Clinical Chemistry

Forever Chemicals, Endless Testing? Expert Advice to Be Prepared for Per- and Polyfluoroalkyl Substances

Article:
Frederick G Strathmann, Susan Burden, Jenna Hua, Andrew Patterson, Robert Middleberg.
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Clin Chem 2024; 70(12): 1402–10. https://doi.org/10.1093/clinchem/hvae165

Guest: Dr. Frederick Strathmann from MOBILion Systems and Smithers Biopharmaceutical Development Services.

Bob Barrett: This is a podcast from *Clinical Chemistry*, a production of the Association for Diagnostics & Laboratory Medicine. I'm Bob Barrett. You may have heard the term "PFAS," which is short for per- and polyfluoroalkyl substances, also frequently referred to as "forever chemicals." These compounds are found in many products we use on a daily basis, from nonstick cookware to water repellent clothes. One of the reasons for using these compounds in the first place, namely their stability, is now being recognized as a potential public health problem. In contrast to some other industrial products, PFAS persistent in the environment and human tissue for a very, very long time, and have been associated with a number of adverse health conditions including endocrine disruption, altered liver function, and certain cancers. While ongoing efforts are directed at clarifying the role of PFAS in these disorders, individuals are understandably interested in measuring PFAS in their drinking water and blood samples to help determine their risk.

This raises several additional questions. Who should be tested and when? Which labs should perform testing and what regulatory standards should these labs abide by? A new Q&A article appearing in the December 2024 issue of *Clinical Chemistry* solicits the thoughts of four experts in toxicology and environmental testing. What's next in the field of PFAS testing and how can clinical laboratorians support the effort to reduce PFAS exposure.

In this podcast, we're joined by the article's moderator. Dr. Frederick Strathmann is the the Senior Vice President of Global Business at MOBILion Systems and the CLIA Laboratory Director and Clinical Consultant for Smithers Biopharmaceutical Development Services. He has previously worked in hospital and reference laboratory settings and is passionate about finding and developing technological solutions to everyday problems by bridging scientific advances with strategic business initiatives. So Dr. Strathmann, let's start with this, given that PFAS is a relatively new topic in the clinical environment, what sparked your interest in having a scientific session at ADLM 2024 and a follow-up Q&A on the same topic?

Frederick Strathmann: One of the biggest challenges in being a toxicologist is the near constant emergence of new substances to worry about. I've been fortunate in my career to be at very forward-thinking organizations historically and my interest in PFAS has really been growing for a while but it wasn't until I started my role at MOBILion where I first really appreciated the magnitude of the problem we are facing globally. My role at MOBILion has taken me well outside of my previous clinical focus into areas such as drug development, food testing, and environmental testing, and it was clear that PFAS was a common topic and an emerging challenge that experts in these various fields were already working to address, and when I saw the volume of testing being done and the rate at which the volume was growing, it was clear to me that you know, the toxicology field was behind in taking this class of compounds as serious as we should. And so that sparked the idea in 2022 in fact, of submitting a session for the 2023 annual meeting but like a lot of emerging topics, timing is everything, the proposal was rejected because there's just so many interesting proposals that get submitted, but in 2023, there was no shortage of passion among my colleagues that were part of that original submission. We were excited to have it accepted for 2024. And then for the Q&A, it's a great topic because it truly impacts all of us. It's unlikely that anyone reading the Q&A is PFAS-free so this is a highly relevant topic. In addition, I was excited to share the topics in the scientific session to a few areas and extend those to go even further into the challenges and solutions that are hot topics in other areas.

Bob Barrett: Now, the experts you selected have some very diverse backgrounds. How did you go about selecting the group of experts for this Q&A?

Frederick Strathmann: For most professionals, there's a direct correlation with time in the field in size of one's professional network. And that's thankfully true for me but my time at MOBILion has really expanded my network well beyond normal expected boundaries. And so, as part of my routine job, I have been fortunate to interact with several outstanding individuals at government agencies, industry laboratories, and even consumer facing companies, which really gave me a deep pool of possible individuals and even though the audience for *Clinical Chemistry* is largely clinical, I thought it was important that viewpoints from outside the clinical world be shared, and so I met Susan Burden at the EPA shortly after one of MOBILion's instruments was installed in their Research Triangle Park facility in the lab of Dr. Marc Steiner. And Susan's understanding of the PFAS challenges, both from a regulatory perspective and an environmental perspective, I

think made her inclusion an obvious choice, and EPA is very much at the forefront of keeping the public safe and it's staggering really what individuals like Susan and her colleagues undertake and the work they do to keep us safe. Similarly, I was fortunate to meet Andrew Patterson from Eurofins and not everyone has likely heard of Eurofins in the clinical world, but if you step outside into the environmental realm, you quickly realize that they have been leading the way in PFAS in other areas for decades.

