# June Advocacy Recap

July 13, 2022

**Alec Bose:**

Hello and welcome to the CAP Advocacy recap, a monthly podcast dedicated to catching you up on the top news for pathologists. I'm Alec Bose from the CAP's Advocacy Communication Team here with your June recap.

This month, we'll look at updates on the VALID Act, examine the CDC announcement for Monkeypox specimen guidelines, and review the decision by the CMS to retain diagnostic codes for next generation sequencing. Later we'll be joined by Dr. Mark Synovec to recap the American Medical Association's annual meeting and what the CAP-led delegation advocated for during the event. But first we go to Congress where the Senate health committee approved a package of bills to reauthorize existing FDA user fees, which includes the VALID Act. This would authorize the FDA to regulate in-vitro diagnostics or IVDs, including laboratory developed tests. Senator Tommy Tuberville of Alabama proposed an amendment that would've exempted academic medical centers from the VALID Act. However, the committee rejected the amendment stating that the bill already included several exemptions to reduce regulatory burden and that exempting some labs from regulation would establish two different regulatory standards for laboratory developed tests.

The legislation will now go to the Senate for further consideration. For facts about LDTs and the VALID Act, as well as further updates, please visit cap.org/advocacy. The CDC has published specimen collection guidelines and real-time PCR test procedures to detect the Monkeypox virus. The specimen collection guidelines, which can be found on the CDC and CAP's website, are for clinical laboratories that have specimens suspected of monkeypox virus. After consultation, laboratories can send appropriately collected specimens to their state or territorial public health for real-time PCR testing. This procedure is designed to detect the Monkeypox virus and is intended for international partners and laboratories interested in pursuing a laboratory developed test. This procedure also includes sequence information for primer and probe development and cycling conditions. We will continue to monitor the situation and report more guidance from the CDC as it's released.

In a win for CAP advocacy, the CMS agreed to retain over 100 diagnostic codes that they previously proposed to remove from the next generation sequencing national coverage determination. In April, the CAP and over 30 other medical laboratory health organizations asked the CMS not to remove the diagnostic codes from the national coverage determination for NGS as it would have resulted in non-coverage of genomic testing for many patients with advanced cancer and thousands of denied Medicare Part B claims. This is a significant victory for patients, pathologists, and other providers who rely on these tests. For more information, be sure to read our advocacy newsletter.

And finally, we turn to the American Medical Association where the CAP-led a delegation to pathologists at the annual 2022 AMA meeting and urged the House of Delegates that physicians lead and practice teams, that pathology continues to be included in formal medical education training, fight for appropriate safeguards for consumer and laboratory testing, and that private insurance companies reimburse physicians fairly. We spoke with Dr. Mark Synovec, a CAP AMA delegate, about his experience at the event and go into further detail about what the CAP was advocating for. So Dr. Synovec, thank you so much for joining us. We really appreciate you joining us.

**Dr. Mark Synovec:**

It's my pleasure. Happy to participate.

**Alec Bose:**

So to start us off, can you give us some background on the AMA House of Delegates and what kind of goes on in that body?

**Dr. Mark Synovec:**

Absolutely. The AMA, it's set up to have a single policy arm, which is the House of Delegates, and then any society in the federation can then submit delegates and alternate delegates to that. It's on apportionment so if you are an AMA member, you are both a member of your state society, so you would be represented by your state, but also by all the specialty societies that you attend. So if you're a CAP member, obviously you have representation through the CAP, but if you're also a member of the ASC-ASCP for example, you would also be represented for that.

So essentially we all get together twice a year, all of those delegates, and we hash out new policies and alternatives of current policies through a deliberative process that anyone that's involved in that can put a resolution in for consideration and then it basically gets debated at the house. We are very fortunate for the CAP, because the CAP is essentially the organizing arm of the pathology section council. So the Washington staff at the CAP do a phenomenal job of preparing all of the delegates for all the information that comes forward for our deliberations as well as meeting logistics. So we couldn't do it without all their hard work.

**Alec Bose:**

And can you talk a little bit about what the main policy the CAP-led delegation was advocating for at this point?

