

1 clinician?

2 So that is a way of testing overall
3 impact. This is actually a formula. You
4 multiply out the percentage of people reached,
5 the effectiveness of the intervention, the
6 adoption, the implementation and maintenance,
7 and you get a final impact factor which gives
8 you what is actually happening at the level of
9 the end-user. It is a really effective way of
10 comparing interventions as well as
11 demonstrating their impact.

12 There is a website that is
13 available and a whole bunch of people testing
14 little pieces of that model. I'll share that
15 with you.

16 MEMBER FINCH: Nancy, I want to go
17 back to your discussion topic No. 2. I'm
18 sitting here trying to think outside of the
19 box, and I'm thinking about collaborations and
20 partnerships with -- this is under non-funding
21 -- with the medical schools, the
22 pharmaceutical schools, the pharmacy schools,

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1 and building some type of partnership that
2 would include where the professor is the
3 mentor to the Ph.D. or M.D. students. They
4 would do a residency or an internship or
5 rotation, or something, with FDA to kind of
6 deal with some of the issues or to answer some
7 of the questions that you may have as it
8 relates to risk communications.

9 I don't think that would be -- no
10 funding, but just resources.

11 DR. OSTROVE: And in fact, we do,
12 at least the Office of Policy and Planning has
13 an internship program. We need to take better
14 advantage of that in terms of bringing people
15 in.

16 One of the problems that we have
17 run into recently has actually been space. It
18 is very low-cost. It is no cost because most
19 of the interns, they're not paid, but we have
20 to find a place for them to sit. That
21 sometimes ends up being the limiting factor as
22 to how many you can accept.

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1 But a very good point.

2 MEMBER FINCH: What if they had the
3 space at their home base institution, and you
4 just provided the information via internet,
5 web-based, but the space would be at the
6 university?

7 DR. OSTROVE: Yes, that's
8 interesting. I think if we had better kind of
9 web camera communications, that that might
10 work a little. I don't know if we are there
11 yet because it might be very difficult for
12 someone in a remote location to really
13 understand what was going on.

14 I mean one of the major things that
15 the interns tend to do is they go to meetings;
16 they get a really on-the-ground sense of the
17 issues. It might be harder to do that at a
18 distance, but it is certainly something that
19 is worth thinking about, absolutely. Thanks.

20 CHAIRMAN FISCHHOFF: Christine and
21 then Ellen.

22 MEMBER BRUHN: A thought on another

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1 group to collaborate with, and that is the
2 medical schools. They do have students who
3 are sometimes talking to real patients. I'm
4 thinking of the medical school -- now I'm
5 speaking anecdotally, not with my food science
6 background, but I have a son who is going
7 through the medical training now.

8 When he was an undergraduate -- oh,
9 no, I mean when he was working on his doctor
10 degree, they required that the students spend
11 time at the free clinics. They had extensive
12 interviews with an audience that is hard to
13 reach. You know, we can talk about all these
14 things your regular audience receives,
15 internet, newspaper, magazines, TV, but it is
16 the hard-to-reach people who may well be
17 coming to the clinics that may be
18 unrecognized.

19 One might consider collaborating
20 with a medical school and using those students
21 to help gather information as to, for example,
22 your point one here, the kinds of information

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1 the patient needs to make an informed
2 decision.

3 They could be thrilled to do that.

4 They may be even able to generate some sort
5 of paper as a result of their activity. So it
6 is not pay, but rather they have both personal
7 rewards and professional rewards for being
8 part of the operation.

9 MEMBER PETERS: I would wonder, if
10 you had someone at the FDA who had time for
11 this -- and I think that is a big if -- but
12 could you offer a different kind of
13 internship, an internship that gave somebody a
14 line on their vitae, on their resume, that
15 said, you know, "I am FDA approved" to do a
16 project?

17 What they get is time from somebody
18 at the FDA to help develop something that will
19 be useful for the FDA, a specific research
20 project. "We want to know whether this
21 modification of the drug facts box is better
22 than the original version or nothing at all."