The amount of resource and innovation they have put towards testing improvements, solving customer needs, is really staggering, and there's no one's input I'd rather have on testing challenges in emerging technology through PFAS than Andrew and his team. And then for Jenna Hua, you know, she's one of those kind of rare individuals that just imprinted on me with her passion for consumer health, having devoted her time and her company's mission to helping consumers make better choices, and she's one of those super smart Berkeley people you sometimes meet, and seeing her on the other end of the spectrum, where she's actively raising awareness around exposures but also providing tangible ways for individuals to take control of their own health, I think is inspiring, and it really represents why we were all in laboratory medicine to begin with. And then, lastly, Dr. Rob Middleberg is someone I've known for many years and worked beside while I was at NMS Labs. He is one of the most brilliant toxicologists I've ever met and NMS has been synonymous with innovation and toxicology, which makes it no surprise they were the first CLIA lab to offer PFAS testing. So reviewing those experts I was fortunate to be able to tap into made me excited to share their insights with more of my colleagues.

Bob Barrett: So, the Q&A in *Clin Chem* will likely mostly be read by laboratorians and clinicians. So what do you expect that audience will appreciate the most about the different viewpoints expressed?

Frederick Strathmann: Primarily what I hope is how much we can and should learn from other areas. You know, Eurofins have derisked and identified new and emerging technology that the clinical laboratory can and should consider adopting to circumvent years of complex development. They have also developed very impactful workflows for biological testing outside of a CLIA lab, which is also a topic we discussed in the Q&A. I also hope an appreciation is gained for how much effort other regulatory agencies have and are putting into defining the problem and pushing forward possible solutions. Understanding what the EPA is doing will better inform laboratorians of the entire context to the problem and also help us understand how changing regulations will potentially

impact patients. And then lastly, seeing what types of consumer facing content is available, what available test menus there are, the questions that are being asked, and the answers are being provided right now to patients and consumers should be educational for those not yet getting questioned about PFAS, but for sure those questions are coming and we need to be prepared.

Bob Barrett: In the article, there's a perceived divide among the experts on the topic of PFAS testing being done in a CLIA certified laboratory. Why did you want to cover this topic specifically and what implications does it have for combating the problems associated with PFAS testing?

Frederick Strathmann: So I think those of us in the clinical field almost take CLIA certification for granted and assume testing on people will and should be done in a CLIA lab, but even before COVID there was a strong demand for alternative options that really started to blur the lines between diagnostic testing and wellness testing, for lack of a better term. And so the recent position statement from ADLM that came out on the 31st of October nicely illustrates the forward-thinking mentality of ADLM and the need to stay current with the evolving expectations of patients and end users of laboratory testing. And Jenna and her work at Million Marker are great example of a company that is founded on the belief that consumers have the right to information that will inform their well-being.

I remember back when I was remodeling an older home, I had concerns about lead-based paint and if my safety measures were sufficient. It took a lot of effort on my part to convince my primary care physician to order a lead blood test. It wasn't about signs or symptoms or diagnosing condition, it was really about easing my anxiety over if my precautions were effective. This is the primary idea behind giving consumers power over their data and their own health, and that is nicely articulated from both sides in the article.

And another aspect is really how challenging PFAS are to measure even [though] they are very literally everywhere. Environmental labs like Eurofins have developed processes to reduce contamination and to ensure quality results and in my opinion, it is unlikely that the average clinical laboratory has sufficient expertise to simply develop and start testing for PFAS with their existing processes that really weren't designed for this type of specific challenge.

Bob Barrett: Was there a topic you were not able to explore with the experts in this article that would be of interest to *Clin Chem* readers?

Frederick Strathmann: I think for me, clinical toxicology is a field that has always been top of mind with the evolving landscape of lab developed testing oversight by the FDA. This article could have spent the entire word count demonstrating yet another example of the problem with the current proposed changes by the FDA, and among the numerous concerns raised by the laboratory community has been the potential to disrupt access to critical testing and a stifling of innovation, and we take PFAS as one of many examples, we are just starting to understand key aspects like PFAS isomer contributions to toxicological profiles. Not to mention the fact that we may not even know which PFAS are the most biologically concerning among the thousands that are known to exist.

And then lastly, non-targeted analyses are emerging as a need to have for environmental testing and that same need will be true for clinical and consumer testing. And this type of testing is the very reason why lab developed tests were ever envisioned in the first place and needs to remain available. So, without a change to the current path we are on, PFAS will be yet another example of excessive regulations blocking availability to needed testing, which in turn will negatively impact patient care.

Bob Barrett: Okay. Well finally Dr. Strathmann, how might PFAS testing be impacted by the FDA's efforts to enforce their current amendments to the oversight of laboratory-developed tests?

Frederick Strathmann: So, like all areas of toxicology, staying at the forefront is critical and requires constant test updates. In addition, PFAS testing is really only beginning to emerge and the FDA regulations will make it burdensome to develop and maintain current and relevant panels. And one of the worst things that we can do is provide out-of-date testing, giving a false sense of security to patients or consumers who believe they're being tested for PFAS yet are not able to get access to test menus that reflect current needs and integrate up-to-date toxicological findings. So by definition, testing for PFAS must evolve as our knowledge about the biological implications of exposure continues to involve. So if test updates lag behind, it will make laboratory testing inaccurate, potentially obsolete, and we may never even see PFAS testing made available to those that need and deserve answers about how exposure to these class of chemicals may be impacting their health.

Bob Barrett: That was Dr. Fred Strathmann from MOBILion Systems in Chadds Ford, Pennsylvania. He moderated a Q&A article on PFAS testing in the December 2024 issue of *Clinical Chemistry* and he's been our guest in this podcast on that topic. I'm Bob Barrett, thanks for listening.