From the President's Desk

Anticipating FDA regulation

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January 2024—I was planning to write about a much more pleasant topic this month, but instead I'll use this column to address something that's gnawing at all of us now: the prospect of FDA regulation of laboratory-developed tests.

It's been more than a decade since the FDA first announced its intention to regulate LDTs, and the pathology community has been grappling with the implications of it ever since. We have watched as an early draft FDA regulatory framework was released and multiple legislative proposals have appeared. The most recent effort was the Verifying Accurate Leading-edge IVCT Development (VALID) Act. While the CAP was not a fan of the act when it was introduced, we worked closely with Congress and the FDA to improve it. After four long years of negotiations, we finally felt the VALID Act would provide enough guardrails around how the FDA could regulate LDTs and enough other wins for pathologists and our patients that we could support it. However, like its legislative predecessors, the VALID Act was not passed by Congress.

Now, the FDA has released its own proposed regulation based on a statute from 1976. This rule would allow the FDA to oversee LDTs without new congressional action—and unfortunately without an updated law that addresses the testing issues laboratories face today. Imagine all the needs filled by LDTs now, and think of how little was known or understood about those needs in 1976.

As I write this, the CAP has just completed analyzing the text of the draft rule and submitting detailed comments about the rule to the FDA. (You can read them at tinyurl.com/CAPcomment.) I don't have space here to go into the myriad details in our comments, but I can say this: We do not support the rule in its current form. Because of its foundation on a half-century-old statute, it lacks the flexibility we need to provide the best possible care to patients today. The statute also doesn't allow for the incorporation of any of the guardrails we fought so hard to get included in the VALID Act—items such as technical certification to eliminate the need for FDA review of a test that uses analytical technology that has already been approved for use in the submitting laboratory, or the ability to down-classify tests to lower risk levels based on mitigating factors such as proficiency testing or evidence in peer-reviewed literature. Without new legislation, the FDA is free, and in certain ways compelled, to be extremely strict in regulating LDTs. As outlined in our comments to the FDA, this would represent a significant burden on pathologists and laboratories.

Dr. Karcher

I anticipate that the FDA rule will unite much of the pathology community in opposing many of the provisions in the proposed regulation. Even before the deadline in December, hundreds of comments had been submitted to the FDA urging changes to the rule and its implementation. The CAP comments are among the most detailed submitted and include numerous recommended revisions in the proposed rule to allow clinical labs to continue to offer these innovative and life-saving tests. We also met with FDA leaders before the comment submission

deadline to discuss how the rule could be changed to better support our members and allow for continued high-quality testing for patients.

Although I can't go into the specifics of our official response here, I'll share the three guiding principles about LDT regulation the CAP has used consistently since the FDA first announced its plans more than 10 years ago. First, and without question most important, is that any regulation must result in great quality of care for patients. Every LDT should be safe and effective. Second, regulation has to allow innovation to continue. These tests are developed in a laboratory for a reason, and it's usually that no company has yet developed and marketed an FDA-approved or -cleared test kit for a specific clinical need. Waiting for companies to develop those tests is not an option when our job is to provide the best possible patient care right now. There will always be a gap between medical progress and the availability of commercial tests, and designing and validating new LDTs is the only way to fill that gap and meet our responsibility to patients. Third, the regulatory burden and cost for labs and pathologists have to be minimized. We cannot do our jobs well if meeting regulatory requirements is too overwhelming or expensive to manage. These have been our pillars for LDT regulation since day one, and they will continue to guide us moving forward.

Since I'm already deep into a topic that gets most of us worked up, let me go a step further to address a reaction I hear too often in conversations about LDT regulation. There is an unfortunate theory that the CAP has ulterior motives—that instead of supporting patients' and members' interests in confronting these efforts, the CAP welcomes LDT regulation as a source of future revenue. This could not be further from the truth. I have been involved in the issue of LDT regulation for 10 years—nearly eight of them as a member of the CAP Board of Governors—and in all that time, across all of those discussions, I have never heard anyone suggest that the CAP could make money from this. Please believe me when I say we have no profit motive in regulating LDTs. The CAP is singularly focused on empowering pathologists and clinical labs to provide innovative tests and high-quality results for patient care.

With this proposed FDA rule, we are all facing something we very much wanted to avoid. I sincerely hope the sheer volume of comments submitted to the FDA, as well as clearly laid out arguments such as those the CAP presented, will make a difference in how the FDA pursues regulation of LDTs. Whatever happens next, I want you to know that the CAP will do everything in its power to protect pathologists and our laboratories with the same commitment we all show to patient care every day.

Dr. Karcher welcomes communication from CAP members. Write to him at president@cap.org.