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1 I mean that, to me, could provide
2 some value for the student. I mean it depends
3 on where the student is. It would probably
4 require a bit of a partnership with the
5 student's advisor at the university, too. But
6 it is sort of a different take on an
7 internship that could work.

8 DR. OSTROVE: Well, do you have any
9 suggestions, for instance, because here's the
10 thing: if we go out and solicit students to
11 look at specific questions, then we are
12 causing it to happen. Then the poor student
13 would have to get OMB clearance for the
14 research.

15 But, on the other hand -- and I
16 mean that is kind of one of the purposes
17 behind just kind of saying, "These are some
18 questions that FDA is interested in, and we
19 would like to do some research on it," and
20 just kind of sending it out there and kind of
21 throwing it into the ether and hoping that
22 some of these people pick up on it.

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1 But, for instance, would there be a
2 way for us to let the academicians who have
3 students who might be interested in some of
4 these know that perhaps there's someone who is
5 available to help them out, if they have an
6 interest in doing work that might be relevant
7 to FDA, regardless of whether it is a specific
8 question that we have in mind, but if it is a
9 question that they have in mind that might be
10 helpful for FDA, to let people know that we
11 are willing to work to kind of provide
12 technical assistance under those
13 circumstances?

14 MEMBER PETERS: I'm not sure if I
15 really have an answer for that. I would
16 probably think about it at that point as
17 working more through the student's advisor, as
18 a way of vetting the project before it ever
19 gets to you. Because gosh knows what you
20 might get otherwise.

21 Yes, but some modification of your
22 internship program might be worth thinking

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1 about a little bit.

2 MEMBER KHANNA: Nancy, I think the
3 best way to approach that is just basically,
4 like you said, throwing it out there and
5 letting people know what the FDA needs, and
6 hoping someone will bite, would be to go
7 through the preventive medicine public health
8 residencies.

9 I really think you're looking for
10 somebody with a little more interest and
11 expertise in the public health arena and
12 someone with a little focus, perhaps a little
13 bit of training.

14 Any resident who completes a public
15 health residency does a year of clinical.
16 Excuse me. The first year is the MPH year,
17 then a clinical year, and then a practicum
18 year. The practicum year is the year that
19 lends itself to these little projects.

20 I did, I think, eight months of my
21 one full year at Kaiser Foundation Health
22 Plan, where I worked on a number of outcome

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1 studies and other little projects like this.
2 I could easily have spent three months of that
3 working on an FDA project, whether it was here
4 or at my home institution.

5 So I think you are looking for
6 someone with a little more focus. I think it
7 is going to be past the medical student level.

8 I think it will be at the public health
9 preventive medicine level, where these
10 students have already demonstrated an interest
11 in being part of the public health voice.

12 MEMBER LAWSON: I was just going to
13 mention, and I'm sure you are probably
14 familiar with the IPA. I guess it is the
15 Intergovernmental Personnel Act or
16 Administration. That is the avenue where not
17 only academic institutions, but other
18 institutions, nonprofit organizations, will
19 have an arrangement with a federal agency for
20 an exchange of student or professional person
21 to work with the agency.

22 That agreement does not require

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1 that the person is located onsite at the
2 agency. And it is preferable, I understand,
3 if it is initiated by the institution, by the
4 interested institution, academic institution
5 or the nonprofit. So that is certainly
6 another way for the students, whether it is
7 medical students, graduate students, or
8 others. But I think that is another way to
9 initiate it, through the IPA, to express the
10 interest, to say what service could be
11 provided.

12 Then there is Agreement of
13 Understanding, how is this going to work, and
14 what is it you expect them to accomplish? But
15 I do think that is one way that you can do it
16 with the agreement.

17 CHAIRMAN FISCHHOFF: Let me thank
18 everyone.

19 We will convene tomorrow at 8:00.

20 (Whereupon, at 4:34 p.m., the
21 proceedings were concluded for the day, to
22 reconvene Friday, May 1, 2009, at 8:00 a.m.)

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