for 6-7 months. However, aside from being coercive and punitive, the other big problem with this strategy is that to really be effective, you would have to mask everyone whether immunized or not—since the vaccine itself is not very effective and immunity appears to wane before the end of flu season. Being immunized does not mean you won't get the flu and then transmit it.<sup>80</sup>

70. On October 11, 2013 the Workers' Member Group of the Hospital's Joint Health and Safety Committee objected strongly to the draft VOM policy and proposed amendments that would have stripped it of its intended VOM purpose.<sup>81</sup>

#### *Concerns about masks*

71. An IPAC Committee Meeting was held on October 9, 2013 that included Johanne Messier-Mann as Chair. Ms. Messier-Mann was the Chief Nursing Executive at SAH and the Manager of the Hospital's IPAC Department. Also in attendance was Dr. Kim Barker who was then the Medical Officer of Health for the District of Algoma. Minutes of that meeting include the following excerpts from discussion of the immunization policy:

- **The group noted that the policy should be honest and transparent and that in light of the fact that masks are not shown to be an effective means of decreasing the transmission of influenza the intention should be more clearly indicated as "to improve influenza immunization compliance"**

....

- The IPAC committee members questioned why this policy is an IPAC policy rather than an Occupational Health and Safety as is the case in other hospitals who have implemented this type of policy. The purpose of the policy is to protect the patients; that is the role of IPAC. There was significant discussion where each member was asked for input; **without evidence that this will decrease transmission, the committee members do not support the policy. There is no evidence that wearing masks reduces transmission.** Masking appropriately for the duration of an outbreak can be very expensive for the organization and does not offer effective protection for the patients.

The committee did not support the policy as an IPAC policy....<sup>82</sup>

(bold added)

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<sup>80</sup> Exhibit 4, tab 11

<sup>81</sup> Exhibit 4, Tab 2

<sup>82</sup> Exhibit 4, Tab 7, p. 2



72. Ms. Marcello had been told prior to the October 9, 2015 meeting that any change to the existing policy would have the “mask piece” written into it.<sup>83</sup> She understood the group in attendance at that meeting agreed that the VOM policy should not be supported.<sup>84</sup>

73. Ms. Manzo was also in attendance at the October 9, 2015 meeting. She confirmed that the group as a whole thought that the purpose of the VOM policy was to get more people vaccinated.<sup>85</sup> She agreed that: “it wasn’t that the mask was to protect the patients, but it was to up the immunization rate to protect the patients”.<sup>86</sup>

74. Mr. Johns did no follow-up concerning the IPAC comment of October 9, 2013 that: “there is no evidence that wearing masks reduces transmission”.<sup>87</sup>

#### *Focus groups*

75. Several focus groups were held with employees in various positions beginning on October 9, 2015. Mr. Johns stated that attendance was as low as two and as high as seven.<sup>88</sup> The number of participants represented a small fraction of the total number of SAH employees.

76. A Briefing Note to the SMT dated November 6, 2013 was prepared by the Chief Nursing Executive Johanne Messier-Mann and Kim Lemay, SAH Director, Human Resources. The Note discloses approval by the Chief of Medical Staff Dr. O’Brien. It included the following:

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<sup>83</sup> Transcript, October 2, 2014, p. 99

<sup>84</sup> Transcript, October 2, 2014, p. 108

<sup>85</sup> Transcript, June 9, 2015, C. Manzo, p. 129, line 22-p.130, line 1

<sup>86</sup> Transcript, June 9, 2015, C. Manzo, p. 129-30

<sup>87</sup> Transcript, June 29, 2015, C. Johns, p. 130

<sup>88</sup> Transcript, June 29, 2015, p. 92

## Background:

- In early 2013, a concern was raised at SMT regarding the immunization rate of employees, volunteers and physicians and subsequent risk to patients. In response to this discussion, Human Resources was asked to investigate, identify and recommend the most aggressive approach that could be taken to progress towards 100% compliance with influenza immunization.
- Human Resources submitted a briefing note to SMT in February 2013 outlining a recommendation to enhance the existing influenza policy.

....

- A team worked through the required steps and actions to successfully implement the new policy for the 13/14 flu season. The revised policy was presented to SMT in September, 2013. SMT directed that further input be sought from the Infection Prevention and Control Committee, the Joint Health and Safety Committee, the MAC and by staff focus groups led by OH&S. All options were considered including wearing a mask.
- **The response from these groups was in support of working on increasing the immunization rates and overwhelmingly not in favour of creating a flu shot or mask policy.**

....

## Analysis

Given the following points, it is recommended that SAH continue with the current immunization policy and work on increasing the immunization rates:

- Best practice stipulates that immunization is the best prevention for the spread of influenza;
- **There is no evidence that wearing masks reduces transmission;**
- The effort of implementing and monitoring compliance to an “if not immunized then mandatory mask” policy would require disproportionate management effort;
- **While other hospitals have seen increases in immunization rates with a flu shot or mask policy it is expected based on the initial feedback and reaction of staff that there would be a significant negative impact to employee and physician engagement which could persist for several years.** Given this due consideration, the staff and physicians need to commit to being vaccinated. **If the immunization rates do not reach a target of 80% for this influenza season, SMT may need to reconsider the implementation of an immunization or mask policy for next season.**<sup>89</sup> (bold added)

*70% immunization rate or VOM*

77. On November 13, 2013 Mr. Gagnon and Dr. O'Brien sent a Message to all SAH employees, physicians and volunteers that included the following:

Last year only 50% of our staff, physicians and volunteers were immunized (or reported they had been immunized). In order to live our iCare values and be “best”, we can—and must—do better.

**In order to boost immunization rates, hospitals in Ontario and elsewhere have begun to adopt policies which require all employees, physicians and volunteers**

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<sup>89</sup> Exhibit 3, Tab E, 23

**(and in some cases, members of the public) to receive the annual flu vaccination or wear a mask.** The data from those who have adopted this policy indicates that it has had a dramatic impact in improving rates of immunization and protecting patients.

....

**Given our low immunization rates last year, it is clear that we need to do something different.** While we seriously considered adopting the same “immunization or mask” policy for SAH at the beginning of this flu season, we also wanted to honour our commitment to hearing from you before making decisions which directly affect you or your work. We sought input from our staff, managers, physicians and others about this potential course of action as well as suggestions to significantly improve our rates of immunization using alternate approaches. There was universal agreement that immunization was important and that we must achieve higher rates of compliance. **In addition, it was strongly felt that moving to an “immunization or mask” policy without first trying other approaches and allowing our people the opportunity to demonstrate your commitment to our patients would be premature.**

(bold above added)

....

**Although we are committed to the success of the approaches suggested in our consultations, if we have not reached the 70% target by December 31, 2013, we will implement the “immunize or mask” policy beginning January 2014.** Also, should we not reach the 80% overall target by the end of March 2014, this policy will be implemented for the entire 2014/15 flu season.<sup>90</sup> (bold in the original)

78. Minutes of the December 13, 2013 Influenza Planning Committee record that: “Discussion ensued on the expected upsurge of staff who may want to receive their flu shot after the policy is implemented”.<sup>91</sup>

79. The Policy was implemented on January 1, 2014 when the target 70% influenza vaccination rate was not met. Neither the Influenza Planning Committee nor the IPAC Committee was consulted about any best evidence concerning the 70% or 80% rates and those committees did not discuss those target rates.<sup>92</sup> Hospital employees had been kept apprised of the level of vaccination rates being achieved on an ongoing weekly basis by the publication of chart presented “flu shot thermometers”.<sup>93</sup>

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<sup>90</sup> Exhibit 3, Tab F, 30; See also Exhibit 246; Exhibit 4, Tab C, 11; Exhibit 3, Tab E, 24

<sup>91</sup> Exhibit 3, Tab C, 12

<sup>92</sup> Transcript, June 29, 2015, C. Johns, p. 85; Ms. Manzo is not aware of any empirical evidence to support selection of 70%. It was a decision taken by the SMT. See: Transcript, June 9, 2015, C. Manzo, pp. 181-2

<sup>93</sup> Exhibit 3, Tab E, 46; Transcript, June 9, 2015, C. Manzo, pp. 44-45

*VOM roll-out: notices, stickers*

80. On January 6, 2014 Mr. Gagnon and Dr. O'Brien issued a further message that included the following and also attached a media release announcing the VOM Policy:

Those who have been immunized can be identified by a sticker on their ID badge indicating their status. Those who may choose not to wear the sticker will also be required to wear a mask as it's important for our patients to be able to immediately identify those who have taken this extra precaution against the flu.<sup>94</sup>

81. Notices were posted throughout the Hospital bearing the title "Attention Patients and Visitors". The purpose was to help explain to visitors why they would be seeing employees wearing masks and to encourage them to wear a mask if they had not been immunized.<sup>95</sup> The Notice began with the following statement:

**You may see some Sault Area Hospital (SAH) personnel wearing masks.** To protect the well-being of patients, SAH has implemented a policy **requiring all personnel to either receive an influenza vaccination or wear a mask during the flu season.** (bold in original).<sup>96</sup>

82. The VOM Policy was maintained in force for the balance of the 2013-2014 flu season until the season was declared ended on April 30, 2014.<sup>97</sup>

*2014-2015 flu season*

83. The VOM Policy was in place in the following flu season from November 15, 2014<sup>98</sup> until May 6, 2015 when it was terminated following discussions with Algoma Public Health.<sup>99</sup> The Policy was maintained 'as is' throughout that season despite knowledge at an earlier date<sup>100</sup> that there was a significant mismatch of the vaccine

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<sup>94</sup> Exhibit 3, Tab F, 38

<sup>95</sup> Transcript, June 29, 2015, C. Johns, p. 42

<sup>96</sup> Exhibit 3, Tab G, 48

<sup>97</sup> Exhibit 3, Tab F, 42; Transcript, June 29, 2015, C. Johns, p. 43

<sup>98</sup> Transcript, June 9, 2015, C. Manzo, p. 158

<sup>99</sup> Exhibit 245; Transcript, June 29, 2015, C. Johns, p.122

<sup>100</sup> Ms. Manzo was aware of a significant mismatch as early as mid-November. Transcript, June 9, 2015, C. Manzo, p. 174

with the most common strain of Influenza A then prevailing.<sup>101</sup> The Hospital did not require everyone to wear a mask whether immunized or not despite the known mismatch.<sup>102</sup>

### *Outbreaks*

84. There were no outbreaks of influenza at the Hospital in 2013-2014 and no incidents of hospital acquired influenza.<sup>103</sup> There were three Influenza A outbreaks on three units during the 2014-2015 flu season<sup>104</sup>. Nine of the twelve patients affected had been vaccinated.<sup>105</sup> Three of the four staff who contracted influenza like illness had been vaccinated for influenza.<sup>106</sup> The measures taken did not require that all nurses wear masks.<sup>107</sup> The only prior influenza outbreak within the last five years had been at the antiquated Plummer site of the Hospital that has now been closed.<sup>108</sup>

### *Existing SAH policies*

85. The Infection Prevention & Control Committee has issued various other policies over the years.

86. The OHA and the Hospital stress that masks are worn in numerous areas of SAH for many different reasons.<sup>109</sup> The existing SAH Infection Control Manual provides for “additional precautions” “to protect staff and patients” “based on the mode of transmission (e.g. contact, droplet, airborne)”.<sup>110</sup> It requires that a surgical

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<sup>101</sup> Transcript, June 29, 2015, C. Johns, p. 121, 124

<sup>102</sup> Transcript, June 9, 2015, C. Manzo, p. 174-5

<sup>103</sup> Exhibit 246

<sup>104</sup> Exhibit 248

<sup>105</sup> Exhibit 5; Transcript, October 2, 2014, N. Marcello, pp. 33-35

<sup>106</sup> Exhibit 138; Transcript, June 9, 2015, C. Manzo, pp. 211-212

<sup>107</sup> Transcript, June 9, 2015, C. Manzo, p. 213

<sup>108</sup> Transcript, June 29, 2015, C. Johns, p. 138; Exhibit 5

<sup>109</sup> OHA/SAH Closing Argument, para. 272, footnote 243

<sup>110</sup> Exhibit 2, Infection Prevention and Control Policy, 11-25, p. 1, Definition

mask and eye protection must be worn if within 2 metres of a patient as a droplet precaution:

- Used for microorganisms that are transmitted by large respiratory droplets
- Droplets can be generated when talking, coughing, or sneezing, and through some respiratory procedures (e.g. suctioning, bronchoscopy, nebulized therapies)
- Droplets are propelled from the patient’s respiratory tract and can travel up to 2 metres.
- Droplets do not remain suspended in the air—once the microorganisms are deposited on surfaces in the patient’s environment, they can be transmitted through contact with the contaminated surfaces
- Examples of microorganisms transmitted through the droplet route: respiratory syncytial virus (RSV), pertussis, influenza<sup>111</sup>

87. The Policy in issue likewise requires that employees infected with the influenza, who must continue to work, “should not work with high risk patients and must wear a mask and gloves and practice good hand hygiene during patient contact”.<sup>112</sup>

### **A Road Map to Expert and Other Evidence**

88. Compared to many other situations involving expert evidence, in this case most people will have some basic reference points that help in tracking the evidence. Virtually everyone has some direct personal experience with the flu. I expect therefore that most people understand at a basic level that: (i) flu is contagious, (ii) flu is more or less contagious at different points, (iii) some kind of transmission is required for flu to spread, (iv) steps may be taken to slow and/or reduce the spread. Against this backdrop, the expert evidence adduced in this matter, while complex, is not entirely inaccessible.

89. In reaching their differing conclusions about VOM policies, stated again in lay terms, the experts were in strong disagreement about the following issues: (i) the

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<sup>111</sup> Exhibit 2, Infection Prevention and Control Policy, II-25, B. Droplet Precautions; See also: C, Droplet-N95 Precautions applicable to the event of a pandemic or emergence of a novel virus where staff must wear a fit tested N95 respirator if within 2 metres of a coughing patient and visitors must wear surgical masks.

<sup>112</sup> Exhibit 3, Tab A, 4, 2.4

extent that unvaccinated HCWs pose a risk to patients of giving them the flu, (ii) whether there is any serious risk that symptom-free HCWs will give patients the flu, (iii) whether masking HCWs serves any real purpose.

90. The following review of the evidence is organized in this way.

91. First, descriptions of influenza are provided. This section is not controversial but it is important to recognize the serious and complex public health challenge that the disease presents.

92. Second, the concept of transmission is explained. This is not a controversial topic either. One must understand the concept of transmission to appreciate why a masking policy is even considered.

93. Third, there is a general policy piece. It identifies the goal of VOM policies and outlines the elements involved. This section is a prelude to the controversy and identifies the experts' disagreement about key elements of the Policy. What is the burden of influenza disease acquired from unvaccinated HCWs? Is there a risk of asymptomatic HCWs spreading the disease to patients?

94. The fourth section relates to the efficacy of vaccination. The experts agree that vaccination is the best available option to combat influenza generally. They agree that the overall range of effectiveness of the vaccine is approximately 60%. But they do not agree that there is proof that the vaccination of HCWs reduces morbidity and mortality in acute care hospitals. This section contains a relatively deep dive, for lay purposes at least, into the medical/scientific evidence surrounding a fundamental precursor to the VOM dispute; namely, is it possible to identify an unvaccinated HCW problem?

95. The fifth section tackles the significant expert dispute over asymptomatic transmission. The OHA/SAH experts assert that the primary reason for requiring

HCWs to wear masks is that influenza virus may be shed asymptotically. Is there evidence to show that this is true, or, sufficient evidence to demonstrate that there is a problem of sufficient proportion to warrant a VOM policy?

96. The sixth section addresses the crucial expert debate about the use of masks. Is there sufficient medical/scientific evidence to support a mask-wearing component? This section also includes a recitation of the fact evidence concerning the alleged adverse effects of masking, the alleged incursion into the privacy interests of employees, and the alleged inconsistent enforcement of the mask-wearing requirement.

97. The seventh section speaks to what happened in the 2014-2015 vaccine mismatch year. ONA claims that a large number of vaccinated employees, none of whom are required to mask, are as exposed to influenza as those who are unvaccinated. The Hospital's failure to require mask wearing by everyone, particularly in a mismatch year, is illogical says the Union. This section includes the experts' opinions concerning the 'why not mask everyone' question.

98. The eighth section shifts to the broader policy context in which the specific VOM Policy exists. Are there vaccination requirements for diseases other than influenza? Have there been other studies or recommendations? Do these speak to the reasonableness of the current Policy?

99. I turn now to the first section.

### **Influenza and Influenza Vaccine Efficacy**

100. There is no dispute about the nature of influenza and the fact that the disease is complex.



101. Influenza is a subset of influenza-like illness (“ILI”) that is, in turn, a subset of acute respiratory illness (“ARI”). Dr. De Serres estimated that influenza constitutes 30% of ILIs on average<sup>113</sup> and Dr. Henry stated that between one third and one half of ILIs were influenza depending on the season.<sup>114</sup> Dr. McGeer explained that the percentage of ILIs likely to be influenza may be higher than 20-35% depending on the point of the influenza season<sup>115</sup>. She went on to say:

There are many viruses that cause respiratory infections. Influenza is by far the most serious of them, in that, it more often leads to complications or serious illness that require medical attention than many of the other upper respiratory infections and, importantly, it’s one of the few that we do have a vaccine that prevents. There is a couple of others like parainfluenza and respiratory syncytial virus or RSV that also cause severe illness and outbreaks on long-term care, and in children in particular, but none of these are currently vaccine preventable.<sup>116</sup>

102. Dr. Henry explained in her initial Report:

In basic terms influenza is an acute, primarily respiratory infection caused by the influenza virus....a respiratory infection caused by influenza A and B viruses. In Canada, it generally occurs each year in the late fall and winter months. Symptoms typically include the sudden onset of headache, chills, cough, fever, loss of appetite, muscle aches and fatigue, runny nose, sneezing, watery eyes and throat irritation. Nausea, vomiting and diarrhea may also occur, especially in children.

Most people will recover within a week or ten days, but some—including those 65 years of age and older and adults and children with chronic conditions—are at greater risk of more severe complications, such as pneumonia. There are many factors which will affect how much impact influenza will have in any given season. One main factor is the circulating strain with influenza A H1N1 and B strains more likely to affect children and influenza A H3N2 having more severe effects on the elderly. In years when H3N2 is the predominant circulating strain of influenza, outbreaks in long term care (LTC) and in elderly populations, both in the community and in hospital, can be particularly severe.<sup>117</sup>

103. Dr. De Serres explained in his Report:

Influenza is viral infectious disease, typically affecting the upper respiratory tract. Epidemics are usually caused by influenza type A or B, whereas type C is an infrequent cause of mostly mild human infection. In humans, type A influenza is further divided into two main subtypes (H1N1 and H3N2) whereas type B is divided into two lineages (Victoria and Yamagata). The hallmark of influenza illness is the abrupt onset of respiratory illness that classically includes fever and cough with extreme malaise and general body aches.

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<sup>113</sup> Transcript, May 19, 2015, p. 87

<sup>114</sup> Transcript, June 23, 2015, p. 34

<sup>115</sup> Transcript, June 24, 2015, p. 82

<sup>116</sup> Transcript, June 22, 2015, p. 128

<sup>117</sup> Exhibit 141, p. 2

....

During the winter season, in addition to influenza, many other respiratory viruses also cause influenza-like illness (ILI) including the respiratory syncytial virus (RSV), the human metapneumovirus (HMPV), the parainfluenza viruses, adenoviruses, enteroviruses, rhinoviruses, coronaviruses and several other viruses.<sup>118</sup>

104. Dr. McGeer explained that influenza preferentially infects the cells at the back of the nose and throat and is almost always limited to those cells; the virus co-opts those cells to reproduce and destroys them in the process. Symptoms start when there is local damage to those cells and immune response can cause inflammation and other systemic reactions. Bacterial pneumonia is a complication because one no longer has the intact lining of the throat for protection. There can be exacerbations of asthma. Complications arising from influenza are generally what cause the most burden of illness.<sup>119</sup> Issues may also arise for persons who have underlying lung disease, heart disease or who are receiving treatment for cancer.<sup>120</sup>

105. Dr. McGeer commented upon the seriousness of the disease in this way:

So, when you study cohorts of people somewhere between one and eight, and one and twelve or fifteen people get infected with influenza every year, very common disease. And most of that disease is pretty mild. You get sick for a few days and then you get better and you go on with your life. But a big enough fraction of it is either severe or complicated that influenza is, in fact, the number one infectious disease cause of death in Canada, and somewhere in the top ten of total burden. We get into details about the argument about, you know, exactly how much influenza there is, and how you count it, but at the low end it's number eight, and at the high end it's number one. It's a big burden disease because of the frequency of infection and because of the complications.<sup>121</sup>

106. A and B strains of influenza, particularly the A strain, mutate quickly and can vary by geographic region. As a result a new vaccine is required annually and its composition must be determined well in advance of any upcoming flu season. The ability to predict what will become a predominant circulating strain is imperfect, in

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<sup>118</sup> Exhibit 66, pp.2-3

<sup>119</sup> Transcript, June 24, 2015, pp. 74-77

<sup>120</sup> Transcript, June 22, 2015, B. Henry, p. 52

<sup>121</sup> Transcript, June 24, 2015, p.72

part because the circulating virus may drift so that the vaccine is no longer a match.<sup>122</sup> Dr. McGeer testified that:

So, coming up to the 2015/16 season, we've got one strain of influenza A (H3N2), one strain of influenza A (H1N1), two different lineages of B, just to make your life difficult, and one or two of those will likely be the predominant influenza strain next winter...There's no way of knowing ahead of time which one. You can make some guesses based on the past years but you can't know for certain.<sup>123</sup>

107. There is no dispute that the best currently available method to prevent the transmission of influenza is the influenza vaccination albeit that the vaccine is not 100% effective. On average, based on all population ages and depending upon the number of years considered, the witnesses accepted that there is an overall range of effectiveness close to 60%.<sup>124</sup> And, notwithstanding debate about the level of proof concerning the measurable outcome of vaccinating health care workers, there is general agreement that present vaccines are the best intervention available for seasonal influenza.<sup>125</sup> There was some discussion by witnesses during the hearing about the possible negative impact of repeat vaccination but this issue appears to be a matter for continuing review.<sup>126</sup>

108. There is also no dispute that, with a vaccination efficacy rate in the range of 60%, many vaccinated HCWs will also contract influenza.<sup>127</sup> The level of protection afforded by the vaccine will depend upon how far the circulating strain has drifted

<sup>122</sup> Transcript, June 22, 2015, B. Henry, p. 48; See also: Exhibit 66, G. De Serres Report, p. 6

<sup>123</sup> Transcript, June 24, 2015, p. 79; See also: Transcript, May 21, 2015, M. Gardam, pp. 196-197

<sup>124</sup> Transcript, June 24, 2015, A. McGeer, p. 24; Exhibit 185, A. McGeer Report, p. 25; Transcript June 22, 2015, B. Henry, p. 59; Exhibit 141, B. Henry Report, p. 4; Transcript May 20, 2015, G. De Serres, pp. 190-191; Transcript, May 21, 2015, M. Gardam, p. 62; Transcript, July 8, 2015, OHA/SAH closing argument, pp. 79-81

<sup>125</sup> See Exhibit 73: Osterholm *et al*, "Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis", *Lancet Infect Dis.* 2012 Jan;12(1): 36-44; Some, as do Dr. McGeer and Dr. Henry, go further. See: Exhibit 157, Griffin, Editorial Commentary, "Influenza Vaccination of Healthcare Workers: Making the Grade for Action", *CID* 2014:58 (1 January), at p. 59: "Vaccination of healthcare workers to protect vulnerable patients and residents of long-term care facilities should be viewed as an evidence-based recommendation."

<sup>126</sup> See: Exhibit 23: McLean *et al*, "Impact of repeated vaccination on vaccine effectiveness against influenza A(H3N2) and B during 8 seasons", *CID Advance Access* published September 29, 2014; Exhibit 144: Neuzil, "How can we solve the enigma of influenza vaccine-induced protection?", Editorial Commentary, *JID* 2015:211:1517-8

<sup>127</sup> Transcript, May 19, 2015, G. De Serres, p. 103

from the vaccine components.<sup>128</sup> It will not protect against ILIs or ARIs that are not influenza.<sup>129</sup>

109. Nor is there any question that the range of effectiveness for the vaccine varies within age and population groups. Dr. Henry explained:

...vaccine provides good protection in healthy adults, which is mostly our health care worker community, and much more modest protection and paradoxically those who need it the most, and many of those people will be the patients, the residents in our health care facilities.<sup>130</sup>

110. Dr. McGeer testified that:

So, if you vaccinate frail, elderly people in nursing homes, their protection against any influenza infection is somewhere probably in the mid 20s. Their protection against hospitalization due to influenza is something like 50 or 60 percent.

So, influenza vaccine reduces the incidence of infection but it also mitigates disease. Part of the reason that may be important is that, when you talk about vaccinated and unvaccinated health care workers getting infection, there are in fact differences. So, vaccinated healthcare workers do get infections with influenza but, when they get infections, those infections will be less severe and they will shed less virus. So there may be some, in fact, some additional element of protection beyond the 60 percent reduction in infection that accrues because people are less ill from the influenza and consequently shedding less virus....

I think the point is that you can, from an individual health care worker point of view, the benefits of influenza vaccination are not just in the prevention of influenza, they are also in the fact that you will be less ill if you do get it. From a transmission to a patient's point of view, it's hard to know what to do on that data.<sup>131</sup>

111. There is general recognition that development of an effective seasonal influenza vaccine is fraught with difficulty. Dr. McGeer repeated a comment in her evidence that sums it up: "Nancy Cox who just retired as the CDC's lead person on influenza is famous for saying, 'when you've seen one influenza season, you've seen one influenza season'".<sup>132</sup> The extent to which the influenza vaccine will be matched to circulating strains of influenza cannot be known until the season unfolds. The 2014-2015 flu season was a particularly bad mismatch year.