**Dr. Mark Synovec:**

Yeah, I think the thing that's important when you talk about what we talked about is noting that you're getting resolutions from all the different specialty societies as well as all the different states, which is really a microcosm of the United States and the diversity of that. We certainly have our primary pathology related issues that we represented, but it's sometimes more important just to be in the tent. So obviously one of the big issues was Medicare payment reform. Obviously, the big issues with that right now is the idea that macro kind of froze these very small increases in payment at the time that we have this very high inflation. And so we certainly spent a lot of time working together with other specialty societies to figure out how we could bolster the AMA position so when they go to Congress, we can speak united and try to get some modifications of that.

The other issue that we have that's a little bit more contentious, but not necessarily as much is the idea that with E/M coding modifications and they were associated revaluation that took money out of the pockets of non-primary care. And even though the goal was [inaudible 00:07:05] practice, et cetera, where it's not to take money from our pod, that's kind of the net effect of that. So the AMA is an advocate to say we need to put more money in the pot, not redistribute it, and we had the ability to speak for that. Another important issue for us that was discussed there, a scope of practice, a lot of different areas that radiate, we're not in the front of that necessarily, but there certainly are areas that we have a major concern on. Another important one was manpower issues. Have a lot of issues with that, and I'm sure many people are aware of the issues that we keep increasing the size of medical schools.

However, there's this bottleneck with GME funding by the government and how are we going to do that? Because having more medical students but not having places for them to go to residency is really a failed policy. And so there was a lot of discussion there that we advocated for as well. Supply shortages, we spent a lot of time talking about that as well. It was interesting that we've seen that in the laboratory for some time, but one of the new issues is epinephrine and that became the poster child for the AMA. However, it was nice that pathologists were there to remind them that we're having trouble with vacutainer tubes and just reagents for a lot of our analysis and they can't really run a lab or we can't run a lab if we can't perform laboratory analysis. So that's a few of the highlights of what we talked about, a whole lot. So that's kind of a brief thumbnail of some of the main issues that came across at the AMA.

**Alec Bose:**

Fascinating and what would you say are some next steps for not just the college but the AMA as they move forward?

**Dr. Mark Synovec:**

Yeah. Well, clearly the biggest one I would say that we were working on is bolstering the AMA position on a physician payment specifically as it relates to Medicare. And so we had a lot of robust discretion. Obviously this is not a new issue to the AMA, but there were new concepts that were thrown out and we will, at the CAP, continue work with the AMA to make sure we can do our best to maintain adequate reimbursement for the services that we provide. See, that's the big one. Obviously we continue to work, many of these are monumental tasks, such as GME funding, is another huge one for us and supply shortages. It's just really interesting to think, and I certainly have learned this through the EMA, thinking that the FDA has this power to be able to control issues with its supply shortages as well as best practices in the production of laboratory and other healthcare supplies.

It's really limited and so the idea of having the AMA ask the federal government to bolster that up was certainly important. So that's a couple anyway. This was our first live meeting post Covid, which created some challenges because we were all masked and it's harder to communicate when you're masked through that, but it was so much better than trying to do it virtually. I think anybody could understand trying to attend eight reference committees virtually and sitting by your computer screen for five days was a challenge, to say the least. So it was nice to get together. There was a lot of relationship building at the AMA, and it's so important for the CAP to be a part of that communication process and develop allies because the nice thing at the AMA is that everyone's a minority. You can't speak from a majority position.

The pediatricians are a minority, the family practice physicians are a minority, and we're just a smaller minority of the federation. So it's important to work together and you can be so much more effective when you're doing that face to face so we were really happy to do that. As a part of that, the CAP actually had the opportunity to interview the candidates for president-elect at the AMA, so we got to sit down and ask pointed questions. It was nice interchange with the three candidates, and we were quite pleased that Jesse Ehrenfeld, who's an anesthesiologist in Wisconsin, won. We've had a relationship with Jesse in the past. He's actually come to the CAP and spoke in the past. He's just a strong candidate and I know that he will be somebody that we can talk to if that time occurs. So all in all, it was a great meeting. We had a lot of great interactions, and we will continue to forge forward and do our best to represent pathologists and the CAP specifically as this debate continues throughout the evolution of healthcare.

**Alec Bose:**

Well, that's a great note to end on. Thank you, Dr. Synovec. We really appreciate you doing this for us.

**Dr. Mark Synovec:**

No problem. Happy to be here.

**Alec Bose:**

That's all for this edition of the CAP Advocacy recap. Thank you so much for listening. For more information, be sure to subscribe to our weekly newsletter and be sure to follow our Twitter account, @CAPDCAdvocacy. Once again, for advocacy communications, I'm Alec Bose, and we'll see you next month.