

1 respect.

2 LT. COLBURN: On the very first document,
3 what indications make the appropriate, we've listened
4 to many presenters both from the FDA and industry
5 today, and I have yet to hear one bit of evidence that
6 decreasing colonization or decreasing contamination
7 actually is a clinical, ends up in a beneficial
8 clinical effect. And my concern is that if we start
9 thinking about approving things for contamination and
10 colonization that actually have no clinical benefit in
11 the long term that it's not appropriate, especially in
12 regards to the question, that I know that's going to
13 come later, about its effect on people's use of PPE.

14 CHAIRMAN JARVIS: I think I agree with the
15 first part. I'm less concerned about the behavioral
16 issue. If you look at the studies now, compliance
17 with hand hygiene, which is recommended by CDC,
18 recommended by Joint Commission, recommended by every
19 infection control society, compliance averages 35 to
20 40 percent. Is that going to drop to 30 percent or 20
21 percent? In one study in Montreal, it was eight
22 percent. It can't get much lower.

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1 And, similarly, when you look at wearing
2 protective equipment outside of the operating room and
3 isolation rooms, it's not as bad but it's close, in
4 which case I don't think that if I had an
5 antimicrobial impregnated mask, gown, glove, or
6 whatever, that it's going to go from 35 percent to 2
7 percent. It's bad already, and I think, at least for
8 me, I would look at these different possible PPEs
9 impregnated with antimicrobial agents more as, I think
10 industry is looking at it both to protect the patient
11 and to protect the healthcare worker. I guess I would
12 look at it more for protecting the patient, and is
13 there something we can do that, given the horrendous
14 compliance with the current recommendations, that if
15 people would start to use these because they think
16 they might be of some benefit, it would improve
17 compliance and reduce patient infections.

18 But I agree with you certainly from the
19 discussions that we've had so far. I'm not sure that
20 gowns impregnated with antibiotics are going to
21 protect the patient from anything. And masks and
22 respirators somewhat the same thing.

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1 DR. LURIE: Yes, I would hate to see a
2 standard established that implied any clinical
3 relevance, unless clinical relevance was proven. And
4 like Washington, which is full lawyers, it's not a
5 long leap to figure out that someone could make up the
6 story that if you didn't have a MRSA-resistant gown
7 then your infection was because you didn't wear that
8 MRSA-resistant gown. And I don't think that makes any
9 sense at all to set that as a standard. I want to
10 second that that, perhaps in the labeling process, I
11 don't know the different elements, but some portion of
12 the clinical relevance of these developments would be
13 noted.

14 DR. GORDON: This outcome status is really
15 a critical issue in everything that we do clinically,
16 and there's a lot of theoretical issues that come up
17 in medicine all the time that make a lot of sense.
18 And then when we start doing it, they don't pan out.
19 Cefuroxime several years ago was a nice new panacea
20 for treating gram-negative, you know, commune-acquired
21 meningitis. It didn't turn out to be as efficacious
22 as the drugs that we had earlier. And I was talking

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1 with a friend of mine yesterday who was saying, you
2 know, every time there's a new blood pressure
3 medicine, people seem to think it's a new thing and
4 the best thing on the block. Just because it's new
5 and different doesn't mean that it provides an
6 advantage.

7 The issue with regard to the impregnated
8 central venous catheters that have been very
9 successful is that, along with that, there's also been
10 huge work in approving sterile procedure and sterile
11 technique and how people are managing these catheters
12 and so forth. So a multi-disciplinary approach to
13 improving the outcome for central venous catheters
14 that were impregnated with antibiotics I think was
15 many things that contributed to it.

16 With what we're talking about here with
17 colonization and with contamination, the things that
18 we're going to throw out in a few minutes anyway, I
19 don't think that our hospital system at all would
20 really be inclined to use anything unless we had some
21 outcomes data that shows that it really helped what
22 happened to our patients. I don't know that that's

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1 the decision of the Panel. You know, that's what
2 we're here for. But just as an editorial in a user,
3 we'd want to see that something works, not necessarily
4 that something decreases colonization or contamination
5 rates, especially for something that's being
6 discarded.

7 DR. EDMISTON: Can we back up for a minute
8 because I function better in sort of an organized
9 fashion. Now, if question one has six parts, correct?

10 This is actually the third of six parts, so the slide
11 before that we should put up. And the comment I want
12 to make, it says, "Please discuss what type of
13 indications may be appropriate for PPE with
14 antimicrobial agents," I don't think we should have
15 said that. I mean, I don't think there should be a
16 decision on the part of this panel to say these
17 devices should only be used in high-risk surgery or
18 should only be used in the ICU. I think the market
19 determines that. So I don't think that is something
20 we should be considering where they should be used.
21 You may argue that your institution may not use it,
22 but other institutions may, and they may decide to use

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1 it in the ICU, they may decide to use it in the PACU,
2 depending on their specific needs.

3 So at least in those first two questions,
4 I'm not sure those are questions that the panel should
5 deliberate on. Is there any comment on that?

6 DR. DAVID: Yes, over here. The
7 indications for use, the way that it rings a bell with
8 me, is also instruction for use. And if that's the
9 case, then the instruction for use, definitely I would
10 highly recommend that we would look at the complete
11 package of the whole thing about the outcome resulting
12 with or without leak tests and things like that, so it
13 will be clear to the user what those claims are. But
14 if it's just the indication for use, as compared to
15 instruction for use, I would agree with you.

16 CHAIRMAN JARVIS: I think we may need to
17 get some clarity from FDA because I believe what they
18 mean by indication for use is more the prevent
19 colonization, prevent contamination, prevent
20 infection, rather than use it in the surgical ICU or
21 don't use it for this population. Could we get some
22 clarification on that?

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1 DR. LIN: Well, I think the indications, I
2 think that probably in the layman's person, you
3 probably set that type of a market, how you want to
4 market your product. I think this morning that the
5 FDA's presentation, they give you some potential so-
6 called indications, how they're going to promote their
7 product, when they add the antimicrobial agent onto
8 the device. And you look at some of the slides that
9 they present this morning, they give you some
10 examples. And our question is this an appropriate
11 labeling claim for FDA for marketing, and that
12 probably will be the first.

13 DR. EDMISTON: See, we already have
14 indications for certain types of surgical gowns. For
15 instance, isolation gowns. They're meant to be used
16 in a certain environment, as opposed to the general
17 ward gowns. So I'm not sure the addition of
18 antimicrobial agent to that is going to change that
19 indication. I can't think of any heightened
20 indication for the use of that gown just because
21 there's an antimicrobial impregnated on the surface.

22 DR. LIN: I'm sorry. Not the indication

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1 for the device. We are more talking about indication
2 of adding antimicrobial agent onto the device.

3 DR. EDMISTON: So the rationale for it?
4 You're talking about the rationale for it?

5 DR. MURPHEY: That's correct. For every
6 510(k) that we see, the manufacturer is asked to tell
7 us, this is part of a 510(k), what are your
8 indications for use, what is the intended use of this
9 product? It's really something that is required as
10 part of a 510(k). For gowns without antimicrobials
11 that addresses for the gown the basic purpose of the
12 gown. In many instances, but certainly not all, that
13 will actually be almost repeating the definition of
14 that device in the regulations, and that's okay. The
15 regulations, of course, do not address the addition of
16 antimicrobial agents to these devices in particular.
17 So we would then ask the manufacturer, "All right,
18 this is your indication for the gown or the glove or
19 whatever. What is your indication for the
20 antimicrobial agent that you have now added to this
21 device?" Does that help?

22 DR. EDMISTON: I get it.

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1 CHAIRMAN JARVIS: Let me ask you in terms
2 of an isolation gown that the mere adding of an
3 antimicrobial agent impregnation to that gown, would
4 that move it over in the process to like a surgical
5 gown and have to go through the surgical gown review
6 process?

7 DR. MURPHEY: Thank you. The
8 classification of surgical apparel left the isolation
9 gown, and this is a classification that was made in
10 the 1970s in Class I. It was assumed at that time and
11 it has been practiced that those devices would have
12 certain barrier protective functions, and we don't
13 review those. They are considered to be Class I. But
14 antimicrobial agents have not been added to those
15 devices as far as we can tell. Now, of course, the
16 regular Class Is we don't review.

17 Doing something to any device which is a
18 Class I device which is going to raise new questions
19 about safety or technology or brand new claims that
20 have never been there before can do what we call in
21 regulatory speak trip the limitations of the class.
22 It can raise a Class I device to a Class II device.

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1 It can change a Class II device into a Class III
2 device, which would require a PMA.

3 Now, usually, the addition of
4 antimicrobial agents by itself may not do that, Class
5 II to Class III. But it certainly can in this case
6 from Class I to Class II because of the safety issues
7 that may come up. And I can think of at least one
8 product where it might come up to raise the product
9 from Class II to Class III, but that's not a PPE.

10 CHAIRMAN JARVIS: Back to the indication
11 issue. You know, is the panel willing to address this
12 issue in terms of, such as reducing contamination and
13 reducing colonization and reducing infection and
14 having three different categories or four or five or
15 whatever, what is the feeling of the group on that?

16 DR. EDMISTON: Well, now you've clarified
17 it, and it takes a little bit of time for me to get
18 it, as you know from the past. But the issue is I
19 think, I think we need a chart of all the things I
20 think we need to consider for masks, gowns, and
21 gloves. And when we think about these indications, if
22 I was coming out with a new surgical mask or gown,

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1 just say gown, and I was saying this gown was, the
2 impregnated material in the gown eliminated the
3 adherence of the viability of MRSA, VRE, or other
4 pathogens, or gram-negatives or said gram-positives
5 and gram-negatives, and the onus would be on me to
6 provide you with primarily in vitro data, the document
7 that's the case; is that true? That would be true.

8 However, if I raised the bar and said that
9 the use of this device reduces the risk of nosocomial
10 infection within the ICU patient population, then that
11 puts a greater onus on me to provide you with that
12 type of data. Just by saying reduces the risk is not
13 sort of a catch-all. You'd require data from me to
14 validate that; is that correct?

15 DR. MURPHEY: That is how we would
16 interpret it, yes.

17 DR. EDMISTON: So I think that it's all in
18 the eye of the beholder. If the vendor comes forward
19 with a device which states, because he's done clinical
20 trials to validate this, that this particular device
21 reduces the risk of nosocomial dissemination within a
22 defined patient population, then, of course, you have

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1 to have clinical data to validate that. So I think
2 that we have a two-tiered system here, at least in
3 terms of how the vendor produces the data. If it's
4 just elimination of the organism from the surface of
5 the device with no claim of reducing infection, that's
6 a different animal than if he makes that claim.

7 So I think that it's inevitable that you
8 will probably see devices in which some claim will be
9 made that it reduces the potential of nosocomial
10 dissemination within a defined patient population.
11 I'm not sure if they're going to use the word
12 colonization. They might. They might, but that would
13 really raise the bar in terms of trying to prove the
14 efficacy of the device.

15 DR. LURIE: If it doesn't stick to your
16 barrier, then you're going to reduce cross
17 contamination. If you just said it reduces cross
18 contamination, you've raised the bar. I think it's a
19 slippery slope that one can argue with words rather
20 than with data.

21 DR. EDMISTON: But actually there are
22 devices already in the market, intravascular devices,

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1 urinary devices, in which data was presented showing
2 decreased adherence to the surface of that device that
3 initially may not have required clinical data to
4 validate it.

5 DR. LURIE: But cross contamination is not
6 going to be an issue for an implanted device, whereas
7 for an external device it would be.

8 DR. GORDON: I don't think it's fair to go
9 and compare the intravascular devices with what we're
10 talking about here, though, because, as we heard and
11 as people recognize, the colonization issue with
12 regard to vascular devices is clearly associated with
13 an increased risk of infection, and we haven't
14 demonstrated the colonization issue leading to
15 infection with these devices as much.

16 MS. SANTHIRAJ: Yes. We use the
17 contamination word for those that do not really touch
18 the patient's body inside the tissues, that as the
19 colonization, preventing colonization of infection
20 would be those devices entering the patient's body or
21 on the surface of the body. So I would rather go with
22 the word contamination, reducing the contamination.

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1 DR. ARDUINO: I'd throw colonization out
2 because colonization implies time and growth of which
3 these are short-term devices, which are not there for
4 lengths of time. So colonization is a bad word or at
5 least not used that way.

6 DR. EDMISTON: No, I'd have to agree.

7 CHAIRMAN JARVIS: Well, but if you take
8 MRSA, for instance, more and more people are beginning
9 to do screening for colonization. We know that if you
10 look at the rates of colonized versus infected, it's
11 multiples, two, three, five, ten times as many
12 colonized as you have infected. So if a manufacturer
13 had a product that reduced, say, MRSA, VRE, gram-
14 negative, or multi-drug resistant gram-negative
15 colonization, knowing that the studies show the
16 patients are at 10, 20, 30 times greater risk for
17 becoming infected if they become colonized. Actually,
18 if I were trying to do a study, a clinical study, it
19 would be much easier for me to prove that I reduced
20 colonization than it would be to prove that I reduced
21 infections just because of the numbers game, if
22 nothing else.

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1 DR. SPINDELL: I guess I'm confused.
2 You're talking about colonization of the patient. I
3 think they're talking about colonization of the
4 device. I think that's two totally separate issues
5 here.