<sup>128</sup> Transcript, June 22, 2015, B. Henry, pp. 69-70

<sup>129</sup> Transcript, June 23, 2015, B. Henry, p. 34

<sup>130</sup> Transcript, June 22, 2015, p. 100

<sup>131</sup> Transcript, June 24, 2015, pp. 102-104

<sup>132</sup> Transcript, June 24, 2015, p.79

## Transmission

112. It is important to understand the concept of transmission because a stated purpose of a mask is to prevent HCWs from giving patients the flu. As explained by Dr. Henry:

The primary purpose of having health care providers wear a mask is to prevent transmission from them to their patients at times when they are shedding virus (prior to symptom onset, if they are working ill, or if they are asymptotically infected).<sup>133</sup>

113. Transmission of influenza from one infected individual to another requires both shedding of virus and transportation. Shedding of virus is not the same thing as effective transmission to another. There must not only be shedding but also a sufficient amount of live replicating virus shed close enough to susceptible individuals to project the viruses onto receiving respiratory mucous.<sup>134</sup>

114. In her Report, Dr. Henry explained these concepts in this way:

Humans have receptors for influenza viruses mostly in the mucosa that lines our nose and throat but also have some that are deep in the lungs. Transmission of infection occurs when influenza viruses penetrate a susceptible host's defences and are deposited on these viral receptors in the upper respiratory tract. To become infected with influenza we must be susceptible to the virus and be exposed to a sufficient concentration (infectious dose) of live particles of the virus.<sup>135</sup>

115. Dr. McGeer said that:

The influenza has to go from acutely infected person to acutely infected person. It does not survive on a long-term basis in any one person so the continuous transmission is critical to its survival. And the one safe thing you can say about transmission of influenza is that being close to somebody with influenza is bad for you. After that, it's actually very difficult to parse what the components are to the transmission event...<sup>136</sup>

116. The point agreed upon by all of the experts is that virus shedding without transmission is of no concern. As explained by Dr. Lemieux:

So shedding would be, I think, more closely aligned to the dissemination word. So shedding simply means that the virus is detected in, in this case, let's say, respiratory

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<sup>133</sup> Exhibit 141, p. 6

<sup>134</sup> Transcript, June 23, 2015, B. Henry, pp. 92-93

<sup>135</sup> Exhibit 141, p. 3

<sup>136</sup> Transcript, June 24, 2015, p. 92

secretions, the fact that it's being expelled from the body or being—it's actually in various body fluids or various secretions, but it in no way speaks to, again, that host or the person who has the illness transmitting to the recipient, who then develops clinical disease, very difficult. Right now I'm shedding bacteria, as an example. I'm sitting here, I'm shedding bacteria by the fact that I exist, but I'm not necessarily giving it to you, I'm not sharing it with you because the mode of transmission is not necessarily there.<sup>137</sup>

117. There are also important questions about proximity of a virus shedder to a potential recipient and about the size of droplets/particles that are produced.

118. When asked how influenza gets into a person's system, Dr. Henry explained that the receptors that allow the virus to attach to cells are very common in the back of the nose and throat but that there are some receptors deep in the lungs that are still under investigation.<sup>138</sup> She also testified that:

For the most part though we think it's when somebody is in a short distance from somebody else and they are coughing, sneezing. Even things like singing and talking sometimes can transmit small droplets that you then inhale and they land on the receptors in the back of the nose and throat.<sup>139</sup>

119. Dr. De Serres said:

Well, transmission is a complex issue because transmission means you have the virus, and you have a proper transportation for the virus because, if you have the virus and you cough, you sneeze, obviously you're producing lots of droplets.

If you're not coughing, you're not sneezing, while speaking you produce some droplets but few, far fewer than when you're coughing, you know. Like when you're speaking you put your hand in front of you, you don't have your hand all wet. When you're coughing it is all wet.

So, we're producing way more droplets which are the major way of transmission of influenza. So, it's not only the presence of the virus, it's also how many virus. If you have tons of virus, if you have few viruses that will be important in terms of transmission. If you have good transportation, so many droplets, that will be important for transmission. If you're close to people, again, that will account for transmission. So, it's the conjunction of that, plus, again, we're talking transmission, that's the acquisition of the infection by the other person but that person, if immune, will not be sick.<sup>140</sup>

120. Dr. McGeer testified that:

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<sup>137</sup> Transcript, May 11, 2015, p. 101

<sup>138</sup> Transcript, June 22, 2015, p. 52

<sup>139</sup> Transcript, June 22, 2015, p. 53

<sup>140</sup> Transcript, May 19, 2015, p. 90

I think in terms of small particles versus large particles...I think the majority of people believe that the weight of the evidence says that most transmission is by droplets, by larger particles but, you know, there is a range of acceptable opinion on that front.<sup>141</sup>

121. Dr. Henry said:

...we looked at a variety of different pieces of evidence and felt that the majority of transmission really from the evidence that we see is through larger droplets. And by large I mean larger than five microns which is tiny still. These are small droplets that you can't necessarily see. The droplets are deposited in the upper airways from people who are either coughing or talking or sneezing or certainly there's probably a lesser extent, people who touch something contaminated and rub their eyes, and that's the majority of transmission.

With the exception of in health care settings when we do things to people that create what we call aerosols or smaller, less-than-five- micron particles, so things like putting in a breathing tube, that can generate these smaller particles and that probably leads to some transmission.

The challenges that the influenza virus needs some—needs moisture to survive. So, as a particle gets smaller, it dries out. It dessicates in the air. And there is not a lot of good evidence to tell us whether those very tiny particles actually have live virus in them or just the virus RNA that we can detect with our testing but don't lead to infection because they are not actually live virus anymore. And in our opinion, from looking at this evidence, was that the majority of the infection are larger enough particles that the virus has some moisture to survive and those are the ones that are deposited in the upper airways.<sup>142</sup>

122. Dr. Gardam agreed that large droplets are a method of transmission<sup>143</sup> as did Dr. Lemieux<sup>144</sup> and Dr. De Serres<sup>145</sup>. When asked whether small droplets are considered to be a method of transmission, Dr. Gardam stated that:

They are. I think they are still a bit more controversial in terms of their relative contribution that they provide. I think that is yet to be elucidated....I think that they're out there. That's the reason why organizations went with N95 respirators for aerosol generating procedures during pandemics...I think we are going to need more research to figure out exactly how important they are and under what circumstances.<sup>146</sup>

<sup>141</sup> Transcript, June 24, 2014, p. 97

<sup>142</sup> Transcript, June 22, 2015, pp. 55-56

<sup>143</sup> Transcript, May 21, 2015, p. 198

<sup>144</sup> Transcript, May 11, 2015, p. 15; Exhibit 36

<sup>145</sup> Transcript, May 20, 2015, p. 48

<sup>146</sup> Transcript, May 21, 2015, p. 244

## Evaluating VOM Policies

123. Before moving to assessing the merits of the VOM policy under review, it may be useful first to consider what might be termed ‘best’ practice for public health policy determination. In his initial Report, speaking generally about public policy analysis, Dr. De Serres explained that:

By way of context, public policy analysis first requires an understanding of the premise of the proposed program—the problem it seeks to address, the program goals, objectives and a list of available options for achieving that. Establishing the goal is a critical first step because all subsequent evidence review and evaluation should be in relation to that specifically articulated program goal. Objectives may then include measurable changes related to outcome (e.g. reduction in illness or its severe consequences) or process (e.g. increasing vaccine uptake). For vaccine preventable diseases, the premise generally requires a substantial disease burden that can be prevented for which a program of immunization that is safe, effective, affordable and acceptable can achieve meaningful and measurable reduction.<sup>147</sup>

124. Dr. De Serres explained what is meant by “burden of disease”:

Well, the burden of disease is an expression to cover all aspects of the disease. So, it may be you become sick, but you stay home. You become sick and then have to consult a physician. You may need to be hospitalized or you may die. Obviously, dying from influenza is the most serious outcome...So, in the studies, for example, they are looking at different outcomes and it’s important because the severity varies.

But burden of disease is to encompass what happens in people who become sick, and we’re talking about people who are sick, not people who are infected. Infected is just you’re in contact, the virus multiplies, but it doesn’t mean you’re sick. You may become sick if you have insufficient protection or no protection, but if you have good protection from past exposure or from the vaccine, you may have no symptom.

So, infection with no disease, with no symptom is not part of the burden of disease. You’re not sick. You’re not aware that anything has happened to you.<sup>148</sup>

125. Moving on to the specifics of a VOM policy for HCWs, Dr. De Serres stated that:

The goal of that policy is ostensibly the reduction of disease burden among patients attributable to unvaccinated HCWs. Embedded within the premise of such a policy is that influenza vaccination will substantially reduce patient disease burden and there are no other practicable program or policy options for achieving the same or greater level of necessary patient protection.<sup>149</sup>

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<sup>147</sup> Exhibit 66, p. 1

<sup>148</sup> Transcript, May 19, 2015, pp. 85-86

<sup>149</sup> Exhibit 66, p.3, para.5



126. He went on to identify as a threshold question the question of whether it is known that unvaccinated HCWs are infecting patients. In his words:

Before assessing by how far patient disease burden can be reduced by the “vaccinate or mask” policy, we first need to know how many patients are being infected by unvaccinated (and/or unmasked) HCWs in the absence of the policy. We need to know how many patients are typically or on average infected by HCWs, and in particular those who are unvaccinated, during the seasonal influenza period which typically spans November to April in the northern hemisphere.<sup>150</sup>

127. In addition to the potential influenza disease burden of unvaccinated HCWs, Dr. De Serres also identified some other significant factors at play in any VOM analysis:

The risk of influenza from unvaccinated HCWs to patients is the end result of a complex interaction of variables and conditions including: the frequency of influenza infections in HCWs; the proportion of infected HCWs with sufficient virus shedding to transmit; the amount of effective droplets produced by symptomatic or asymptomatic HCWs; the frequency, duration and closeness of contact between HCW and patients; and the level of pre-existing protective immunity in patients to protect themselves. Each of these factors will further vary for seasonal versus pandemic influenza, by seasonal subtype and by age, comorbidity etc. The risk to patients would be further reduced if HCW adopt other behaviours which also reduce the probability of transmission (e.g. staying home when sick, wearing a mask when in contact with patients, minimizing the time in close contact with patients).<sup>151</sup>

128. As will later be seen, at least two of these factors were the subject of serious disagreement by the experts who testified in this proceeding. They do not agree about the disease burden carried by unvaccinated HCWs. They do not agree about asymptomatic transmission.

### **HCW Disease Burden**

129. The experts all agree that the question of the disease burden carried by unvaccinated HCWs is important because, at root, any VOM policy is ultimately grounded on the assumption that the disease burden from this source is significant. However, there is major disagreement about the medical/scientific evidence. The ONA experts do not accept that the evidence supports the proposition that

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<sup>150</sup> Exhibit 66, p.3, para.7

<sup>151</sup> Exhibit 66, p.4, para.10

increasing HCW influenza immunization rates serves to protect patients from morbidity and mortality. The OHA/SAH experts maintain that the evidence is strong.

130. Dr. De Serres went on in his Report to explain more fully why he holds the view that accurate quantification of the disease burden of unvaccinated HCWs is important:

I am not disputing that HCW have a professional duty to protect their patients, that healthcare acquired influenza exists, that the influenza vaccine protects or that unvaccinated HCW may occasionally transmit influenza to their patients. However, to justify a mandatory intervention abrogating HCW rights, the ethical dilemma and burden of proof rests on the proportionality, intrusiveness and effectiveness of the intervention in relation to the magnitude of the disease burden caused by unvaccinated HCW. My work as an epidemiologist is to quantify risks and my work as a policy analyst is to weight those risks against other considerations.

After weighing the scientific evidence, I conclude that accurate quantification of the influenza disease burden in patients attributed to unvaccinated healthcare workers is missing. This information is fundamentally required in assessing the proportionality of the effectiveness of the intervention and the number of workers whose rights may be infringed each year by the 'vaccinate or mask' policy....

Some may argue that in the absence of knowing the actual number of patients infected by unvaccinated HCWs, even a single patient potentially infected warrants any and every measure possible. However, such an extreme perspective is tantamount to a pursuit of 'zero risk'. Such 'zero risk' pursuits are elusive and slippery slopes that generally end in more and more draconian measures geared toward achieving the nearly impossible at a high cost in terms of target group trust and morale and professional credibility.<sup>152</sup>

131. Dr. McGeer has not estimated the number of hospital acquired deaths due to influenza and does not know the number.<sup>153</sup> She accepts that any VOM policy could only affect a subset of the annual total of influenza deaths.<sup>154</sup> She explained that:

The preventable disease that is...The influenza that you would prevent with this policy is associated with the protection of patients from health care workers who either choose because of the vaccine-or-mask policy to be vaccinated when they might not otherwise have done so and health care workers who choose to wear a mask during the influenza season when in the absence of a policy they would not have done so.<sup>155</sup>

<sup>152</sup> Exhibit 66, p. 12, paras. 34-35

<sup>153</sup> Transcript, June 25, 2015, p. 86; Transcript, June 25, 2015, pp. 146-150

<sup>154</sup> Transcript, June 25, 2015, p. 89

<sup>155</sup> Transcript, June 25, 2015, p. 122

132. The focus of the discussion here, to be clear, is upon unvaccinated HCWs. No one doubts that there are other potential vectors for the transmission of influenza to patients; for example: family members, other visitors, fellow patients, not to mention vaccinated HCWs who contract influenza nevertheless.

133. On an earlier occasion Dr. De Serres had joined Dr. Danuta Skowronski and Dr. David Patrick in a Letter to the Editor which included the following comment:

Community-based statistics of influenza morbidity are mostly irrelevant to mandatory HCW immunization because this burden of disease is predominantly acquired outside of the health care setting. Estimates of patient disease burden within the nosocomial setting and specifically due to unvaccinated HCWs would be more relevant, but are not available.<sup>156</sup>

134. Dr. Henry agreed with this observation by Dr. Skowronski and Dr. Patrick who are her colleagues at the British Columbia Centre for Disease Control:

I do agree, as we've discussed earlier, influenza is mostly transmitted in the community and we don't have data on the difference between vaccinated and unvaccinated healthcare workers and individual transmission events...in healthcare settings.<sup>157</sup>

135. Dr. Henry agreed that no VOM policy would influence influenza in the community<sup>158</sup>. Dr. McGeer denied that she had used or recommended the use of community burden in the assessment of development of such a policy.<sup>159</sup>

136. In the final analysis, Dr. McGeer accepted Dr. De Serres' concern about the difficulty of establishing the burden of disease attributable to unvaccinated HCWs but deemed it irrelevant because of her interpretation of the published randomized controlled trials ("RCTs") and other studies:

Dr. De Serres approaches the question of the potential patient safety benefits of healthcare worker immunization by suggesting that we first need to establish the burden of hospital-acquired influenza in patients, and then understand what proportion of that burden is associated with unvaccinated health care workers. He points out, and very rightly, that this is an extraordinarily difficult challenge. I would, in fact, submit that it is even more difficult than he suggests, because of the complexity and communicability of influenza....

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<sup>156</sup> Exhibit 93, Canadian Medical Association Journal, November 12, 2012.

<sup>157</sup> Transcript, June 23, 2015, pp. 155-156

<sup>158</sup> Transcript, June 23, 2015, pp. 163-164

<sup>159</sup> Transcript, June 24, 2015, p. 176

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The fact that we have been unable to measure the specific burden of influenza caused by transmission from healthcare workers is no longer relevant—there is now compelling evidence from the strongest type of studies (5 randomized controlled trials) that vaccination of healthcare workers reduces patient mortality and morbidity.<sup>160</sup>

137. What Dr. McGeer’s Report refers to as “now compelling evidence from the strongest type of studies (5 randomized controlled trials)” is completely rejected by the Union’s experts. Indeed, accepting the assessment of its experts, ONA asserts that: without the RCTs<sup>161</sup> that they depend upon, the OHA/SAH case is “entirely unsubstantiated” and a VOM policy “which relies entirely on it as scientific foundation cannot be seen as reasonable evidence based policy”.<sup>162</sup>

138. Dr. De Serres led the attack on the RCTs cited by the OHA/SAH experts and began by challenging the widely varying published estimates of deaths per year in Canada due to influenza.<sup>163</sup> Dr. De Serres cited meta-analyses published by others, conducted his own analyses, and provided a detailed critique of each RCT cited by the OHA/SAH experts.<sup>164</sup> It was his opinion that the long-term care RCTs “suffer from serious methodological problems and provide results that are mathematically impossible under any reasonable hypothesis”<sup>165</sup> and that the sole RCT conducted in an acute care setting “is a methodological mess with respect to the estimation of

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<sup>160</sup> Exhibit 185, Report, A. McGeer, pp.45-46

<sup>161</sup> Exhibit 50: Potter *et al*, “Influenza vaccination of health care workers in long-term care hospitals reduces the mortality of elderly patients”. *J Infect Dis.* Jan;175(1): 1-6; Exhibit 81: Carman *et al*, “Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial”. *Lancet.* 2000 Jan8;355(9198):93-7; Exhibit 82: Hayward *et al*, “Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomized controlled trial”. *BMJ* 2006 Dec 16;333(7581): 1241-6; Exhibit 83: Lemaitre *et al*, “Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial”. *J Am Geriatr Soc.* 2009 Sep;57(9):1580-6; Exhibit 86: Riphagen-Dalhuisen *et al*, “Hospital-based cluster randomized controlled trial to assess effects of a multi-faceted programme on influenza vaccine coverage among hospital healthcare workers and nosocomial influenza in the Netherlands, 2009 to 2011”. *Euro Surveill.* 2013 Jun 27;18(26):20512

<sup>162</sup> ONA Final Argument Overview, paras. 93, 107

<sup>163</sup> Exhibit 66, Report, G. De Serres, p.3, para. 8; Exhibit 70, Reply Report, G. De Serres, Part C

<sup>164</sup> Exhibit 66, pp.7-11

<sup>165</sup> Exhibit 70, p.32

benefit to patients”.<sup>166</sup> He stated that: “Given the very serious flaws in the 4 RCTs conducted in LTCFs and the single RCT in acute care, I conclude that the scientific basis for the efficacy of increasing HCW vaccination to protect patients against deaths is extremely poor”.<sup>167</sup> And, in his original Report, Dr. De Serres had concluded that:

..data about the effectiveness of vaccinating HCWs to protect patients is still of poor quality. A careful review of the RCTs conducted primarily in long term care settings reveals that most of the substantial all-cause mortality reduction after interventions to increase HCW immunization cannot possibly be attributed to the vaccine itself but rather relate to unknown factor(s) associated with implementing the intervention—what is known as methodologic bias....For acute care hospitals, the evidence that a policy mandating vaccination or mask in HCW would be effective to prevent patient influenza cases is also lacking and is at best indirect and also with strong indication of methodologic bias...In LTCF [long term care facilities], HCW provide prolonged and intense personal care to each patient, increasing the risk of influenza transmission. It is therefore likely that the risk of transmission from HCW to patients in acute care hospitals would be lower than in LTCF decreasing the benefit of the intervention if imposed equally in these settings.<sup>168</sup>

139. Dr. De Serres explained in detail why he preferred the conclusions of the Cochrane group<sup>169</sup> following their meta-analyses of the issue as opposed to those of the authors of a U.S. Centre for Disease Control publication.<sup>170 171</sup> The 2010 Cochrane review concluded that: “there is no evidence that vaccinating HCWs prevents influenza in elderly residents in LTCFs”.<sup>172</sup> The US CDC [Ahmed] review concluded that:

Using GRADE the quality of the evidence for the effect of HCP [health care provider] vaccination on mortality and influenza cases in patients was *moderate* and *low* respectively. The evidence quality for the effect of HCP vaccination on patient hospitalization was *low*. The overall evidence quality was *moderate*.<sup>173</sup> (italics in original)

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<sup>166</sup> Exhibit 70, p.33

<sup>167</sup> Exhibit 70, p.35

<sup>168</sup> Exhibit 66, pp.12-13, para. 36

<sup>169</sup> Exhibit 85, Thomas *et al*, “Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions”, Cochrane Database Syst Rev.2013 Jul

22;7:CD005187; Exhibit 84, Thomas *et al*, “Influenza vaccination for healthcare workers who work with the elderly: a Cochrane review”, Cochrane Database Syst Rev. 2010 Feb 17;(2):CD005187

<sup>170</sup> Exhibit 87, Ahmed *et al*, “Effect of Influenza Vaccination of Healthcare Personnel on Morbidity and Mortality Among Patients: Systematic Review and Grading of Evidence”. Clin Infect Dis. 2013 Nov 13 Epub ahead of print

<sup>171</sup> Exhibits 66, 70

<sup>172</sup> Exhibit 84, Abstract

<sup>173</sup> Exhibit 87, Conclusions, p.50

140. ONA also points to other critiques of these trials and studies<sup>174</sup> emphasizing the World Health Organization report's assessment that the four long term care RCTs had "very serious" limitations in study design and other "serious" deficiencies concluding that: "Our confidence in the estimate of effect of influenza vaccination of HCW on influenza and related outcomes in elderly living in long term care facilities is low".

141. Dr. Gardam and Dr. Lemieux also raised concerns including questioning the applicability of long-term care studies to acute care settings.<sup>175</sup>

142. Dr. McGeer had quite a different opinion of the RCTs, one that she had maintained before Arbitrator Diebolt, and that she expressed with renewed vigour given a later commentary and meta-analysis, published after the Diebolt Award was released, that she saw as supportive.<sup>176</sup> Dr. McGeer was cross-examined extensively about the details of these studies and was prepared to concede some of their limitations but did not give ultimate ground. She explained her view that from a data perspective the Ahmed review and the Cochrane review say exactly the same thing.<sup>177</sup> She also tackled head on the reasons provided by the Cochrane investigators for their conclusion that the data should not be believed.<sup>178</sup> In her opinion:

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<sup>174</sup> See: Exhibit 110, Osterholm *et al* [Center for Infectious Disease Research & Policy, CIDRAP] "The Compelling Need for Game Changing Influenza Vaccines: An Analysis of the Influenza Vaccine Enterprise and Recommendations for the Future", October 2012, [cidrap.umn.edu](http://cidrap.umn.edu); Exhibit 167, CMAJ 2012; Exhibit 147B, "Weekly epidemiological record", World Health Organization, 23; November 2012. No.47, 2012. 87. 461-476, Table 5b; Exhibit 93, De Serres, Skowronski, Patrick, Letter to the Editor, November 12, 2012, CMAJ

<sup>175</sup> Transcript, January 26, 2015, C. Lemieux, pp. 78-81; Transcript, May 21, 2015, M. Gardam, pp. 52, 126-127

<sup>176</sup> Ahmed at Exhibit 87; Exhibit 157, Griffin, "Influenza vaccination of healthcare workers: making the grade for action", Editorial Commentary, CID: 2014: 58

<sup>177</sup> Transcript, June 24, 2015, p. 124

<sup>178</sup> Exhibit 185, Report, A. McGeer, pp.28-35; See also Appendix B to Appendix C of Exhibit 185 where Dr. McGeer also provided extremely detailed commentary on the Cochrane Review some of which is set out in the Diebolt Award.

In sum, there is no question that influenza vaccination of healthcare workers providing care for residents/patients in long term care protects residents from significant morbidity and mortality. This reduction is achieved by preventing the introduction of influenza into these facilities by staff, and by reducing the risk of transmission of influenza among staff and between staff and patients.

The results of these four trials led many to ask whether the protection of patients would extend to patients in acute care and community care. The relevant differences between these settings and long term care facilities for the elderly are that some patients may not be as compromised as long term care facility residents, and that they may be more likely to have exposure to influenza external to patient care. However, the biologic rationale for healthcare worker immunization does not vary from one healthcare setting to another, and many patients in acute care hospitals and in the community are as vulnerable as those in long term care.

....

Since an infected healthcare worker can transmit influenza to persons he or she comes into contact with, it must be true that preventing influenza in patient care staff reduces the risk that they will transmit influenza to patients. I believe that, because of the potential for other exposures to influenza in patients in the community, the protection afforded by vaccinating health care providers in community and acute care hospital settings is likely less than that provided by vaccinating health care providers in residential long term care. Nonetheless, while the size of the benefit to patients in ambulatory care settings is unknown, I believe that in almost all circumstances there would be some risk reduction.<sup>179</sup>

143. Dr. McGeer did acknowledge an important difference between long-term care and acute care settings however:

...as you move from a very enclosed setting of long-term care where health care workers may make a very large difference to ambulatory care at the far end where a patient has just taken the subway and might have children at home and has lots of other places they can be exposed to influenza, you clearly alter the balance of what's at risk from health care workers versus what's the risk from other people.

Still within that though, if I'm a health care worker seeing you as a patient in my office, I think most of us would agree that we have some obligation, because of the nature of that relationship, not to be a part of your risk for influenza. And so, you know, even—it may well be true in an ambulatory care setting that protecting the patients from me does not alter their total risk of influenza because they may get it from other places, and so you may not be reducing it or you may be reducing it by a fairly small amount, I think many of us would agree that we still have an obligation because of the power and influence of that relationship to not be a source for our patients.<sup>180</sup>

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<sup>179</sup> Exhibit 185, Report, A. McGeer, pp.34-35

<sup>180</sup> Transcript, June 24, 2015, pp.142-143

144. Dr. McGeer maintained her opinion<sup>181</sup> that the significance of the RCT conclusions should be considered supported by other observational and experimental studies<sup>182</sup> in addition to those referred to in the Ahmed meta-analysis.<sup>183</sup> She testified that:

And while a lot of the observational evidence in different settings is not directly related to what happens in health care, it is always important in the interpretation of randomized controlled trials and data to have looked at all of the data and to ask whether there is consistency or variability across different settings and different situations...so the consistency of those findings I think is important in thinking through the evidence and assessing the extent to which the randomized controlled trials should be believed.<sup>184</sup>

145. In her Report Dr. Henry also referred to observational studies as supporting the data she said was derived from the RCTs<sup>185</sup> but acknowledged that these studies related to long term care and not acute care settings.<sup>186</sup> She was cross-examined at length concerning the studies referenced in this section of her Report<sup>187</sup>, some that dealt with other closed community settings, and agreed that they were “clearly not referring to a healthcare setting”.<sup>188</sup>

146. Witness commentary concerning the observational/experimental studies relied upon in the McGeer/Henry Reports is set out in Appendix A to this Award. I conclude from a review of these studies, and the expert witness commentary, that they do not disclose a consistent position. They address a wide range of issues in a

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<sup>181</sup> Transcript, June 24, 2015, p. 140

<sup>182</sup> Exhibit 161, Vanhems *et al*, “Risk of Influenza-like illness in an acute health care setting during community influenza epidemics in 2004-2005, 2005-2006, and 2006-2007: a prospective study”, *Arch Internal Med* 2011;171(2):151-157; Exhibit 159

<sup>183</sup> Exhibit 87, p. 54, Table 2: Oshitani *et al*, “Influenza vaccination levels and influenza-like illness in long-term facilities for elderly people in Niigata, Japan during an influenza A(H3N2) epidemic” *Infect. Control Hosp Epidemiol* 2000; 21:728-30; Enserink *et al*, “Absence of influenza A(H1N1) during seasonal and pandemic seasons in a sentinel nursing home surveillance network in the Netherlands”, *Am Geriatr Soc*: 2011; 59:2301-5; Wendelboe *et al*, “Importance of employee vaccination against influenza in preventing cases in long term care facilities”. *Infect Control Hosp Epidemiol* 2011; 32:990-7; Exhibit 161, Benet *et al*, “Influenza vaccination of healthcare workers in acute-care hospitals: a case control study of its effect on hospital acquired influenza among patients”. *BMC Infect Dis* 2012; 12:30

<sup>184</sup> Transcript, June 24, 2015, p. 135

<sup>185</sup> Exhibit 141, p. 19

<sup>186</sup> Transcript, June 23, 2015, pp. 69-71

<sup>187</sup> Transcript, June 23, 2015, pp. 68-88

<sup>188</sup> Transcript, June 23, 2015, p. 88



wide range of settings. Some are not supportive of the OHA/SAH experts' claim. Some provide weak support at best. Some have nothing to do with the issue in question. Some have acknowledged study design limitations.

