**Voice-over:** *BioWorld Insider Podcast*.

**Lynn Yoffee:** This is *The BioWorld Insider Podcast*. I'm Lynn Yoffee, *BioWorld*'s publisher. Before COVID, the CDC's Advisory Committee on Immunization Practices, also known as ACIP, wasn't exactly a rarely visited quiet backwater. It all always had a full schedule and important decisions to make, but COVID changed the way the committee works. There are now twice as many meetings compared to pre-COVID times. Some public health policy observers have questioned whether the increased responsibility meets the CDC's needs and whether the CDC pays enough attention to the committee.

Today, joining *BioWorld*'s staff writer Lee Landenberger is William Schaffner who joined ACIP in 1982 and has rarely missed a meeting since. As a result, he has plenty of insights to offer on how the committee works. Dr Schaffner is a professor of preventive medicine at the Department of Health Policy, and a professor of medicine in the Division of Infectious diseases at the Vanderbilt University School of Medicine in Nashville.

He is the current medical director and past president of the National Foundation for Infectious Diseases. He is the foundation's liaison representative to ACIP and sits in on the advisory committee's meetings. You may have seen him on ABC News, CNBC, C-SPAN, and elsewhere as a consultant on infectious diseases, but today he's with us to talk about how this committee works. Lee, over to you.

**Lee Landenberger:** Thanks, Lynn. It's a pleasure to be sitting with William Schaffner today. *BioWorld* has covered ACIP regularly for years, and we've seen its responsibilities change some too. Dr Schaffner has been with ACIP for a while. Let me make sure I've got that right, Dr Schaffner. You started attending ACIP meetings in what? '82?

**Dr William Schaffner:** Yes, that's right, Lee. Thanks for your introduction, Lynn, also. Yes, I was a point a full member of the Advisory Committee on Immunization Practices in 1982. I fulfilled my tour of duty, and since then, I've been associated with the committee in a capacity that's called a liaison representative. You see, the committee has full voting members, but then also has a group of people who are associated with the committee. They're accredited to the committee on behalf of a series of professional organizations and societies. We, liaisons, participate fully in the discussions but we don't vote. Just the full committee members vote.

**Lee:** You had been a full committee member as well, is that correct?

**Dr Schaffner:** Yes. In the beginning, starting in 1982, I think it's a four-year tour of duty, I was a full voting member and then have been interested enough in the ACIP's work that I've continued as a liaison representative on behalf of one or another professional organization. I'm there now and have been for quite some time on behalf of the National Foundation for Infectious Diseases

**Lee:** Because of COVID, the committee's public profile is a lot higher than it was before. A lot of folks are hearing more about it or hearing about it maybe for the first time, even those who work in the industry. Can you give me and them an idea of what ACIP is designed to accomplish?

**Dr Schaffner:** Sure. I'm going to step back a little bit. Let's start first with the Food and Drug Administration. Before a vaccine can be licensed, or in this case with COVID get an emergency use authorization, it has to go through the Food and Drug Administration, and they too have an external advisory committee. Once the FDA authorizes the use of a vaccine, the question then comes up, and this is true for all vaccines, who ought to get this vaccine under what circumstances? Then the baton gets passed to the CDC, the Centers for Disease Control and Prevention. They have an advisory committee. That's the one we're talking about today, the Advisory Committee on Immunization Practices.

It's been around since 1962 and has offered recommendations about how vaccines of all kind from infancy through senior citizenship ought to be used. They debate those issues and then issue recommendations, which by and large become the standard of practice.

**Lee:** The pandemic probably changed some things at ACIP. They meet a lot more frequently than I used to. We said twice as much. It's maybe even more than that, isn't it?

**Dr Schaffner:** With COVID, there's just been an avalanche of specially called meetings. Both of the workgroups, the COVID vaccine workgroup meets weekly for two hours or two and a half hours discussing COVID vaccine issues.

There's a separate workgroup that just deals with COVID vaccine safety issues, and the full committee has had more specially called meetings than-- I've just lost count. There have been a whole slew of them dealing with these issues as the issues come up and have evolved during this very intense period obviously in response to the pandemic and the gathering information about the vaccines.

**Lee:** I'm fascinated by what the voting members get to see because these workgroups that you mentioned meet behind the scenes before the meeting start for weeks or whatever in advance, and they're crunching data and they're making decisions. Then they're giving this data to the committee for its recommendations. Are the committee members seeing that data right on the spot there as it goes out, or do they get it in advance so that they can think about it and come up with questions?

**Dr Schaffner:** It depends on the committee members. There are 15 members. You have to have each workgroup chaired by a full committee member and there are usually other committee members who are on that workgroups. Those people have seen all the data and been privy to all the discussions within the workgroups before they're presented to the full committee. Obviously, there are other committee members who are members of other workgroups. During COVID, the usual work of the ACIP has to continue, and so there's an enormous amount of work to be done.