6 DR. ARDUINO: And colonization of the
7 device is inappropriate. I mean, using that
8 terminology is inappropriate here.

9 CHAIRMAN JARVIS: See, I viewed it as
10 preventing contamination of whatever it is you have, a
11 glove, a mask, or whatever, and then preventing
12 colonization was the patient or the healthcare worker,
13 which direction you're going to, and infection with
14 your patient or healthcare worker.

15 DR. SPINDELL: And I would agree with
16 that, if that's the definition we're going to put in
17 here. But right now, maybe it was just me, but my
18 understanding was it was colonization of the device.

19 DR. EDMISTON: That's how the FDA is
20 perceiving it, correct? No.

21 CHAIRMAN JARVIS: Well, then if that's the
22 case, I would agree with Dr. Arduino. It makes no

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1 sense.

2 DR. EDMISTON: I think they can provide
3 data very readily to show decreased contamination of
4 the device primarily by in vitro studies.

5 DR. SPINDELL: Again, it gets back to my
6 original question is, you know, does decreased
7 contamination of the device actually do anything for
8 patients? I think we have to remember that, even
9 though the FDA is going to look at this as far as
10 risks to health, adverse risk from the antibiotics,
11 there is some risk. There's never going to be zero.
12 So would it be responsible to go ahead and say you can
13 approve it for the contamination with no evidence of
14 clinical benefit where there is a potential risk for
15 harm for the user? And I think that's the issue that
16 the panel has to look at.

17 DR. LIN: I just wanted to remind the
18 panel that this morning that when the FDA reviewer
19 presented for different type of device, they sort of
20 gave some example of that type of so-called,
21 quote/unquote, the "indication for use" for this type
22 of device. I will give you some example. Page 16.

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1 Look at slide 61, type of so-called indication that
2 for antimicrobial coated medical glove that we have
3 seen in the public domain. And this is the type of
4 information that we need the panel to give us some
5 advice are those type of indications appropriate for
6 antimicrobial-coated PPE? That's for medical growth,
7 and page 21, slide number 83, that's for mask N95
8 respirator. And on page 25, slide number 97 will give
9 you some example. That's just the type of indication
10 we use that we are talking about antimicrobial-coated
11 PPE that we need some advice from you. Are those
12 potential indications, those come to FDA, would FDA
13 appropriate or accept those type of product?

14 DR. EDMISTON: If I'm a vendor who makes
15 those claims and I'm going to have to provide you with
16 clinical data to validate, that's a valid claim. So I
17 think there's no question that, if I come to question
18 these claims, I will have to provide you with clinical
19 data to validate that position.

20 DR. LIN: Well, I think right now that the
21 question the FDA would like the panel to help answer
22 are those claims or indications of use appropriate for

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1 this type of product?

2 CHAIRMAN JARVIS: Certainly, if you look
3 on page 16, the potential promotional indications for
4 medical gloves, it reduces hospital-acquired
5 infections. You'd have to have clinical data to prove
6 that. Prevents cross contamination. I don't know
7 what that means. Does that mean colonization? Does
8 that mean that the glove becomes contaminated? Does
9 it mean that the glove and something else in the
10 environment becomes contaminated? That one I find
11 kind of confusing; I don't know what it means.
12 Pathogens, prevents a pathogen from sticking. That's
13 totally in vitro. And then prolonged shelf life is
14 also in vitro. So could you provide some
15 clarification on what do you mean by cross
16 contamination? Do you mean colonization with a
17 patient, or do you mean contamination in the
18 environment, or what?

19 DR. LIN: Well, this morning, mentioned
20 that, for example, that antimicrobial, then you touch
21 one patient, then you move to another area and then
22 touch, that's what they mean cross contamination, like

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1 a web site or some promotional material.

2 CHAIRMAN JARVIS: Well, I guess there's
3 two ways you could measure that. Is it that I'm
4 saying that it reduces, say it's a glove, I'm
5 reducing contamination of the glove. Or if you say
6 cross contamination, then I see the glove going
7 somewhere else. So I think, if we went with these, I
8 think I'd need some clarity on that. Scott?

9 LT. COLBURN: I was just making a point
10 for the audience that the page numbers don't correlate
11 the same, but the slide numbers should be very close.
12 You have six slides on a page, there's four up here,
13 so I saw a lot of flipping of papers. Just to help
14 you out.

15 DR. LURIE: I'm confused by this cross
16 contamination issue because what you just described
17 violates what we generally call universal precautions.
18 You don't wear gloves between different patients, so
19 I think that just confuses the whole piece more. I
20 think we would all --

21 DR. LIN: This is not the FDA's turn. We,
22 as I mentioned before, this is what we discover in a

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1 promotional literature. One thing Dr. Murphey pointed
2 out in her presentation, we have not created those
3 type of devices yet. But this is the type of
4 indication we have seen somewhere. And our question
5 to the panel: are those indications or labeling
6 appropriate for this type of product? And that is the
7 question we'd like help on.

8 MS. LEACH: Unfortunately, we know that
9 healthcare workers do wear gloves and touch multiple
10 patients and also touch multiple environmental
11 surfaces and, thus, contaminate those environmental
12 surfaces.

13 DR. LURIE: Right. But I think if we're
14 going to address specifically these four, which I
15 guess is what you're asking, I think that, in my mind,
16 to reduce hospital-acquired infections, it needs
17 clinical data, to prevent cross contamination would
18 probably need clinical data. To prevent pathogens
19 from sticking is an in vitro question, and that would
20 give an in vitro answer. And the prolonged shelf life
21 advice is something that I suppose the company would
22 decide. But I'm also confused because I thought we

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1 were trying to give you a larger guidance picture
2 rather than an individual piece. But I think my view
3 of these is it really does run the whole spectrum of
4 whether it's a clinical decision or an in vitro
5 decision or a marketing decision. But, at least from
6 what I've understood from discussion today, I don't
7 think most of these things are legitimate claims.

8 DR. EDMISTON: Well, they're only
9 illegitimate if you don't have the data to prove it.
10 So I think the onus is going to be on industry. If
11 they want these claims, they're going to have to come
12 forward with this information. I think of a paper
13 that was published recently by Bob Weinstein on the
14 use of this chlorhexidine impregnated cloth, and I
15 believe the FDA gave an indication for this cloth as a
16 pre-operative skin preparation. But Bob decided to
17 use it as a device in his ICU to reduce colonization
18 with VRE within his ICU, using it instead of the
19 traditional bath-in-the-bag but using this cloth
20 instead for the patients. And he demonstrated in the
21 article that he was able to reduce VRE colonization
22 within his ICU at Cook County.

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1 I think if a vendor came forward and said
2 this is what we planned for the use of this device,
3 then that kind of data would be the kind of data that
4 you would need to evaluate the efficacy of that
5 indication. So this is all driven by what they ask
6 for, and I think your questions, you've really hit on
7 the sentinel issues here because if they do propose to
8 incorporate antimicrobial substance, whether
9 antibiotics or antiseptics, and these are the claims,
10 then there will have to be clinical data brought forth
11 to validate that claim.

12 DR. SPINDELL: I guess one of my concerns
13 is, one of the questions I believe is not only what
14 proof do you need but what actual indications should
15 the FDA consider? And, again, my concern goes back
16 that if you consider allowing manufacturers to come
17 through with claims that have nothing to do with the
18 end effect on the clinical patient, we're going to get
19 a whole lot of things proven because I think the in
20 vitro data would be pretty easy to get. And not to
21 have all the stuff approved in the market, that's not
22 really helping patient care at all, and that's my

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1 concern.

2 CHAIRMAN JARVIS: I agree with you, but I
3 think that's the case now already. And as was
4 mentioned, it's going to be driven by hospitals
5 deciding that they want to purchase a product or not.
6 And some have a higher level of requirement. It
7 doesn't matter how much in vitro data you give them,
8 they're never going to change. And others are willing
9 to try something early on.

10 DR. EDMISTON: See, it's obvious to those
11 of us who are in hospitals that the value assessment
12 committees are all being driven by evidence based, and
13 it's unusual now for a new device to be introduced
14 into the hospital without some type of data validating
15 the efficacy of that device. So industry realizes
16 this, and, if they're going to bring these devices to
17 the market in the future, they're going to have to
18 have specific data to validate these claims.

19 CHAIRMAN JARVIS: Are there any other
20 questions on any of these other indications for masks
21 or gowns? Dr. Lin, can you remind us of what page the
22 count is on, indications on gowns?

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1 DR. LIN: Slide number 97. This is a
2 potential indication that we have seen. We have seen
3 some promotional literature indicating that when
4 antimicrobial-coated gown can enhance protection of
5 our patient from infectious microbe. For example, if
6 somebody in your hospital say, well, I have this
7 product with this kind of indication or this kind of
8 promotional claim, how do you feel about this type of
9 claim?

10 DR. EDMISTON: Well, from an OR
11 perspective, I don't think we think about gowns in
12 that perspective, do we? You know, we don't think of
13 it at all from that perspective, so I can't imagine
14 this particular claim being presented for a gown. I'd
15 look upon a claim for a gown using to prevent contact
16 transmission of an infectious microbe within the
17 general hospital patient population or the ICU or some
18 other floor. But when we talk about our drapes and
19 our gowns that are used in the operating room, you
20 know, the patients are prepped. The patients either
21 have, most of them now are using incise drapes. So
22 the idea of the gown being protective really isn't

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1 relevant in this arena. Am I wrong about this?

2 DR. LURIE: Right. I don't think that
3 there's any enhanced protection. As long as the gown
4 is impenetrable to fluids, I don't think there's any
5 enhanced protection to the personnel. I think incise
6 drapes are a good example. We watched incise drapes
7 be impregnated with iodophors at a certain generation,
8 and there was no clinical efficacy of that. And I
9 think that that's a very good example of a nice idea
10 that went nowhere, and I'm sure that in vitro there
11 were decreased bacteria on the skin, but in clinical
12 testing there's no clinical advantage to it. But I
13 think that these claims that you've outlined here on
14 slide 97, in my view, would have to be proven
15 clinically, and I don't think they could be.

16 DR. EDMISTON: I was just reminded of
17 something by my colleague next to me, which I'm going
18 to sort of shovel off to my infection control
19 colleagues. Would there be a benefit for a patient
20 going to the OR who is colonized with VRE or MRSA?
21 Because the second part of that says enhanced
22 protection of OR patient and personnel from infectious

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1 microbes. What do you all think about that?

2 DR. LURIE: They already come down in
3 isolation gowns. They go to isolation rooms. They're
4 washed with alcohol-based products that kill these
5 bacteria. Again, I think the onus, as you said, the
6 onus proof is on the manufacturer.

7 MS. LEACH: For staff to get it from the
8 patients, that's not usually the way we worry about.
9 Staff are healthy. They're not as susceptible to
10 getting the infections, to getting the colonization.
11 It's not going to get through to mucous membranes or
12 cuts in the skin. So I think that's really a stretch.

13 CHAIRMAN JARVIS: Yes, I think there are
14 very few data, but my guess is that the number of
15 healthcare workers who became colonized or infected
16 with MRSA or VRE or gram-negative organisms from a
17 surgical patient in the operating room are few and far
18 between. I don't think it would be relevant.

19 DR. GORDON: Yes, this really gets back to
20 universal precautions. Hospital workers are colonized
21 at a much higher rate, and it's not just confined to
22 surgical patients. It's really following proper

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1 technique, and they'd have to show an enhanced
2 benefit, which I would doubt that they would.

3 CHAIRMAN JARVIS: Any other issues on
4 gowns?

5 DR. EDMISTON: The prevent contact
6 transmission of infectious microbes, that's a study
7 that could be done, but that would be an
8 extraordinarily expensive study requiring molecular
9 epidemiology and other types of techniques to validate
10 the efficacy of that. So, again, these questions
11 didn't come out as thin air I know. You know, I
12 suspect you've seen requests come through from vendors
13 with this specific indication. Let me ask you this
14 question from a non-proprietary perspective. Are you
15 seeing any data coming from vendors with these
16 indications?

17 DR. LIN: Well, as Dr. Murphey pointed out
18 this morning, we have not created those types of
19 devices yet. We haven't seen those type of data in.
20 We know those type of product has been marketed
21 somewhere other than the United States, but we know
22 someday that will come to the United States.

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1 DR. EDMISTON: I would suspect, if a
2 vendor came along, a Kimberly Clark, or some of the
3 other vendors came along with this claim, that this
4 would require a significant clinical effort to
5 validate that. It would be a very, very expensive
6 study, just knowing what the cost of molecular
7 epidemiology is today. That's the only way you can do
8 this study efficiently.

9 CHAIRMAN JARVIS: And which slide number
10 was mask and respirators?

11 DR. LIN: Page 21, slide 83.

12 CHAIRMAN JARVIS: Protects the filtration
13 material from bacteria and fungi, it protects against
14 specific bacterial and viral agents, antimicrobial
15 agents in the filter material can isolate and kill
16 microorganisms, and element metal ions in the device
17 act as effective antimicrobial agents against viruses
18 and bacteria. These seem like they're all in vitro.
19 Again, to get back to your issue of do they actually
20 do anything to reduce either patient or healthcare
21 worker infection or colonization?