### **Asymptomatic Transmission**

147. There was considerable expert disagreement about asymptomatic transmission although there was no dispute about the importance of the issue in assessing the merit of VOM policies.

148. To repeat, according to Dr. McGeer in her Report, the primary purpose of having unvaccinated HCWs wear a mask is to address transmission when they are shedding virus either prior to symptom onset or if they are asymptotically infected.<sup>189</sup>

149. As will be seen, there is dispute as to the extent that asymptomatic transmission poses a theoretical risk, a minimal risk, or a real risk commanding a response. The parties do not agree as to the size of the window in which such transmission might occur. They do not agree about the likelihood, frequency, or strength of asymptomatic transmission and whether or not scientific study has progressed to a point where it can say anything meaningful in an evidence-based way about these matters.

150. In their joint Reply Report, Dr. Gardam and Dr. Lemieux explained the central importance of the issue in this way:

A presumption that asymptomatic transmission is a significant factor is of great importance to Drs. McGeer and Henry's arguments. Without the significance of asymptomatic transmission, it is hard to understand how requiring otherwise well, unvaccinated staff to wear a mask during the entire influenza season will provide any significant protection for patients or other healthcare workers.<sup>190</sup>

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<sup>189</sup> Exhibit 185, p. 36

<sup>190</sup> Exhibit 21, p. 7

151. ONA counsel highlighted the point in her final oral argument after posing a rhetorical question about whether the mask policy made sense:

Because the mask policy is asking people for four to six months of the year to wear it when they're asymptomatic....they [OHA/SAH] are going to need to have legitimate evidence-based evidence that there is a concern about asymptomatic transmission because, if there isn't, then what's the point in wearing a mask? So, their case hinges on this.<sup>191</sup>

152. The question of asymptomatic transmission is made even more complex by the recognition that vaccinated, as well as unvaccinated, individuals may acquire influenza and that vaccinated persons may be protected from severe illness but still have attenuated illness.<sup>192</sup>

153. Dr. McGeer stated: "We know that people shed influenza in asymptomatic infections and before they develop symptoms....we need to worry about people who are asymptomatic or minimally symptomatic even if we are sending home people who are ill."<sup>193</sup> On the other hand Dr. McGeer also noted that the science was imperfect:

...there's still things about influenza transmission we just don't understand well...one of this issues is we are, in that model, currently we're getting more asymptomatic than symptomatic infections. It might be related to the dose somehow of what you're getting exposed to. So, it's complicated and we don't understand. We are a very long way I think is the short answer.<sup>194</sup>

154. One exchange of views is set out in the paragraphs immediately following.

155. Dr. De Serres acknowledged that a person may shed virus while asymptomatic<sup>195</sup> but commented in his Report that:

There is scant evidence to support that such 'virus shedding' of influenza leads to effective transmission of the disease before an infected individual becomes symptomatic, and if it does occur, it is not the predominant concern. The transmission risk is greatest

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<sup>191</sup> Transcript, July 7, 2015, p. 74

<sup>192</sup> Exhibit 66, p.7, para.19

<sup>193</sup> Transcript, June 24, 2015, pp. 156-157

<sup>194</sup> Transcript, June 24, 2015, p. 101

<sup>195</sup> Transcript, May 20, 2015, p. 120, p. 203

when cases with influenza are symptomatic, notably with projectile symptoms such as cough or sneeze...<sup>196</sup>

156. Dr. McGeer responded this way:

While it seems logical, as Dr. De Serres states, to conclude that transmission risk is greatest from individuals who are severely ill and coughing and sneezing, the truth is that we simply do not know much about transmission risk at a population level. For instance, individuals who are severely ill with coughing and sneezing may be much more likely to stay home and to practice respiratory etiquette, so may not actually contribute all that much to population transmission, and individual heterogeneity may mean that some asymptomatic high viral load shedders are very important in transmission.<sup>197</sup>

157. In his rebuttal Dr. De Serres relied upon a literature review stating that:

From the Carrat review<sup>198</sup> we know that individuals with symptoms shed far more virus than individuals who remain free of symptoms (asymptomatic) and that the amount of virus shedding increases with the severity of symptoms

.....

[responding to Dr. McGeer's statement that 'the truth is we simply do not know much about transmission risk at a population level']

If one does not know the proportion of influenza transmission caused by the pre-symptomatic, unvaccinated HCW then I reiterate that it is difficult to establish an ethical or evidence-based rationale to require mask wearing by unvaccinated HCWs every hour of every work day for nearly half the year, every year while remaining symptom free.

158. While giving oral testimony about possible asymptomatic transmission, citing Carrat *et al*<sup>199</sup> Dr. De Serres stated that:

So, really, in this asymptomatic period, the time you're contagious, the amount of virus you have is lower than when you're contagious, and transportation...in terms of contagion, nobody can say exactly, okay, that day we have 25 percent of the transmission, this day we have 20 percent, this day we have 10 percent. We don't have that. But for influenza transportation, number of virus matter...you may say, well, they may transmit while asymptomatic, it's possible. I wouldn't deny that someone may because there are examples of people who did transmit while they were [as]symptomatic but that's generally not the case. The transmission will happen because you had enough virus, you have enough transportation.<sup>200</sup>

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<sup>196</sup> Exhibit 66, p. 5, para.14

<sup>197</sup> Exhibit 185, p. 47

<sup>198</sup> See Exhibit 75: "Time Lines of Infection and Disease in Human Influenza: A Review of Volunteer Challenge Studies", American Journal of Epidemiology (January 29, 2008)

<sup>199</sup> Exhibit 75

<sup>200</sup> Transcript, May 19, 2015, pp. 138-139

159. Dr. Henry stated: “people can release virus into the community that’s potentially transmissible to others even before they show symptoms themselves”.<sup>201</sup> She also explained that: “it’s absolutely clear that the first couple of days after symptoms start is when you’re most transmissible to others. But there is evidence to support that it can be transmitted before you show symptoms yourself”.<sup>202</sup>

160. In direct examination Dr. Henry stated that the pre-symptomatic period was “clearly not the most infectious period but we do know that it happens”.<sup>203</sup> She also agreed in cross-examination that transmission required an element of proximity and a sufficient amount of live replicating virus.<sup>204</sup>

161. At another point, the following series of questions and answers ensued during Dr. Henry’s cross-examination:

Q. With respect to transmission while asymptomatic, and I want to deal with your authorities with respect to that, would you agree with me that there is scant evidence to support that virus shedding of influenza actually leads to effective transmission of the disease before somebody becomes symptomatic?

A. I think we talked about that yesterday, that there is some evidence that people shed prior to being symptomatic, and there is some evidence of transmission, that leading to transmission, but I absolutely agree that that is not the highest time when shedding and transmission can occur.

Q. So were you—I put it to you that there’s scant evidence, and that was Dr. De Serres’ evidence, so—but that there’s very little evidence about that, do you agree?

A. There is—as we talked about yesterday, there is not a lot of evidence around these pieces, I agree.

Q. And clearly transmission risk is greatest when you’re symptomatic, when you’re able to cough or sneeze?

A. Transmission risk is greatest, as we’ve said, when you’re symptomatic, especially in the first day or two of symptom onset.<sup>205</sup>

162. Dr. McGeer commented that:

It is true on balance that if I am ill and symptomatic I will be shedding more particles than if I am not. An individual coughs and sneezes create a great many more particles that can travel for long distances. What’s not, I think, clear in that discussion is that there’s a huge

<sup>201</sup> Transcript, June 22, 2015, p. 99; Exhibit 141, pp. 6-7

<sup>202</sup> Transcript, June 22, 2015, p. 155

<sup>203</sup> Transcript, June 22, 2015, p. 100

<sup>204</sup> Transcript, June 23, 2015, p. 91

<sup>205</sup> Transcript, June 23, 2015, pp. 91-92

intra individual variability in the number of particles that are emitted by any one individual. And that variability is actually significantly greater than my internal variability when I go from asymptomatic to coughing and sneezing....some people shedding asymptomatic influenza will probably shed much more than other people who are severely symptomatic.<sup>206</sup>

163. Dr. Gardam agreed that: “there is a lead time of when you start to shed virus before you develop some symptoms”<sup>207</sup> but when asked if one produces large droplets when asymptomatic, replied:

Not a lot. You have to be kind of spraying on people. The large droplets are things that are—typically they follow a ballistic trajectory, so if you’re speaking or coughing and they land. The airborne ones go out and they float around the room. So if you think of the difference between me talking to you now, inevitably there are a couple of droplets coming out of my mouth and they are landing on the table versus me coughing or me sneezing, it would be orders of magnitude different.<sup>208</sup>

164. In their joint Reply Report Dr. Gardam and Dr. Lemieux disagreed strongly with Dr. McGeer’s assessment of the importance of asymptomatic transmission of influenza. Relying upon a meta-analysis of human infection studies by Carrat *et al*<sup>209</sup>, they opined that one could not say that asymptomatic transmission never occurs but that it was “unlikely to be of clinical significance”. They noted that: “the production of virus and the development of symptoms are closely linked together, and that the vast majority of the time patients have high viral levels, they are also symptomatic”.<sup>210</sup>

165. Dr. Gardam expressed this view of the asymptomatic justification for VOM when giving evidence:

Well, asymptomatic flu transmission, that was something that didn’t really, people didn’t talk much about that until these policies started to come in place, and suddenly, frankly, I feel people needed a reason to get you to wear that mask. And the reason was, well, you might be developing the flu, you don’t have symptoms yet, but you can still transmit it. Well, first of all, if that’s true, given the effectiveness of the vaccine, everybody should wear the mask. Makes no sense to me.<sup>211</sup>

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<sup>206</sup> Transcript, June 25, 2015, pp. 38-39

<sup>207</sup> Transcript, May 21, 2015, p. 134

<sup>208</sup> Transcript, May 21, 2015, pp. 244-245

<sup>209</sup> Exhibit 21, p. 6; Exhibit 75; Attachment to Exhibit 109

<sup>210</sup> Exhibit 21, p. 6

<sup>211</sup> Transcript, May 21, 2015, pp. 66-67

## 166. He went on to say:

...in order to figure this out, you need to know exactly when someone was infected. Essentially, yes, the virus in your nasal secretion starts to go up before you develop symptoms. But the two are actually quite parallel, they go up in parallel. And they go up on a log curve. So for each one to two, to three to four you're going up tenfold. So within a few hours of being infected and starting to have multiplying virus, you start to get some symptoms. So, yes, there's a little window in there where you don't have any symptoms and you've got a small amount of virus, but you have a thousandfold more virus once you have symptoms, and it can stay up there for several days, and that's the time when you're sneezing and coughing and ill. I have to think that that's the time when you're spreading most of your flu...I have to assume that's when you're most infectious. So masking when you're sick makes sense to me, but why are you masking when you're well—that just doesn't make sense to me.<sup>212</sup>

## 167. In oral testimony Dr. Lemieux gave her opinion that:

In fact, the transmission of influenza is very tightly correlated with symptom onset. There is only a very, very brief period when the virus may be shed or may be created within the human body when you're not symptomatic. It is a very short window of time....During that very short period of time when you're asymptomatic, so even for that short window, which is at most a day, probably less than a day, if you're not symptomatic, it's very hard for virus to get from point "A" to point "B". I mean, it doesn't have legs. It doesn't walk on its own. It's not going to march over from myself to yourself. So it needs a vehicle to be transmitted. And if you're asymptomatic, that ability to take the virus from me and send it to you (sneezing, coughing, respiratory secretions) is not there. So even in that short window of time, the chance of it getting from me to you is pretty tenuous. The third part of that is, the levels of virus during that short period between shedding and symptom onset are much lower. The real peak of when we have lots of virus there ready to move is when we're symptomatic.<sup>213</sup>

## 168. Dr. Lemieux also stated more succinctly:

And so the crux of saying that everybody has to wear a mask all the time when there is a tiny little period of time when virus may, and I'm stressing may be transmitted, and many reasons why it's less likely to be transmitted, again, seems very flawed to me.<sup>214</sup>

169. In cross-examination, ONA counsel reviewed the authorities relied upon by Dr. McGeer or Dr. Henry as the bases for their opinions on this issue together with some material not referenced by them: Loeb *et al* (2012)<sup>215</sup>; Suess *et al* (2011)<sup>216</sup> ;

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<sup>212</sup> Transcript, May 21, 2015, pp. 67-68; Later on Dr. Gardam made it clear that "I'm not suggesting that there's evidence that it [wearing a surgical mask] works for preventing the asymptomatic spread of the flu": Transcript, May 21, 2015, pp. 98-99

<sup>213</sup> Transcript, January 26, 2015, p. 82-83

<sup>214</sup> Transcript, January 26, 2015, p.84

<sup>215</sup> Exhibit 106: "Longitudinal Study of Influenza Molecular Viral Shedding in Hutterite Communities", J Infect Dis. 2012 )ct 1: 206(7): 1078-84

Freitas *et al* (2009)<sup>217</sup>; Esbenshade *et al* (2013)<sup>218</sup>; Wilde *et al* (1999)<sup>219</sup>; Elder *et al* (1996)<sup>220</sup>; Sheat (1992)<sup>221</sup>; Gu *et al* (2011)<sup>222</sup>; Carillo-Santistevé *et al* (2010)<sup>223</sup>; Lau *et al* (2010)<sup>224</sup>; Hermes *et al* (2011)<sup>225</sup>; Patrozou and Mermel (2009)<sup>226</sup>.

170. ONA also introduced a Letter to the Editor of the Canadian Medical Association Journal dated November 12, 2012 that was co-authored by Dr. Danuta Skowronski. Dr. Skowronski is the medical lead for influenza and emerging respiratory infections who is part of Dr. Henry's team at the British Columbia Centre for Disease Control. Dr. Henry acknowledged that Dr. Skowronski had more experience with respect to vaccine effectiveness than herself.<sup>227</sup> The letter, co-authored by Dr. De Serres, included the following observation: "The evidence that pre-symptomatic or asymptomatic infections contribute substantially to influenza transmission remains scant."<sup>228</sup>

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<sup>216</sup> Exhibit 107: "Comparison of shedding characteristics of seasonal influenza virus (sub) types and influenza A(H1N1) pdm09; Germany, 2007-2011", PLoS One. 2012; 7(12): e51653

<sup>217</sup> Exhibit 158: "Pre-symptomatic transmission of pandemic influenza H1N1 2009: investigation of a family cluster, Brazil", Epidemiol Infect. 2013 Apr; 141(4): 763-6

<sup>218</sup> Exhibit 170: "Respiratory virus shedding in a cohort of on-duty healthcare workers undergoing prospective surveillance", Infect Control Hosp Epidemiol 2013; 34(4); 373-378

<sup>219</sup> Exhibit 171: "Effectiveness of influenza vaccine in healthcare professionals: a randomized trial", JAMA. 1999 Mar 10; 281(10): 908-13

<sup>220</sup> Exhibit 172: "Incidence and recall of influenza in a cohort of Glasgow healthcare workers during the 1993-4 epidemic: results of serum testing and questionnaire", BMJ 1996; 313(7067): 1241-1242

<sup>221</sup> Exhibit 225: 'An investigation into an explosive outbreak of influenza-New Plymouth', Communicable Disease New Zealand 1992; 92:18-19

<sup>222</sup> Exhibit 226: "Pandemic (H1N1) 2009 transmission during presymptomatic phase, Japan", Emerg Infect Dis. 2011 Sep; 17(9):1737-9

<sup>223</sup> Exhibit 227: "2009 pandemic influenza A(H1N1) outbreak in a complex of schools in Paris, France, June 2009", Euro Surveill. 2010 Jun 24; 15(25)

<sup>224</sup> Exhibit 228: "Viral shedding and clinical illness in naturally acquired influenza virus infections", J Infect Dis. 2010 May 15; 201(10): 1509-16

<sup>225</sup> Exhibit 229: "Lack of evidence for pre-symptomatic transmission of pandemic influenza virus A (H1N1) 2009 in an outbreak among teenagers; Germany, 2009", Influenza and Other Respiratory Viruses 5(6), e199-e503

<sup>226</sup> Exhibit 230: "Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?", Public Health Reports/ March-April 2009/Volume 124: 193-196

<sup>227</sup> Transcript, June 22, 2015, pp. 164-165

<sup>228</sup> Exhibit 93

171. The medical/scientific literature referred to or relied upon by the OHA/SAH on the asymptomatic question with witness commentary is set out in Appendix B. Once again, these studies/investigations were undertaken in a wide variety of settings most of which had nothing to do with HCWs and some of which involved a very few people. There were design limitations. Some of them expressed serious doubt about, or found no evidence of, asymptomatic transmission. The results were certainly not consistent.

### **Masking**

172. The written submissions filed by the parties stake out polar opposite evaluations of the scientific evidence going to the key question of the use of masks to reduce the risk of transmission. Those positions were remarkably unconditional in their characterization.

173. The OHA and SAH submitted that: “The scientific evidence in this case provides a solid and compelling foundation for the reasonableness of the Policy”.<sup>229</sup>

ONA submitted that: “Though time consuming, we submit that the totality of evidence suggests there is no evidence in support of the mask policy.”<sup>230</sup> “The mask element cannot be supported on any medical evidence as Dr. McGeer ultimately conceded.”<sup>231</sup>

174. It must be noted that the witnesses called by the proponents of these opposing submissions were more nuanced and did not support such unconditional characterizations. While conceding that “there’s quite a limited literature” on a key aspect of the issue<sup>232</sup>, Dr. McGeer certainly did not concede that there was “no evidence in support of the mask policy”.

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<sup>229</sup> Closing Argument, para. 366

<sup>230</sup> Final Argument Overview, paras. 126, 128

<sup>231</sup> Final Argument Overview, para. 259

<sup>232</sup> Transcript, June 25, 2015, p. 32



175. Dr. McGeer explained that:

Essentially all of the systematic studies of mask wearing have not met their primary end points. But in most of them there is some evidence of an effect. So, I think there are a couple of systematic reviews that are also referenced and generally people's conclusion is there is some evidence that wearing a mask will reduce your risk of influenza. It's not great evidence. It's clearly not complete protection, and it's hard to put a number on it, but you can't walk away from this saying there is no evidence that wearing a mask prevents you from influenza.<sup>233</sup>

176. Professor Brosseau agreed that there was qualitative evidence to support the conclusion that masks reduce the transmission of large droplets.<sup>234</sup> She acknowledged the 2007 consensus finding of an Expert Panel of which both she and Dr. Gardam were members, that: "Surgical masks worn by an infected person may play a role in the prevention of influenza transmission by reducing the amount of infectious material that is expelled into the environment."<sup>235</sup>

*OHA/SAH evidence*

177. Dr. McGeer and Dr. Henry presented the position of the OHA and the Hospital based upon their understanding of the relevant literature. Neither of them asserted that they had particular expertise with respect to masks or had conducted studies testing masks.<sup>236</sup>

178. On the subject of masks, after conceding that "I'm not a huge fan of the masking piece"<sup>237</sup>, Dr. Henry ultimately concluded as follows:

...as my report says, there's not a lot of evidence to support mask use and that's why it is a secondary measure, where clearly the most important measure is immunization...However, I think there are some studies...that look at the potential for a mask to prevent the emission of droplets and then the potential for a mask to prevent somebody from inhaling droplets....I'd have to go back and look, but I agree, there's very

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<sup>233</sup> Transcript, June 24, 2015, p. 152

<sup>234</sup> Transcript, June 6, 2015, p. 89; Exhibit 50: cover letter, L. Brosseau Report.

<sup>235</sup> Transcript, June 6, 2015, p.80;

<sup>236</sup> Transcript, June 25, 2015, A. McGeer, p. 234; Transcript, June 22, 2015, B. Henry, p. 163

<sup>237</sup> Transcript, June 23, 2015, p. 111

scant evidence about the value of masks in preventing the transmission of influenza. The value of masks as source reduction has been proven.<sup>238</sup>

179. Dr. McGeer is of the view that “there is good evidence that wearing a mask limits the release of large droplets”<sup>239</sup> but was not as definitive as Dr. Henry about masks and proof of source control:

...when we talk about vaccine and mask policies the primary purpose of the vaccine mask policy is the protection of another person from somebody who’s wearing a mask...when particles are emitted they come out large. When they’re breathed in on the other end and they’ve had three or six feet to dry on the way and that makes a very substantial difference to the size and the distribution of those particles. So the truth of the matter is that none of us are really experts in source control. There’s quite a limited literature. Dr. Milton, whose paper we’ve looked at, is probably one of the people who knows the most about it, having spent a lot of time in the last few years. But I don’t think Dr. Brosseau would claim expertise in mask for source control.<sup>240</sup>

180. In final argument the OHA/SAH counsel put it succinctly this way: “It’s [mask evidence] not as fulsome as all of the evidence about vaccination. But to answer your question, there is some evidence, so they fall on their own sword saying no evidence.”<sup>241</sup>

181. On the focused question of the utility of masks for the stated Policy purpose of source control and the protection of patients, Dr. McGeer stated in her Report filed pre-hearing that:

There is good evidence that wearing a medical mask reduces the volume of large and small particles that people routinely exhale. There is also experimental evidence from at least two studies that surgical masks, when worn by persons infected with influenza, reduce the concentration of influenza virus expelled into the ambient air.

....

A second potential effect of masks is the protection of the wearer from droplets or aerosols in the air from a patient with influenza...

....

Other clinical studies have suggested that masks, in association with adherence to good hand hygiene, have some impact on transmission of influenza infection. These studies are not definitive. No study has found a statistically significant effect for the primary trial

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<sup>238</sup> Transcript, June 23, 2015, pp. 145-146

<sup>239</sup> Transcript, June 24, 2015, p. 148

<sup>240</sup> Transcript, June 25, 2015, p. 32

<sup>241</sup> Transcript, July 8, 2015, p.115, p.116

question; however, all have limitations, and, most found some indication of effect in secondary analyses.

Two systematic reviews of the protective effect of wearing masks on influenza concluded that there is evidence to support that wearing of masks or respirators during illness protect others, and a limited amount of data to support the use of masks or respirators to prevent becoming infected. (footnotes in original omitted)<sup>242</sup>

182. In support of these opinions, Dr. McGeer cited the following articles: Mansour and Smaldone (2013)<sup>243</sup>; Skaria and Smaldone (2014)<sup>244</sup>; Milton *et al* (2013)<sup>245</sup>; Johnson *et al* (2009)<sup>246</sup>; Canini *et al* (2010)<sup>247</sup>; Makison Booth *et al* (2013)<sup>248</sup>; Loeb *et al* (2009)<sup>249</sup>; MacIntyre *et al* (2011)<sup>250</sup> MacIntyre *et al* (2009)<sup>251</sup>; Cowling *et al* (2009)<sup>252</sup>; Simmerman *et al* (2011)<sup>253</sup>; Suess *et al* (2012)<sup>254</sup>; Larson *et*

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<sup>242</sup> Exhibit 185, pp. 36-37 citing

<sup>243</sup> Exhibit 56: "Respiratory source control versus receiver protection: impact of facemask fit", *J. Aerosol Med Pulm Drug Deliv.* 2013 Jun; 26 (3): 131-7

<sup>244</sup> Exhibit 120: "Respiratory source control using surgical masks with nanofiber media", *Ann Occup Hyg.* 2014 Jul; 58(6): 771-81

<sup>245</sup> Exhibit 28: "Influenza virus aerosols in human exhaled breath: particle size, culturability, and effect of surgical masks", *PLoS Pathog.* 2013 Mar; 9(3): e1003205

<sup>246</sup> Exhibit 27: "A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection", *Clin. Infect Dis.* 2009 Jul 15; 49(2): 275-7

<sup>247</sup> Exhibit 215: "Surgical Mask to prevent influenza transmission in households: a cluster randomized trial", *PLoS One.* 2010 Nov 17; 5(11): e13998

<sup>248</sup> Exhibit 29: "Effectiveness of surgical masks against influenza bioaerosols", *J Hosp Infect.* 2013 May; 84(1): 22-6

<sup>249</sup> Exhibit 30: "Surgical Mask vs. N95 respirator for preventing influenza among healthcare workers: a randomized trial", *JAMA.* 2009 Nov 4; 302(17): 1865-71

<sup>250</sup> Exhibit 216: "A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in healthcare workers", *Influenza Other Respir Viruses.* 2011 May; 5(3): 170-9

<sup>251</sup> Exhibit 217: "Face mask use and control of respirator virus transmission in households", *Emerg Infect Dis.* 2009 Feb; 15(2): 233-41

<sup>252</sup> Exhibit 31: "Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial", *Ann Intern Med.* 2009 Oct 6; 151 (7): 437-46

<sup>253</sup> Exhibit 218: "Findings from a household randomized controlled trial of hand washing and face masks to reduce influenza transmission in Bangkok, Thailand", *Influenza Other Respir Viruses.* 2011 Jul; 5(4): 256-67

<sup>254</sup> Exhibit 32: "The role of facemasks and hand hygiene in the prevention of influenza transmission in households: results from a cluster randomized trial: Berlin, Germany 2009-2011", *BMC Infect Dis.* 2012 Jan 26; 12:26

*al* (2010)<sup>255</sup>; Aiello *et al* (2010)<sup>256</sup>; Cowling *et al* (2010)<sup>257</sup>; bin-Reza *et al* (2012)<sup>258</sup>; Zhang *et al* (2009).<sup>259</sup>

183. In responding to Dr. Brosseau in her pre-hearing Report she also cited the following additional references: Bridges *et al* (2003)<sup>260</sup>; McLure *et al* (2000)<sup>261</sup>; Bischoff *et al* (2007).<sup>262</sup>

184. In her pre-hearing Report Dr. Henry responded to a request that she discuss the evidence that masks protect patients from influenza this way:

There is good evidence that surgical masks reduce the concentration of influenza virus expelled into the ambient air (a 3.4 fold overall reduction in a recent study) when they are worn by someone shedding influenza virus. There is also evidence that surgical masks reduce exposure to influenza in experimental conditions.

....

Clinical studies have also suggested that masks, in association with hand hygiene, may have some impact on decreasing transmission of influenza infection. These studies are not definitive as they all had limitations. The household studies are limited by the fact that mask wearing did not start until influenza had been diagnosed and the patient/household was enrolled in the study, such that influenza may have been transmitted prior to enrollment. A study in student residences is limited by the fact that participants wore their mask for only approximately 5 hours per day. Two systematic reviews of the cumulative studies conclude that there is evidence to support that wearing of masks or respirators during illness protects others, and a very limited amount of data to support the use of masks or respirators to prevent becoming infected...