A couple of other things should be said. The full committee members as well as the liaisons must adhere to a rather rigid set of conflict of interest rules that the CDC has set down. The members, for example, may not participate in any kinds of grants and vaccine trials related to topics that are under discussion, and even we liaisons have what we can do substantially restricted. The other thing we should note is that the ACIP full meetings are a model of transparency.

Every person in the United States can tune in via the internet, watch the full committee meetings from beginning to end, look at the data just as the committee members do, hear those discussions, and figure out what are the issues that have come to the attention of the committee members, and that they're questioning people about. That's wonderful. During each meeting, time is set aside for public comment.

If you wish to make a comment about any aspect of the committee's activities, you can apply. There are usually more applications than there's time. On a random basis, applicants are chosen to make their public comments. The committee operates, and has for years and years, as a model of openness and transparency.

**Lee:** It seems to be successful despite this ramped-up schedule and an avalanche of data. I wanted to ask you what your thoughts about the CDC's needs since the pandemic began, they've probably increased. I'm curious since the ACIP workload has increased, are both their needs being met and do both serve the public well?

**Dr Schaffner:** Let me get to that, but a word of background first. Your listeners are probably wondering who are these people and what do they get compensated for? The full committee members do get some compensation back. I don't know what it is today, but it must be similar to what I received when I was a full committee member. I called it an honorarium. I used to joke that there was more honour than there was rarium.

**Lee:** [laughs].

**Dr Schaffner:** The needs of the CDC have been, in my view, exceedingly well served by the dedication of not only the CDC staff, which keep this committee working. They function as the secretariat. They do all the administrative work making sure that the meetings take place, et cetera, as well as all of the external members and liaisons. They have at often very short notice, I can speak for myself, have had to reorganize their schedule because the ACIP or one of its workgroups has called a meeting. We'll change what other things we've had on our calendars in order to fulfil our obligations to the ACIP.

**Lee:** There's also that question about the disclosures too. That's another thing where you need to tell everybody how much money you're making and who you're connected with. I suppose that probably turns some folks away too. They're like, "I'd rather not." Sacrifice I'm not sure is the right word, but it's yet another thing that they need to do that's important.

**Dr Schaffner:** When committee members or applicants or suggested nominees are put forward on a periodic basis, the nominees are all instructed about the conflict of interest obligations. They have to consider that because they may be in the midst of a large clinical trial related to vaccine A, B, or C and whether they can withdraw from that during their time on the ACIP or whether their commitment to the trial is such that they want to continue.

That will help them decide whether to keep their own name in nomination. Yes, those are reality checks for sure. Even we who are liaison representatives recognize we don't get compensated, as I say, but there are things we may not do. We have to accept that if we're going to sit around the outer table when we used to get together in place and participate in these discussions. We accept doing that.

**Lee:** Give me some idea. If you're an ACIP member and you're pondering a COVID vaccine, for instance, the data comes from workgroups and I think the data also comes from the vaccine developer, is that right? Give me an idea of how the workgroup takes the data and then makes a conclusion and then passes it along to the committee. What happens then?

**Dr Schaffner:** The workgroup first of all will consider the epidemiologic and clinical characteristics of the disease that is intended to be prevented. For example, one of the issues before the ACIP at the present time is whether vaccines ought to be given to children of various ages. The epidemiology of this disease, the occurrence of COVID in children and its severity, will be assessed first. What is it we're trying to prevent? Is this a public health problem of importance?

Then we'll look at the vaccine, and we will receive all of the information, and perhaps more if more has been developed, that was presented to the Food and Drug Administration, everything regarding how this vaccine works, both at the laboratory bench and animal models in early and the larger clinical trials. We will pay attention to effectiveness, how well does the vaccine work? What can we anticipate telling the general public? Of equal importance, and sometimes overlooked, is safety. How safe are these vaccines? What immediate and local reaction, sore arm, redness around the injection site, and other potential rarer but nonetheless severe adverse events might be associated with these vaccines?

That's discussed. Then a whole series of subsidiary issues. What's the cost-benefit analysis? What's the feasibility? Can we implement a vaccine recommendation in a practical fashion? We live in the real world. This is not a theoretical exercise. What will be the acceptability on the part of healthcare providers in administering the vaccine, and also the patients or their parents who have to get either themselves or their children vaccinated? There's a structured way that the ACIP evaluates the quality of the evidence, how strong as the evidence? Then they go through an evidence to recommendations framework.