22 DR. SPINDELL: You know, the first one,

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1 are we really worried about protecting the filtration
2 material from bacterial and fungi or the patient or
3 the user from bacterial and fungi concentration?

4 DR. ARDUINO: With a respirator, I always
5 think it's the person wearing the respirator.

6 DR. SPINDELL: That's exactly right, but
7 that's not what the claim says. The claims says the
8 filter material.

9 CHAIRMAN JARVIS: Any thoughts on the rest
10 of these indications?

11 DR. LURIE: Well, I always have thoughts.
12 I think we've all been educated on the huge leakage
13 that comes through these things, and I think we've all
14 understood that, even if these had 100-percent
15 protection, that nothing got through, we'd still be
16 exposed to the same ten percent of air coming through
17 from the sides and that it probably doesn't have any
18 enhancement such as these, and, at the present time,
19 doesn't have any clinical relevance.

20 DR. EDMISTON: Mr. Chairman, could I ask
21 that Mr. Perkes come on up again to the podium? He's
22 that lab testing guy. I want to ask him some

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1 questions. You knew that was coming. Like I said,
2 you're the man, okay? So in this particular instance
3 where we're looking at the impregnation of an
4 antiseptic or an antimicrobial on the surface of the
5 filter material, are there current testing
6 methodologies in your laboratory? If I were to
7 present this to you and say, okay, I have a surgical
8 mask here which I think, which I think, because of
9 this antimicrobial agent that I applied on the surface
10 of it, will prevent or diminish, diminish the release
11 of nasopharyngeal shedding, so organisms, once they
12 hit this substrate, they'll be killed. Is there
13 testing methodology that you could take that mask and
14 say, well, we'll test this to prove this is the case?

15 DR. PERKES: Yes, there is currently a
16 bacterial method that the military developed, and ASTM
17 has adopted that method to measure filtration
18 efficiency. Besides that, the only other thing
19 available is there is a method for a liquid contact
20 developed by AATCC, and those are really the only two
21 methods currently available.

22 DR. EDMISTON: What's your background?

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1 DR. PERKES: I'm a microbiologist.

2 DR. EDMISTON: Good. I got a question for
3 you.

4 DR. PERKES: All right.

5 DR. EDMISTON: Remember when you were
6 taking microbiology and took genetics, there was a
7 technique called replica plating? Remember that?

8 DR. PERKES: Yes.

9 DR. EDMISTON: Okay. Let's suppose I'm a
10 manufacturer and I have this substrate I've
11 impregnated with an antimicrobial substance, and I'm
12 comparing it to a non-antimicrobial substance. Would
13 a technique like replica plating possibly be used to
14 demonstrate the efficacy of the impregnated versus the
15 non-impregnated device?

16 DR. PERKES: I don't know. I don't have
17 an answer for that. I'd have to think about it a
18 little bit. On the surface, it appears yes, but I'd
19 have to think a little more on that. Sorry.

20 DR. EDMISTON: Now, so that's the problem
21 we have in that there are really no good test
22 methodologies that could be used to look at the

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1 biological component of this.

2 DR. PERKES: Correct. There is a test
3 method, but, again, it's a short-term, short-term
4 contact test, meaning, basically, a minute contact
5 with the filter, and you measure the efficiency based
6 off of that. That would be kind of a platform to go
7 off of if we were to develop a method. But, again,
8 coming up with a method is very costly and time
9 consuming.

10 DR. EDMISTON: Is there an efficacy to
11 looking at time effect, too? For instance, a topical
12 skin antiseptic, do you do those studies, too, in your
13 laboratory?

14 DR. PERKES: Yes, I believe we do.

15 DR. EDMISTON: So there's this cutoff of
16 10 minutes, 30 minutes, and six hours for log
17 reduction.

18 DR. PERKES: Yes.

19 DR. EDMISTON: Would something like that
20 be applicable, in your opinion, for these devices?
21 For instance, his surgical mask, he may wear it for a
22 vascular procedure anywhere between two to four hours,

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1 depending on how long he's operating. So it would
2 probably make sense if you're going to design a
3 surgical mask that has an impregnated technology to
4 have some time cut points in terms of efficacy; would
5 that be true?

6 DR. PERKES: Yes, we agree. There's,
7 however, some technical difficulties with establishing
8 that type of protocol. And so we have thought about
9 that, yes.

10 MS. KRZYWDA: Just so I understand it, is
11 all of your testing in your lab in vitro?

12 DR. PERKES: Yes.

13 DR. EDMISTON: What's the FDA's definition
14 of a reasonable test? For instance, if we don't have
15 standard methodologies, but, yet, I'm manufacturing a
16 mask, what is your interpretation of a reasonable
17 methodology that would be acceptable for review?

18 DR. MURPHEY: Well, there are many
19 instances in which a brand new product or a new
20 technology comes to FDA, and we have to look at
21 situation where there are no precedents. What we look
22 at is does the method make sense? Is the method well

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1 described? What is the evidence that what we are
2 looking at can be replicated time after time after
3 time? What is the reproducibility and reliability of
4 the test? What, if anything, do we know about the
5 range of error of measurements used in this test? Is
6 it based, is it a modification of something that we
7 already know rather well? How clear are the end
8 points that we are looking at? Do the test methods
9 replicate to a reasonable degree, and, of course, it
10 may be impossible to replicate exactly what's going on
11 clinically, but do they replicate to a reasonable
12 degree the conditions of use of the device, whatever
13 it is? Are we looking at the entire device? This is
14 a real technical question for certain devices, and, in
15 the end, we have to give clearance or non-clearance to
16 the entire device, rather than to a particular layer
17 or a particular component of the device. We have to
18 look at what does the device do in its entirety? Is
19 it able to show that, in fact, it is substantially
20 equivalent to its legally-marketed predicate? That it
21 has supported any additional claims that it is making
22 over and above those of the predicate? And that it

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1 appears to be reasonably safe and effective for use.
2 It is challenging.

3 DR. EDMISTON: In the case of the
4 antimicrobial impregnated mask, there's really no
5 predicate.

6 DR. MURPHEY: That's correct.

7 DR. EDMISTON: So you would, in essence,
8 be taking my testing data, looking at my performance
9 and quality assurance data, and comparing that to the
10 testing itself?

11 DR. MURPHEY: Yes.

12 DR. EDMISTON: You probably would have
13 even a third party look at this to look and determine
14 whether it was efficacious. So the idea of providing,
15 for instance, if we said we looked at these
16 indications in terms of protecting against specific
17 bacterial and viral agents, antimicrobial agent on a
18 filter can isolate and kill organisms, if we're able
19 to provide substantial in vitro data which fulfills
20 the rigors of your criteria, then, in most cases, that
21 would be sufficient, correct?

22 DR. MURPHEY: Probably.

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1 DR. EDMISTON: Okay. Because I think what
2 I'm getting here is that this panel is not going to be
3 able to come up with a standard testing methodology
4 because none exist based on the testifying and
5 evidence of the experts in the field.

6 CHAIRMAN JARVIS: Let me just say it looks
7 like when I look at the potential indications for
8 gowns, gloves, masks, or respirators, they really fall
9 into three categories. Either I'm putting that device
10 out because I think it will reduce infections, whether
11 they be patient or healthcare workers, and we all
12 agree that is driven by clinical data. The second is
13 I claim that it reduces colonization. Again, it's
14 going to require clinical data. And the third is I'm
15 claiming that this does not become contaminated,
16 however you want to define contamination. It
17 basically kills bugs, captures bugs, does something to
18 the bugs so that when I wear this device there are
19 fewer there than its predicate device. And wouldn't
20 just those three categories of indication be
21 sufficient for all of these devices, and then it's up
22 to the manufacturer or vendor to comply with it and

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1 provide either in vitro data for contamination or in
2 vivo data for colonization or infection?

3 DR. EDMISTON: And I think there is
4 unifying data across the field. For instance,
5 biocompatibility, toxicity. That goes right across
6 the field, but that's a separate component, which I
7 think needs to be evaluated individually for every
8 single device.

9 CHAIRMAN JARVIS: So if everybody agrees,
10 I think the indications would be three for all the
11 devices: reduces infections, prevents infections,
12 however you want to word it; reduces or prevents
13 colonization; or reduces or prevents contamination.

14 DR. SPINDELL: And when you say
15 colonization, you mean patient --

16 CHAIRMAN JARVIS: Patient or healthcare
17 worker, depending on -- not device.

18 DR. SPINDELL: Right. I think you ought
19 to specify that.

20 DR. LIN: Please keep in mind that, as Dr.
21 Murphey pointed out this morning, the PPE to wear or
22 the part that the PPEs use is totally different from

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1 those device that is permanent or long-term, for
2 example, the catheter. It's quite different. So now
3 is the question of prevent infection is really, truly
4 appropriate for PPE type of device. I think please
5 keep that in mind, as compared to an implanted device,
6 that probably would be appropriate claim for
7 antimicrobial-coated device. But for a PPE, prevent
8 infection, what does that really mean to you, as the
9 healthcare --

10 DR. EDMISTON: Well, actually, what you're
11 just saying, PPE, personal protective equipment,
12 you're talking about a device that protects the
13 wearer, not the patient, correct? But actually we've
14 expanded this discussion, haven't we? Now we're
15 talking about the device and the role it has on the
16 patient. Is that an appropriate expansion?

17 DR. MURPHEY: It probably is. When you
18 look at our definitions in the regulations and you
19 look particularly at the definitions for surgical
20 apparel and gloves, they speak about preventing the
21 transmission of microbes, blood and body fluids, and
22 particulates to the patients and to the healthcare

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1 workers. We recognize that, certainly in the OR,
2 transmission can be a two-way street in terms of risk.

3 And I think this is really true in the patient care
4 area, as well. It varies with the PPE and with the
5 situation. In the setting of invasive procedures,
6 yes, there is risk to the patient and there is risk to
7 the healthcare worker. In the setting of non-invasive
8 procedures, I think that you can, that you really need
9 to very clearly define who's being protected from
10 what.

11 DR. EDMISTON: Well, non-invasive
12 procedures would be gown-wearing, for instance in the
13 ICU. And I think Dr. Jarvis has really encapsulated
14 the issues very clearly, is that if we're going to
15 really expand this issue, that even the ICU patient
16 population is vulnerable to colonization through
17 contamination of PPE. So I think that encapsulation
18 includes both the wearer and also the patient.

19 DR. MURPHEY: We would not disagree with
20 that.

21 DR. EDMISTON: Okay.

22 CHAIRMAN JARVIS: Okay. Let me summarize

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1 question number one. I think we're in agreement that
2 the indications would be three: preventing or reducing
3 infection; preventing or reducing colonization in the
4 patient, not the device; contamination of the device,
5 preventing or reducing colonization in the patient,
6 and preventing or reducing infection. And I guess
7 both the colonization and infection could both mean
8 patient and healthcare worker, but it's people, not
9 the device. I think in terms of indications, or not
10 indications but how you would test that, we're at a
11 loss since there's nothing out there right now.
12 Certainly in vitro data will probably drive the
13 reduces contamination, and the colonization and the
14 infection would have to be complemented with in vivo
15 data, as well. Is there anything else anybody would
16 add to that? If not, why don't we move, we'll try to
17 do question two, and then we'll take a break.
18 Question two is for each of the following types of PPE
19 with added antimicrobial agents, please discuss what
20 time frame would be appropriate for demonstrating
21 antimicrobial efficacy in order to kill or inhibit
22 microbes, reduce the risk of transferring microbes

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1 from one site to another. And the questions include
2 both medical gloves, both examination and surgical
3 gloves; surgical masks; surgical respirators; and
4 medical gowns, both surgical and isolation gowns.

5 I think as has been mentioned in contrast
6 to impregnated catheters, which have a longer duration
7 of use, the majority of these, with the possible
8 exception of surgical gloves and surgical masks and
9 surgical gowns that could be used for hours, the
10 majority of the others are going to be used for
11 minutes. So in terms of showing efficacy, in terms of
12 decontamination, which is probably going to be the
13 most important one, it's going to have to be pretty
14 quick. Any ideas on time?

15 DR. EDMISTON: There's no doubt in my mind
16 this is totally an in vitro phenomena. This will be
17 an in vitro phenomena, and I think that the time
18 frame, the time frame is a slippery slope here because
19 I refer myself to topical skin antiseptics because I
20 know the data pretty well in terms of time frame and
21 looking at log reduction. So there's no doubt in my
22 mind any reasonable, reasonable study, protocol, that

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1 documents the log reduction on the surface using a
2 defined inoculum, whatever that reasonable inoculum
3 is, over a time interval. And I think the time
4 intervals, again, represent a reasonable period of
5 time.

6 Obviously, you have to start somewhere,
7 and I think for topical antiseptics it starts at three
8 minutes, and then at ten minutes, and then there's a
9 six hour component associated with that. So there has
10 to be a time component because I'm always concerned,
11 as was brought up by a number of individuals, is this
12 liquid interface because we know we use these devices
13 not just on dry surfaces but we also use them in body
14 cavities, which is another issue, and we also use it
15 to care for patients who are releasing blood and body
16 fluids. So, obviously, a simulated use strategy using
17 a reasonably designed protocol that we discussed
18 previously using time intervals. And the time
19 intervals are random. I just sort of draw from my
20 experience with skin antiseptics, which is three, ten,
21 and six hours, but it probably could be anything on
22 the short end and then on the long end.