In summary, there is evidence supporting the use of wearing of masks to reduce transmission of influenza from health care workers to patients. It is not conclusive, and

<sup>255</sup> Exhibit 219: "Impact of non-pharmaceutical interventions on URIs and influenza in crowded, urban households", Public Health Rep. 2010 Mar-Apr; 125(2): 178-91

<sup>256</sup> Exhibit 220: "Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial", J Infect Dis. 2010 Feb 15; 201(4): 491-8

<sup>257</sup> Exhibit 121: "Face masks to prevent transmission of influenza virus: a systematic review", Epidemiol Infect. 2010 Apr; 138(4): 449-56

<sup>258</sup> Exhibit 122: "The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence", Influenza Other Respi Viruses. 2012 Jul; 6(4): 257-67

<sup>259</sup> Exhibit 33: "Protection by face masks against influenza A (H1N1) pdm09 virus on trans-Pacific passenger aircraft, 2009", Emerg Infect Dis. 2013; 19(9). Doi: 10.3201/eid1909.121765

<sup>260</sup> Exhibit 222: "Transmission of influenza: implications for control in health care settings", Clin Infect Dis. 2003 Oct 15; 37(8): 1094-1101

<sup>261</sup> Exhibit 223: "The effect of facial hair and sex on the dispersal of bacteria below a masked subject", Anaesthesia. 2000 Feb;55(2): 173-6

<sup>262</sup> Exhibit 224: "Preventing the airborne spread of *Staphylococcus aureus* by persons with the common cold: effect of surgical scrubs, gowns, and masks", Infect Control Hosp Epidemiol. 2007 Oct; 28(10): 1148-54

not of the quality of evidence that supports influenza vaccination. Based on current evidence, patient safety would be best ensured by requiring healthcare providers to be vaccinated if they provide care during periods of influenza activity. However, if healthcare workers are unvaccinated, wearing masks almost certainly provides some degree of protection to their patients.<sup>263</sup> (footnotes in original omitted)

185. In rendering this opinion Dr. Henry relied upon many of the same authorities cited by Dr. McGeer<sup>264</sup> and also: Harnish *et al* (2013)<sup>265</sup>.

186. Witness commentary concerning the mask and related literature is set out in Appendix C. It is fair to say, once again, that the findings of the authors vary considerably. Some studies are admittedly irrelevant. None of them present ‘best’ evidence. At best, there appears to be limited evidence of what to a layperson may seem obvious: a mask may prevent the transmission of large droplets.<sup>266</sup> Two literature reviews refer specifically to “limited data”<sup>267</sup> and to “the limited evidence base supporting the efficacy and effectiveness of face masks to reduce influenza virus transmission”.<sup>268</sup>

#### *ONA evidence*

187. Citing a journal article<sup>269</sup> of which she was a co-author, Dr. Brosseau opined in her pre-hearing Report that:

There are a very small number of studies examining the efficacy of surgical or medical masks for protecting patients from infection. In all cases, there were no significant differences in surgical wound infection rates with and without surgical masks. In modern surgical settings the most important controls for preventing infections are engineering or administrative in nature—including very high air exchange rates, well-designed air flow patterns that carry particles away from the patient and health care workers, aseptic techniques, hand-washing etc.

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<sup>263</sup> Exhibit 141, pp. 6-7

<sup>264</sup> See: authorities cited at footnotes 243, 245, 246, 248, 249, 252-254, 256-258

<sup>265</sup> “Challenge of N95 filtering facepiece respirators with viable H1N1 influenza aerosols”, *Infect Control Hosp Epidemiol.* 2013 May; 34(5): 494-9

<sup>266</sup> See: Exhibit 27, Johnson.

<sup>267</sup> See Exhibit 122, bin Reza, cited also in in Appendix C.

<sup>268</sup> See Exhibit 121, Cowling (2010), cited also in Appendix C.

<sup>269</sup> Exhibit 55: Oberg T, Brosseau L.M, “Surgical mask filter and fit performance”, *Am J Infect Control* 2008; 36(4): 276-22

Given their poor filter and fit characteristics, surgical masks are not likely to prevent the release of particle emitted by the wearer. Coughing, sneezing and talking produce a wide range of particle sizes, all of which can be infectious. The smaller-sized particles will easily bypass the filter and facepiece of a surgical mask—and are likely to remain airborne for long periods of time. Thus, it is very unlikely that wearing a surgical mask will lower the risk of patient illness from an infectious healthcare worker.<sup>270</sup> (footnote in original omitted)

188. In cross-examination Dr. Brosseau agreed, having been referred to the Johnson<sup>271</sup> study, that: “there is in fact qualitative evidence in support of reduction of transmission of large droplets”.<sup>272</sup> Her Reply Report however explained her opinion more fully:

However, large droplets that impact on the face are only one route for the transmission of influenza infections from one person to another. Seasonal influenza viruses cause disease by infecting receptor cells found in the epithelial tissues in the nose, throat and upper airways of the lungs.

To transmit an infection by large droplets, cough or sneeze droplets would need to land directly in the open mouth or nose of a nearby patient. This is a very low probability event, as it is rare that a healthcare worker would sneeze or cough directly into the face of a patient. And in the rare event of such an occurrence, the patient will most likely have their mouth closed and their nostrils—by the nature of their geometry—facing away from the worker.<sup>273</sup>

....

Milton’s data<sup>274</sup> also illustrate that surgical masks offer little or no reduction in small infectious aerosols from the wearer.

Surgical masks do not minimize the release of small inhalable particles. (underlining in original)

189. Dr. Brosseau had the following comments concerning mask performance generally:

I have not tested these filters in particular, using what I would consider worst case, best practice kinds of tests. But based on my experience with examining the filtration performance of very similar types of masks that I’ve published, it is very likely that these masks [the type of masks used at SAH] these fitters will not have very good filter performance, filter efficiency.<sup>275</sup>

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<sup>270</sup> Exhibit 47, p. 4

<sup>271</sup> Exhibit 27

<sup>272</sup> Transcript, June 6, 2015, p. 89

<sup>273</sup> Exhibit 50, Response to Comments, first unnumbered page

<sup>274</sup> Exhibit 28

<sup>275</sup> Transcript, May 11, 2015, p. 155

*alleged adverse effects of masking/privacy/enforcement*

190. Dr. Brosseau described a so-called ‘grunge factor’. It was her opinion<sup>276</sup> that many people would not be able to wear either a respirator or mask for a full 8 hours “due to buildup of heat and humidity inside the facepiece”:

I have not worn a surgical mask in my own personal life. But based on what I know about their fit and filter performance, I would imagine, just as with the respirator, you’ll get—you know, against your face, you’ll get buildup of heat and humidity and, you know eventually it can be uncomfortable. Although the fact that it doesn’t fit very well against the face means you’ll have a lot of air movement through the internal part of the face. So, eventually, though, these will become what one of my colleagues refers to as the grunge factor. It just isn’t something you want on your face any longer, because it’s full of moisture, and so eventually you’ll need to change it out.<sup>277</sup>

191. Dr. Brosseau’s testimony and original Report also referred to an academic study<sup>278</sup> to support her own experience although she acknowledged<sup>279</sup> that she “has no experience with long-term surgical mask wearing and could locate few data”:

Based on my experience with half-mask respirators, wearing anything on the face that requires work during both inhalation and exhalation will eventually become uncomfortable. High temperature and relative humidity exhalation air will eventually lead to heat and moisture build-up inside the facepiece. When this type of respirator must be worn for lengthy periods of time, industrial hygienists recommend wearing a respirator with an exhalation valve, which decreases the work required during exhalation and alleviates the buildup of temperature and moisture.

One might postulate that a surgical mask with poor filter performance (and thus low breathing resistance) and poor fit may be comfortable enough to tolerate for lengthy periods of time. The data do not support this hypothesis, however.<sup>280</sup>

192. Dr. Lemieux was asked why she commented that very few people would want to wear a mask for 6 – 7 months and replied, referring to her own experience with masks:

First of all, there is the marking, here I am not having my flu shot, so there’s a marking aspect of it, that people would be very hesitant to want to be labeled as a non-flu-immunized person.

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<sup>276</sup> Transcript, May 21, 2015, pp. 177-178

<sup>277</sup> Transcript, May 21, 2015, p. 177

<sup>278</sup> Exhibit 32, p. 7; Transcript, May 21, 2015, p. 178

<sup>279</sup> Exhibit 50, p. 1

<sup>280</sup> Exhibit 47, p. 4

But, secondly, masks are not that comfortable. I have worn them. I have worn them for extended periods in the operating room and they really are not comfortable. They pull at your ears, they make it difficult to take full breaths. If you have underlying respiratory problems, such as asthma, obstructive lung disease, it can make you distinctly short of breath to have these masks on. They pinch at your nose, to the point where people will frequently pull them down because they don't like the pressure on their nose. And I've certainly been in that camp where I've been pulling my mask down. And with prolonged wearing, because...they are essentially made of a tissue, paper-type substance, some masks being slightly more plasticized than others, but essentially it is paper, they get wet. And as you breathe, you're breathing out a lot of humidity and they get damp. So when you're wearing them for a number of hours, they get kind of soggy and they get even more heavy, more uncomfortable, and people will instinctively pull them down. They just are not pleasant to wear at all.<sup>281</sup>

193. Ann Cook RN testified by will-say statement<sup>282</sup> alone. She did not receive the influenza vaccination in 2014-2014 due to an allergy for which she provided medical documentation<sup>283</sup>. Her will-say included the following:

RN Cook also experienced negative physical effects from wearing the mask. She found wearing the mask uncomfortable due to the build-up of heat and humidity from breathing her own trapped breath. She suffers from asthma and found that wearing the mask for many hours regularly made her feel dizzy, light-headed and very tired. In January and April 2014, RN Cook experienced bronchitis for two separate week-long periods. This was the first time she had been ill and taken sick days in 10 years (for one of those bouts as the other happened just prior to extended weekend vacation time) and she attributes her bronchitis in part to the mask-wearing requirement.<sup>284</sup>

194. Dr. McGeer expressed another opinion:

The second issue is the potential issue of discomfort wearing masks. If you don't live in a hospital you may think that wearing a mask is something that we don't do on a regular basis but, in fact, there are lots of people in hospitals who wear masks all the time. In my hospital we do complex sarcoma surgery. There are times when a patient will be asleep under anesthetic for 30 hours continually and a series of teams of nurses and physicians and respiratory therapists will be operating. And all of those people are wearing masks for their entire shift except when they take breaks. And we expect them to be highly functional, able to communicate and we have never worried about that. The truth is that masks are not that uncomfortable to wear and the evidence is that you can communicate effectively in not all circumstances. There are clearly circumstances where you need to make exceptions. That's what medicine is all about. But in the great majority of circumstances they are neither terribly uncomfortable nor a significant impediment to communication.<sup>285</sup>

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<sup>281</sup> Transcript, January 26, 2015, p. 64

<sup>282</sup> Exhibit 14

<sup>283</sup> Exhibit 14, para. 6

<sup>284</sup> Exhibit 14, para. 10

<sup>285</sup> Transcript, June 25, 2015, p. 33; See also: Exhibit 185, Report, A. McGeer, p. 42



195. Glenda Hubley acknowledged in cross-examination that she was “well aware that masks are worn by physicians, surgeons in the operating room, dentists, other healthcare workers in other parts of the hospital” and that she had never refused to work because she had to wear a mask in the operating room.<sup>286</sup>

196. Attached to Ms. Hubley’s will-say<sup>287</sup> was a copy of a “Seasonal Influenza Vaccination Disclosure Form” that included provision for “consent to the release of my influenza immunization status to my manager (or designate) for the purpose of outbreak planning and management”. That provision is contained in the section to be completed by employees who have received their immunization at a location other than the SAH Occupational Health and Safety Service. The same consent is required of employees who choose to decline influenza vaccination. It is preceded by the following statement that employees are required to acknowledge: “I, \_\_\_ understand that SAH is committed to offering employees the seasonal influenza vaccination because research indicates that employees who are not immunized pose a serious health risk to patients, family and community during influenza season”. An “Influenza Vaccination Consent” form is also in place for all employees, physicians, volunteers, students, and ‘other’ at SAH. It includes the following: “I consent to the release of my influenza immunization/antiviral prophylaxis status to my manager (or designate) for the purposes of overseeing the influenza management policy and outbreak planning.”<sup>288</sup>

197. Ms. Manzo agreed in cross-examination that “the use of a sticker...would then identify whether or not I as a healthcare worker have taken the vaccine” and that such a sticker would be visible to all, managers, visitors, and patients.<sup>289</sup>

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<sup>286</sup> Transcript, October 9, 2014, p. 124

<sup>287</sup> Exhibit 17

<sup>288</sup> Exhibit 137

<sup>289</sup> Transcript, June 9, 2015, pp. 114, 138

198. Pam Poldmaa is a registered nurse who works at SAH in the Program for Assertive Community Treatment (“PACT”). The Program involves adult clients with complex bio-psycho-social needs due to severe and persistent mental illness. PACT nurses were instructed that the Policy made mandatory the wearing of procedure masks during all client contacts including in client homes, the nurse’s car, in the PACT office waiting room, and during all outings in public places in the community.

199. Ms. Poldmaa testified about the negative impact of mask wearing upon the therapeutic nurse-patient relationship when dealing with paranoid suspicious people with a lot of fixed delusions.<sup>290</sup> She also described a particular safety concern that had arisen; she removed her mask when concerned that a patient might hurt her.<sup>291</sup> Ms. Poldmaa confirmed that she was subsequently advised that she was not required to wear a mask in public areas. She also stated that she told her manager that: “I felt I was being publicly put on display for choosing not to get the flu shot. I told her I felt I was being bullied into it and harassed.”<sup>292</sup>

200. As previously noted, Ann Cook RN testified by way of will-say.<sup>293</sup> She stated that her role, as ONTrac Patient Blood Management Coordinator, consists primarily of assessing patients’ health to determine readiness for surgery and providing health teaching about their blood transfusion options. She said that oral communication was extremely important and that the majority of her clients are elderly and many have difficulty hearing. She explained that she had experienced significant difficulty in effectively carrying out her nursing duties.

201. ONA also filed an academic study that included the following conclusion:

The findings of this study are important in weighing up the benefits and risks of protective facemasks within doctor patient consultations and daily clinical practice. Facemasks offer limited protection in preventing infection and aerosol transmission through mucous membranes (ie. conjunctivae). Meanwhile, a negative impact on the

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<sup>290</sup> Transcript, October 9, 2014, p. 15;

<sup>291</sup> Transcript, October 9, 2014, pp. 17-18

<sup>292</sup> Transcript, October 9, 2014, p. 14

<sup>293</sup> Exhibit 14

patient's perceived empathy and relational continuity can reduce potential therapeutic effects...For countries in which wearing facemasks is uncommon care must be taken in conveying infection risk advice to healthcare professionals and caution in adopting guidelines regarding universal mask use (e.g. flu epidemics) particularly for medical physicians or other healthcare professionals where optimization of the therapeutic relationship is essential.<sup>294</sup>

202. Ms. Cook also asserted that she:

Further experienced daily breaches of her privacy in her personal health information. Patients regularly asked her why she was wearing a mask, to which she replied that it was hospital policy because she was not able to have a required immunization shot. Many patients did not believe this explanation and believed RN Cook and others in the clinic also wearing masks were working while ill and therefore posing a risk to patients. One patient directly accused RN Cook of making him sick while working while ill...<sup>295</sup>

203. ONA also led evidence that it said supported the conclusion that the Policy was not consistently enforced. Ms. Marcello testified that she had seen employees wearing masks dangling underneath their chins<sup>296</sup> and with masks modified with the bottoms cut off so that they do not fit securely<sup>297</sup> to the knowledge of supervisors<sup>298</sup>. She said that she has raised concerns regarding masks being worn improperly with several different supervisors.<sup>299</sup> Mr. Johns did not take steps to see if the Policy was being complied with after hearing that evidence.<sup>300</sup> Ms. Manzo acknowledged in cross-examination that she had observed incidents where masks weren't being used properly. The responsibility for enforcing the Policy rests with managers. Audits have not been conducted nor auditors trained to monitor the use of masks.<sup>301</sup>

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<sup>294</sup> Exhibit 221, Wong *et al*, "Effect of facemasks on empathy and relational continuity: a randomized controlled trial in primary care", BMC Family Practice 2013, 14:200

<sup>295</sup> Exhibit 14, para. 8

<sup>296</sup> Transcript, October 2, 2014, p. 79

<sup>297</sup> Transcript, October 2, 2014, p. 81

<sup>298</sup> Transcript, October 2, 2014, pp. 82, 118

<sup>299</sup> Transcript, October 2, 2014, p. 119

<sup>300</sup> Transcript, June 29, 2015, p. 117

<sup>301</sup> Transcript, June 9, 2015, pp. 192-195

## 2014-2015 Mismatch Year

204. In the 2014-2015 flu season there was a significant mismatch between the influenza vaccine and the dominant circulating virus in Canada, that is, A(H3N2).<sup>302</sup> Dr. Henry described the mismatch as “probably the biggest difference between the vaccine strain and the circulating strain that we [have] had in a long time”.<sup>303</sup> ONA submits that the basic failure of the vaccine in that year left virtually all HCWs equally exposed to the flu whether or not they had been vaccinated. Therefore, the continued application of the VOM Policy only to unvaccinated HCWs made no sense.

205. Dr. McGeer acknowledged that:

before the season, we knew that the H3N2 strain had drifted from what was in the vaccine and that drift was substantial...we didn't know before the season which influenza strain was going to be associated with infections, right, You can't tell that. It could still have been an H1N1 or B season and there was no way to be certain.<sup>304</sup>

206. For his part, Dr. De Serres testified that he advised the Ministry of Health in Quebec in the spring of 2014 that a “bad season”, “most likely” a H3N2 season that would severely hit elderly people was anticipated. The components of the vaccine however had not been changed from the previous season. In the result the vaccine did not protect against H3N2; that is, there was “no protection”. The bulk of influenza in the 2014-2015 season was H3N2 in Canada.<sup>305</sup> Dr. McGeer confirmed that: “what Dr. De Serres said was a surprise, was that that the degree of mismatch translated into our estimates in Canada of no protection”.<sup>306</sup> Dr. Lemieux referred to

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<sup>302</sup> Exhibit 62: Skowronski *et al*, “Interim Estimates of 2014/15 Vaccine Effectiveness Against Influenza A(H3N2) from Canada’s Sentinel Physician Surveillance Network”, Euro Surveillance (January 2015); Exhibit 63: McNeil *et al*, “Interim Estimates of 2014/15 Influenza Vaccine Effectiveness in Preventing Laboratory-Confirmed Influenza-Related Hospitalization from the Surveillance Network of the Canadian Immunization Research Network”, Euro Surveillance (January 2015)

<sup>303</sup> Transcript, June 22, 2015, p. 62

<sup>304</sup> Transcript, June 24, 2015, p. 104; See also: Transcript, June 26, 2015, pp.112-113

<sup>305</sup> Transcript, May 19, 2015, pp. 56-61

<sup>306</sup> Transcript, June 26, 2015, p. 112

a sentinel surveillance report that indicated a vaccine effectiveness rate of 12-14% for people aged 18 to over 50 [the presumed age range of most HCWs].<sup>307</sup>

207. Dr. Henry agreed that, as early as November 2014, her colleague Dr. Skowronski had publicly indicated concern about a significant mismatch for the H3N2 strain, but stated that the vaccine also had the B strain and the H1N1 strain that were well matched. She agreed that the H3N2 strain causes the most morbidity and mortality in older people. She acknowledged that there was no change to the mask requirement in British Columbia nevertheless; that is, vaccinated as well as unvaccinated persons were not required to mask. She agreed that, against the dominating A(H3N2) virus, one nurse who had the vaccine would be no more protected than the nurse standing beside her who did not have the vaccine against that strain.<sup>308</sup>

208. In addressing this mismatch season Dr. McGeer commented as follows:

So, when you knew that degree of mismatch was coming, you still didn't know what the degree of protection was going to be during the season and most people were—I think usually vaccine efficacy with mismatch drops to 40 or 50 percent. People looked at this and said this looks worse than usual. And so when the U.S. estimate of 20 percent came out at the beginning of January, that was within the range of what people thought it was going to be, okay. It's got an upper confidence limit of 35 percent, It's a bad mismatch but it's not no efficacy at all.

And the Canadian data being no efficacy at all was I think a substantial surprise to everybody, probably not by the time the results came out...when your influenza vaccine fails to protect well against the big infecting strain, it's a really bad season, a lot of hospitalizations, a lot of deaths, a lot of outbreaks in hospitals and nursing homes. And so I think people were worried about what that number was but we really—we didn't know until the first week of February that our estimates for Canada were zero.<sup>309</sup>

209. Dr. McGeer was asked the following question in cross-examination: “And at your hospital then, knowing that there was a significant mismatch, did you ask that

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<sup>307</sup> Transcript, January 26, 2015, p. 55; Exhibit 22

<sup>308</sup> Transcript, June 22, 2015, pp.249-254; Transcript, June 23, 2015, p. 188

<sup>309</sup> Transcript, June 24, 2015, p. 107

all the employees wear masks, not just unvaccinated ones?”. Her reply was: “We did not, no.”<sup>310</sup>

### **Why Not Mask Everyone?**

210. ONA in evidence and in argument submitted repeatedly that the illogicality of the VOM policy was demonstrated by the failure of the Hospital to require the wearing of masks by everyone. The Union submitted that the failure of the Hospital to alter the application of the Policy when the extent of the 2014-2015 vaccine mismatch became known made this point stronger still.<sup>311</sup>

211. As early as July 11, 2013 the Chief of Staff at SAH is recorded as saying:

If the intent is to prevent the spread of influenza virus then everyone should wear a mask; if the intent is to persuade everyone get the vaccine then the policy is reasonable. If you really don't want to pass the flu around everyone should wear a mask considering the vaccine is only 65% effective.<sup>312</sup>

212. Dr. Gardam expressed his point of view succinctly:

The concept to me of asking people to wear a mask while doing work for the entire year because they didn't get the flu shot, when the CDC over the last 10 years has said the effectiveness is 40 percent, doesn't make sense to me. So if you get the flu shot, even though the majority of you are not protected, because that's the nature of our mediocre vaccine, you're okay, you don't need to wear a mask. But, if you didn't get it, you have to wear a mask the whole season...Given the effectiveness of the vaccine, that doesn't make sense to me. I mean, this year it was almost absurd, where you had a stated effectiveness of negative 8 percent in the Euro surveillance that came out, but you still don't have to wear a mask if you got your flu shot...That didn't make sense to me at all.<sup>313</sup>

213. Dr. Gardam also commented on the mismatch year in this way referring to the Toronto Academic Health Science Network (“TAHSN”) implemented VOM policy:

As we started to hear that the vaccine wasn't working this year, everything was to be forwarded to Alison [Dr. McGeer] to make comments upon. That's what I reacted to, is that there were opportunities to say stop the bus, let's think about what we're doing. Once we had a good sense, which we had back in December, that this was not going to be a good year for the flu shot. I would have loved to have seen a reassessment of the policy

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<sup>310</sup> Transcript, June 26, 2015, p. 113

<sup>311</sup> ONA Final Argument Overview, paras. 130-135, 144

<sup>312</sup> Exhibit 4, Tab 6, p. 3

<sup>313</sup> Transcript, May 21, 2015, p. 66

at that point, but obviously people had gone too far down that road to be able to back up...

....

And some of the cognitive dissonance concepts of the idea you got a flu shot in a year when it didn't work, but you don't wear a mask—I can't understand that.<sup>314</sup>

214. Dr. De Serres put it this way in his reply Report:

Notwithstanding that most of these unvaccinated HCWs will not be infected with influenza through the winter, the mask-wearing alternative is represented as a necessity to ensure patient safety. If, however, one is to buy the argument that unvaccinated HCWs should endure the ask in order to protect patients, one is compelled to extend that concern to the other multitude of equally dangerous viruses for which there is no vaccine (RSV, metapneumovirus etc.) as well as to the substantial proportion of HCWs who will remain susceptible to influenza despite having been immunized with influenza vaccine acknowledged by most experts to be suboptimal.<sup>315</sup>

215. Dr. De Serres said the following in his testimony after noting that vaccinated persons will shed virus if they get influenza. He was asked in that context if a VOM policy made sense that did not require the masking of everyone and responded:

The short answer is it makes absolutely no sense. Well, you know it is meant to coerce health care workers. This year in British Columbia they were aware in January that the vaccine wasn't protecting. Was there anything about taking off the mask from unvaccinated individuals or what would be logical to force vaccinated health care workers to be masked? No, absolutely not. Only unvaccinated health care workers had to wear a mask. Why? Not because the others were better protected. Their risk was equivalent to unvaccinated health care workers. It was maintained to shame them, to impose a burden on them, not because it was about protecting patients. It's a way to try to get around, you know, having absolutely to get the vaccine, no option. We give you an option but, in fact, it's an option that is illogical. If we are logical, if we are talking about patient care, patient safety, even if you're vaccinated..if the mask you think is protecting, everybody should wear it because, you know, 40 to 50 percent of those who are vaccinated are as much at risk to acquire and shed virus as those who unvaccinated. So, for me, it is illogical, if it is done in good faith, but I think it's meant primarily to be coercive, to force vaccination.<sup>316</sup>

216. Dr. Lemieux expressed the same opinion.<sup>317</sup>

217. Dr. McGeer responded to the question of 'why not mask all HCWs' at some length:

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<sup>314</sup> Transcript, May 21, 2015, pp. 238-239

<sup>315</sup> Exhibit 70, pp. 9-10

<sup>316</sup> Transcript, May 19, 2015, p. 146

<sup>317</sup> Transcript, January 26, 2015, p. 66

Again, this gets back to policies and understanding seasons, and it's also partly about what the point of a policy is. So, this policy is about prevention of influenza. That's not to say, speaking of other respiratory viruses, that's not to say that other respiratory viruses aren't important. But when you're making changes in practice, you can't necessarily go for everything. You're making changes that are of specific benefit based on specific evidence. And the truth is that other respiratory viruses have a much lower burden. We don't have as good estimates. It's a little harder to justify policies about other respiratory viruses compared to influenza.

So, if we're talking about policies to protect patients from influenza in a year with a good match between the vaccine and the virus, you will get protective efficacies in young, healthy adults that are...somewhere between 70 and 80 percent.

In addition, you'll get less severe disease and, therefore, maybe less transmission when there is break-through disease. So, then in vaccinated health care workers there is not much benefit to be had from an influenza perspective in wearing a mask because you've already got 80 percent of your protection from just the vaccine...

