

Questions and Answers

Richard A. Goodman, MD, JD, MPH

Why don't we try to take as many questions as we can fairly quickly because we started a bit late. Let me just ask for a raise of hands. I see a couple up here in the front. Do we have a microphone floating on the floor again? Yes, so bring the microphone up to front here, and as you frame the question, please identify yourself and focus the question to the panelists.

Question: Absent a bioterrorism event, can you foresee smallpox being added as a vaccine for children or for mass vaccination?

Alfred DeMaria, Jr., MD

No, I cannot because there is no smallpox in the world. It is one of the greatest triumphs of public health, the eradication of smallpox from the world. As far as we know, there is only smallpox virus in two places in the world under secure conditions. However, we cannot rule out the possession of smallpox virus in the hands of people who might release it into a susceptible world. The problem is, and the only reason why I think some people have to be vaccinated to respond to smallpox, is that we are talking about 30% mortality overall, but unvaccinated, smallpox has about 50% mortality in all studies. Just the threat of smallpox being out there in the wrong hands would not justify mass vaccination because of the risk of the vaccine. We stopped vaccinating in the United States in 1972, even before smallpox was eradicated in 1978-1979, because, even though that death rate was extraordinarily small and it was a very rare event, more people were dying from the vaccine. So, the risks of vaccination do not justify mass vaccination now.

However, if there is any evidence that smallpox is circulating in the world, there is no question that mass vaccination would be indicated. I think for initial control, smallpox probably is controllable with isolation and quarantine if it is done properly, but I do not think there is a justification for mass vaccination or even vaccination at will in the absence of smallpox.

Question: The Cambridge ordinance of a \$5 fine is not consistent with today's communicable disease control in that they could refuse but not mix with population because of susceptibility.

Richard A. Goodman, MD, JD, MPH

That is an insightful observation, any response from anybody in the panel to that?

James G. Hodge, Jr., JD, LL.M.

I would be happy to provide a very brief response, Richard, by saying that I think the ordinance as structured was patently weak for other issues as well. This question highlights one of the weaknesses of the Cambridge ordinance. What we do not know (and perhaps Wendy might be

able to guide us) what would have happened to Jacobson had he contracted smallpox. My guess is he would have been isolated similarly to anyone that contracted smallpox.

Audience Comment: Good manufacturing processes for vaccines in the 21st century do exist today.

Richard A. Goodman, MD, JD, MPH

Thank you. Any other questions?

Question: If you have a shaky old statute, isn't it better to bring it into the modern era legislatively rather than go through the elaborate rule making process which leaves you still relying on the old statute?

Richard A. Goodman, MD, JD, MPH

Well, I am going to actually ask U.S. Attorney David Nahmias to just respond in part, while asking someone from our Office of the General Counsel to identify themselves in a moment to respond to your question specifically.

David E. Nahmias, JD

U.S. Attorneys are very careful not to propose legislation or get into the shoes of our other agencies. I guess from my perspective, the more clarity and development of the written law pursuant to modern constitutional and legal standards, the better because, again, my biggest concern is having to go into court on an emergency basis and convince a judge who may be fairly skeptical of the radical action we are asking or at least outwardly appearing radical action we are asking the court to take, to infringe individuals' rights, and the more we can point to a clear direction from the legislature, the more weight we will have. With smallpox, I think people understand; tuberculosis, which it sounds like is still a basis for quarantining people, people understand. I worry about influenza and going into court and trying to convince a judge that we need to quarantine 1000 people because they have the flu and whether a district court with no particular background in public health would understand the emergency nature of that, and so the more clarity we have in the laws and regulations, the better chance we have in a crisis to convince a court to take the action that we think is necessary from a public health scene.

Richard A. Goodman, MD, JD, MPH

I appreciate the legal practitioner's perspective. Is there someone from HHS Office of the General Counsel who can respond to this? Ms. Kocher? Thank you very much.

Paula Kocher, JD

Hi, I am Paula Kocher from the Office of the General Counsel of the CDC Branch. I am going to have to say what Eric Hargan, our Deputy General Counsel, said this morning in the quarantine session, which is that we are not in a position to talk about that right now.

Richard A. Goodman, MD, JD, MPH

Now you see why I deferred. Thank you. Any additional questions or comments? We can take perhaps one more and then we need to break so people can get to the next round of concurrent sessions. If not, then I would like to thank the presenters and the panelists and all of you in the audience.