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1 DR. LURIE: I think they also have to work
2 when they're wet. Not just humidity, but wet. I
3 think all these components get wet. The respirators
4 collect moisture, as do masks and the gloves, and I
5 think that would also be something that needed to be
6 tested.

7 CHAIRMAN JARVIS: And also a variety of
8 organisms and a variety of concentrations where, in a
9 body cavity, you might have very high concentrations;
10 on a surface, you might have very low concentrations.

11 DR. EDMISTON: And I know the FDA, for the
12 skin antiseptics, you know, it used to be you had to
13 do a lot of bugs, and now the requirement is less.
14 But it has to be clinically relevant bugs, and the
15 reason I say that is because many of our ATCC test
16 strains that we use are no longer clinically relevant
17 because of the high rates of resistance that we see
18 within our patient populations. So I think we would
19 have to use clinically-relevant organisms which
20 represent a spectrum of organisms we see in the
21 clinical environment, including multi-drug resistant
22 strains. Would you agree with that?

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1 DR. LURIE: I'm not sure that I do. I
2 think that may be too high a bar for what we're trying
3 to accomplish here. I mean, we're just trying to say
4 that it's better than standard gloves, and the
5 fallback is standard gloves or standard masks or
6 standard respirators. And I think that bugs are
7 always going to change their resistance patterns, and
8 I think to set a standard in 2007 that's going to be
9 different in 2009 is an unreasonable standard for
10 industry.

11 CHAIRMAN JARVIS: But you'd at least like
12 to know that the bugs that are selected do have some
13 clinical relevance, and if you're using a Bacillus
14 species, for instance that that Bacillus species
15 actually acts like VRE or MRSA or bugs that you
16 commonly encounter.

17 DR. LURIE: Absolutely.

18 DR. EDMISTON: And the ATCC strains that
19 we currently use as susceptibility patterns, for
20 instance, examples of Staphylococcus epidermis we use
21 is sensitive to cephaslin. But I can tell you the
22 Staph. epis we recover from your patients are probably

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1 resistant to cephaslin. So I think the clinical
2 relevance of the strains is extremely important.

3 CHAIRMAN JARVIS: And we've kind of
4 broadly described some of the characteristics of
5 testing that would be necessary. Do you see there
6 needs to be differences in the testing between gloves,
7 gowns, masks, respirators? Or would it be a one-size
8 fits all?

9 DR. EDMISTON: I don't have an answer to
10 that. I think, if you're going to make a claim that
11 the device reduces the surface contamination of
12 clinical strains, including MRSA, VRE, I think the
13 testing methodology probably could be very similar.
14 But keep in mind the substrates may be different, so
15 they may have to tweak the testing procedures to
16 accommodate the specific substrates. That's why I
17 asked the question about replica plating because you
18 could use any type of fabric in that kind of strategy.
19 But, again, would that be a reproducible strategy for
20 a variety of devices?

21 CHAIRMAN JARVIS: Yes?

22 MR. HEINBUCK: Replica plating is

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1 generally used when we do these kind of tests. I
2 mean, that's commonly the way it's done, although it's
3 a little more technically advanced with all the
4 automation that we have. One of the things we're
5 talking about now is antimicrobial surfaces, are they
6 better than non-antimicrobial surfaces, and we haven't
7 talked anything about controls of how you prove the
8 antimicrobial is actually better than the untreated
9 surface. So when we do all our tests, that's the
10 general baseline control because if you smear
11 microorganisms on the surface, a certain portion are
12 going to die anyway. So you need that control in
13 place, as well. And I don't know if we need to
14 address that.

15 CHAIRMAN JARVIS: Well, I think that I was
16 at least assuming, and I don't know that others
17 weren't as well, that it would be compared with a
18 predicate device.

19 DR. EDMISTON: Or non-impregnated device.

20 MR. HEINBUCK: What we found when we've
21 looked at other people's data in certain projects
22 we've done is they'll give us the reduction without

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1 any control, so just based on, you know, and that's
2 totally inappropriate.

3 CHAIRMAN JARVIS: I would agree.

4 DR. EDMISTON: Before you go, can I ask
5 you a question? Could one size fit all in terms of,
6 for instance, you said replica plating is a standard;
7 they use that quite a bit. So that could be used for
8 testing the substrate of a mask, the substrate of a
9 gown, the substrate of a glove; is that true?

10 MR. HEINBUCK: Yes. The actual
11 measurement technique for determining the number of
12 microorganisms before and after, that has to be
13 replica plating, you know, or I suppose you could do
14 some broth stuff as well. But that, as far as the
15 one-size fits all, you're correct. But the actual
16 test itself, how you're going to apply the
17 microorganisms and what form they are, that's what you
18 have to give some thought to.

19 DR. EDMISTON: Now, when I say replica
20 plating, there may be a confusion here. I'm talking
21 about taking that substrate, putting it on a -- I'll
22 think of it in a second -- putting it on a dowel or

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1 something in which it's stabilized, and then that
2 dowel is touched to the surface of an auger plate.
3 I'm not talking about the kind of replica plating that
4 we do with dilutions.

5 MR. HEINBUCK: Oh, okay. So I was
6 thinking of dilution plating.

7 DR. EDMISTON: But dilution, I know
8 dilution is a standard. But that could be used, you
9 take a defined amount of the substrate, and then you
10 do a vortex it or --

11 MR. HEINBUCK: You put it in a buffer,
12 too, vortex it, sonicate it, whatever you have to do
13 to extract the microorganisms, and then you plate it.

14 DR. EDMISTON: And do log reduction
15 plates.

16 MR. HEINBUCK: Yes. Now, what you have to
17 be careful about is you don't get 100-percent recovery
18 from these surfaces. That's one of the problems you
19 have. And also if you have a coated surface with an
20 antimicrobial, is it actually killing the
21 microorganisms or do you have different recoveries
22 from the surface as they've given you better binding

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1 characteristics. So, you know, when we present our
2 data, I never say log kill. I always put it in log
3 reduction because I can't be 100-percent sure of what
4 exactly the mechanism is of the reduction.

5 DR. EDMISTON: And it's important to
6 differentiate between a static agent and a tidal
7 agent, of course, when you're looking at these because
8 if the claim is going to mean that they kill the
9 organisms but, in reality, they just suppress the
10 growth, that's a different --

11 MR. HEINBUCK: Right. And we've seen some
12 of that in some of the tests we do, as well. We see
13 some static.

14 DR. ARDUINO: Do you use neutralization?

15 MR. HEINBUCK: Well, see, that's a good
16 question because, in general, you always neutralize
17 after you do your test, but we don't always get
18 information from the people we do testing on on what
19 the actual active agent is. So, like if we're using a
20 chloramine-based technology, well, then you can use 5-
21 sulfate to do neutralization. If we don't, then you
22 just have to go into like a protein solution and hope

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1 that neutralizes. But, you know, if we don't have a
2 specific agent and a specific neutralization
3 technique, well, then you can just do the best you
4 can.

5 CHAIRMAN JARVIS: Any other issues on
6 this? In general, what we would recommend is that the
7 testing include both dry and wet states; a variety of
8 clinically-relevant organisms; includes controls; and
9 includes a variety of time points, obviously starting
10 from pretty short to maybe minutes and then hours.
11 Any other inclusions anyone can think of? If not, why
12 don't we take a ten-minute break? I've got about
13 2:45, so about five to three we'll go on to question
14 number three. Thank you.

15 (Whereupon, the foregoing matter went off
16 the record at 2:46 p.m. and went back on the record at
17 3:00 p.m.)

18 DR. JARVIS: Okay, why don't we start.
19 And Dr. Lin is going to make an announcement first.

20 DR. LIN: I want to take this opportunity
21 to present two plaques. One to Dr. Arduino and Dr.
22 Edmiston, too. And maybe I will read -- one is on

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1 behalf of the FDA Commissioner and Associate
2 Commissioner for External Affairs, and Director for
3 Center for Devices and Radiological Health.

4 And I want to read the letter of
5 appreciation. And I would like to express my deepest
6 appreciation for your effort and guidance during your
7 term as a member and chair.

8 For Dr. Edmiston, a chair of the General
9 Hospital of Medical Device Advisory Committee. The
10 substance of this Committee's work, and we impose our
11 conviction that responsible regulation of a consumer
12 product depends greatly on the experience, knowledge,
13 ability, background, and viewpoint that are
14 represented on this Committee.

15 In recognition of your distinguished
16 service to the Food and Drug Administration, I am
17 pleased to present you with a plaque.

18 So I would like to present it on behalf of
19 the FDA.

20 (Applause.)

21 LIEUTENANT COLBURN: For the members of
22 the audience, Dr. Edmiston and Dr. Arduino are current

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1 consultants to the panel but are not current full-time
2 voting members but were previously on the terms that
3 ended at the end of 2005, I believe.

4 Dr. Edmiston was also the former Chair to
5 the panel, and therefore we wanted to recognize them
6 for their efforts and contributions over the past
7 years.

8 DR. EDMISTON: Can I say something?

9 (Laughter.)

10 First of all, this has been a great
11 privilege for me. And I want to thank my colleagues
12 at the FDA for allowing me to spend time with them. I
13 have great respect for your mission. I know how hard
14 you work. And again, this really humbles me in terms
15 of the administration of this. So again, I want to
16 thank you very much for your support of me in the
17 past. And I feel quite honored to have had the
18 privilege to have worked with all of you.

19 Thank you very much.

20 DR. ARDUINO: Chiu, I'd like to thank you
21 too for your support in the past. And I look forward
22 to continued work with you in the future and to

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1 continue on in this consultant advise, if I may.

2 DR. LIN: Thank you both.

3 DR. JARVIS: All right. Now we're going
4 to tackle question number 3, which is for surgical
5 masks or surgical N95 respirators with antimicrobial
6 agents. Please comment on whether performance testing
7 should be expected to support significant reduction of
8 an aerosol or an infectious inoculum, compared to a
9 control device simply demonstrated an ability to kill
10 microbes on the surface of the device. As surgical
11 mask and surgical N95 respirators conventionally have
12 at least three layers, the middle layer is serving as
13 the filter for the device, please also discuss whether
14 the location of the antimicrobial agent on the device
15 should be, should determine in part at least the type
16 of performance testing needed.

17 So if we start with the first part of that
18 question, should performance testing support
19 significant reduction of an aerosol and infectious
20 inoculum compared to a control device, or simply
21 demonstrate an ability to kill microbes on the surface
22 of the device?

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1 DR. ARDUINO: Is there overlap of this in
2 the previous question?

3 DR. SPINDELL: Given some of the
4 information we had about this leakage around the mass,
5 I'm more concerned that, you know, that this is really
6 a non-value added activity. It looks like a speck in
7 the pond compared to the other types of ways that this
8 mask may be ineffective.

9 So I'm not even sure that, my question is
10 whether this should even be something that the FDA
11 should look at, period.

12 DR. EDMISTON: I think we had testimony
13 that there was no methodology available for looking at
14 aerosols.

15 DR. SPINDELL: No, my question is with a
16 ten percent, I don't want to get the term wrong, that
17 increasing, putting antibiotics that may minuscule
18 increase the safety when, you know, there's a big hole
19 in the sides. Is it really even worth something that
20 the FDA should take their time to review these type of
21 products?

22 DR. EDMISTON: Or is the manufacturer

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1 coming up to do the testing?

2 DR. SPINDELL: Exactly, yes.

3 DR. EDMISTON: Well, I don't think it's
4 really the FDA's purview to decide whether or not the
5 industry is going to come forward with a device of
6 this type. I think what they really want to know is
7 whether or not if I come up with this kind of device
8 am I going to be required to do specific testing.

9 So, you know, we can all take our own
10 perspective in terms of whether or not these devices
11 may be relevant, but again, you're not going to put a
12 roadblock in front of me if I want to come up with a
13 device, even though you may, within your group feel
14 this may not be a device that's going to have any
15 merit in the clinical environment. Is that true?

16 DR. MURPHEY: That is correct. FDA
17 certainly does not determine whether or not a
18 particular device should be presented for evaluation.

19 That's not our job. Our job is to look at the device
20 and determine whether or not it is as safe and
21 effective as its legally marked predicate and whether
22 or not its claims are supported by appropriate

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1 performance testing.

2 DR. ARDUINO: In that case, shouldn't the
3 performance testing be at least equal to the predicate
4 device without the antimicrobial?

5 DR. MURPHEY: Well, for those aspects of
6 performance that have nothing to do with the
7 antimicrobial, we would indeed expect that.

8 The challenge for these devices where
9 there are no predicates cleared within the microbial
10 agents is that the manufacturer or the first device to
11 come in with an antimicrobial on it does not have the
12 opportunity to see what a prior device did in terms of
13 supporting its performance claims.

14 DR. GORDON: So, I think it's going to
15 become an issue of labeling them, right? If I was
16 making a mask, could I go and, and I had a significant
17 reduction of an aerosol of an infection inoculum,
18 could I say I'm selling a mask that cuts down the
19 inoculum by ten percent but not say, by the way, I
20 haven't increased the overall exposure by more than,
21 you know, a percentage of a percentage? Would they
22 have to say that or could they just go out and say we

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1 decreased the transmission through the mask, call it
2 that, and then you can make your own assessment?