In a mismatch year, in a year like this year, there may very well be an argument for masking everybody. To my mind, we need more evidence in order to do that because the evidence for masking is not nearly as good as the evidence for vaccine, but I think it's actually something that we will talk about and start to think about and start to ask whether it might be a benefit. In a year in which protective efficacy is 40 or 50 percent, that is really difficult at the moment...

....

And then do masks do the same thing as vaccination? And from that perspective, I think it's important to recognize that the mask as an alternative does not carry anything like the same evidence that if we mask everybody, that patient mortality would go down? The answer to that is no. We do not have that evidence. The masking alternative is honestly a somewhat desperate attempt to find the solution to the problem that we want to respect health care workers' choices about vaccination.<sup>318</sup>

218. During her cross-examination<sup>319</sup> Dr. Henry acknowledged that:

- unvaccinated persons are asked to wear a mask because they could be asymptotically shedding virus
- asymptomatic shedding is less than when one has symptoms; “the major risk is when you're symptomatic”
- in the 2014-2015 mismatch influenza season, “the risk of being infected and therefore shedding asymptotically would be the same” between two workers, one vaccinated and one unvaccinated but only the unvaccinated worker was required to wear a mask.

219. Dr. Henry answered the ‘why not mask everyone’ question this way:

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<sup>318</sup> Transcript, June 24, 2015, pp. 109-112

<sup>319</sup> Transcript, June 23, 2015, pp. 99-101



It is [influenza vaccination] by far, not perfect and it needs to be improved, but it reduces our risk from a hundred percent where we have no protection to somewhat lower. And there's nothing that I've found that shows there's an incremental benefit of adding a mask to that reduced risk.....there's no data that shows me that if we do our best to reduce that incremental risk, the risk of influenza, that adding a mask to that will provide any benefit. But if we don't have any protection then there might be some benefit when we know our risk is greater.

When we look at individual strains circulating and what's happening, I think we need it to be consistent with the fact that there was nothing that gave us support that providing a mask to everybody all the time was going to give us any additional benefit over putting in place the other measures that we have for the policy. It's a tough one. You know, it varies by season.<sup>320</sup>

.....

It is a challenging issue and we've wrestled with it. I'm not a huge fan of the masking piece. I think it was felt to be a reasonable alternative where there was a need to do—to feel that we were doing the best we can to try and reduce risk.

I tried to be quite clear in my report that the evidence to support masking is not as great and it is certainly not as good a measure.<sup>321</sup>

220. In final argument, referring to the mismatch year, the OHA/SAH counsel stressed that the mask is used as an alternative for those who choose not to vaccinate, that the Policy and its reasonableness can't be based on one-year assessments, that it was not "even by midstream absolutely clear that the vaccine against one strain was not going to provide any protection", and that "it's also not clear when it's providing protection against other strains".<sup>322</sup>

### **Broader Policy Requirements and Recommendations**

221. The OHA/SAH also looks to positions taken by other institutions and bodies to support its selection of a VOM policy. I now turn to review some of them and others as well.

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<sup>320</sup> Transcript, June 23, 2015, p. 108

<sup>321</sup> Transcript, June 23, 2015, p. 111

<sup>322</sup> Transcript, July 8, 2015, pp. 120-122

*Statutory/regulatory requirements*

222. By statute a medical officer of health has authority to settle requirements in an order “to decrease or eliminate the risk to health presented by the communicable disease”.<sup>323</sup> What is noteworthy is what is missing. Neither mandatory influenza vaccination nor mask requirement orders have been made applicable for HCWs. There is however a requirement for proof of measles vaccination as a condition of employment.<sup>324</sup>

223. Subsection 6(1)(h) of the General Regulation under the *Ambulance Act* provides:

6.(1) An emergency medical attendant and paramedic employed, or engaged as a volunteer, in a land ambulance service shall,

....

(h) hold a valid certificate signed by a physician that states that the person is immunized against diseases listed in Table 1 to the document entitled “Ambulance Service Communicable Disease Standards”, published by the Ministry, as that document may be amended from time to time, or that such immunization is contra-indicated.<sup>325</sup>

224. At one time there was a specific requirement in Ontario that ambulance attendants have influenza vaccination, unless such vaccination was contra-indicated. This is no longer the case.<sup>326</sup>

225. The Ontario government has not designated influenza as a disease against which children must be vaccinated in order to attend school.<sup>327</sup> Measles, mumps, tetanus and other diseases are designated.

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<sup>323</sup> *Health Protection and Promotion Act*, R.S.O. 1990, c. H.7, ss. 22(2)

<sup>324</sup> *Public Hospitals Act*, O. Reg. 965, ss. 4(2); Measles Surveillance Protocol for Ontario Hospitals, revised May 2014

<sup>325</sup> *Ambulance Act*, O. Reg. 257/00, ss. 6(1) (h), Ambulance Service Communicable Disease Standards, Table 1, Part A

<sup>326</sup> *North Bay General Hospital*, November 23, 2003 (Goodfellow)

<sup>327</sup> *Immunization of School Pupils Act*, R.S.O 1990, c. I.1, s. 1, s. 3; O. Reg. 261/13 “Designated Diseases”

226. The College of Nurses (“CNO”) has not required that nurses secure influenza vaccination as a professional standard to be met nor have other provincial bodies with regulatory powers over healthcare professionals. The CNO ‘Practice Guideline Influenza Vaccinations’ (June 2009) states that: “The College does not establish the requirements for immunization of health care workers. These requirements are established by individual workplaces and by legislation.”<sup>328</sup>

*Other guides, reports, studies, recommendations*

227. Dr. Brosseau was a member of the Council of Canadian Academies Expert Panel on Influenza and Personal Protective Respiratory Equipment. The Panel conducted “An Assessment of the Evidence” in 2007. Its consensus report included the following:

Surgical masks worn by infected persons may play a role in the prevention of influenza by reducing the amount of infectious material that is released into the environment...Their biggest limitation is that they do not provide an effective seal to the face, thereby allowing inhalable particles access to the respiratory tract. In addition, the efficiency of the filters of surgical masks in blocking penetration of tracheobronchial or alveolar-sized particles is highly variable and their efficiency in blocking nasopharyngeal-sized particles is unknown.<sup>329</sup>

228. A 2012 Position Paper issued by AMMI Canada [Association of Medical Microbiology and Infectious Diseases Canada], of which Dr. McGeer was a joint author, took the position that vaccination against influenza is ethically justified as a condition of employment. The paper included no mention or discussion of the need for masking.<sup>330</sup>

229. A 2013 prospective cohort study performed during the 2009 influenza A(H1N1) pandemic was aimed to determine whether adults working in acute care hospitals were at higher risk than other working adults for influenza and to assess risk factors for influenza among HCWs. Dr. McGeer was lead author. There were no

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<sup>328</sup> Attachment to Exhibit 17, Will-Say of Glenda Hubley

<sup>329</sup> Exhibit 123, p. 7; Transcript, June 6, 2015, L. Brosseau, pp. 76-81

<sup>330</sup> Exhibit 40

recommendations in the study of risk factors amongst healthcare workers that everyone be masked.<sup>331</sup> *Inter alia* the study noted that:

The mode of transmission of influenza remains a matter of ongoing debate. Although most experts believe that droplet and aerosol transmission are the most common modes of spread of influenza...Appropriate hand hygiene practice should continue to be recommended to prevent influenza transmission.<sup>332</sup>

Within an HCW group, we were able to identify activities that could help focus prevention. Increasing efforts to improve hand hygiene and the use of protective equipment during aerosol-generating medical procedures would further reduce the risk for influenza among HCWs.<sup>333</sup>

230. A third edition of “Best Practices for Infection Prevention and Control Programs in Ontario” was published in May 2012 by the Provincial Infectious Diseases Advisory Committee (“PIDAC”) of the Ontario Agency for Health Protection and Promotion.<sup>334</sup> There is no recommendation for a VOM policy among the numerous recommendations found in this document although PIDAC recommends annual influenza vaccination as a condition of continued employment in, or appointment to, health care organizations.<sup>335</sup>

231. A document, Annex F, “Prevention and Control of Influenza during a Pandemic for All Healthcare Settings”<sup>336</sup>, produced by a working group of which Dr. Henry was a member<sup>337</sup>, was produced for the Public Health Agency of Canada. This set of recommendations related to protection in a pandemic when the entire population is naïve to a newly circulating strain of influenza, meaning that everyone would be in the same situation as unvaccinated people in the context of seasonal influenza.<sup>338</sup> Dr. Henry agreed that this document did not recommend personal

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<sup>331</sup> Transcript, June 26, 2015, A. McGeer, p. 116

<sup>332</sup> Exhibit 62 at p. 612: Kuster *et al*, “Risk Factors for Influenza among Health Care Workers during 2009 Pandemic, Toronto, Ontario, Canada”, *Emerging Infectious Diseases*. Vol. 19, No.4, April 2013, pp. 608-615

<sup>333</sup> Exhibit 62, p. 614

<sup>334</sup> Exhibit 197

<sup>335</sup> Exhibit 197, p. 32

<sup>336</sup> Exhibit 143

<sup>337</sup> Transcript, June 22, 2015, B. Henry, p. 219ff

<sup>338</sup> Transcript, June 22, 2015, B. Henry, pp. 220-221

protective equipment for HCWs unless they were within two metres of a symptomatic person, permitted asymptomatic visitors without restrictions, indicated that asymptomatic personnel could safely work, and explicitly indicated that masks were *not* required for asymptomatic persons who had been exposed to infected roommates.<sup>339</sup> There were no recommendations for the use of masks outside of an outbreak situation.

232. A 2009 publication by the CDC (Centers for Disease Control and Prevention), “Interim Guidance for the Use of Masks to Control Influenza Transmission”<sup>340</sup> stated that: “no studies have definitively shown that mask use by either infectious patients or health-care personnel prevents influenza transmission” but recommended that “a surgical or procedure mask should be worn by health-care personnel who are in close contact( i.e. within 3 feet) with a patient who has symptoms of a respiratory infection, particularly if fever is present, as recommended for standard and droplet precautions”.

*Toronto Academic Health Science Network (TAHSN)*

233. On February 24, 2014, the TAHSN Healthcare Worker Influenza Immunization Working Group released a Report that included recommendations and extensive commentary concerning vaccination and VOM policies.<sup>341</sup>

234. The TAHSN Report describes VOM policies as offering HCWs a choice between obtaining annual influenza vaccine and wearing a mask, a choice said to provide workers with more autonomy with respect to the management of influenza in their practices than would a vaccination-required policy<sup>342</sup>. It states that VOM policies “have been associated with reductions in the number of institutional

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<sup>339</sup> Transcript, June 22, 2015, B. Henry, pp. 219-237

<sup>340</sup> Exhibit 11

<sup>341</sup> “Healthcare Worker Influenza Immunization”, Attached as Appendix C to Exhibit 185, Report, A. McGeer. (“TAHSN Report”)

<sup>342</sup> TAHSN Report, p. 16

outbreaks”<sup>343</sup>. It asserts that VOM policies “articulate conditions of employment very similar to those already in place for Diphtheria, Tetanus, Pertussis, MMR, Varicella, and Hepatitis B”.<sup>344</sup>

235. On the other hand, the TAHSN Report acknowledges a number of other issues including:

Critics point to mixed evidence of the vaccine’s efficacy, since the ethical defensibility of vaccination-required or vaccination-or-mask policies are linked to the vaccine’s efficacy.

....

At the level of the individual HCW the main ethical argument against vaccinate-or-mask policies is linked to respect for autonomy. Vaccinate-or-mask policies are generally considered to be a violation of autonomy. Constraints on autonomy are justified only if the benefits (i.e. prevention of serious harm) outweigh the harms, and only if those same benefits cannot be achieved without constraining freedom of choice. It is acknowledged that a vaccinate-or-mask policy is less of an infringement on autonomy than a vaccination-required policy.<sup>345</sup>

236. The Report went on to canvass what it described as Ethical Considerations in Operationalizing an Influenza Vaccination of HCWs Program. These included the following:

**Duty not to harm others** – Generally speaking, HCWs have a moral obligation not to harm others and to contribute to a safe work environment. This implies a duty not to infect someone when one knows this can easily be prevented. While there are limits to what one could reasonably expect of a HCW in order to limit the chance that the worker would infect another, it would be ethically defensible to expect adherence to activities that are of minimal risk or burden to the HCW.

....

**Proportionality** – Restrictions on freedom of staff are ethically defensible to the extent that they are proportionate to the risk they are intended to prevent. Restrictions to individual liberty and measures taken to protect the public from harm should not exceed what is necessary to address the actual level of risk to or critical needs of the community.

....

**Individual liberty** – Restrictions to individual liberty may be necessary to protect the patients and other HCWs from serious harm. Restrictions to individual liberty should: be proportional, necessary, and relevant; employ the least restrictive means; and be applied equitably.

**Privacy** – Individuals have a right to privacy in health care. When operationalizing a vaccination program, attention should be given to impact on disclosure of personal health

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<sup>343</sup> TAHSN Report, p. 17

<sup>344</sup> TAHSN Report, p. 17

<sup>345</sup> TAHSN Report, p. 18

information. For example, could there be challenges related to stigmatization against those who choose to wear a mask over vaccination, or families who only want caregivers who have been immunized.<sup>346</sup>

237. The Summary paragraphs on the VOM section of the Report included the following:

It may be helpful to think of the ethical defensibility of influenza vaccination for HCWs programs as sitting along a continuum. Voluntary programs that include strong educational and incentive components would be the preferred first approach. If ineffective, policy could move along to stage of vaccinate-or-mask with careful attention to how to mitigate harms associated with potential pushback...

....

When HCW immunization rates remain low in spite of state-of-the-art educational and incentive programs, a vaccinate-or-mask approach would be ethically defensible.<sup>347</sup>

238. The Report went on at some length to consider what it termed Human Resources, Labour Relations and Legal Considerations and commented upon the Diebolt Award. The Report concluded that:

The key requirements in formulating a “vaccination-or-mask” policy are reasonableness and consistency with the collective agreements. There are reasonable grounds to assert that both of those requirements can be met by Ontario hospitals. In order to do so, Ontario hospitals will need to establish key factual aspects, including the fact that the alternative use of a mask also reduces the risk of transmission of influenza to patients and the fact that the alternative use of the mask serves both patient safety and accommodation needs.<sup>348</sup>

239. The TAHSN Report contains numerous footnoted references that are said to support the propositions advanced. However, no references are cited concerning the use of a mask to reduce the risk of transmission of influenza to patients or that the introduction of VOM policies has been associated with reductions in the number of institutional influenza outbreaks. Nor does the Report note that influenza is not designated by Regulation for mandatory immunization unlike the other diseases referenced and said to be comparables.

240. In their joint Report dated December 5, 2014, Dr. Gardam and Dr. Lemieux had the following exceptionally blunt comments about the TAHSN process:

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<sup>346</sup> TAHSN Report, p. 18

<sup>347</sup> TAHSN Report, p. 19

<sup>348</sup> TAHSN Report, p. 23

...we feel it important to illustrate how the process was in fact highly biased and determined at the outset to block any alternative viewpoints.

Despite UHN being the largest TAHSN member, and the physicians within the UHN infection prevention and control department having expertise regarding influenza immunization (including one of us co-chairing the TAHSN pandemic influenza planning committee which was the forerunner of the staff vaccination committee), neither of us was included in the discussion regarding possible policy options. A UHN senior staff member did sit at the TAHSN table during policy discussions and repeatedly told the committee that there were alternative views and potentially more effective policies that should be considered. Our UHN senior staff member informed us that, despite these attempts, the TAHSN policy was not open for debate. Only two members of the TAHSN committee have infectious disease experience (Drs. McGeer and Kevin Katz, who share the same opinion of the policy) with the majority of the other members being senior administrators. The UHN representative on the committee has told us that, in her opinion, Dr. McGeer was solely relied upon to translate the evidence for the other members of the committee, few of whom had the requisite training to understand or critique the complexities. Any scientific questions that arose were directed exclusively to Dr. McGeer to answer from her authoritative position.<sup>349</sup>

241. Dr. Gardam also spoke about his concerns when he gave oral testimony.<sup>350</sup>

In re-examination he explained:

The process issues are very important to me because this is at the crux of all of this, is that we have a policy in front of us which that that support it say has ample evidence to support it, there really is no downside to that, yet this policy has been created in the organizations that I'm aware of, it's been created behind closed doors. There hasn't been a lot of open discussion about it. There aren't a lot of people that really have a lot of expertise in this area, so it's pretty easy to have discussion without people with expertise. And it's multiplying. And so it went from B.C.. it went to New Brunswick, now it's come to University of Toronto Hospitals, it's now in Saskatchewan. And it really bothers me because each place is saying, Well, these people adopted this policy, there is an inherent assumption that they went through all the process of really sorting that out. Because that's what we tend to do in medicine. Once it's been adopted three or four times, why do we have to go back and look at the original evidence anymore, you've done that....the next time it comes up, I want people to start over. I want them to actually bring in people from different opinions and get them in the room and really hash out what is the best way to protect our patients. Not what is the best way to get people vaccinated, but what is the best way to protect our patients, of which a component will be vaccination.<sup>351</sup>

242. Dr. Gardam referred to his own hospital, UHN:

I think all of that relates to the fact that people didn't hear that there were other alternatives. In my own hospital, I spoke with my senior team for probably 10 minutes and they're like, okay, so there is another opinion. We want to think about this before we jump on board. So we decided for this year we weren't going to go along with the TAHSN

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<sup>349</sup> Exhibit 21, p. 2

<sup>350</sup> See for example: Transcript, May 21, 2015, pp. 95, 103-107

<sup>351</sup> Transcript, May 21, 2015, pp. 235-236



report. I can't help but think if people heard alternative opinions that they may not have been quite so quick to jump on this.<sup>352</sup>

## Legal Submissions

243. The following outline of the parties' very lengthy submissions<sup>353</sup> is necessarily very sharply abbreviated. It does not include most of the numerous authorities that were cited in their complementary written arguments.<sup>354</sup>

### *ONA*

244. The Union submits that the Hospital has failed to meet its evidentiary burden to establish that the Policy is rationally connected to a legitimate purpose. It called no mask expert. The Policy does not meet accepted *KVP* requirements in that:

- It is inconsistent with the collective agreement.
- It is based on irrational considerations.
- It involves an infringement of employees' rights to privacy and personal autonomy.
- Less intrusive rules would suffice; the Policy is not proportionate.
- The Policy was not consistently enforced.

245. ONA argues that:

- The Policy undermines the negotiated right of employees to choose whether or not to be vaccinated by, in effect, coercing an election to vaccinate.
- The mask evidence asserted by the Hospital's experts disappears under close review.
- If the legitimate purpose of masking is to prevent transmission of influenza, then logically it should require everyone to mask. Moreover, the Hospital failed to apply its VOM Policy to vaccinated employees in 2014-2015 although it knew that the vaccine in that year was ineffective against the dominant influenza strain.
- The Policy is not applicable in all areas of the Hospital and to visitors.

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<sup>352</sup> Transcript, May 21, 2015, pp. 239-240

<sup>353</sup> Transcript, July 7, 2015 (ONA); Transcript, July 8, 2015 (OHA/SAH)

<sup>354</sup> Final Argument Overview (ONA); Closing Argument of the OHA and SAH

- The process followed at SAH goes directly to the reasonableness of the Policy: the VOM policy was effectively determined at the outset by CEO Gagnon when he directed adoption of “the most aggressive stance we could take which will stand the test of arbitration”; the Hospital failed to consult its IPAC consultants and bypassed the IPAC department; the Chief of Medical Staff, the Chief Nursing Executive, and Medical Officer of Health expressed concerns; Mr. Gagnon’s selection of a 70% required vaccination rate to forestall implementation was arbitrary.
- The Hospital’s existing infection prevention and control policies were adequate.
- By placing a sticker on a public badge, by mandating the wearing of a mask if not vaccinated, by postings that advise patients and visitors that a mask can be equated to non-vaccination, the Hospital is infringing upon employees’ right to privacy of their medical information.
- The consent form required is not sufficient to cover this public disclosure. It coerces consent in the sense that the negative consequence of mask wearing is the alternative.
- There are less intrusive measures that could be taken including non coercive measures to encourage vaccination, front line engagement tactics to have staff own the issue, policy development based on ‘best evidence’ of influenza transmission; a review of sick leave policies to encourage employees not to come to work if sick.

246. The Union refers to *Irving* and relies upon *Peace Country Health*<sup>355</sup> submitting that it provides the appropriate analytical framework for applying *KVP* where an employee’s right to privacy and personal autonomy is involved. It suggests that an employer’s valid business objectives and good intentions are insufficient justification to intrude upon employees’ medical privacy: *Federated Cooperatives Ltd.*<sup>356</sup> An employer must provide sufficient objective evidence to establish a link between the policy and the employer’s justification for the policy: for example, see: *West Lincoln Memorial Hospital*<sup>357</sup>; *Casino Niagara*<sup>358</sup>.

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<sup>355</sup> (2007), 89 C.L.A.S. 107 (Sims)

<sup>356</sup> (2010), 194 L.A.C. (4<sup>th</sup>) 326 (Ponak) at para. 30

<sup>357</sup> (2004), 126 L.A.C. (4<sup>th</sup>) 52 (Luborsky) at paras. 16-17

<sup>358</sup> (2005), 142 L.A.C. (4<sup>th</sup>) 78 (Knopf) at para. 12

247. ONA points as well to *Meiorin*<sup>359</sup> in support of its submission that it is not sufficient for an employer to claim a safety interest to support a workplace policy or practice. The Union submits that, although fitness tests for firefighters had a valid purpose in promoting safety, it was held that the research upon which the tests were based was incomplete, “impressionistic” and did not take into account human rights issues in establishing the required standard. The policy was struck down.

248. ONA refers to several leading authorities with respect to employee privacy rights: *Monarch Fine Foods Co. Ltd.*<sup>360</sup>; *Alberta (Information and Privacy Commissioner)*<sup>361</sup>; *St. Joseph’s Health Centre*<sup>362</sup>. It also points to the provisions of a number of statutes: *Personal Health Information Protection Act, 2004*<sup>363</sup> (“PHIPA”); *Freedom of Information and Protection of Privacy Act, s. 2*<sup>364</sup> (“FIPPA”); *Occupational Health and Safety Act, ss. 28(3), 63(2)*<sup>365</sup>; *Health Care Consent Act, s. 2, 10, 11*<sup>366</sup>. As stated, the Union’s theory concerning these issues is grounded on the submission that the medical vaccination status of employees is publically communicated both by the very fact of mask wearing and by the sticker on the badges they must wear. A Hospital posting advises patients and visitors of the VOM Policy and makes this clear. The argument is that a VOM policy that imposes consequences upon a refusal to vaccinate amounts, in effect, to coerced consent. Coerced consent is not proper consent.

249. The Union also submits that Dr. McGeer’s evidence should be regarded as compromised given that she is “a fervent advocate for influenza vaccination”<sup>367</sup>. Dr. Henry was instrumental in the introduction of the VOM policy in British

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<sup>359</sup> *British Columbia (Public Service Employee Relations Commission)*, [1999] 3 S.C.R. 3

<sup>360</sup> (1978), 20 L.A.C. (2d) 419 (M.Picher)

<sup>361</sup> 2013 SCC 62

<sup>362</sup> (2005), 76 O.R. (3d) 22 (Ont. Div. Ct.)

<sup>363</sup> S.O. 2004, c.3, Sch. A

<sup>364</sup> R.S.O. 1990, c. 31

<sup>365</sup> R.S.O. 1990, c. 0.1

<sup>366</sup> S.O. 1996, c. 2, Sch A.

<sup>367</sup> Final Argument Overview, para. 84

Columbia.<sup>368</sup> It argues that an adverse inference should be drawn against the Hospital given that the following potential witnesses were not called: Joanne Messier-Mann, Chief Nursing Executive; Dr. Heather O'Brien, Chief of Staff; Dr. Kim Barker, Medical Officer of Health, Algoma; Kim Lemay, Director of Human Resources; Jack Willet, Manager and Influenza Planning Committee member.<sup>369</sup>

### *OHA/SAH*

250. The OHA and the Hospital submit that the Policy relates to an important patient safety issue. They argue that the Diebolt Award is indistinguishable, good law, and should be followed. Arbitrator Diebolt has already determined that VOM policies meet the *KVP* test for reasonableness.

251. Insofar as *KVP* and *Irving* are concerned the OHA/SAH submit that the Policy meets accepted tests for reasonableness and that it appropriately balances the Hospital's interest with employee privacy interests. As previously found by Arbitrator Diebolt, influenza can be a serious, even fatal, disease and masking has a patient safety purpose. They submit that: "the scientific evidence in this case provides a solid and compelling foundation for the reasonableness of the Policy".<sup>370</sup> The ONA Central Collective Agreement recognizes a joint obligation to protect patient and employee health and safety. Implementation of the Policy was the exercise of a legitimate management right codified in the Local Collective Agreement.

252. Reasonableness should be assessed using the *Dunsmuir* approach for judicial review. Placing particular reliance upon comments by Arbitrator Hope quoted in *Canada Safeway Ltd.*<sup>371</sup>, the OHA/SAH submit that: "the Arbitrator's focus is to

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<sup>368</sup> Final Argument Overview, Appendix C, p. 61; Transcript, June 22, 2015, pp. 184, 188

<sup>369</sup> Final Argument Overview, para. 89

<sup>370</sup> OHA/SAH Closing Argument, para. 366

<sup>371</sup> [1998] B.C.C.A.A.A. No. 378 (Kelleher)

determine whether the Policy falls within a range of acceptable and rational solutions; it is not to assess whether the same policy would have been implemented by ONA”.<sup>372</sup> The statutory framework also supports the conclusion that steps should be taken to eliminate “undue risks” and “minimize hazards inherent in the hospital environment”.<sup>373</sup>

253. There is no evidence to provide a factual foundation for the allegation that there was no informed consent to vaccination, let alone to disclosure of immunization status. There are exclusion provisions in both *PHIPA*<sup>374</sup> and *FIPPA*<sup>375</sup> that preclude operation of those statutes. As a matter of fact, the sticker identifier shows only the SAH logo and the fiscal year and provides no information about immunization status.<sup>376</sup> Managers were given only a list of vaccinated employees who had consented to release of personal health information.<sup>377</sup> There is no evidence that informed consent was not given by any affected nurse.

## Discussion

### *Experts*

254. The relevant legal principles governing the admissibility of expert opinion evidence were well stated by the OHA/SAH<sup>378</sup> and are not disputed. The expert evidence adduced in this case was central to both positions. It would have been impossible to try the case properly without it. Each side however questions the weight that should be accorded the evidence provided by the other’s experts.