They do this in a very careful, thorough fashion each time. You have an open structure that I think even laypeople who are listening carefully, you have to attend to this, but you can listen carefully and you can understand how it is that the committee membership assesses the quality of the evidence and the need for the vaccine, its effectiveness and safety as they come to their conclusion, making recommendations as to who and when they ought to get vaccinated.

**Lee:** Does the AdCom always get the complete data that it needs to offer guidance to the director?

**Dr Schaffner:** [laughs] I'm laughing. A friend of mine who was a member of the committee said being a member of the committee is a little like drinking from a fire hose because you get a constant stream of data that you have to incorporate. He said, "Every time you go away from the fire hose, you wish you had more data."

**Lee:** [laughs].

**Dr Schaffner:** We always wish that we had more data. For example, Lee, let's be quite specific so your listeners get this in mind, we don't know now still what the duration of protection is from vaccination and/or boosting. That's usually a pretty critical element of making vaccine decisions. What we've had to say is this problem, this public health problem, this pandemic, is of such urgency we can't wait for that to be decided. We're going to start vaccinating people. Obviously, we have.

Stay tuned. As we get more information, we will tell you and the committee did. They said, "Now, hello, everybody, you need to get a booster." People keep asking, "Will I need another booster?" The committee says, "Stay tuned, we don't know that yet. We'll let you know when we know. You'll know we know when you tune in to the meetings because it will all be done in complete transparency."

The short answer to your question is I cannot remember a vaccine decision of any kind where the committee didn't wish they had a little more data, or maybe a lot more data, on this or that aspect, but [laughs] you have to make decisions right now because we live in the real world, and then we'll modify things down the road if we have to. This process has worked remarkably well now for 60 years. This committee that we're talking about has been the model for similar committees that have been set up in other countries around the world.

**Lee:** You talk about making a decision right now. It's my understanding that probably the CDC director listens in or watches these meetings and pays close attention to everything, and then the director gets the guidance and then sets policy. Is that accurate?

**Dr Schaffner:** Close. It is an advisory committee and we are advisory to the director of the CDC. The director then makes decisions and sends that up to the Department of Health and Human Services, and they get a look at it too. On occasion, these recommendations have gone to the White House and the political leadership of the country has looked at them also. The committee is advisory but 99.9% of the time, the committee's recommendations are endorsed by the centre's director and subsequently up the chain in the federal structure.

**Lee:** Got it. Since there's this added workload and all this extra data from the pandemic, does anything need to change in the process ACIP to be better informed or to make better guidances?

**Dr Schaffner:** There've been lots of discussions from time to time depending upon even the routine workload of the committee. Public health has focused very traditionally over decades and decades on maternal and child health. That's critical to public health, securing the health of women who are pregnant and then their newborn children, and then children as they grow up and increasingly adolescents. Now more and more vaccines are being developed that are focused not so much on the pediatric population but on the adult population. That's an arena in which public health has never been quite as elaborately involved as in maternal and child health.

The committee is working in the adult immunization space, if you will, and is getting more and more sure-footed as it does that, but we who are internists and associated with the committee still have some suggestions about how the committee could function even better in that context. That's perhaps a subject for another discussion because we as a society haven't committed to providing resources for adult immunization the same way we have provided resources for pediatric and maternal vaccination. Some of the difficulties that the ACIP has had relate to financing of who's paying for the vaccine and who's paying for the administration fee?

**Lee:** Those are pandemic-related problems that we would see right now.

**Dr Schaffner:** We don't see those, and that's because the United States Government has paid for all the vaccines, so that issue disappears. That makes it a much more comfortable issue for the ACIP to make recommendations really throughout the entire age spectrum.

**Lee:** Got it. That's the last of my questions, Dr Shafner, was there something that we didn't mention or you think needs a little more elaboration?

**Dr Shafner:** I would just emphasize, again, the really extraordinary commitment of the full members and all of my colleagues who are liaisons to this process. It's not very often that in a public policy arena, a group of people who are well-intentioned and extremely experienced will get together, have a free and, as I said, completely open discussion about what the issues are. Then come together, compromising on a set of recommendations that are designed to work, and then those recommendations really are implemented and become the standard of practice. It's an extraordinarily rewarding activity, and at what I think is medicine's highest goal, namely the prevention of disease.

**Lee:** Thanks, Dr Shafner. It's always a pleasure talking to you. I greatly appreciate your time.

**Dr Shafner:** Lee. It's been a pleasure for me. Likewise. Thank you.

**Lee:** Oh, you're welcome. Lynn, back to you.

**Lynn:** This has been a fascinating discussion. Certainly, *BioWorld* has been covering the development of drugs and vaccines for more than three decades. We're relatively familiar with the process, but because of the pandemic, never before has the regulatory process for the approval of vaccines or drugs been under such scrutiny. We really appreciate your detailed explanation about behind the scenes and how this works.

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