3 The concern, I think from some of our
4 prospective is that the public might not be as
5 brighter and sightful, and certainly I wasn't until I
6 learned about the side, the 10 percent issue today,
7 about the lack of additional benefit that we're
8 perceiving we're going to get from the antimicrobial,
9 antimicrobial involvement in the mask, and the fact
10 that the way it marketed could affect how it's
11 utilized and might pull the wool over people's eyes at
12 that.

13 DR. MURPHEY: Certainly we would want to
14 make sure that the wording of a particular claim for a
15 particular device was very clear in terms of
16 indicating what that claim meant.

17 And again, because there are at present no
18 clear masks or respirators within microbial agents for
19 FDA, we would be to a certain extent guessing on what
20 the ultimate claim wording would be.

21 But it is not unusual for us to say with
22 other devices express your claim in terms of what it

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1 is that your testing has demonstrated. For instance,
2 for barrier performance claims for surgical gowns, the
3 current ANSI Standard PB 70 allows a manufacturer to
4 look at performance at potentially four different
5 levels. Now, FDA discourages comparative claims
6 because you really can't be sure that even if you've
7 tested everything on the market today and you're
8 better than everything else there isn't something that
9 isn't going to be clear tomorrow that's better than
10 you are.

11 So manufacturers can't say we need the
12 highest standards of PB 70. They can say we need
13 level 4 performance testing, and this is what level 4
14 performance testing is. And we would ask that they
15 explained in an understandable way in the labeling.

16 So it's what is it that your test
17 performance has actually demonstrated, and then state
18 that in a clear cut manner. It's very important to us
19 that labeling not misrepresent what a device can and
20 cannot do.

21 DR. LURIE: So then, you know, if one said
22 that it reduced the inoculum and inhaled air mixture,

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1 would that, it seems to me that phrasing something
2 like that would address Dr. Spindell's and Dr.
3 Gordon's issues that, in fact, what you're really
4 breathing in has a much lower inoculum. It would
5 somewhat change the standard, but I think it would
6 address my concerns and perhaps yours also.

7 DR. SPINDELL: I would agree. I mean I
8 think you said we don't have a controlled device. I
9 think we do have a controlled device. A controlled
10 device is a current mask in the field without the
11 antibiotics. And if you go with the antibiotics, then
12 I think the minimum we want to see is that there's a
13 significant reduction in the total inoculum, including
14 the ten percent compared to the previous non-
15 antibiotic mask.

16 DR. MURPHEY: I would simply point out to
17 you, however, that in vitro testing you're not going
18 to be able to measure the total inward leak of the
19 fit, or the failure of fit, of the mask or respirator.

20 When you're dealing with in vitro testing,
21 you're dealing with what can happen to organisms on
22 the surface of a device, or if your antimicrobial is

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1 not on the surface and you need to challenge it in
2 some way, this is why we're asking the question about
3 aerosol testing.

4 The way that you would measure total
5 inward leak of any device, whether it have an
6 antimicrobial agent on it or not, would be with it
7 actually being worn. And NIOSH, of course, does that
8 in fit testing of N95 respirators. However, there
9 they are challenging with a harmless aerosol, sodium-
10 chloride crystals, because you in fact measure what is
11 the aerosol on the outside and then you have a second
12 measurement taken inside th respirator as it's
13 currently being worn.

14 To do that for a pathogenic aerosol would
15 be a bit challenging.

16 DR. LURIE: I'm not sure that it would be
17 challenging. We all see Venturi masks in the ICU and
18 it's easy to setup a Venturi valve with a ten percent
19 leak on it. And I'm not an expert at testing these,
20 but it seems to me that it would be very easy to put a
21 little Venturi valve that would change the flow
22 according, well keep the same percentage according to

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1 the flow and allow for exactly that leak.

2 DR. JARVIS: Dr. Truscott?

3 DR. TRUSCOTT: Just addressing that --

4 DR. JARVIS: Can you hit the button at the
5 top?

6 DR. TRUSCOTT: Yes, thank you. The total
7 inward leakage done in England and Europe is exactly
8 as Dr. Murphey is expressing. But we're correlating
9 it too with live viruses on mannequin and then also
10 doing it with particles and seeing that correlation.
11 And it is much better than this ten percent that
12 everybody keeps talking about, as far as reducing it.

13 And you're absolutely right, if you're
14 going to put antimicrobial, you darn well better have
15 a good fit, and an extremely tight fit. So
16 unfortunately I'm hearing hair being pulled out that
17 it's absolutely worthless to even where a respirator
18 and I think it's gone away too far.

19 But there are tests, also as far as
20 getting the organisms in an aerosol, capturing into
21 the respirator, and taking the one minute test, the 3-
22 minute test, the 30-minute test, see how long it takes

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1 to kill tuberculosis versus rhinovirus or something.

2 Just all those tests are being done.

3 DR. EDMISTON: So you're comfortable with
4 the current methodology to recover these, not just
5 particulous, but viable particles to determine whether
6 or not there could be a reduction or release?

7 DR. TRUSCOTT: It's a correlation study.
8 We do the viral testing on a mannequin. Dr. Grinchman
9 does it at University of Ohio, Cleveland. Dr. Meyers
10 does the particulate studies.

11 In looking at the mannequin study, where
12 you do the inert particles, plus you do the viruses,
13 you are able to get a correlation on come through.
14 And then you turn around and do live people because
15 they're going to smile, and move, and everything else.

16 And you do that with real particles rather than
17 viruses. And it seems to be working very well.

18 DR. EDMISTON: What about going the other
19 way in terms of some of these other masks, for
20 instances, a traditional surgical mask, if there's a
21 proposal of putting an impregnated technology on a
22 traditional surgical mask, is there a methodology

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1 available that could give us reasonable answers in
2 terms of the reduction of the release of some of these
3 organisms, like Staph aureus, Staph eip, and others?

4 DR. TRUSCOTT: I'm sure that there is
5 because even the mannequins are built with a suction
6 capability so that it's coming in this way as well.

7 So I think you'd be going, oh, I'm sorry,
8 the other way would work too as far as a capture in a
9 public chamber, but I have not done that, we have not
10 done that yet.

11 DR. EDMISTON: We published a paper a few
12 years ago looking at microbial shedding in the
13 operating room. And that used a non-traditional
14 approach to looking at microbial capture by setting up
15 a series of cascade impactors within the vicinity of a
16 surgical wound. Now, that's not a non-traditional
17 approach, so the issue would be the methodology like
18 that, would that be appropriate for looking at and
19 answering this particular question.

20 In my mind, I'm not really sure, based on
21 the experience that we've had. But at least we can
22 demonstrate microbial shedding.

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1 DR. TRUSCOTT: And perhaps even just the
2 fall out plates, or in this case the cascading
3 pinchers, if you're able to limit the space where it's
4 coming out, you probably might maximize the efficiency
5 of it.

6 Thank you.

7 DR. JARVIS: Thank you. Any other
8 questions or issues?

9 Dr. Aziz?

10 DR. AZIZ: Nothing.

11 DR. JARVIS: Dr. Santhiraj, any issues on
12 this?

13 (No audible response.)

14 Okay. So in regard to the first part of
15 the question, I think it's somewhat dependent on what
16 the claim is. If it is significantly reduce either
17 viral, or bacterial, or fungal contamination, rather
18 colonization or infection in the healthcare worker,
19 then I think you're really stuck with the first part
20 of doing aerosol testing.

21 On the other hand, if you're arguing that
22 the antimicrobial is solely there to reduce cross-

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1 transmission from the mask, or respirator to patient,
2 then the first part would be perfectly adequate, or
3 the second part would be perfectly adequate to
4 demonstrate it would kill it.

5 So I think we really need to do both
6 depending on what the claim is.

7 DR. LURIE: I think if you want it to be a
8 personal protective device, then I think we can define
9 it more closely. You know, it has to have more than
10 in vitro efficacy. And so, well as I have been doing
11 all day, I would --

12 DR. JARVIS: Again, if we have the three
13 layers of indication of reducing colonization,
14 reducing infection, or reducing contamination, I think
15 we agreed before that --

16 DR. LURIE: Yes, in that context, yes, I'm
17 sorry, in that context, I agree.

18 DR. JARVIS: Anything else on that part of
19 the issue?

20 DR. EDMISTON: That would sound to me,
21 based on what I've just heard, would be primary in
22 vitro studies.

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1 DR. JARVIS: Correct. And then the second
2 part of that question relates to if the filter is in
3 the middle layer, discuss whether the location of the
4 antimicrobial agent on the device should determine at
5 least, in part, the type of performance testing.

6 I'm not sure that I see there really is a
7 need for that.

8 Does anybody disagree?

9 (No audible response.)

10 Okay.

11 Go ahead?

12 DR. TRUSCOTT: Just really, really fast,
13 something that's on the inside in the middle, it
14 really has to be almost instantaneous effect. I mean
15 it's decreasing the airflow coming through. So that's
16 a very stringent test on timing. But something that's
17 on the outside, it's more for preventing contamination
18 during mask or respirator removal, or spreading if I'm
19 coughing or touching it or adjusting it. So they
20 really are quite different tests. That one you could
21 use the regular ASTM test of contact and how long it
22 takes to kill, I think, so they really are quite

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1 different concepts, airflow versus contact.

2 DR. JARVIS: I think that's why we said we
3 would need to do the one, the other, or both,
4 depending on what the claim is.

5 DR. TRUSCOTT: Sorry, I misunderstood. I
6 thought you meant they do the same thing.

7 DR. SPINDELL: No, I was just going to
8 agree that it doesn't really matter. It depends on
9 what the claim is of what the test is going to be
10 done, not where the layer is.

11 DR. JARVIS: Exactly. So Dr. Lin, is that
12 adequate or do you need further discussion on that?

13 DR. LIN: Dr. Murphey, why do you think
14 that -- I think that the question here is that, as you
15 know, that the surgical mask or layer, now you put
16 that antimicrobial agent is located in the middle
17 layer, does that mean that's the layer that you test,
18 or test the material alone is sufficient. And that
19 pretty much is the question.

20 DR. JARVIS: Well, I think if I understand
21 that correctly, you know, depending -- I think all of
22 us have said in the past you want to test the end use

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1 device that's going to be used, for instance a
2 surgical mask, if it's a sterile surgical mask, then
3 it would be after it is sterilized. If it's a non-
4 sterilized surgical mask, then just as it's processed
5 and it really wouldn't matter in terms of the
6 layering. It depends more on what the claim is by the
7 vendor that drives what testing would be done.

8 DR. LIN: You probably misunderstood. As
9 in the final finished part, the three layer all
10 together, but when you do the in vitro testing
11 sometimes -- since that layer, that particular layer
12 is contained under antimicrobial agent, then we just
13 test the particular layer, not whole device. Now,
14 would that be appropriate?

15 DR. EDMISTON: I think part of the
16 submission would be they would provide data to you
17 with their impregnated materials showing bacterial
18 adherence or prevention of bacterial appearance, or
19 bacterial killing on that substrate. So I think I
20 tend to agree with you in the sense that, or maybe
21 just clarifying the question that part of it, part of
22 the submission would have to include data specific to

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1 that substrate surface, whether it's the middle, or
2 the front, or the end. So I suspect that would just
3 be part of a normal submission showing the activity
4 under in vitro conditions using whatever method is
5 available, whether replica plating or what we
6 discussed earlier.

7 So I think that would be, that in vitro
8 component is extremely important. However, the in --

9 DR. JARVIS: Let me ask you a question on
10 that though. Say I have a respirator and the
11 antimicrobial impregnation is in the middle layer, my
12 understanding is you're taking that middle layer out
13 and doing the testing without the other two layers
14 there. Wouldn't you want some comparability data to
15 show that, in fact, the respirator, the way I'm going
16 to wear it with all three layers works the same as
17 taking that middle layer out and testing it?

18 DR. EDMISTON: That would be a, I think
19 that would be a, and you have people in the industry
20 who disagree with this come on forward because I can
21 always learn a lot from this experience, but I would
22 think that would be a staged response in that, first

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1 of all, you want to validate. In the early stages you
2 validate that the antimicrobial agent is indeed on
3 that surface and it does inhibit growth or kill
4 organisms. And then in the incorporated device, as
5 you're describing, then the aerosol testing would be
6 used.

7 MR. RENGASAMY: I guess a couple
8 questions. Regarding the first one, you talked about
9 a significant reduction in the number of aerosol
10 particle going to the antimicrobial and the control
11 filter, that wouldn't be any different within the
12 number of particles going through the filter. The
13 penetration with the two different filters will be
14 more around the same. There won't be any difference
15 no matter what the technology is.

16 DR. JARVIS: I think that's fine. I think
17 what we're saying is if the vendor claims that the
18 antimicrobial impregnated device will reduce the risk
19 of penetration or have a faster kill that if you
20 compare it with the non-antimicrobial impregnated
21 device or a control if it ends up being the same then
22 the claim is bogus.

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1 You need to provide some scientific
2 justification that the device that's impregnated has
3 more capability of doing what you say it does than the
4 non-impregnated device. And if you're saying that it
5 has nothing to do with antimicrobial on it, that the
6 only thing that matters is the filtration, then I
7 don't think anybody is going to ever come to you, come
8 to the FDA with a device that has superior efficacy.