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<sup>372</sup> OHA/SAH Closing Argument, para. 353

<sup>373</sup> OHA/SAH Closing Argument, para. 379; *Public Hospitals Act: Hospital Management*, RRO 1990, Reg. 965, ss. 4(1) (d) (v)

<sup>374</sup> ss. 4(4)

<sup>375</sup> ss. 65(6)(3)

<sup>376</sup> Transcript, C. Johns, June 29, 2015, p. 156

<sup>377</sup> Transcript, C. Manzo, June 9, 2015, pp. 186-187

<sup>378</sup> OHA/SAH Closing Argument, paras. 88-97; *R. v. Mohan*, [1994] 2 SCR 9; *White Burgess Langille Inman v. Abbott and Haliburton Co.*, 2015 SCC 23 (CanLII).

255. The OHA/SAH suggest that the manner in which ONA secured its expert evidence was problematic.<sup>379</sup> It also challenges Dr. Brosseau’s expertise if it is said to relate to the use of a mask to reduce influenza transmission from a HCW to a patient in an acute care hospital. It says that Dr. De Serres, Dr. Gardam, and Dr. Lemieux purported to opine on the very issue in this proceeding: whether the Policy is reasonable. Their description of the Policy as coercive and punitive constitutes the expression of personal views that mark their evidence as not “totally objective”. Dr. De Serres has acknowledged that he has no expertise with respect to the use of a procedure/surgical mask. Dr. Gardam has not engaged in scientific research regarding the use of a mask in the prevention of HCW influenza transmission nor has Dr. Lemieux. Dr. Lemieux is tendered both as a fact and expert witness that the OHA/SAH also says is problematic.<sup>380</sup>

256. ONA notes that the OHA/SAH called no mask expert evidence at all. Dr. McGeer is a known advocate of mandatory influenza immunization and Dr. Henry was instrumental in the introduction of the VOM policy into British Columbia. Their objectivity is suspect. ONA says that: “Dr. McGeer has a history of making inflammatory and hyperbolic statements about the dangers of influenza and the risk caused by unvaccinated HCWs, specifically accusing them of having a ‘license to kill’”.<sup>381</sup>

257. I am satisfied that the evidence of all of these witnesses should be accepted as proper expert opinion evidence, albeit recognizing some inevitable limitations and ignoring some of the comments that might be seen as conclusory having regard to the issues in this case. The OHA/SAH raised concerns about “counsel-prepared” will-says and other objections at preliminary stages but I am satisfied that there has

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<sup>379</sup> Transcript, July 8, 2015: “The use of a will-say for claimed expert opinion evidence...is highly problematic...It’s not an answer to that, too, to say that the will-say statement was provided to the witness for review and comment. The fact remains it was prepared by an advocate.”

<sup>380</sup> OHA/SAH Closing Argument, paras. 98-135; Transcript, July 8, 2015, p.54

<sup>381</sup> Final Argument Overview, Appendix C

been adequate compliance with the requirements of *Moore v. Getahun* 2015 ONCA 55, a judgment that issued subsequently to the preparation of this material. I also accept that ONA counsel faced practical difficulties when seeking the assistance of local expert witnesses that explains how their relationship unfolded. Dr. Gardam explained at some length why it was necessary that he testify under subpoena.<sup>382</sup>

258. The only witness for whom specialized mask expertise is claimed is Dr. Brosseau. I accept that the focus of her research has been industrial hygiene with focus on fit and filter, principally concerning respirators. I do not rely upon her opinion, to the extent that it was specifically expressed without corroboration, about the transmission of influenza from a HCW to a patient. I accept that she is as competent, and likely more competent, than the other experts to speak to such mask literature as exists.

259. I have no doubt about Dr. De Serres's expertise as a leading Canadian epidemiologist nor about that of Dr. McGeer. They have both conducted extensive research concerning influenza and related subjects. Dr. Henry, Dr. Gardam, and Dr. Lemieux are all actively engaged in the infectious diseases field and have major responsibilities in major health care institutions. They bring years of practical experience concerning influenza and other respiratory diseases and demonstrated deep knowledge of the currently available research and literature.<sup>383</sup> They collectively provided assistance in understanding the relevant research and literature in the only practical way possible; that is, by providing their informed opinions and by explaining the conclusions identified in their respective Reports by reference to that scientific material. The curricula vitae of these experts are truly remarkable.

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<sup>382</sup> Transcript, May 21, 2015, pp.102-103

<sup>383</sup> OHA/SAH's description of Dr. Henry's expertise, having "engaged in a very substantial review of the relevant scientific literature regarding influenza, its transmission and the prevention of its transmission particularly given her significant practical experience" [OHA/SAH Closing Argument, para. 143; Transcript, July 8, 2015, p.69] is entirely apt and would apply in my view also to Dr. Gardam and Dr. Lemieux. OHA/SAH counsel agreed that Dr. Gardam has "considerable experience and expertise in infectious diseases". See: Transcript, July 8, 2015, p.61

260. As previously noted much earlier in this Award, Arbitrator Diebolt was also favoured with expert testimony. However, given the parallel expertise of Dr. De Serres, Dr. Gardam, and Dr. Lemieux, I am not able to reach the same conclusion as he did that the evidence of Dr. McGeer and Dr. Henry on transmission issues should be preferred as having what he called “special relevance”.<sup>384</sup>

*Experts and arbitrators: deference or choice*

261. As noted at the outset of this Award, these grievances raise the issue of a labour arbitrator’s engagement with expert evidence when assessing the reasonableness of workplace policies that establish terms and conditions of work for employees who are delivering patient care. The OHA/SAH, relying on *Dunsmuir* and other judicial review authorities, submit that some form of *Dunsmuir*-like deference should apply in assessing the expert evidence tendered in support of the VOM policy.

262. I disagree. *Dunsmuir* principles of deference should not be imported into first level rights adjudication. The analogy to *Dunsmuir* is misplaced. The nature and degree of that misplacement can be examined through the three concepts of deference, expertise, and reasonableness.

263. First, the OHA/SAH’s position conflates *decision-making deference* with the question of what *weight* should be attached to an expert’s evidence. These are very different projects.

264. The concept of and rationale for deference that apply in administrative law have no application to and are not transferrable to understanding an adjudicator’s engagement with expert opinion evidence. In administrative law, the notion of

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<sup>384</sup> Diebolt Award, para. 185



*deference* is integral to the very rationale for creating a rights-enforcement system composed of expert tribunals supervised by courts on judicial review. While administrative tribunals have particular contextual, subject matter, and/or technical expertise, what is crucial is that those tribunals and the supervising courts are both *legal decision-makers* that are engaged in the *same singular project of rights adjudication within a given legislative framework*. There, the concept of deference is grounded in principles of adjudicative economy and efficiency that recognize the rationale for creating expert tribunals while ensuring compliance with the constitutional requirement for judicial oversight. And in that context, deference is applied with considerable nuance and contextual sensitivity as the vast and subtle jurisprudence of administrative law well demonstrates.

265. The OHA/SAH's adoption of the notion of deference wrongly suggests that a labour arbitrator should defer to the choices or conclusions that a *witness* makes within their particular realm of expertise. The analogy is flawed because arbitrators and witnesses have different realms of expertise and are engaged in distinct 'decision-making' projects. A witness may make choices and reach conclusions within their area of expertise but the parameters, expertise and duties that inform those choices are different from the parameters, expertise and duties that are engaged by a legal claim that arbitrators must resolve in the course of rights adjudication. It is not a question of one decision maker (arbitrators) deferring to another (expert witnesses) because their mandates are completely distinct. To exercise that form of deference would be an abdication of a labour arbitrator's mandate and obligation to the parties.

266. Instead, it is better to understand the arbitrator's orientation towards expert evidence by remembering why expert opinion evidence is admissible as an exception to the exclusionary rule against opinion evidence and what role it plays in adjudication. Expert witnesses are permitted to provide opinion evidence because their specialized knowledge may be required to assist the adjudicator to reach true inferences from facts stated by witnesses.

267. Since its 1994 ruling in *R. v. Mohan*, and most recently in *White Burgess Langille Inman*, the Supreme Court of Canada has cautioned against the danger that in the face of expert evidence “the trier of fact will inappropriately defer to the expert’s opinion rather than carefully evaluate it”.<sup>385</sup> Instead, the Court has reiterated that “[t]he trier of fact must be able to use its ‘informed judgment’, not simply decide on the basis of an ‘act of faith’ in the expert’s opinion”.<sup>386</sup> In all cases, the role of the expert witness is to provide “fair, objective and non-partisan opinion evidence” that assists adjudicators in assessing all the evidence before them and drawing true inferences.<sup>387</sup>

268. But, the expert witness is not to substitute for the adjudicator’s independent assessment of the legal issue to be decided. Accordingly, rather than “deference”, the real questions are what *weight* should an arbitrator give to particular expert opinion evidence and does that expert opinion evidence assist in drawing inferences. As set out above, the parties agreed that it is necessary to assess and choose between the conflicting scientific evidence. That assessment and such choice are not questions of “deference” but an exercise of an arbitrator’s normal judgment with respect to the weight, relevance and credibility of competing evidence.

269. Secondly, the OHA/SAH’s adoption of the reasonableness test from *Dunsmuir* again risks confusing the question of deference and the limited scope of the expert witness’ expertise and risks diluting the well-established *KVP* test.

270. The OHA/SAH’s position suggests that as long as the VOM Policy is based on “some” expert evidence and “falls within a range of possible, acceptable outcomes” it will be compliant with a reasonable exercise of management rights. However, the articulation of what is “reasonable” in *Dunsmuir* is not a free-floating

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<sup>385</sup> *White Burgess Langille Inman*, 2015 SCC 23, at para. 17

<sup>386</sup> *White Burgess*, at para. 18

<sup>387</sup> *White Burgess*, at paras. 2, 10

“reasonableness” test. It specifically describes what *degree of deference* is appropriate when taking into account the distinct roles played by an administrative tribunal of first instance and a reviewing court within a vertical process of rights adjudication and review. Also, the question of whether an expert witness’ opinion is “reasonable” equally presents the wrong frame. It must be stressed that an expert witness’ expertise has a different focus and is incomplete for the purposes of determining the legal rights at issue in a grievance. For example, an expert witness’ opinion may be “reasonable” *in a colloquial sense* in view of the parameters that inform the specific scientific project to which the expertise relates. But this does not translate into a *legal conclusion of reasonableness*. It is important to use these terms with precision and to be very clear about the point in the decision-making process to which they relate.

271. At the end of the day, the well-established *KVP* test that identifies what is a reasonable exercise of management rights is the legal test that applies. As the Supreme Court of Canada stated in *Irving*, assessing what is reasonable requires a particular balancing of interests that is attuned to the labour relations context:

Determining reasonableness requires labour arbitrators to apply their labour relations expertise, consider all of the surrounding circumstances, and determine whether the employer’s policy strikes a reasonable balance. Assessing the reasonableness of an employer’s policy can include assessing such things as the nature of the employer’s interests, any less intrusive means available to address the employer’s concerns, and the policy’s impact on employees.<sup>388</sup>

#### *KVP reasonableness*

272. ONA and the OHA/SAH both present *Irving’s* explication of *KVP* reasonableness, just cited, as providing the appropriate foundation for the analysis that is required.<sup>389</sup>

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<sup>388</sup> [2013] 2 S.C.R. 458, at para. 27; specifically acknowledging a submission of the Alberta Federation of Labour

<sup>389</sup> OHA/SAH Closing Argument, paras. 311-312; ONA Final Argument Overview, para. 3

273. Arbitrator Diebolt provided the following succinct descriptions that I readily adopt:

The Policy, in my view, is a case of a unilaterally imposed set of rules. Therefore, it is necessary to establish that it is a legitimate exercise of the Employer's residual management rights recognized and retained in Article 4. That means the Policy must meet the tests set out in *KVP*. Further, because it contains elements that touch on privacy rights, it must meet the privacy tests articulated in *CEP, Local 30 v. Irving Pulp & Paper Ltd.*, 2013 SCC 34. If those tests are met the Policy will be a valid exercise of the Employer's management rights.<sup>390</sup>

....

In any event, where privacy interests are affected by a unilateral policy implemented as an exercise of management rights, the most recent articulation of the relevant tests is set out by the Supreme Court of Canada in *Irving*, which addressed a policy of random alcohol breath testing in a dangerous work environment. The majority cited *KVP* with approval, noting both arbitrators and appellate courts have applied its reasonableness test. It wrote in part:

[24] The scope of management's unilateral rule-making authority under a collective agreement is persuasively set out in *Re Lumber & Sawmill Workers' Union, Local 2537, and KVP Co.* (1965), 16 L.A.C. 73 (Robinson). The heart of the "KVP" test, which is generally applied by arbitrators, is that any rule or policy unilaterally imposed by an employer and not subsequently agreed to by the Union, must be consistent with the collective agreement and be reasonable (Donald J.M. Brown and David Beatty, *Canadian Labour Arbitration* (4<sup>th</sup> ed. (loose-leaf), vol. 1, at topic 4:1520.

More specifically, the majority reviewed with approval a number of past arbitral approaches to policies affecting employee privacy. It noted arbitrators have engaged in a "balancing of interests" approach. In the arbitration awards under review, the board weighed the employer's interest in random alcohol testing as a workplace safety measure against the harm to the privacy interests of employees. The board asked whether the benefit to the employer from random testing in the dangerous workplace was proportional to the harm to employee privacy. The majority of the Court also noted past decisions in which arbitrators had asked whether less intrusive measures had been exhausted.<sup>391</sup>

274. Arbitrators have also made clear, as the OHA/SAH submits<sup>392</sup>, that the test for reasonableness is an objective one and does not depend upon the subjective views of the employer, the union or any employee or group of employees.<sup>393</sup>

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<sup>390</sup> Diebolt Award, para. 155

<sup>391</sup> Diebolt Award, paras. 161-162

<sup>392</sup> OHA/SAH Closing Argument, para. 349

<sup>393</sup> York University (2012), 221 L.A.C. (4<sup>th</sup>) 48 (Surdykowski) at para. 32

275. As did Arbitrator Diebolt, I turn now to *KVP* where it was said that a unilateral employer rule must satisfy the following requisites:

- 1) It must not be inconsistent with the collective agreement.
- 2) It must not be unreasonable.
- 3) It must be clear and unequivocal.
- 4) It must be brought to the attention of the employee affected before the company can act on it.
- 5) The employee concerned must have been notified that a breach of such rule could result in his discharge if the rule is used as a foundation for discharge.
- 6) Such a rule should have been consistently enforced by the company from the time it was introduced.<sup>394</sup>

276. In the instant case, requirements #3 and #4 have been clearly met and #5 is not relevant. As far as #6 is concerned, I am satisfied that the limited evidence led alleging inconsistent enforcement is not nearly sufficient to support a finding of breach given the size of this Hospital and bargaining unit. I propose therefore to say no more about it.

277. The primary dispute between the parties concerned the reasonableness of the Policy. The Union raised challenges on a variety of grounds each of which will be addressed with abbreviated reference to the evidence adduced.

278. Before doing so, I identify certain non-controversial propositions disclosed in the evidence. No one doubts the obligation of the Hospital to take all reasonable precautions to protect the health and safety of patients. No one doubts that influenza is a serious disease that may lead to serious, even fatal, consequences for certain otherwise compromised patients. With varying levels of assent given the developing science, none of the experts appear to question the first sentence of the published Policy: "Influenza immunization is the single most effective way of

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<sup>394</sup> *KVP Co.* (1965), 16 L.A.C. 73 (Robinson) at para. 34

preventing the spread and acquisition of influenza.”<sup>395</sup> All of the experts accept that, depending upon the number of years considered, the overall vaccine effectiveness rate is about 60%; they agree that many vaccinated HCWs will also contract influenza albeit in attenuated form in some cases. They agree that the 2014-2015 influenza season was an exceptionally poor year for vaccine match with the strain of the disease then prevailing in Canada. The parties agree that the validity of a general VOM policy should not stand or fall on the basis of the experience of a single year.

### *Purpose of the Policy*

279. As set out above, ONA asserts that the improper purpose of the Policy is to promote an increase in influenza immunization rates without an independent patient safety offset that would otherwise justify a mask-wearing requirement. To be clear, the Union does not contest the legitimacy of efforts properly made to encourage voluntary acceptance of vaccination by HCWs. Further, these grievances do not address outbreak situations specifically addressed by the Collective Agreement.

280. On the issue of driving an increase in vaccination rates, Arbitrator Diebolt had the following to say:

Pausing here, in my view, the facts that: (1) influenza can be a serious, even fatal, disease; (2) that immunization reduces the probability of contracting the disease, and (3) that immunization of health care workers reduces transmission of influenza to patients all militate strongly in favour of a conclusion that an immunization program that increases the rate of healthcare immunization is a reasonable policy.

....

**In sum, it is clear that a vaccination or masking policy will increase immunization rates. That said, it would be troubling if the only purpose or effect of the Policy’s masking component were to motivate health care workers to immunize. In that event, masking would only be a coercive tool.** On all the evidence, however, I am persuaded that masking has a patient safety purpose and effect and also an

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<sup>395</sup> Exhibit 3, Tab B, 4, p. 1.

accommodative purpose for health care workers who conscientiously object to immunization.<sup>396</sup> (bold added)

281. I will come to the final part of Arbitrator Diebolt's second paragraph in due course but turn first to his first three sentences identified in bold.

282. The genesis of the VOM Policy at SAH cannot seriously be doubted on a documentary record that is extensive, detailed and supported by the uncontradicted oral evidence of several witnesses.

283. I credit without hesitation the statement in Mr. Gagnon's will-say that earlier "critical incidents have shaped his beliefs and actions, and those of SAH with regard to safety"<sup>397</sup>. His will-say was compelling. However, I also find that Mr. Gagnon had decided, by as early as January 2013, that a VOM policy would be introduced at SAH. Only VOM detail and a date for implementation remained. The bedrock VOM requirement had been determined. Notwithstanding questions raised at various times by the Chief of Staff, the Chief Nursing Executive, and the Algoma Medical Officer of Health, VOM was pursued without waver until the Policy was made effective on January 1, 2014. UHN experts retained "to provide expert advice to Infection Prevention and Control at SAH on specific infection control issues" were not consulted.

284. On the face of the record, I have little to no doubt that the dominant, likely sole, motivation for the introduction of the Policy at SAH was to drive up immunization rates. The concern was the risk to patient safety of influenza transmission. The response to that concern was to take all possible steps to increase vaccination rates at the Hospital. VOM was adopted as the vehicle to achieve that objective. What little doubt I have about this conclusion is allayed by what happened at the Hospital in the Fall of 2013. The record is plain that Mr.

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<sup>396</sup> Diebolt Award, para. 188

<sup>397</sup> Exhibit 246, para.3

Gagnon determined that the Policy would be introduced if the target 70% immunization rate had not been reached by December 31, 2013. He also announced that the Policy would continue in 2014-2015 if an 80% target were not met by the end of March 2014. What is equally noteworthy is what is missing from the record. There is no discussion of any kind about the positive efficacy of masks throughout 2013 on the detailed record of events at SAH.

285. The motivation for VOM at SAH is entirely consistent with what has been acknowledged elsewhere. In her Report Dr. McGeer states that larger and more complex organizations have difficulty in achieving and sustaining superior rates of vaccination and that: “Programs which require that healthcare workers who choose not to be (or cannot be) vaccinated wear a mask when in patient care areas during the influenza season are associated with increases in vaccination rates.”<sup>398</sup> In the TAHSN Report, the recommendation is to use voluntary programs as a “preferred first approach” and “if ineffective, policy could move along to [the] stage of vaccinate-or-mask...”.<sup>399</sup> The TAHSN Report goes on to say: “When HCW immunization rates remain low in spite of state-of-the-art educational and incentive programs, a vaccinate-or-mask approach would be ethically defensible.”<sup>400</sup>

286. The OHA/SAH accept at least the general tenor of this description. It is conceded that low influenza vaccination rates were the backdrop that “animated the implementation of the Policy at SAH”<sup>401</sup>. In final argument counsel, while disputing the relevance of the 70% vaccination rate for purposes of assessing reasonableness, stated that the Policy:

was animated by the same considerations which occurred in BC Health [Diebolt Award], concerns on low influenza vaccination rates of healthcare workers in healthcare facilities. That backdrop animated the development of the policy at Sault Area Hospital as well.<sup>402</sup>

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<sup>398</sup> Exhibit 185, p. 40

<sup>399</sup> TAHSN Report, Exhibit 185, Appendix C, p. 19

<sup>400</sup> TAHSN Report, Exhibit 185, Appendix C, p. 19

<sup>401</sup> OHA/SAH Closing Argument, para. 37

<sup>402</sup> Transcript, July 8, 2015, p.28; See also: p. 39



287. However, Dr. McGeer and Dr. Henry defended VOM policies on another basis. As previously stated, they assert that the primary purpose of VOM policies is to prevent transmission from unvaccinated HCWs to their patients prior to symptom onset, or, in cases of asymptomatic infection.

288. Review of this stated purpose requires an assessment of the evidence said to support it, to which I now turn. I have endeavoured earlier in this Award and in the Appendices to set out a summary of that evidence at least in outline form; there is no point in repetition.

*Risk posed by unvaccinated HCWs*

289. There was vigorous disagreement about the scientific merit, and relevance to acute care hospitals, of the findings of several RCTs conducted in long term care facilities. These RCTs are said to confirm that influenza vaccination of HCWs will produce substantial all-cause mortality reduction. Dr. McGeer and Dr. Henry also rely upon several observational and experimental studies in other settings. Dr. McGeer maintains that: “since an infected healthcare worker can transmit influenza to persons he or she comes into contact with, it must be true that preventing influenza in patient care staff reduces the risk that they will transmit influenza to patients”.<sup>403</sup>

290. While the latter statement seems axiomatic, Dr. McGeer and Dr. Henry concede that there are differences between the very enclosed setting of long-term care and ambulatory or hospital care. These differences alter the balance of what is at risk from a HCW as opposed to from other people.<sup>404</sup> While the OHA/SAH experts opine that these observational and experimental studies provide support for the RCT findings, they appear to me in some cases to be quite remote and of extremely

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<sup>403</sup> See above, at para. 142

<sup>404</sup> Transcript, June 24, 2015, A. McGeer, p. 142; See above, at para. 143

limited assistance. Other experts in the field have challenged their relevance and judged some of them harshly.

291. The RCTs have also been the object of detailed criticism from other reviewers and investigators as earlier related. Dr. McGeer and Dr. De Serres, to say the least, engaged in vigorous debate as to the merit and relevance of these RCTs. I do not propose to describe, let alone make any finding concerning the quite arcane aspects of their disagreement about Dr. De Serres' calculations as to the suggested numbers needed to vaccinate in order to prevent one death in Canadian acute care facilities, his application of the epidemiological dilution principle, and his explanation of why he supports the Cochrane Review's<sup>405</sup> highly critical assessment of the RCTs. I accept Dr. McGeer's observation that determining the proportion of hospital acquired influenza that is associated with HCWs is an extraordinarily difficult challenge given the complexity and communicability of influenza.

292. However, broad controversy concerning the merit of the subject RCTs arose in the scientific community well before the commencement of this litigation and has not dissipated since the release of the Diebolt Award notwithstanding the Ahmed review. Indeed the experts have continued to debate Ahmed itself.

293. On the evidence heard in this proceeding, I am not able to conclude that Dr. McGeer's opinion--that the specific burden of influenza caused by transmission from HCWs is no longer relevant given the RCT findings--should necessarily prevail to the extent that that issue is important to the outcome of this arbitration.

#### *Asymptomatic transmission*

294. The experts do not agree about this issue either although they do agree that the scientific evidence in support of the claim, that asymptomatic transmission is

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<sup>405</sup> Exhibit 85

important, is limited. Dr. McGeer concedes that: “the truth is we simply do not know much about transmission risk at a population level”.<sup>406</sup> Dr. Henry states that there is “some evidence that people shed prior to being symptomatic and some evidence of transmission” but “there is not a lot of evidence around these pieces”.<sup>407</sup> Dr. De Serres says that there is “scant evidence”.<sup>408</sup> Dr. Skowronski, whose expertise is acknowledged by Dr. Henry who is her colleague, co-authored a letter to the Canadian Medical Association Journal stating that: “The evidence that pre-symptomatic or asymptomatic infections contribute substantially to influenza transmission remains scant.”<sup>409</sup>

295. The experts also commented upon the degree of risk attendant upon pre-symptomatic or asymptomatic virus shedding. Dr. Henry and Dr. McGeer concede that symptomatic patients will shed more particles but Dr. McGeer speculates that individual heterogeneity may mean that some asymptomatic high viral shedders are very important in transmission. On the other hand, Dr. De Serres, Dr. Gardam, and Dr. Lemieux all point to the Carrat meta-analysis to support their opinion that asymptomatic transmission is unlikely to be of clinical significance. Dr. Lemieux described the period of asymptomatic time to be a “very short window” of less than a day. Dr. Gardam said that an asymptomatic individual does not produce a lot of large droplets.

296. The several authorities relied upon by the OHA/SAH experts for their opinions on this subject, or to which they were referred, are identified previously in this Award. It is apparent that some of these studies were not about asymptomatic infection or were not cited in support of the proposition that influenza can lead to asymptomatic infection. Others concluded that viral shedding without apparent

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<sup>406</sup> See above at para. 156

<sup>407</sup> See above at para. 161

<sup>408</sup> See above at para. 155

<sup>409</sup> See above at para. 170

symptoms was infrequent. There were household studies and others involving a very small number of people.

297. Based upon my review of this material noted above and canvassed in more detail in Appendix B, and bearing in mind the concessions made about the quality of this evidence by Dr. McGeer and Dr. Henry, it appears to me that conclusions stated in the Patrozou review remain accurate:

Although asymptomatic individuals may shed influenza virus, studies have not determined if such people effectively transmit influenza...Based on the available literature, we found that there is scant, if any, evidence that asymptomatic or presymptomatic individuals play an important role in transmission.<sup>410</sup>

*Use of masks to reduce transmission risk*

298. The experts also agree that there is limited evidence on the significant point of the utility of masks in reducing transmission risk.

299. Although she referred to “good evidence” in her Report, Dr. McGeer gave oral testimony that: “It’s not great evidence...it’s hard to put a number on it, but you can’t walk away from this saying there is no evidence that wearing a mask prevents you from influenza”. She also said: “So the truth of the matter is that none of us are really experts in source control. There’s quite a limited literature.”<sup>411</sup>

300. Dr. Henry is “not a huge fan of the masking piece” and agreed that: “there’s very scant evidence about the value of masks in preventing the transmission of influenza”. It is her view however that, although the evidence is “not conclusive”, “if healthcare workers are unvaccinated, wearing masks almost certainly provides some degree of protection to their patients”.<sup>412</sup>

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<sup>410</sup> Exhibit 230, Synopsis.

<sup>411</sup> See above at para. 179

<sup>412</sup> See above at paras. 178 and 184

301. Dr. Brosseau observed that “there are a very small number of studies examining the efficacy of surgical or medical masks for protecting patients from infection” although she conceded in cross-examination that “there is in fact qualitative evidence in support of reduction of transmission of large droplets”, that she describes as a “very low probability event”. She said that in her experience the masks used at SAH<sup>413</sup> would very likely not have very good filter performance or efficiency.<sup>414</sup>

302. The literature relied upon by Dr. McGeer and Dr. Henry, and the comments of the various experts thereon, have also been previously identified and are referenced in Appendix C. There is no point in repeating what has earlier been recorded about the testimony they gave. I conclude that the most that could be said is that there is agreement that a mask is likely to prevent the transmission of large droplets at close range. I accept on the evidence of all of the experts, as did Arbitrator Diebolt<sup>415</sup>, that masking will act as a barrier and provide some patient protection when an infected person, coughing or sneezing, transmits large droplets to another person. Having said that, sick HCWs are not supposed to be at work although, of course, we know that this occurs.<sup>416</sup> I accept that the real life prospect of infected HCWs sneezing or coughing close to, or directly into, the face of patients is slim not to say that it could never occur.

303. Having considered that material and the witness commentary, I conclude as did the authors of the bin-Reza systematic review:

There are limited data on the use of masks and respirators to reduce transmission of influenza... None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection.<sup>417</sup>

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<sup>413</sup> Samples of the masks used at SAH were introduced into evidence: Exhibits 9, 10

<sup>414</sup> See above at paras. 188-189

<sup>415</sup> Diebolt Award, para.189

<sup>416</sup> As previously noted, the Policy actually contemplates that some infected employees must work (i.e. absence of worker poses a risk to patient safety): Exhibit 3, Tab A, 4, 2.4

<sup>417</sup> Exhibit 122. This was a “systematic review of the scientific evidence” published in 2011. The comment continues to be apt. It acknowledges that: “Some evidence suggests that mask use is best

*Mask-wearing issues*

304. Once again, the evidence on the impact on HCWs of long-term mask wearing has been previously reviewed above.

305. While I accept Dr. McGeer's explanation that surgical/procedure masks are worn routinely in hospitals in a variety of circumstances, the direct evidence particularly of RN Cook, that masks are unpleasant if worn for extended periods, persuades me. Her evidence, supported by the personal experiences of Dr. Lemieux and Dr. Gardam, seems to me to be irrefutable. It has a clear ring of practical truth.

306. Insofar as ONA's evidence concerning the difficulty of performing some nursing duties while wearing masks is concerned, I agree with the approach taken by Arbitrator Diebolt. If the Policy were sustained, I accept that such difficulties could and would be accommodated. If they were not, such issues could be made the subject of separate focused grievances. I do not believe that the general validity of the Policy should be tested by exceptional situations.

*Why not mask everyone?*

307. As previously explained, ONA submits that the illogicality of the VOM Policy at SAH is disclosed by the absence of a requirement to mask everyone. The Union does not of course agree that the Policy would be acceptable should the Hospital have done so.

308. Dr. De Serres, Dr. Gardam, and Dr. Lemieux provided sharp commentary on this issue in their pre-hearing material and in their testimony. It is argued that, with a vaccine efficacy rate of 60% on average, there are many vaccinated HCWs who

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undertaken as a package of personal protection especially hand hygiene." See Appendix C, paras. 404-408 below.

stand in the same shoes as their unvaccinated colleagues insofar as risk of influenza is concerned. In a mismatch year, the number of equivalently situated persons only rises, potentially to the 2014-2015 extreme outcome. If hospital authorities were convinced about the utility of masks for the purpose alleged, why not mask everyone?

309. Dr. Henry and Dr. McGeer were asked this question and, with respect, I found their answers, set out in full above<sup>418</sup>, to be less than convincing. Their more terse comments however seemed right to me. Dr. McGeer said: “The masking alternative [to vaccination] is honestly a somewhat desperate attempt to find the solution to the problem that we want to respect health care workers’ choices about vaccination.” Dr. Henry stated: “It’s a challenging issue and we’ve wrestled with it. I’m not a huge fan of the masking piece. I think it was felt to be a reasonable alternative where there was a need to do—to feel that we were doing the best we can to try and reduce risk.” Neither explained to my satisfaction, or to my understanding, why masking should not be required generally if the risk of HCW transmission is as serious as they maintain and if masks actually serve as an effective intervention. In my view their explanations do not adequately answer the contrary point of view expressed by Dr. Gardam, Dr. Lemieux, and Dr. De Serres.<sup>419</sup>

310. For the same reason, ONA also raises the issue of why the Policy does not apply to visitors and to HCW/patient interaction in other areas of the Hospital, for example, cafeterias.

#### *Conclusion re reasonableness*

311. Having considered all of the evidence led in this proceeding to the best of my ability, I reach a different conclusion than did Arbitrator Diebolt on the broad issue of reasonableness.

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<sup>418</sup> See above para. 217 (A. McGeer); para. 219 (B. Henry)

<sup>419</sup> See above at paras. 212-216

312. In short, I am not satisfied that the patient safety purpose and effect of masking has been established as it was before Arbitrator Diebolt. In that circumstance, I am left to conclude that the VOM requirement reduces to “coercive tool”, a situation that Arbitrator Diebolt said “would be troubling” if made out.

313. I find the Policy at SAH to be unreasonable for the following reasons.

*purpose*

314. The VOM Policy was introduced at SAH for the purpose of driving up immunization rates. The Hospital pursued a VOM policy despite concerns raised by senior medical staff including the Chief of Staff and the Chief Nursing Executive. The Hospital failed to consult with infectious prevention and control experts on retainer. CEO Gagnon announced that the Policy would be implemented should an immunization rate of 70% not be achieved. There is no evidence of any medical or scientific rationale for such a condition or for the 70% target rate selected.

315. In short, the laudable goal of preventing hospital-acquired influenza by enhancing vaccination rates was advanced by adoption of a VOM policy, what I see as a colourable means of accomplishing a legitimate objective. From the beginning masks were cast as a “consequence” for failure to vaccinate.<sup>420</sup> They were not advanced at SAH as useful instruments for patient safety in and of themselves.

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<sup>420</sup> See: CEO Gagnon’s reference to “consequences” as early as January 30, 2013, Exhibit 3, Tab D,15; See: Transcript, June 22, 2015. Dr. Henry commented in her direct examination that U.S. studies show that voluntary efforts to increase vaccination rates are of limited value. The only studies that show increased HCW immunization rates over a long time have included “consequences if people don’t get immunized”, vaccinate or wear a mask during influenza season; See also Exhibit 199, Dr. McGeer, “Why Vaccination Matters”, mask requirement referred to as “consequence” for refusal to vaccinate, U.S. hospitals, pp.51-53



*quality and weight of evidence*

316. Arbitrator Diebolt preferred the employers' evidence before him on the question of whether the immunization of HCWs reduces transmission of the disease to patients. He did so for four reasons: (i) the union experts overlooked a considerable body of evidence beyond the RCTs, (ii) laboratory and ethical issues pose a barrier to the conduct of RCTs in acute care facilities and, therefore, it is sensible to have regard to other forms of evidence, (iii) because an infected HCW can transmit influenza to others it must be true that preventing influenza in HCWs reduce the risk of transmission to patients, (iv) "given the areas of expertise of McGeer and Henry their evidence on the transmission issues have special relevance".<sup>421</sup>

317. For reasons previously provided, I am unable to prefer the quality of the expert opinion advanced by the OHA/SAH employer to that of ONA on the basis of comparative expertise concerning the key issues in dispute. Fair recognition of the collective research and practical expertise of Dr. De Serres, Dr. Gardam, Dr. Lemieux, and Dr. Brosseau implies not the slightest disrespect to that of Dr. McGeer and Dr. Henry.

318. The testimony of the ONA experts supported the union expert evidence set out in some detail in the Diebolt Award. What is extremely clear is that the evidence underpinning an assessment of the burden of disease caused by unvaccinated HCWs has come under heavy criticism from several reputable sources apart from the experts who appeared in this case. Arbitrator Diebolt found that union witnesses overlooked transmission evidence beyond RCTs. The ONA experts did not overlook such evidence. In my opinion the extremely limited, not to say absolute lack of, assistance of such evidence was demonstrated. While I do not find it necessary to

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<sup>421</sup> Diebolt Award, paras. 179-182

delve into the intricacies of the debate on this issue and to choose between the proponents, I am not able to prefer the views of Dr. McGeer and Dr. Henry.

319. The union position before Arbitrator Diebolt was that: “there is real doubt and little if any reliable evidence to show that silent shedders transmit influenza or that masking would inhibit such transmission.”<sup>422</sup> After weighing the competing evidence before him, Arbitrator Diebolt concluded otherwise. On what appears to be a greater depth of evidence review conducted in this proceeding, I take the opposite point of view. In my opinion ONA has established, on its own evidence and through the admissions of the OHA/SAH experts in cross-examination, that there is scant scientific evidence concerning asymptomatic transmission, and, also, scant scientific evidence of the use of masks in reducing the transmission of influenza virus to patients.

320. A question arose about what should follow if the evidence on masks was weak: ‘Is *any* evidence sufficient to sustain the policy or where is the line drawn?’<sup>423</sup> To paraphrase the answer of the Hospital: ‘something has to be found if HCWs fail to vaccinate, some evidence of source control protection is sufficient’. To quote directly:

You should be comforted that Arbitrator Diebolt had the same issue. And he said, it’s not as fulsome, it’s not as complete, there’s not as many years studying this, there’s some evidence. He found the qualitative evidence was there. In terms of the spectrum, I’m not sure whether it has to be some or any, but the point being it is absolutely not on to say there is no evidence...this is an acute care hospital with a number one obligation of patient safety—and I’ll use the word that Dr. McGeer used—struggling, therefore with the fact that they have to recognize there’s a collectively bargained provision in 18.07 that acknowledges a right to refuse, it’s not required to vaccinate...But they are, therefore, having to recognize we have to find something, if you choose not to vaccinate, that provides we’re comforted with some protection as source control...even if you said it’s, to my view, not as strong as Arbitrator Diebolt says, that you still have to find there is some evidence and they’re seeking some solution of protection.<sup>424</sup>

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<sup>422</sup> Diebolt Award, para.190

<sup>423</sup> Transcript, July 8, 2015, p.126

<sup>424</sup> Transcript, July 8, 2015, pp.127-128

321. The word “some” of course is an adjective that may convey a wide range of meaning depending upon the context of its use. “Some” might mean ‘very little’ or ‘quite a lot’. I am not able to conclude that “some” evidence, evidence as scant as appeared here, is sufficient to bear the weight of a Policy such as this one.

322. The assertion that a mask requirement serves a valuable or essential purpose, albeit that there is only “some” evidence, is also weakened by actual employer practice. If the mask evidence were as supportive as claimed, it would suggest that vaccinated HCWs should also wear masks given the limited efficacy of the vaccine even in relatively ‘good’ years. The SAH Chief of Medical Staff raised this question at the outset. The Hospital’s failure to consider re-evaluating the Policy’s application when the extent of the 2014-2015 vaccine mismatch became known raises the same issue. The OHA/SAH expert responses to these questions set out in full above<sup>425</sup> were short of satisfying.<sup>426</sup>

*the ‘ask’*

323. Wearing a mask for an entire working shift, virtually everywhere, no matter the patient presenting circumstances, is most unpleasant. While I readily accept that the wearing of a mask for good reason may reasonably be expected of HCWs, an *Irving* “balancing of interests” is required. The Policy makes a significant ‘ask’ of unvaccinated employees; that is to wear an unpleasant mask for up to six months at a time. As noted, the evidence said to support the reason for the ‘ask’—evidence concerning asymptomatic transmission and mask effectiveness--may be described at best as “some” and more accurately as “scant”. I conclude that many of the articles footnoted in support of the strong opinions set out in the OHA/SAH expert

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<sup>425</sup> See above at paras. 217 and 219

<sup>426</sup> The Policy’s exceptions for visitors, and certain other HCW/patient areas of the Hospital, were not explained in evidence although the Union had raised these issues. OHA/SAH counsel speculated in an answer to a question in argument that there may have been enforcement considerations. See: Transcript, July 8, 2015. p.137

Reports provide very limited or no assistance to those views. The required balancing does not favour the Policy.

*existing policies*

324. There has been no showing as to why current Hospital policies are not adequate or could not be amended, if necessary to the extent necessary, to carry out the stated patient safety purpose of the Policy. They already speak to precautions required where there may be transmission of droplets to another person within two metres. There were no influenza outbreaks at the new Hospital site prior to the introduction of the Policy. Ironically, an outbreak, that occurred on three units after VOM implementation, affected 16 patients and staff of whom 75% had previously received influenza vaccination. The current Infection Control Manual that includes a mask component is said to apply to patients and staff although the focus is plainly upon patients with infection.<sup>427</sup>

*inconsistency with collective agreement*

325. I have found that the Policy was instituted for the purpose of increasing vaccination rates to a target figure deemed acceptable by the Hospital and that there is insufficient evidence to support its introduction on any other basis. In that circumstance, I conclude that the Union has established that the Policy is inconsistent with the collective agreement and therefore fails item #1 of the *KVP* test as well. The Policy is not a reasonable rule as would otherwise be permissible pursuant to Article B-1 (e) of the ONA/SAH Local Agreement.

326. ONA and the OHA/SAH have negotiated a detailed influenza outbreak protocol that includes recognition of the benefit of influenza vaccine. It also, in Article 18.07, recognizes the right of nurses to refuse any required vaccination. The

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<sup>427</sup> Exhibit 2, IPAC Policy II-25, B and C

imposition of a mask requirement, without sufficient justification relating to the use of masks, is tantamount to an impermissible penalty upon a nurse choosing to exercise that right. In this regard, I note Dr. Henry's recognition that the wearing of a mask could be reasonably regarded as a "consequence" for failure to consent to vaccination.<sup>428</sup> The Policy is inconsistent with Article 18.07 (c) in that it operates to undermine the right of nurses to refuse any required vaccination.

*accommodative purpose*

327. Rather than finding, as did Arbitrator Diebolt, that a VOM policy provides a legitimate "accommodative purpose for health care workers who conscientiously object to immunization"<sup>429</sup>, I conclude that the Policy more closely resembles an unacceptable Hobson's choice. I am not persuaded by Dr. McGeer's speculation that a VOM policy focuses employees' attention and may encourage truly voluntary immunization, nor, am I convinced that the continuance of a minority employee group who choose to mask disproves the effectively coercive aspect of VOM.<sup>430</sup> I note the evidence of RN Poldmaa who told her manager that: "I felt I was being publicly put on display for choosing not to get the flu shot. I told her I felt I was being bullied into it and harassed."<sup>431</sup>

*practices elsewhere*

328. I find little comfort in references to practices elsewhere.<sup>432</sup> Dr. Gardam's concerns about the TAHSN process and the recommendations of other bodies are

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<sup>428</sup> See also Exhibit 199 where Dr. McGeer speaks to "consequences" also. See also references above at Footnote 420.

<sup>429</sup> Diebolt Award, para.188

<sup>430</sup> Transcript, July 8, 2015, pp. 123-124

<sup>431</sup> Transcript, October 9, 2014, p. 14

<sup>432</sup> See: Exhibit 185, A. McGeer Report, p. 54; See also: Diebolt Award at paras. 194-196

concerning<sup>433</sup> although I do not depend upon his extremely critical recitation. What I find more noteworthy is that the provincial authorities have not taken steps in Ontario to designate influenza for mandatory HCW immunization or to require or recommend the consideration or implementation of some form of a province-wide VOM policy. There is a clear statutory basis for the designation of diseases requiring vaccination.

### *Privacy issues*

329. In view of my conclusion that the VOM Policy is unreasonable and contravenes *KVP* principles, it is not necessary that ONA objections to the Policy on the ground that it violates employee privacy rights be addressed. For reasons of completeness, if my conclusion concerning the Policy's reasonableness is in error, I make the following brief comments.

330. Assuming the validity of the Policy, and assuming the voluntariness of the employees' consent, I would have reached the same conclusion as Arbitrator Diebolt on the narrower privacy issue, albeit under separate provincial legislation.

331. In the face of these identified assumptions, I would have accepted the submission of the OHA/SAH that the information at issue would have been excluded from protection under the *Personal Health Information and Privacy Act* ("*PHIPA*") by virtue of ss. 4(4) of that Act and would have been similarly excluded from protection by virtue of ss. 65(6) para. 3 of the *Freedom of Information and Protection of Privacy Act* ("*FIPPA*").

332. Subsection 4(4) of *PHIPA* excludes certain information from the application of the Act as follows:

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<sup>433</sup> See above, paras 240-241; If Dr. Gardam's assessment is correct, there is a serious public health policy determination process problem concerning this issue.

4. (4) Personal health information does not include identifying information contained in a record that is in the custody or under the control of a health information custodian if,

- (a) the identifying information contained in the record relates primarily to one or more employees or other agents of the custodian; and
- (b) the record is maintained primarily for a purpose other than the provision of health care or assistance in providing health care to the employees or other agents.

333. Subsection 65(6) para. 3 of *FIPPA* similarly excludes certain information from the Act's ambit:

65. (6) Subject to subsection (7), this Act does not apply to records collected, prepared, maintained or used by or on behalf of an institution in relation to any of the following:

....

- 3. Meetings, consultations, discussions or communications about labour relations or employment-related matters in which the institution has an interest.

334. While not binding, a decision of an analyst from the Office of the Information and Privacy Commissioner of Ontario is instructive on these points.<sup>434</sup> The decision deals with a nurse's complaint about a VOM policy at North York General Hospital in which individuals who received the influenza vaccine had identifying stickers on their badges or a lanyard of a different colour. The nurse argued that this improperly made her persona health information public knowledge. Broadly stated, under the VOM Policy, vaccination information is collected about employees and is maintained for a purpose other than the provision of health care to those employees. As a result, it is excluded under ss. 4(4) of *PHIPA*. The information is also collected, maintained and used by the SAH for the purpose of implementing a VOM Policy setting out terms and conditions of work and so relates broadly to labour relations or employment-related matters in which the institution has an interest. As a result, it is also excluded under ss. 65(6) of *FIPPA*.

335. Ultimately, though, these observations on the privacy legislation are *obiter* and do not affect the determination of these grievances because I have ruled that the VOM Policy as a whole fails to comply with *KVP* principles and so constitutes an unreasonable exercise of management rights. In the course of that determination, I

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<sup>434</sup> Complaint HC 14-108 re North York General Hospital, March 26, 2015 (Rioux)

have also ruled that I am not convinced that the VOM Policy encourages truly voluntary immunization and/or disclosure of immunization status.

### **Final Comments**

336. I return now to the issue raised at the outset of this Award.

337. Let there be no doubt that the intentions and opinions of CEO Gagnon, Dr. McGeer, and Dr. Henry are entitled to great respect. However, the VOM Policy—a mandated regimen for how patient care is to be delivered—is at the same time a unilaterally imposed term and condition of employment and it is properly and squarely within an arbitrator’s jurisdiction to assess it as such. While this has not been an easy case because of the volume of expert evidence and the quality of the competing expertise, the only forum in which it can be required that labour relations considerations be addressed is before an arbitrator.

338. To review the labour relations implications of the VOM Policy does not disregard or discount the medical expertise. It simply recognizes that the medical expertise has a different focus that is incomplete for the purposes of the legal question at issue. While important in assessing what is reasonable, the medical expertise is not controlling in and of itself because it does not engage the labour/human rights/privacy expertise that balances employee rights with scientific information.<sup>435</sup>

339. It is surely the case that there are better ways of resolving complex policy issues such as this, in which many stakeholders have an interest, but this does not in any way displace or discredit the legitimate role of labour arbitration. It is very likely that the science will evolve and opinions about the prevention and control of influenza disease may coalesce into more of a consensus than has been achieved to

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<sup>435</sup> The TAHSN Report acknowledges certain of these interests as noted above. See: Exhibit 185, Appendix C.



date. But, there are lines to be drawn in the meantime. Where their working lives are directly affected, the interests of employees require consideration, and, typically, their unions have recourse to rights arbitration to test judgments that have been made.

340. *Irving* balancing demands nuance and it is not sufficient to claim that scant, weak, “some”, or imperfect data is better than nothing. While the precautionary principle (“reasonable efforts to reduce risk need not wait for scientific certainty”<sup>436</sup>) surely applies in truly exceptional circumstances, one could not live in a society where only ‘zero risk’ was tolerated. It cannot be right that a labour arbitrator should effectively abdicate by simply applying *Dunsmuir*-type deference to expert opinion planted in shallow soil.

341. It is also important to stress once again what this arbitration case was not about. The Award does not address the merits of influenza vaccination--a matter about which the experts agree and about which ONA and the OHA have reached specific agreement in the Central Collective Agreement. Nothing in this Award is intended to dissuade anyone from the benefit of annual influenza immunization whatever may be the vaccination efficacy rate in any particular year.

## **Decision**


342. On the evidence before me, I find the VOM provisions of the SAH Policy to be unreasonable. Accordingly, for all of the foregoing reasons, I declare SAH to be in breach of Article B-1 (e) of the ONA/SAH Local Agreement and Article 18.07 (c) of the ONA Central Agreement.

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<sup>436</sup> Cited in Diebolt Award, para. 196; See also: Transcript, January 26, 2015, pp.84-86 where Dr. Lemieux provides an extended explanation as to why the principle does not apply to influenza in her opinion where it would concerning SARS, Ebola, MERS and the like.

343. Any question concerning the need, if any, for additional relief is remitted to the parties for their consideration. I remain seized of remedial issues.

Dated at Toronto, this 8<sup>th</sup> day of September, 2015

  
James Hayes

## APPENDIX A

*Literature cited in relation to HCW disease burden issue: witness commentary concerning observational/experimental studies*

*Kuster*<sup>437</sup>

344. Dr. McGeer was a co-author. She acknowledged that one of the results of the study was that: “We did not identify an increase in the risk of influenza among workers in acute care hospitals compared to office space workers during the 2009 pandemic”.<sup>438</sup> She agreed that there were no recommendations in this study of risk factors amongst healthcare workers that everybody be masked.<sup>439</sup>

345. Referring to Kuster, Dr. Henry said: “There is one study that was done that finds a little bit of evidence that we as health care workers might be more at risk because of our contacts within the health care setting than people who aren’t health care workers”.<sup>440</sup>

346. Dr. De Serres explained that the study demonstrated that: “obviously there was concern that people would be at much greater risk because of their exposure at work and, in fact, what was found in that paper that the most influential factor was acquiring influenza in your household, not at work.”<sup>441</sup>

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<sup>437</sup> Exhibit 62

<sup>438</sup> Exhibit 62, p.614; Transcript, June 26, 2015, p.113

<sup>439</sup> Transcript, June 26, 2015, p.115

<sup>440</sup> Transcript, June 22, 2015, p.97

<sup>441</sup> Transcript, May 19, 2015, p.47

*Vanhems*<sup>442</sup>

347. This prospective study concluded that: “results indicate that the risk of HA-ILI [hospital acquired influenza like illness] increased with the level of exposure to contagious patients and HCWs. Preventive actions, including hygiene measures and vaccination, might reduce HA-ILI and influenza incidence during hospital stays.”<sup>443</sup>

348. There was no mention of masks as a possible preventive action.

349. Dr. McGeer commented:

I think you can argue it’s not surprising that there’s transmission of respiratory viruses in health care, but the truth is that we have not had the demonstration of that before. So, this is a very clear demonstration that we transmit viruses that cause influenza-like illness on acute care medicine floors, and that the presence of a person, whether they are a patient or a health care worker on that floor with influenza-like illness creates a significant risk for other patients on that floor.<sup>444</sup>

*Benet*<sup>445</sup>

350. This observational study looked back at information to see if there was an increased risk of acquiring influenza depending on whether there were other people (HCWs or patients) on the ward with influenza.