9 MR. RENGASAMY: Because the antimicrobial
10 complement of the respirator is not involved in the
11 filtration part of the story. It's not filtering any
12 particles. It is just cleaning the microorganisms.
13 So it has nothing to do with the filtration mechanisms
14 in that sense.

15 So it is not, because biological, as well
16 as inert particles, they are here as particles. It
17 doesn't matter whether it is a biological particle or
18 an inert particle. The mechanism is the same and the
19 particles that go through the filters, depending on
20 filter efficiency.

21 DR. EDMISTON: I think the issue is
22 significant reduction in viable, viable particles,

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1 because the use of the antimicrobial is to reduce the
2 viable number of particles, the individuals exposed to
3 it. Does that, does that make more sense?

4 MS. SANTHIRAJ: Yes.

5 MR. RENGASAMY: You can say that, yes.

6 MS. SANTHIRAJ: Yes, like 95 percent of
7 the organisms are filtered, and out of them, maybe 80
8 percent are reduced with the antimicrobial. That's
9 what we mean here.

10 MR. RENGASAMY: But when you say 90 for
11 the filter, you know already 5 percent of the
12 particles may go through. The penetration would be
13 less than 5 percent. If you add a n antimicrobial
14 complement to the filter, it's not going to change the
15 number of particles that is going through the filter
16 portion.

17 DR. EDMISTON: Well, if you compared it to
18 a non-impregnated device, that 5 percent of the non-
19 impregnated device, a percentage of those would be
20 viable. However, in the impregnated device with an
21 antiseptic or antimicrobial, we would expect, if this
22 is the claim, that there would be fewer viable

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1 organisms going through that impregnated device than
2 the non-impregnated device.

3 DR. SPINDELL: That doesn't it really
4 matter what the claim, to me, it seems what the claim
5 is. What claim are they going for?

6 So getting back to Dr. Jarvis' point, I
7 think this is really not -- the answer is still the
8 same. What is the claim, how do you meet your claim?

9 The claim is less particles going through and it
10 doesn't, and it doesn't meet the claim.

11 DR. JARVIS: So I think we understand what
12 you're saying, but the vendors, manufacturers, if they
13 want a claim that antimicrobial will reduce the number
14 of viable organisms going through that filter, even
15 though you and I may believe that it's not going to
16 matter what I put on that filter, it's the filter
17 itself that's the only thing that's important, then
18 the manufacturer has to prove through in vitro studies
19 that they have reduced the number of organisms going
20 through.

21 MR. RENGASAMY: In order for the micro-
22 organisms to be killed when it goes through the

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1 filter, it doesn't kill the filter, the fiber, the
2 mechanism of particle filtration is the particles
3 diffused through the media containing the fiber
4 material. When it hits the fiber, it is caught. It
5 doesn't go out of the filter. Only when it doesn't
6 touch the filter media, it gets out of the filter.

7 So I doubt whether the particles that are
8 going to come off the filter will have any interaction
9 with the antimicrobial complement of the filter. I'm
10 just guessing, but it looks like it.

11 DR. SPINDELL: And that's what the
12 manufacturer has to prove. I mean I don't think
13 anybody, I think we're in violent agreement here. You
14 know, you may doubt anybody can do that, but it's up
15 to the manufacturer to show that.

16 MR. RENGASAMY: It's a very, it looks like
17 it's a very easy question to answer. When you do the
18 assay, there is already a lot of plus and minus
19 situations. So it's very difficult to come up with a
20 clear answer, this is doing good or this is not doing
21 good.

22 You can say this way, I can do an assay

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1 and say, it is doing a great job. Another person can
2 do the same assay under a slightly different condition
3 and he will come up with a conclusion that it's not
4 doing a big difference. So these are not really easy
5 answers to get from the studies.

6 DR. JARVIS: But presumably any
7 manufacturer that's providing the data, FDA will
8 require enough tests to be done that that variability
9 between the non-impregnated and impregnated should be
10 washed out. You wouldn't expect that it only be in
11 the impregnated and not in the other. It's going to
12 be in both. And that's FDA that has to worry about
13 how many tests.

14 DR. EDMISTON: So Dr. Jarvis, in terms of
15 this particular question right here, what you're
16 really saying is that you don't think that testing the
17 substrate by itself is a significant variable here.
18 It should be the complete device and measure what is
19 going in, in terms of viability at the end. If that's
20 what the indication or the claim for is the device.

21 DR. JARVIS: Yes, I can see where you
22 might use just the filter itself for the testing, but

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1 I would like to see data showing that the final
2 product that I'm going to put on does the same thing
3 as that filter by itself.

4 DR. EDMISTON: I'd agree with you.

5 DR. AZIZ: But I think the question here,
6 the way I'm reading it again, is asking about the
7 location of the agent. We didn't ask about the
8 filtration and all the other things. I mean, you
9 know, the outcome is the outcome. And that will take
10 us back to question number 1 with the indications. I
11 mean I think if we just go back to the question here
12 and take a really good look at it, and when it's
13 asking for the location, whether the location will
14 make any difference, I don't think that's for us to
15 answer and just keep it like that.

16 DR. JARVIS: Well, I would argue that it
17 doesn't make any difference.

18 DR. AZIZ: It doesn't.

19 DR. JARVIS: Because the vendor makes the
20 claim.

21 DR. AZIZ: Right.

22 DR. JARVIS: We have said what test has to

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1 be passed, or FDA says what tests have to be passed,
2 and if it's on the outside, the inside, or the middle,
3 it either passes or it doesn't pass.

4 Is there someone else in the audience?

5 (No audible response.)

6 All right, Dr. Lin, any questions on that
7 or is that okay?

8 DR. LIN: That's fine.

9 Dr. Murphey, do you have any?

10 (No audible response.)

11 LIEUTENANT COLBURN: I just wanted to make
12 a point to the audience that if you need to address
13 the panel that you grab the attention of myself or the
14 chair, and then when you do come to speak, state your
15 name and who you're from for the poor people around
16 the side there trying to find out who you are while
17 they're typing away here, as this is being recorded
18 for your benefit later.

19 DR. JARVIS: Okay. The next question is
20 number 4. For antimicrobial agents of the surgical
21 mask and N95 respirators, please discuss the safety
22 issues for the device, where and/or how these might be

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1 evaluated; including but not limited to the effects on
2 the oral nasal and oral mucosa, and effects on the
3 lower respiratory tract.

4 I guess I'll take a first start. I think
5 with all of these, some of the issues that we heard
6 before were, you know, toxicity issues, allergy
7 issues, issues in terms of elution of whatever is
8 impregnated coming off of that device, and I think FDA
9 certainly needs to have that information.

10 And for potentially devices that will be
11 used on either immuno-compromised patients, or
12 pediatric patients, or neonatal patients, you
13 certainly need to have that kind of information. And
14 I guess Dr. David had even mentioned data on potential
15 adverse impact of whatever antimicrobial agents are
16 being used to impregnate the device on potentially
17 pregnant females.

18 DR. SPINDELL: Would this-- does the
19 panel feel, because this is an important question
20 here, that this would require in vivo testing of the
21 device? And should we make that as part of our
22 recommendation?

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1 DR. EDMISTON: This is, I think this is an
2 extremely important issue.

3 And Dr. Lin, you're a toxicologist. Now
4 take your FDA hat off for a moment, all right. You're
5 just a regular panel member. How do you feel about
6 this? Isn't this a very significant component,
7 especially with a mask that is fitting very tight?

8 DR. LIN: This is the reason that we bring
9 that issue to the table. In that when you have an
10 antimicrobial agent caught on any layer of a mask and
11 you, it's tie it, and you breathe in some of those
12 chemicals that reach out and would get into any
13 respiratory tract, now the question is do we need to
14 do that type of test. And two, how do we do it.

15 DR. EDMISTON: Well, you know, I usually
16 am not quite as much of a nay-sayer as some of my
17 colleagues, but I can see if you had a device
18 impregnated with an antimicrobial agent or an
19 antibiotic, and you're inhaling these sub-inhibitory
20 levels of an antibiotic into the nasal passages that
21 could actually promote issues of resistance. So I
22 think there is significant, significant consideration

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1 about both the toxic effect and does the intimate
2 contact between the nasalpharyngeal with this mask,
3 does this possibly create an environment where
4 resistant organisms could develop.

5 DR. LIN: How is that?

6 DR. LURIE: I personally would be quite
7 uncomfortable breathing these copper ions, and silver
8 ions, and iodine ions all the day long. I don't have
9 any idea what the long-term effects would be on my
10 lungs and I would really rather not do that, be a
11 subject in that test. But I think that stuff has to
12 be tested. They've got to be leaching out. If you're
13 wearing a mask for three to four hours, it's going to
14 get damp, it's going to get moist. I don't care what
15 attachment system you have, you're going to end up
16 breathing it.

17 DR. JARVIS: Well, and some might suggest
18 that --

19 MS. SANTHIRAJ: Some might get the
20 asthmatic effect also. Asthmatic, allergic reactions.

21 DR. JARVIS: Exactly. And you may need to
22 look at it differently for surgical masks versus exam

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1 masks or respirators that are used for a short period
2 of time.

3 Now, if you're talking about going into an
4 isolation room, you won't be wearing it for two or
5 four hours, but you'll wear sequential ones for maybe
6 even longer period of time over the entire period of a
7 week that you're going in and out of an isolation
8 room.

9 DR. LURIE: But I can't imagine we're
10 going to have different sets of masks for short-term
11 and long-term use.

12 DR. JARVIS: No, I would think they would
13 be the same.

14 DR. GORDON: And I would think also they
15 need to be followed for some period of time, not just
16 for a few wearings or a week or two because a
17 cumulative effect is a concern certainly.

18 DR. JARVIS: I think we have a couple
19 people in the audience, first here and then over
20 there.

21 MS. KRZYWDA: I just wanted to follow up
22 on your comment. I think that long-term is very

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1 important because a cumulative effect may even be
2 years down the road, as we've seen with other things.

3 MR. HEINBUCK: This is Brian Heinbuck
4 again. We know for a lot of these agents that we put
5 into masks and what not and those threshold limit
6 values are allowable, allowable dosage that you're
7 allowed to be exposed to. And that can be measured in
8 a lot of these devices. And I know in some of the
9 devices that we've tested we have measured them and
10 it's not, the manufacturers that have had to put in
11 the appropriate protection devices so you're not
12 necessarily inhaling them. They're actually contained
13 within the mask.

14 So potentially, you know, your
15 recommendation can be just have the mask not exceed
16 the threshold limit value for the particular
17 disinfectant.

18 DR. SPINDELL: When you say threshold, are
19 you talking about an aerosol threshold, or an oral
20 threshold, or a blunt level threshold?

21 MR. HEINBUCK: I'm talking-- so I'm a
22 microbiologists. The chemists we have on staff did

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1 this work, but I know that when she did the
2 measurements they were below the value. But I can't
3 talk on the specifics of that, but certainly
4 recommendations can be made for obviously the aerosol
5 dose.

6 DR. SPINDELL: Because my concern would be
7 the oral dose ends up in the GI tract. And that's a
8 whole different story than, I don't think you can
9 correlate that to what dose might get into the
10 nasalpharyngeal area and the toxicity.

11 MR. HEINBUCK: Right, and I don't know the
12 answer to that.

13 And just one other thing I wanted to
14 address. We talked, Dr. Edmiston, I think, talked
15 about potential resistance by breathing the
16 antimicrobial. If you could clarify that a little
17 bit, we know that a lot of these disinfectants, such
18 as chlorine, you know, has been around forever for
19 disinfecting drinking water and to my knowledge
20 there's no resistant organisms to chlorine; and I
21 can't imagine in this context there would be
22 resistance to a particular antimicrobial as well.

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1 DR. EDMISTON: What if, what if a
2 manufacturer came forward with a technology involving
3 a minocyclcin rithampin bound mask. That would be a
4 different scenario, wouldn't it?

5 MR. HEINBUCK: Well, yes, I would agree
6 with that. But for these broad spectrum type
7 antimicrobials or disinfectants, perhaps, I don't
8 think you'll have a problem.

9 DR. EDMISTON: No, I agree with you.

10 DR. JARVIS: Over here first.

11 MR. PAGE: Tom Page from Cupron again. In
12 response to Dr. Lurie and the reference to long-term
13 effects of copper and silver, I just wanted to echo
14 what the gentleman said about there being exposure
15 data out there, PELs developed by OSHA, I mean for
16 accompanys that have been around for a long time, there
17 is all kinds of sort of mucosal membrane and other
18 data that exists. And I would argue that sort of to
19 ignore that data, I mean let's say for copper, to
20 ignore the data would be sort of unnecessarily, you
21 know, create a hurdle that really has been already
22 jumped many, many times. So I would argue that --

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1 DR. LURIE: Well, I would argue that
2 everybody's personal experience when you, when people
3 wear copper jewelry they get skin rashes and whatnot.

4 MR. PAGE: Right.

5 DR. LURIE: And I think that you're
6 talking about making millions of these things and then
7 putting them out to everybody, you're going to have a
8 significant allergy rate. You're going to have a
9 significant reactivity rate. And I think it is
10 reasonable to discuss. And, you know, 1 out of 1,000
11 and 1 out of 10,000 people is going to pulmonary
12 reaction or an immuno-reaction. And I'm not sure what
13 we're preventing with all this to begin with.

14 So we're looking at causing problems that
15 we may not be preventing anything with this new
16 technology. So I think it is important to err on the
17 side of caution.

18 MR. PAGE: Right, I mean look, in terms of
19 allergic reactions, first of all, we've done plenty of
20 work in animals, on the guinea pig and rabbit and
21 found basically, consistently zero allergic reaction,
22 but that's with specific reference to our technology.

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1 I mean, I agree that these issues of
2 allergy and, you know, all the different areas of the
3 mouth and the nose which would be exposed to the
4 particular compound have to be looked at.

5 All I am saying is that where there is
6 existing data, let's say for compounds which are very
7 well known, copper, silver perhaps, I'm just
8 suggesting that that data should be used and observed.

9 I'm not making a claim that's less modest than that.

10 DR. JARVIS: Okay. Thank you.

11 DR. ARDUINO: Like other devices, like
12 implantables we do leech testing to make sure there is
13 no things coming up. Will we be doing leechables on
14 masks?

15 DR. LIN: Well, I think that's certainly
16 one thing that we would consider for the masks.
17 That's a question we would like input from, from the
18 panel, is this reasonable to request this type of
19 testing.

20 DR. SPINDELL: I think, you know, at least
21 in the industry we're always looking at the risk-
22 benefit ratio and the risk-benefit products coming

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1 forward. And to get to Dr. Lurie's point is right now
2 I don't think we've seen any scientific data to say
3 there's a benefit to this, so that for any risk is a
4 big issue, even if it's a small number here. And I
5 think at least until there's a proven benefit to this,
6 we should be extremely strict on the requirements for
7 safety.

8 MR. GORANOV: Konstantin Goranov, NOVEKO
9 International.

10 Yes, I would like to kind of ensure the
11 panel of the development of those antimicrobials. And
12 before actually we think about the antimicrobial
13 formulas, we think about the safety of the other
14 things we put into those substrates. And that's a
15 very, very important issue for everybody who is
16 involved in the developing stage. The ethical issues
17 have probably formed before the business.

18 And in terms of leech off of those
19 chemistries, yes, we are very, very aware of the
20 potential effects, side effects, and we try to select
21 the chemistries and the delivery mechanisms that
22 minimize the exposure to the wearer. And we do have

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1 scientific data at the moment to say whether one
2 particular chemistry works better or less. It's
3 gotten to the issue of long-term effect and we're very
4 much aware of this. We develop special techniques to
5 prove to the best of our judgment what will be the
6 long-term effect on our wearer and the particular
7 environment. But that actually is done in very
8 exaggerated circumstances.

9 If we take on the PPM level of the anti-
10 additive on the substrate, we can use 10 times, 100
11 times high concentration just for the test. The
12 question is, is that acceptable to the panel and FDA?

13 If we exaggerate the concentration and try to
14 basically short-term evaluation, predict long-term
15 effect?

16 DR. EDMISTON: I think in addressing Dr.
17 Lurie's consideration is that when an anti-infective
18 is brought to the market, usually between 5,000 and
19 10,000 individuals are involved in clinical trials,
20 and quite often we don't see the adverse effect until
21 once it's been released on several million individuals
22 who have had exposure to that drug.

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1 So I have to harken the comments of my
2 colleagues as being significant in that the risk, the
3 potential risk from a toxicologic perspective needs to
4 be very well clarified because, take somebody who has
5 emphysema, take somebody who has COPD, who may be
6 wearing these masks, is there any risk in that patient
7 or that device wearer population who may have those
8 health, adverse health effects? So toxicology has to
9 be an important issue. And the TLV is fine, but at
10 the same time, if you have additional data or your
11 models have long term chronicity studies, those are
12 extremely important. That's sort of a basic tenet in
13 toxicology are long term chronicity studies. And
14 those might be actually relevant in this type of
15 technology.

16 DR. SPINDELL: I'm also concerned, I don't
17 think we should, we would blankly or probably anybody
18 blankly say high dose testing of a short period of
19 time added to its long-term effects unless somebody
20 disagrees with that.

21 MR. GORANOV: Yes, certainly we don't have
22 some type of magic standard protocol to work with and

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1 any advice and any directions will be highly
2 appreciated.

3 DR. JARVIS: Okay, thank you. Any other
4 discussion on this issue? Any other questions, Dr.
5 Lin?

6 DR. LIN: I think that's it. Thank you.

7 DR. JARVIS: Okay. If we move to question
8 number 5, so it's really a repeat of number 4.

9 Are there any additional issues, Dr. Lin,
10 on 5 that we have not addressed so far?

11 DR. LIN: The question number 4 has to do
12 with masks. Now, this is for medical gloves,
13 particularly surgeon's gloves, what do you do?

14 DR. AZIZ: I think number 5 is addressing
15 more to the patients. Am I reading this correct,
16 especially the second part where it talks about
17 pediatric and immuno patients? I mean are we --

18 DR. EDMISTON: You want to go back to
19 question 4, Dr. Lin? Is that, you felt that?

20 DR. JARVIS: It says particular 5 is
21 addressing surgical gloves. And I guess it raises the
22 question of are there different issues that we feel

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1 needs to be addressed in terms of toxicology, leeching
2 out of a mask, versus a gown, versus a glove that's
3 used for isolation room, versus a glove used for
4 surgery, or should it be the same across the board.

5 DR. LURIE: You're looking at me, thank
6 you. I think there is a lot more, I think just
7 recognize that there's a lot more variety in gloves.
8 I think if you go to an operating room you can choose
9 between 5 or 10 manufacturers. We recognize latex
10 allergies. We recognize different powders give people
11 different rashes. And I think one might be able to
12 select an antimicrobial glove, just like you can
13 select a thicker glove or a thinner glove. And that
14 might, in fact, there might be more variability and
15 more breathing space here because I think that's
16 generally a place where there's more variety offered.

17 DR. SPINDELL: But I still think, I assume
18 the bottom line is, if I'm not mistaken, is we think
19 that these gloves need to be tested for its effects,
20 short-term toxicity, allergy, long-term toxicity,
21 especially surgical gloves that's on the exterior
22 surface because it's going to get into people's blood

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1 streams.

2 DR. LURIE: Absolutely, the history of
3 surgical gloves goes way back to Semmelweis and Lister
4 where they coated gloves with carbolic acid. There
5 was a period when I trained when they were coated with
6 corn starch, I think it was, and then we found out
7 that they caused all kind of intra-abdominal
8 peritonitis and granulation. So I think all the
9 standard testing that we talked about would certainly
10 be true.

11 MS. KRZYWDA: I just wanted to harrow that
12 response too because gloves are different in that you
13 use them in body cavities. And you usually don't use
14 the mask and a respirator that way, so it does really
15 impact not just the wearer of the glove, but in this
16 case strongly the patient.

17 DR. EDMISTON: Can I ask a question? Is
18 there a glove manufacturer, is there a glove person in
19 the audience?

20 We've got two of them? I think you both
21 better come up here.

22 The question that I have is you all have

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1 had a lot of experience with probably designing non-
2 allergenic gloves and the testing that is involved to
3 make sure that these gloves are non-allergenic. What
4 we're talking about is putting antimicrobials onto a
5 glove surface. Is there testing available that could
6 rationally separate whether or not the user would have
7 an adverse event associated with exposure to that
8 agent?

9 Any one of you can start.

10 MR. SCAGLIONE: Mike Scaglione with WRP.
11 You're making an assumption that we put the
12 antimicrobial on the outside surface of the glove and
13 that's not necessarily the case.

14 You could put it on the inside surface.
15 You could embed it within the film. There is
16 technology where you put it between two layers of a
17 glove. So there's a lot more to your question than --

18 DR. EDMISTON: Right, I realize that. But
19 the question is are there testing methodologies that
20 can be used to determine whether or not the user may
21 have an allergic or an adverse event with exposure to
22 that molecule that's inside that glove?

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1 MR. SCAGLIONE: Given that the
2 antimicrobial claim has never been allowed for gloves,
3 there's not a bank of tests that the glove
4 manufacturers typically perform on antimicrobials to
5 determine whether there's an allergic reaction to it
6 of any sort. It's not part of the 510(k) procedure,
7 and therefore it's a cost that the manufacturers are
8 not bearing right now.

9 DR. EDMISTON: When you develop a non-
10 allergenic glove though, how do you make a comparison
11 between that and a glove that may induce an allergic
12 response?

13 MR. SCAGLIONE: There used to be a hypo-
14 allergenic claim long ago. And the test for that was
15 the 200 patient Drays testing. That was found to be
16 ineffective and therefore, it was discontinued because
17 it wasn't necessarily predictive of whether you'd have
18 an allergic reaction because latex allergies are
19 different than a chemical allergy.

20 So now the only, there is no hypo-
21 allergenic claim. So we test for the existence of
22 protein or the level of protein in a glove to

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1 determine whether you'd have a type 1 protein allergy.

2 And that's all the tests that's done.

3 There is a standard bank of guinea pig and
4 rabbit tests for general reactions as part of the
5 510(k) procedure.

6 DR. EDMISTON: Could that type of testing
7 be modified or used to look at those issues in these
8 antimicrobial impregnated gloves?

9 MR. SCAGLIONE: I don't know. I'm not a
10 microbiologist or an allergist to know. Yes, Dr.
11 Truscott might have a much better answer.

12 DR. TRUSCOTT: Just yes, if you modified
13 any of the guinea pig sensitization test or
14 maximization test. Also, the quantities, based upon
15 the historical aspects of what quantity causes some of
16 the issues. But also the guinea pig swell test for
17 the type 1 reaction.

18 DR. EDMISTON: Is that, would that also be
19 appropriate testing for pediatric and neonatal
20 populations?

21 DR. TRUSCOTT: You're probably going to
22 end up having to adapt and going to a new mouse or

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1 looking at the skin permeation.

2 MS. BECK: My question is a little bit
3 different.

4 My name is Robin Beck with BioBarrier and
5 we're working on putting a layer of antimicrobial in
6 between two layers of latex or synthetic for gloves.

7 And my question is if we talk about a
8 reduction of viable pathogens when a sharp goes
9 through a surgical gloves, a suture needle, or a
10 scalpel, if we can prove a reduction of viable
11 pathogens from one side of the glove to the other,
12 would we fall into your category, your earlier
13 category of three categories of colonization,
14 prevention, because proving our mathematical reduction
15 would probably be in vitro and proving prevention of
16 infection would be in vivo.

17 DR. SPINDELL: I would, you know, I would
18 say that depends on the claim you're going for. If
19 you're going for preventing infection, I think we
20 would want, I think I'd like to see that you actually
21 do prevent infection. If your claim is that it will
22 prevent the bacterial or viral load associated with a

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1 needle stick, then that's a different story.

2 MS. BECK: It would be a viral load
3 because it would be a dose related.

4 DR. SPINDELL: But I am saying that would
5 be --

6 MS. BECK: Okay.

7 DR. SPINDELL: -- my understanding that
8 would be --

9 DR. JARVIS: That could be in vitro.

10 DR. SPINDELL: That could be in vitro, but
11 that would be the only claim or indication of use you
12 would have.

13 MS. BECK: Okay, thank you.

14 DR. JARVIS: Dr. Murphey?

15 DR. MURPHEY: I would just like to remind
16 the panel that there was a second slide associated
17 with this question. It really is directed more to the
18 different patient populations that could be exposed to
19 antimicrobials and their toxicity. This is more
20 common with gloves than some of the other devices.

21 DR. JARVIS: One, I think the issue of
22 immuno-compromised patients and pregnant females both

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1 fall under this same kind of grouping, as either
2 patients or wearers.

3 Are there any other issues related to the
4 second part of the question?

5 (No audible response.)

6 Dr. Lin, have we answered that one all
7 right?

8 (No audible response.)

9 Okay. The last question is please discuss
10 whether there is reasonable possibility that the
11 presence of an antimicrobial agent on TPE might lead
12 that TPE wearer to be less likely to follow correct
13 infection control procedures and proper techniques.
14 If such a risk seems possible, what steps could be
15 taken, including product labeling, to help reduce such
16 a risk?

17 DR. EDMISTON: I'm not sure how to
18 respond, well, I guess I know how to respond to this.

19 What I would say is I can't believe that the
20 development of a device like this is going to either
21 improve or diminish one's approach to standard
22 precautions. I mean standard precautions is

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1 fundamental within our healthcare environment.

2 I can tell you going way, way back, 10 to
3 12 years ago, when I first saw the use of these other
4 impregnated devices I was very skeptical of them. I
5 thought they were band-aids that would just do the
6 right thing. And I think we've learned that these
7 other impregnated devices can be helpful, especially
8 in our high-risk patient population.

9 So we're not going to diminish the
10 importance of infection control by bringing these
11 devices to market, and I'm not really sure if there
12 is, I think it's always wise for industry to say the
13 use of these devices do not, do not reduce the need
14 for appropriate adherence to infection control
15 policies. That would be an appropriate comment, but
16 I'm not sure that would be a comment that the FDA
17 would require.

18 Can I ask you that question? Would that
19 be a comment that you would require?

20 DR. MURPHEY: I think it is difficult to
21 say what we would require right now not having seen
22 one of these devices. I think this is a question for

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1 which we would like feedback from the panel and also
2 from a product sponsor.