351. Dr. McGeer testified that the article demonstrated that: “patients on wards where more than 35 percent of workers were vaccinated were much less likely to develop hospital-acquired influenza than patients on floors where less than 35 percent were vaccinated”.<sup>446</sup>

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<sup>442</sup> Exhibit 191

<sup>443</sup> Exhibit 191, p.156

<sup>444</sup> Transcript, June 24, 2015, p.138

<sup>445</sup> Exhibit 161

<sup>446</sup> Transcript, June 24, 2015, p.139; See also; Transcript, June 22, 2015, B. Henry, p. 154

352. By way of comparison, it should be noted that the vaccination rate at SAH was well above 35% before implementation of the Policy.<sup>447</sup>

*Loeb*<sup>448</sup>

353. This study involved a relatively closed Hutterite community.

354. Dr. Henry agreed that the Hutterite community is “nothing like an acute care hospital like Sault Area Hospital”.<sup>449</sup> She said that it was a “useful sort of test case...it’s more like a family unit, so it helps understand what can happen in transmission potentially in a closed setting”.<sup>450</sup>

355. When it was suggested to Dr. McGeer that Osterhom and others had concerns about drawing conclusions from Hutterite studies, she replied:

I don’t think any of us think that you can take data from Hutterite colonies or schoolchildren and apply them directly to acute care hospitals. The fact that you can’t apply them directly does not mean that their results don’t have some value in thinking about what happens in close contacts in acute care hospitals.<sup>451</sup>

*Pollara*<sup>452</sup>

356. Dr. McGeer confirmed that the authors of this observational study said that they were unable to determine whether HCWS or visitors contributed to transmission.<sup>453</sup>

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<sup>447</sup> As of December 29, 2013 the composite flu shot percentage for employees, physicians and volunteers was 60%. See: Exhibit 3, Tab E, 46

<sup>448</sup> Exhibit 159

<sup>449</sup> Transcript, June 23, 2015, p.84

<sup>450</sup> Transcript, June 23, 2015, p.85

<sup>451</sup> Transcript, June 26, 2015, pp.216-217

<sup>452</sup> Exhibit 236

<sup>453</sup> Transcript, June 26, 2015, p.218

*Patriarca*<sup>454</sup>

357. Dr. McGeer agreed that this study did not deal with staff vaccination. It was included in error.<sup>455</sup>

*Chan*<sup>456</sup>

358. Dr. McGeer confirmed that this article concerned a single outbreak and that the index patient had symptoms before the HCWs. It was unknown as to whether any of the patients or HCWs had previously received vaccine. The article is “not about the fact that healthcare workers start outbreaks, it is about the fact that when you have influenza outbreaks, both healthcare workers and patients develop illness”.<sup>457</sup>

*Salgado (2004)*<sup>458</sup>

359. Dr. McGeer said that: “I’m not sure I would even call it a study. This is a description of change over time in a hospital that introduced an influenza vaccination program for healthcare workers.” It was not possible to determine which of the multiple interventions introduced effected any change. “You can only say that there is a temporal association between the increase in vaccination and the decrease in the percentage of hospital-acquired infections in patients.”<sup>459</sup>

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<sup>454</sup> Exhibit 235: Salgado *et al*, “Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians”, *Infection Control and Hospital Epidemiology*, Vol. 25, No. 11 (November 2004), pp. 923-928

<sup>455</sup> Transcript, June 26, 2015, p.210

<sup>456</sup> Exhibit 237

<sup>457</sup> Transcript, June 26, 2015, pp.220-221

<sup>458</sup> Exhibit 239

<sup>459</sup> Transcript, June 26, 2015, pp.226-227

*Van Buynder*<sup>460</sup>

360. Dr. Van Buynder was involved with Dr. Henry in implementing the VOM policy in British Columbia. The study concerned one health care unit and demonstrated that, following the policy, there had been an all-cause reduction in employee sick hours. Dr. Henry acknowledged that the study had limitations. She agreed that it did not control for important cofounders such as health status or health behaviours such as smoking.<sup>461</sup>

*Salgado (2002)*<sup>462</sup>

361. Dr. Henry explained that: “this was one of the first papers that came out that actually quantified the fact that influenza does happen in acute hospital settings”. The question had been whether, compared to long-term care homes, there was a “need to monitor for influenza in acute care facilities where the patient population is much more transient...”<sup>463</sup>

*Shugarman*<sup>464</sup>

362. Dr. Henry explained that this study demonstrated that vaccination of both patients and HCWs was important in the reduction of transmission.<sup>465</sup> It looked at influenza like illness and not specifically at influenza.<sup>466</sup>

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<sup>460</sup> Exhibit 142

<sup>461</sup> Transcript, June 22, 2015, pp.262-267

<sup>462</sup> Exhibit 153

<sup>463</sup> Transcript, June 22, 2015, p.101

<sup>464</sup> Exhibit 160

<sup>465</sup> Transcript, June 22, 2015, pp.145-146

<sup>466</sup> Transcript, June 23, 2015, p.73; See also: Transcript, June 26, 2015, A. McGeer, p.213

*Stevenson (2001)*<sup>467</sup>

363. Dr. McGeer was a co-author of this study. Dr. Henry agreed that it demonstrated an effect of increased vaccination rates in facilities with fewer than 100 beds but not in those that had more.<sup>468</sup>

*King*<sup>469</sup>

364. This was a study involving school-based vaccination. Dr. Henry stated that this study looked at ILLs and was not placebo-controlled. The study acknowledged its limitations. She agreed that such programs are significantly different than hospital-based vaccination programs.<sup>470</sup>

365. When it was suggested to Dr. McGeer that reliance on school-based evidence was problematic, she explained:

If you are looking at making a decision about acute care hospitals, the closer the situation is to acute care hospitals the more directly applicable it is. But no, I would not agree that the evidence related to whether vaccinating people reduces illness in their close contacts is irrelevant despite the fact that it is in a different setting.<sup>471</sup>

*Monto*<sup>472</sup>

366. Dr. Henry agreed that this observational study: “is not a very strong study in design...it’s just a piece of the evidence that’s out there that needs to be considered”.<sup>473</sup> “It’s clearly not referring to a healthcare setting.”<sup>474</sup>

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<sup>467</sup> Exhibit 164

<sup>468</sup> Transcript, June 23, 2015, p.62

<sup>469</sup> Exhibit 168

<sup>470</sup> Transcript, June 23, 2015, pp.76-78

<sup>471</sup> Transcript, June 26, 2015, p.215

<sup>472</sup> Exhibit 169

<sup>473</sup> Transcript, June 23, 2015, pp.86-87

<sup>474</sup> Transcript, June 23, 2015, p.88



*Grund*<sup>475</sup>

367. Dr. McGeer said that: “they consider it circumstantial evidence that healthcare workers were involved in the outbreak but you can’t be sure that healthcare workers didn’t have, that the respiratory illness they had during the outbreak wasn’t due to something else, and the antibodies were due to illness at another time.”<sup>476</sup>

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<sup>475</sup> Exhibit 238

<sup>476</sup> Transcript, June 26, 2015, p.224

## APPENDIX B

*Literature cited in relation to asymptomatic transmission issue: witness commentary*

*Loeb*<sup>477</sup>

368. Dr. Henry described this article as: “one of those studies that help support that there is some asymptomatic shedding of virus that could be transmissible to other people”.<sup>478</sup>

369. Dr. McGeer confirmed that this study was conducted in a closed Hutterite community, that the authors concluded that “viral shedding without apparent symptoms was infrequent, occurring in 10 per cent of episodes”, and that “the viral loads of asymptomatic participants were lower and of shorter duration than those who were symptomatic, suggesting that asymptomatic transmission may be less frequent and less efficient than symptomatic transmission”. She agreed that this rate of asymptomatic infection was similar to that identified in the Lau study<sup>479</sup> at 14% but suggested that the authors would have “missed some episodes of asymptomatic infection” because to detect such infection “you have to do a lot of swabbing of people and that is both expensive and relatively unpleasant”.<sup>480</sup>

*Suess*<sup>481</sup>

370. Dr. Henry in chief described this as a household study conducted during a pandemic that illustrated that “people can release virus into the community that’s potentially transmissible to others even before they show symptoms themselves”.<sup>482</sup>

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<sup>477</sup> Exhibit 106

<sup>478</sup> Transcript, June 22, 2015, p. 98

<sup>479</sup> See: Exhibit 228

<sup>480</sup> Transcript, June 26, 2015, pp. 77-80

<sup>481</sup> Exhibit 107

<sup>482</sup> Transcript, June 22, 2015, p. 99

371. Dr. McGeer confirmed that: “This study was not dealing with whether transmission occurred from asymptomatic people”. She agreed that the authors identified as a limitation of the study that “most analysis of shedding characteristics were done among ILI patients which are likely not representative of all influenza patients” and that they could not measure the difference between viral shedding in asymptomatic and symptomatic people.<sup>483</sup>

*Freitas*<sup>484</sup>

372. This was an outbreak report relating to a family. The asymptomatic individual hugged, kissed and shared a bed with the persons who contracted influenza. None of her co-workers were infected.

373. Dr. Henry asserted that the report demonstrated that influenza could be transmitted prior to symptom onset<sup>485</sup> but acknowledged that this was a single situation and that none of the index case’s co-workers got sick.<sup>486</sup> Dr. McGeer agreed that this was an investigation and not a study and acknowledged that “there is a greater risk of transmission in households than between workers”.<sup>487</sup>

*Esbenshade*<sup>488</sup>

374. Dr. Henry agreed in cross-examination that this article was not about asymptomatic infection leading to influenza and was included in her Report only “to show that healthcare workers do actually work while they’re infected”.<sup>489</sup>

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<sup>483</sup> Transcript, June 26, 2015, pp. 69-77

<sup>484</sup> Exhibit 158

<sup>485</sup> Transcript, June 22, 2015, p. 127

<sup>486</sup> Transcript, June 23, 2015, pp. 104-107

<sup>487</sup> Transcript, June 26, 2015, pp. 95-97

<sup>488</sup> Exhibit 170

<sup>489</sup> Transcript, June 23, 2015, p. 118

*Wilde*<sup>490</sup>

375. Dr. Henry confirmed that this study was included to demonstrate that “hospital employees report to work despite having febrile illness and that this supported their [the authors’] contention that efforts to vaccinate healthcare professionals were important”.<sup>491</sup>

*Elder*<sup>492</sup>

376. Dr Henry agreed in cross-examination that this study was not cited in support of the proposition that influenza can lead to asymptomatic infection.<sup>493</sup>

*Sheat*<sup>494</sup>

377. This was an outbreak report arising from telephone interviews of 26 people who bagged fertilizer for a day while one was not feeling well. 16 of them had ILI afterward. Many reported having shared drinking containers.

378. Dr. McGeer said that this was “an illustration of a case in which there appeared to be transmission of influenza before the person recognized that they had an acute respiratory disease”. She agreed that: “there is a dearth of data on transmission before the onset of infection because it’s so hard to study. There’s—we all agree on that”. She agreed that healthcare workers do not share bottles or water or liquids in containers with patients.<sup>495</sup>

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<sup>490</sup> Exhibit 171

<sup>491</sup> Transcript, June 23, 2015, p. 121

<sup>492</sup> Exhibit 172

<sup>493</sup> Transcript, June 23, 2015, pp. 123-124

<sup>494</sup> Exhibit 225

<sup>495</sup> Transcript, June 26, 2015, pp. 85-86

*Gu*<sup>496</sup>

379. This investigation involved students who had played video games on a train sharing the controller.

380. In Dr. McGeer's opinion the authors "weren't looking for asymptomatic transmission" but she accepted their conclusion that people in this outbreak "were transmitting disease before they were symptomatic". She agreed that the investigation concerned a total of eight people.<sup>497</sup>

*Carillo-Santistev*<sup>498</sup>

381. This outbreak investigation concerned a group of school children who went to the United Kingdom from Paris. An effort was made to identify the source of an ILI infection that might have been either a teacher or a 10-year-old girl. Dr. McGeer confirmed the conclusion of the authors that: "Further work is needed to better define conditions under which the pandemic virus may transmit in a school setting and in households".<sup>499</sup>

*Lau*<sup>500</sup>

382. Dr. McGeer confirmed this report's conclusion that: "Our results suggest that 'silent spreaders' (i.e. individuals who are infectious while asymptomatic or presymptomatic) may be less important in the spread of influenza epidemics than previously thought". She stated that their 14% figure was less than anticipated.<sup>501</sup>

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<sup>496</sup> Exhibit 226

<sup>497</sup> Transcript, June 26, 2015, pp. 87-91

<sup>498</sup> Exhibit 227

<sup>499</sup> Transcript, June 26, 2015, pp. 91-95

<sup>500</sup> Exhibit 228

<sup>501</sup> Transcript, June 26, 2015, pp. 99-101

*Hermes*<sup>502</sup>

383. Dr. McGeer did not reference this study in her Report. She agreed that the fact pattern resembled others that she had relied upon. However, she testified that the fact that the authors “did not find presymptomatic transmission...in a relatively small group of patients...it’s not important and useful information; it just doesn’t help you with whether presymptomatic or asymptomatic transmission is important at some level”.

384. She agreed that the findings of these authors: “was opposite of the one that you gave us. There was no evidence of presymptomatic transmission.”<sup>503</sup>

*Patrozou*<sup>504</sup>

385. The published synopsis of this literature review stated that:

We performed a systematic review of published studies describing the relationship between viral shedding and disease transmission. Based on the available literature, we found that there is scant, if any, evidence that asymptomatic or presymptomatic individuals play an important role in transmission. As such, recent articles concerning pandemic planning, some using transmission modeling, may have overestimated the effect of presymptomatic or asymptomatic influenza transmission. More definitive transmission studies are sorely needed.

386. Dr. McGeer noted that this review was written before the 2009 pandemic and that none of the later case studies (4) would have been included.<sup>505</sup>

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<sup>502</sup> Exhibit 229

<sup>503</sup> Transcript, June 26, 2015, pp. 101-103

<sup>504</sup> Exhibit 230

<sup>505</sup> Transcript, June 26, 2015, pp. 103-111

## APPENDIX C

### *Mask and related literature: witness commentary*

#### *Johnson*<sup>506</sup>

387. As previously noted, with an important qualification, Dr. Brosseau confirmed the opinion of Dr. McGeer<sup>507</sup> and Dr. Henry that the study provides “some limited qualitative evidence” that a mask may prevent the release of large droplets. Dr. Henry testified that: “this study showed, in a small number of people, that both surgical masks and the respirator were good at trapping the droplets in, that they didn’t come through the mask when somebody coughed”.<sup>508</sup>

388. Dr. Brosseau noted that the study involved individuals coughing directly into Petri dishes with and without a mask. She stated that: “the Johnson study really gives you no data about the capture by a filter or a surgical mask of these smaller infectious particles”.<sup>509</sup> She described the study this way:

That Petri dish is probably just capturing the very large ones that are going straight out of the mouth...bases on my knowledge of aerosols and samplings and particle size, that it is those large droplets that are emitted straight outward during coughing that were captured by the Petri dish. Anything that was smaller that would have been emitted to the side or through the filter would not have been captured by that Petri dish.....this study offers qualitative support that a surgical mask may be able to stop the release of large particles greater than 5 to 10 microns from a person who is coughing or sneezing directly into the mask worn over their mouth and nose.<sup>510</sup>

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<sup>506</sup> Exhibit 27

<sup>507</sup> Transcript, June 24, 2015, pp. 148-149

<sup>508</sup> Transcript, June 22, 2015, p. 84

<sup>509</sup> Transcript, May 11, 2015, p. 191

<sup>510</sup> Transcript, May 11, 2015, pp. 189-190

*Milton*<sup>511</sup>

389. The Abstract for this study reads in part:

The CDC recommends that healthcare settings provide influenza patients with facemasks as a means of reducing transmission to staff and other patients and a recent report suggested that surgical masks can capture influenza virus in large droplet spray. However, there is minimal data on influenza virus aerosol shedding from patients with seasonal influenza....Overall, masks produced a 3.4 fold (95% CI 4.1 to 19) reduction in viral aerosol shedding....Surgical masks worn by patients reduce aerosols shedding of virus. The abundance of viral copies in fine particle aerosols and evidence of their infectiousness suggests an important role in seasonal influenza transmission. Monitoring exhaled virus aerosols will be important for validation of experimental transmission studies in humans.

390. Dr. Brosseau concluded that the Milton study demonstrated that surgical masks “offer little or no reduction in small infectious aerosols from the wearer”.<sup>512</sup>

391. Dr. McGeer commented that a 3.4 fold reduction is:

not a big enough reduction to really matter in her [Dr. Brosseau’s] world of occupational hygiene...To me, living with influenza, where nothing is perfect, and everything has to be judged on its relative benefit a 3.5 fold reduction is not half bad, okay. So, I think it is incorrect to say the surgical mask does not reduce the emission of small, inhalable, infectious particles. It does reduce it. It just doesn’t reduce it as completely as it reduces the emission of larger particles at the same time.<sup>513</sup>

*Makison Booth*<sup>514</sup>

392. The witnesses confirmed<sup>515</sup> that this study was conducted with dummies and focused on the performance of masks in protecting the wearer. Dr. Lemieux said that she did not view the article as “being particularly on point”.<sup>516</sup>

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<sup>511</sup> Exhibit 28

<sup>512</sup> Exhibit 50, Response to Comments, at first unnumbered page

<sup>513</sup> Transcript, June 24, 2015, pp. 98-99; See also: Transcript at pp. 149-150 where reference is made to a 2.8 fold reduction in small particles as a “non-trivial reduction”.

<sup>514</sup> Exhibit 29

<sup>515</sup> Exhibit 50, Report, L. Brosseau, Response to Comments, at second unnumbered page; Transcript, June 26, 2015, p. 14

<sup>516</sup> Transcript, January 26, 2015, p. 163



*Loeb*<sup>517</sup>

393. Dr. Lemieux explained that this study was a non-inferiority trial stating that:

This study simply looks at whether a surgical mask is any different than a N95 respirator preventing influenza among healthcare workers. It's really just comparing one to the other. And the only conclusion that can be drawn from this particular study is that a mask is as good as a N95...in terms of rates of laboratory confirmed influenza among healthcare workers. It says nothing about protecting patients. It says nothing about asymptomatic transmission and it really doesn't address the crux of any of the issues I think we're trying to get at today.<sup>518</sup>

394. Dr. Lemieux also went on to make an observation that she said applied to a number of studies, including *Loeb*, that she did not see as helpful to consideration of the merits of a VOM policy:

These studies look at more than one intervention to control influenza transmission. If you're combining a number of interventions—and in this case, on the face of it, face masks and hand hygiene—it's virtually impossible to tease out what the relative impact is of one versus the other. We know that combined they have an impact. We can't specifically say that face masks had a predominant effect, we just know that both together did. I don't think it speaks at all to specifically whether masking as an intervention in healthcare workers will have a priority impact on transmission.<sup>519</sup>

*Mansour*<sup>520</sup>

395. Dr. Brosseau explained that the study involved placing types of masks and respirators with varying fits on mannequins, located about three feet away using small radioactive aerosols, with the source mannequin generating an aerosol. She testified that:

So what they're basically saying is if you put anything on the source, a loose surgical mask, a tight fitting surgical mask, an N95 respirator or a sealed N95 respirator sealed to the face, the receiver gets no exposure, it's zero....if the infectious source, whether you're wearing a surgical mask or an N95 respirator and you seal the respirator to your face, you can reduce the amount of transmission basically at the receiver. Now I should be clear, while these are small particles, what we're not measuring is what is the size distribution of the particles at the point where the exposure is being measured...I wish they had just taken this one more step and measured the size distribution of the particles at the point where the exposure filter is, because that would have told us the story about large versus small particles. But what this is telling you is that a source can wear

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<sup>517</sup> Exhibit 30

<sup>518</sup> Transcript, May 11, 2015, pp. 99-100

<sup>519</sup> Transcript, May 11, 2015, p. 104

<sup>520</sup> Exhibit 56

anything, and that at least—and this agrees with what I’ve been saying, at least all the large particles are eliminated.<sup>521</sup>

396. Dr. Henry also noted the lack of exposure to droplets and stated further that the fit of a mask or respirator “made a difference in terms of preventing droplets from being expelled”.<sup>522</sup>

397. Dr. McGeer noted that “as the fit gets better on either the source or receiver the number of particles that get through to the receiver’s respiratory tract goes down”.<sup>523</sup>

*Cowling (2009)*<sup>524</sup>

398. As explained by Dr. Henry, this was a randomized control trial done in household settings. She stated that: “not surprisingly”, “Things like hand hygiene, cleaning your hands regularly were important but use of face mask along with hand hygiene seemed to provide some benefit in prevention of a whole host transmission of influenza”.<sup>525</sup>

399. Dr. McGeer commented at some length on the applicability of studies not conducted in acute care settings:

I think there is an argument that says that if you look at, you know, in this setting, in households, in university residences, on aircraft, if you look at the case control study there, all of them have some evidence that a mask provides some protection....I mean, they’re unquestionably not the best evidence. I’m very sympathetic to Dr. Brosseau’s world of order and organization, and you don’t get that level of organization when you do studies in households. It’s difficult to interpret studies when there are issues with adherence...but to my mind it doesn’t alter the fact that there is some evidence that wearing a mask, particularly wearing a mask in combination with good hand hygiene, can reduce your risk of infection at least in some circumstances.<sup>526</sup>

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<sup>521</sup> Transcript, May 11, 2015, pp. 201-203

<sup>522</sup> Transcript, June 22, 2014, pp. 88-9

<sup>523</sup> Transcript, June 25, 2015, p. 224

<sup>524</sup> Exhibit 31

<sup>525</sup> Transcript, June 22, 2015, p. 89

<sup>526</sup> Transcript, June 24, 2015, pp. 153-154

*Suess*<sup>527</sup>

400. This was a cluster randomized household trial conducted in Berlin unrelated to hospitals or healthcare. It concluded that: “household transmission of influenza can be reduced by the use of non-pharmaceutical interventions such as facemasks and intensified hand hygiene when implemented early and used diligently”.<sup>528</sup>

*Zhang*<sup>529</sup>

401. This study concerned influenza infections that developed in passengers after travelling on flights from New York to China. The authors concluded that: “We recommend a more comprehensive intervention study to accurately estimate the protective effect of face masks for preventing influenza virus transmission on long-distance flights”.<sup>530</sup>

402. When asked to comment on what this study has to say about VOM, Dr. Lemieux said that it indicates that wearing a mask will provide some level of protection against clinical disease around a person known to be symptomatic.<sup>531</sup>

403. As previously stated, Dr. McGeer conceded that this study was “unquestionably not the best evidence”<sup>532</sup>. She noted that the investigation self-reported several limitations.<sup>533</sup>

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<sup>527</sup> Exhibit 32

<sup>528</sup> Exhibit 32, Abstract

<sup>529</sup> Exhibit 33

<sup>530</sup> Exhibit 33, p. 1408

<sup>531</sup> Transcript, May 11, 2015, p. 105

<sup>532</sup> Transcript, June 24, 2015, p. 154

<sup>533</sup> Transcript, June 26, 2015, p. 58

*bin-Reza*<sup>534</sup>

404. This 2011 article is titled “The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence”. Included for review were “randomized controlled trials and quasi-experimental and observational studies of humans published in English with an outcome of laboratory-confirmed or clinically-diagnosed influenza and other viral respiratory infections”.<sup>535</sup>

405. The Abstract of this systematic review noted that:

There are limited data on the use of masks and respirators to reduce transmission of influenza.... None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.<sup>536</sup>

406. This was another study described by Dr. McGeer as “unquestionably not the best evidence” [in support of the Policy].<sup>537</sup> Dr. McGeer confirmed the conclusion of the authors that: “None of the studies established a conclusive relationship between masks/respirator use and protection against influenza infection.”<sup>538</sup>

407. Dr. Henry stated that this article demonstrated that there was “not a lot of direct evidence” but that “there was some evidence that it provides some benefit”. She explained that, because “there is not a lot of direct evidence...that’s why I think why we include studies that are not necessarily in a health care setting”.<sup>539</sup>

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<sup>534</sup> Exhibit 122

<sup>535</sup> Exhibit 122, Abstract

<sup>536</sup> Exhibit 122, Abstract

<sup>537</sup> Transcript, June 24, 2015, p. 154

<sup>538</sup> Transcript, June 26, 2015, pp. 56-57

<sup>539</sup> Transcript, June 22, 2015, p. 91

408. Dr. Brosseau testified that: “this review also does not support the—it doesn’t present any strong evidence for either surgical masks or N95 respirators mostly because the studies are not powered or not done correctly”.<sup>540</sup>

*Cowling (2010)*<sup>541</sup>

409. This literature review under Discussion included the following conclusions that were reviewed with Dr. McGeer in her cross-examination:

Our review highlights the limited evidence base supporting the efficacy or effectiveness of face masks to reduce influenza virus transmission....In future similar studies it would be important to consider the potential for leakage around the sides of the mask in addition to direct penetration of infectious viral particles through the mask, if the results are to have practical implications for reduction of transmission in community and other settings. Further studies are needed to investigate how mask and respirator performance varies with temperature and humidity, or under working conditions when moisture in exhaled breath or sweat may build up in face masks and hinder filtration or fit.<sup>542</sup>

*Canini*<sup>543</sup>

410. Dr. McGeer agreed that this study provides “no evidence at all” concerning the effectiveness of face masks in the context of seasonal epidemic”.<sup>544</sup>

*MacIntyre (2011)*<sup>545</sup>

411. Dr. McGeer confirmed that this study, for the reason given by the authors<sup>546</sup>, concluded that: “As a consequence, it is not possible to make any definitive judgment on the efficacy of masks on this basis.”<sup>547</sup>

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<sup>540</sup> Transcript, June 6, 2015, p. 16

<sup>541</sup> Exhibit 121

<sup>542</sup> Exhibit 121, p. 453-454

<sup>543</sup> Exhibit 215

<sup>544</sup> Transcript, June 25, 2015, p. 236

<sup>545</sup> Exhibit 216

<sup>546</sup> Exhibit 216, p. 176

<sup>547</sup> Transcript, June 26, 2015, p. 21

*MacIntyre (2009)*<sup>548</sup>

412. This was a household study concerning which Dr. McGeer confirmed that “the very authors of this report urge caution in applying it to healthcare settings”<sup>549</sup>:

We urge caution in extrapolating our results to school, workplace, or community contexts, or where multiple, repeated exposures may occur, such as in healthcare settings. The exact mechanism of potential clinical effectiveness of face mask use may be the prevention of inhalation of repeated respiratory pathogens but may also be a reduction in hand-to-face contact. Our study could not determine the relative contribution of these mechanisms.<sup>550</sup>

*Simmerman*<sup>551</sup>

413. This randomized control household trial concluded that: “Influenza transmission was not reduced by interventions to promote hand washing and face mask use”.<sup>552</sup>

414. Dr. McGeer said this about this study in cross-examination: “You can argue that because adherence was so poor, the negative trial really doesn’t matter and maybe I should not have wasted people’s time on it...”<sup>553</sup>

*Larson*<sup>554</sup>

415. This was another household study, one of primarily Hispanic households. The authors concluded that:

There was no detectable additional benefit of hand sanitizer or face masks over targeted education on overall rates of upper respiratory infections but mask wearing was associated with secondary transmission and should be encouraged during outbreak situations.<sup>555</sup>

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<sup>548</sup> Exhibit 217

<sup>549</sup> Transcript, June 26, 2015, p. 27

<sup>550</sup> Exhibit 217, p. 239

<sup>551</sup> Exhibit 218

<sup>552</sup> Exhibit 218, p. 256

<sup>553</sup> Transcript, June 26, 2015, p. 31

<sup>554</sup> Exhibit 219

<sup>555</sup> Exhibit 219, p. 178

416. Dr. McGeer commented that:

I would rate it probably in this list of studies as second lowest on the list after Simmerman in terms of its value in assessing transmission but it is one of the studies that has recently been done that attempts to assess whether hand hygiene and masks alter the risk of transmission of influenza and other respiratory infections.<sup>556</sup>

*Aiello*<sup>557</sup>

417. Dr. McGeer agreed<sup>558</sup> that the authors concluded that: “Neither face mask use and hand hygiene nor face mask alone was associated with a significant reduction in the rate of ILI [influenza-like illness] cumulatively.”<sup>559</sup>

*Bridges*<sup>560</sup>

418. Dr. McGeer agreed that this article does not assist in any way with respect to assessing the effectiveness of masks.<sup>561</sup>

*McLure*<sup>562</sup>

419. Dr. McGeer stated that this article is “additional evidence that face masks when worn by individuals prevent the egress of microbes, bacteria in this case, and viruses which are in the same emitted particles and contamination of the environment around them”.<sup>563</sup>

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<sup>556</sup> Transcript, June 26, 2015, pp. 37-38

<sup>557</sup> Exhibit 220

<sup>558</sup> Transcript, June 26, 2015, p. 42

<sup>559</sup> Exhibit 220, p. 491

<sup>560</sup> Exhibit 222

<sup>561</sup> Transcript, June 26, 2015, p. 62-63

<sup>562</sup> Exhibit 223

<sup>563</sup> Transcript, June 26, 2015, pp. 63-64

*Bischoff*<sup>564</sup>

420. This study related to the efficacy of surgical scrubs, gowns and masks. It concluded that: “In contrast to the efficacy of scrubs and gowns, there is only weak evidence of the efficacy of face masks”.<sup>565</sup>

421. Dr. McGeer explained that:

The point of this study is that for staph aureus, which colonizes the skin as well as the nose and mouth, in fact most of the shedding from healthcare workers occurs from the skin, it doesn't occur from the mouth. So it's not surprising that surgical masks don't have an impact on surgical site infections, particularly those due to staph aureus because, in that setting, protection from people's mouth bacteria is not that important.<sup>566</sup>

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<sup>564</sup> Exhibit 224

<sup>565</sup> Exhibit 224, p. 1152

<sup>566</sup> Transcript, June 26, 2015, p. 66