3 Is there a likelihood that this could be a
4 risk? If it could be a risk, is there a way to
5 perhaps mitigate such a risk? Is labeling, as you
6 have described, a way to address such a risk?

7 MS. LEACH: I think it definitely is a
8 risk and I think that you can see that historically in
9 the change when we started using gloves and how many
10 people think that just wearing gloves means they don't
11 need to wash their hands.

12 So if we now have antibiotic coated
13 gloves, that means even more gee, I don't need to wash
14 my hands. So I think this is definitely a risk and
15 I'm not at all sure that labeling is going to do much
16 good because how many of the an end users actually see
17 the labels on these products. They reach into the
18 box, grab a pair of gloves and put them on.

19 The other thing I want to bring up is I'm
20 afraid that there's a risk of going the other
21 direction. People are becoming, many healthcare
22 workers are becoming very skeptical of changes of

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1 high-tech things. Dr. Lurie said he would be
2 uncomfortable wearing a mask that was silver or copper
3 coated for fear of what it would do to him. And I
4 have heard this similar concern expressed by
5 healthcare workers that they don't want to be the
6 first to try out new products like this. They don't
7 want to be wearing gloves that have new ingredients in
8 them or are new technology because they don't want to
9 be the ones to find out that there are problems down
10 the road.

11 And so I would be concerned that we would
12 have people using PPE less if those were the only PPE
13 available or if they had to make a choice and it was
14 too difficult to figure out which one they didn't
15 want, they'd just choose neither.

16 DR. JARVIS: Right and I think I agree
17 with you in terms of labeling. Most practitioners
18 never see the labeling at all. But I think what you
19 could require or that manufacturers could do is make
20 as an integral part of their marketing an education
21 program where they emphasize all the other infection
22 control practices that we feel are so important and

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1 put whatever their devices and context of that. I
2 think many critical care specialists thought
3 impregnated catheters meant well, but you don't need
4 to do full barrier precautions or new hand hygiene, or
5 a subtype technique, or doing anything. You just
6 throw this thing in and it deals with anything else.

7 And I think, as you mentioned earlier, Dr.
8 Gordon, it was really the package of doing all these
9 other things in addition to doing the antimicrobial
10 impregnated catheters. And in fact, in many
11 populations, the antimicrobial impregnated catheter
12 was of no value whatsoever initially to all those
13 other things.

14 So I think if manufacturers could include
15 education that would be really helpful.

16 I want to echo Ms. Leach's comments. And
17 we now have green gloves and purple gloves and it's
18 really amusing to go around and see those boxes are
19 always full. People do not want to take out something
20 that's new that they've never seen. And I clearly
21 don't take them either. Whatever prejudices we have
22 about keeping the same old stuff, it's hard to take

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1 new things.

2 MS. LEACH: Although I'm not saying that
3 they shouldn't be labeled. I mean I think it's
4 important that the labels are there, but I just, I'm
5 not sure how much of a difference that's going to end
6 up making to the end users.

7 MS. KRZYWDA: I'd like to also extend a
8 thought to the panel. Would labeling include or would
9 education when you get these devices include where you
10 dispose of them? I mean do you dispose of them in any
11 trash can or would they be special places you dispose
12 of them? Obviously if they're contaminated with
13 blood, you're going to put them in an appropriate
14 container, but many of them would just be taken off
15 and tossed away, I presume, gowns and things like
16 that.

17 DR. JARVIS: Well, I think in that case it
18 really fits into medical waste management, which is
19 legislated at the state level rather than FDA.

20 Are there any other comments?

21 MR. GORANOV: Konstantin Goranov, NOVEKO
22 International. To your last question about disposal,

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1 I think one of the features sanity cargo devices bring
2 to the healthcare profession is the waste management
3 in terms of disposals. And to maybe, we have to be
4 more specific what exactly we can dispose and how we
5 can dispose. But generally, in the sense, if devices
6 already has the antimicrobial additive and it's
7 probably disposed into the surfaces or the interior,
8 those products can be disposed pretty much in a
9 general garbage or general whatever waste materials
10 are, because those devices more or less will
11 contaminate and they will actually, if used in the
12 right environment, actually have much high
13 concentration of microbial or materials, or there will
14 be unusual colonizations or so forth. Well, however,
15 with the appropriate antimicrobial additives,
16 basically this fact will be vastly reduced because the
17 antimicrobials will eliminate the colonies. It will
18 prevent the growth, so most likely we don't have
19 anything within a few hours. That's pretty much
20 across the antimicrobials used today.

21 So it's an added benefit to waste
22 management, costs and so forth. We see that's a very

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1 great value added. That's my comment.

2 DR. JARVIS: Okay, thank you.

3 Are there any other issues?

4 Dr. Lin, is there anything else you want
5 us to address?

6 MR. LAVENTURE: Just a quick question,
7 coming back to my original statement --

8 LIEUTENANT COLBURN: Could you state your
9 name please?

10 MR. LAVENTURE: -- about perception versus
11 scientific --

12 LIEUTENANT COLBURN: Give your name?

13 MR. LAVENTURE: George Laventure, Air
14 Force Research Lab. I think this is a perfect example
15 of where the confusion comes in.

16 Will the FDA actually define for us a
17 common user so we can advise our people? I believe
18 the perception of green or purple is a real thing in
19 terms of people. Until they are aware that they are
20 getting some level of increased protection they're not
21 going to wear these things. And so if the
22 manufacturers that are developing these enhanced

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1 protection, how does the FDA or whoever quantify to us
2 layman that there's significant benefit in using these
3 products and, therefore, the need of why you'd want to
4 use them and why you'd want to develop all this test
5 methodology to evaluate that their claims are true?

6 DR. SPINDELL: I don't think, and I don't
7 want to paraphrase, but he's not using this, that he
8 doesn't understand the new benefit, he's concerned
9 about increased risk. So I think there's a difference
10 there between understanding whether there's benefit or
11 not and the unknown risk.

12 MR. LAVENTURE: Yes, I can appreciate that
13 and that's part of what we're trying to seek is with
14 this new technology we certainly don't want to make it
15 worse. But it would be nice, not only to have the
16 claim on the paper that it does something, but
17 somebody to have developed the scientific data that
18 shows a two log reduction or penetration
19 characteristics being different is significant. You
20 had discussion about the respirator where you have
21 leakage in the gloves; that's probably a cleaner
22 issue. You don't have all the side stuff coming in,

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1 it's just penetration through the material itself.

2 Maybe you could make a stronger argument
3 in terms of clarity of what the barrier provides or
4 doesn't provide, but it would be helpful to us that
5 the significance of this improved science does
6 something that we can relate to.

7 DR. SPINDELL: Right. And I think that
8 gets back to our original question one is there was
9 concern that I heard voiced, and I know I said it too,
10 is that killing two log may be great on paper but has
11 nothing to do with improving the health. And I think
12 that's why there was so much talk about having
13 clinical evidence that not only -- to me it's two
14 parts, A, did it work in killing the microbes, but
15 actually killing those microbes actually benefit
16 patients and healthcare providers.

17 MR. LAVENTURE: Because we'd love to be
18 able to advise our Surgeon General that this is a step
19 ahead and this is what you'd get.

20 DR. JARVIS: I think what you're going to
21 see is that there's going to be in vitro data and then
22 these devices will be approved, they'll be out in the

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1 marketplace. And if you're looking at a decrease in
2 healthcare worker infection, a decrease in patient
3 infection, or a decrease in colonization, unless you
4 spend millions and millions of dollars and do a
5 randomized control trial with a huge number of
6 individuals, I mean if you're looking at colonizations
7 down here, in terms of numbers, infections is here,
8 and patients and healthcare workers infections are
9 about five stories above there because the risk is so
10 low, so the likelihood that you're going to have that
11 kind of clinical data I would bet in the next five
12 years is zero.

13 MR. LAVENTURE: Right. And one other
14 point for you to consider is that we were looking at,
15 as part of the TSWG effort that Brian talked about, of
16 reusable gloves, reusable respirators in case of a
17 pandemic where those supplies may be limited.

18 So one of the advantages, if you could
19 recharge this like we have done in the laboratory on
20 some chlorine based chemistries, you could maybe apply
21 it to the glove or the respirator and you could
22 actually reuse these things for the general populous

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1 as well as the regular healthcare workers. That could
2 be a real benefit in an epidemic type environment.

3 DR. JARVIS: It may be worthwhile FDA
4 addressing that because my guess is when you move from
5 a single use device to a multi-use or reusable device,
6 you have increased the amount of data that industry
7 has got to provide, hugely in the job of FDA immensely
8 as well.

9 DR. MURPHEY: You're absolutely correct,
10 Dr. Jarvis. This would be a brand new claim, which
11 we've not really seen yet. Looking, taking a single-
12 use disposable device and turning it into a reusable
13 device would really require the sponsor of that device
14 to prove all aspects of performance over whatever the
15 time period for reuse would be. You would be looking
16 not only at the antimicrobial performance over time,
17 but also the basic performance of the device, its
18 actual characteristics over time.

19 We are very aware that NIOSH has said for
20 the occupational use of respirators, and this is not
21 the healthcare use of respirators, well you can keep
22 using them until they don't work very well, or they

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1 smell, or they don't fit very well. Those are fairly
2 non-specific criteria.

3 For us, for a device to be reusable, we
4 need validated data that either use over time or
5 reprocessing of the device, whichever it is that it's
6 going to be, is not going to affect any of the basic
7 performance characteristics of that device. Now, for
8 say a surgical mask, that means you've worn it once,
9 you want to wear it again the next day. You're going
10 to have to show what that reuse does, whether it's
11 simulated or actual reuse on a volunteer to the
12 bacterial filtration efficacy, the particulate
13 filtration efficacy, the fluid resistance, the
14 flammability, the bio-compatibility, and the
15 differential pressure. And you're going to have to do
16 that for each period of time. And then if there's an
17 antimicrobial involved, you're also going to have to
18 look at its performance characteristics over those
19 periods of time as well.

20 It's a great deal of testing. It's a
21 significant challenge to the device sponsor. That's
22 not to say that it couldn't be done, but this is one,

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1 this is the reason that at the moment these devices
2 are labeled as single use disposable because we do not
3 have data today to show that they can be safely reused
4 or effectively reused.

5 DR. EDMISTON: Let me kind of go back to
6 this question, question 6 and try to put things on
7 track again.

8 I agree with my colleagues about the risk
9 of bad behavior with the introduction of these
10 devices, but I really kind of think that's part of our
11 job in terms of educating our staff. But I should
12 remind you that I'm not sure industry can, other than
13 put an altruistic comment on the label indicating this
14 is what you should do, you should not consider this as
15 a band-aid for everything.

16 And the reason why I say that is, as you
17 know, we've all gone to needleless connectors on our
18 IV systems and we've seen increase in sepsis
19 associated with needleless containers, hubs. Why have
20 we seen increase in sepsis associated with needless
21 hubs? Because the hubs, in an attempt to decrease
22 sharps injuries among our staff, these hubs need to be

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1 disinfecting for a minimum of 30 seconds prior to the
2 connection being made. And that's not occurring, even
3 though that's the recommendation, those processes
4 aren't occurring.

5 And I view that as an issue I have to deal
6 with in my institution and I'm not sure that's an
7 issue that industry has to deal with. That really
8 represents practice patterns, inappropriate practice
9 patterns within my institution.

10 So I think altruistically the industry
11 could place a comment saying the impregnation of
12 antimicrobial does not supercede the importance of
13 basic infection control practices. It's just another
14 layer of protection

15 DR. JARVIS: Are there any other issues on
16 number 6?

17 (No audible response.)

18 If not, does this panel have any other
19 comments, questions, have anything?

20 (No audible response.)

21 Okay. I wish to thank the speakers and
22 members of the panel, presenters from industry, and

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1 public attendees for their participation and
2 preparation for this meeting.

3 Before we adjourn today, Dr. Lin would
4 like to say a few words.

5 DR. LIN: Okay. I find out today that
6 this discussion is very, very useful. I see this very
7 healthy this discussion amount, FDA, manufacturer, and
8 other federal agencies. And I really applaud the
9 panel to stimulate this kind of discussion.

10 So on behalf of FDA and the CDRH, I want
11 to thank you and the panel for a very wonderful and
12 very useful information for our Agency.

13 Thank you very much.

14 LIEUTENANT COLBURN: I'd like to add to
15 Dr. Lin's comments and also congratulate our panel
16 members. Many of the panel members here it's their
17 first panel and I think they've done a wonderful job
18 preparing and engaging in the speakers.

19 And I'd also like to thank Dr. Jarvis.
20 This is his first time being Chair of our panel and
21 has done an exemplary job.

22 And I would like to thank everyone else

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1 from the industry and public for coming forward and
2 look forward to future meetings with you.

3 Thank you.

4 DR. MURPHEY: The infection control
5 devices branch would like to echo that. We really
6 appreciate your discussion and your comments and
7 guidance today. This will be very helpful to us in
8 the future as we prepare for the review of these
9 devices.

10 Thank you.

11 DR. JARVIS: Thank you all very much for
12 your attention and participation.

13 Since there's no further business, I would
14 like to adjourn the 37th Meeting of the General
15 Hospital on Personal Use Devices Panel.

16 Thank you all very much.

17 (Whereupon, the meeting was adjourned at
18 4:14 p.m.)

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