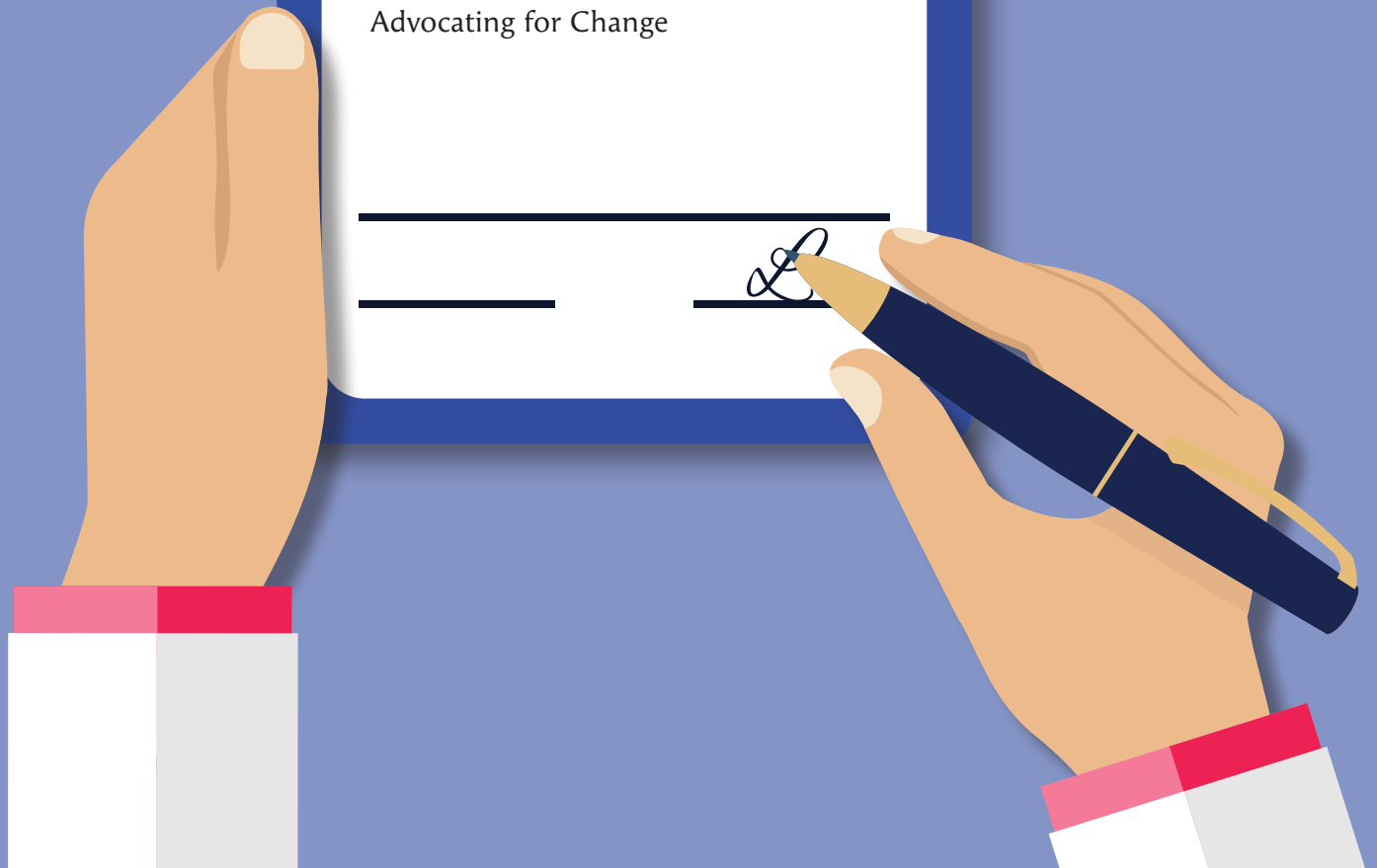

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**Medication
Safety**

Medication Error Reporting
Education
Advocating for Change

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A Prescription for Safety

Medication Error Reporting, Education, and Advocating for Change

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In 1974, pharmacist Michael Cohen learned of a serious adverse event with insulin at a hospital and began sharing information about it with other pharmacists to prevent the error from happening again. Twenty years later, he founded the Institute for Safe Medication Practices (ISMP) with the same goal: collecting healthcare workers' stories and reports about medication errors to improve patient safety.

We spoke with Cohen, guest editor of this issue, about ISMP's ongoing initiatives and the biggest challenges in medication and vaccination safety facing pharmacists today.

Eugene Myers: ISMP has a long history of working with healthcare students to educate them about medication errors and safety. Why is this such an important focus of your work?

Michael Cohen: For one thing, we operate the ISMP National Medication Error Reporting

Program. Education is part of every healthcare professional's responsibility. One way to do that, and an especially important area, is sharing of information about medication errors. So as they go about their professional life, anything you become aware of that could really be important to others to know about from a safety standpoint should be considered as a report of a medication error. For example, if you experience a medication error or identify something that might be potentially harmful, even though there hasn't actually been a problem yet—if that gets reported that can help not just your colleagues, but you as well.

In Pennsylvania we're very fortunate to have the Patient Safety Authority [PSA] doing very similar work, but in a broader way, not just medication errors. The PSA is concerned about any type of patient safety event, but we focus only on medication errors—so just from that standpoint alone there's great importance in what we are doing.

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How does ISMP engage with PharmD students in particular?

Here in Philadelphia, we actually do a course at Temple University, School of Pharmacy, as well as Thomas Jefferson University. We also interact with and do live events for different schools; we're doing one in a couple of weeks for Purdue University and we just did one for the University of Texas. We've also done them for other schools upon request. We provide all types of education: background on the reporting program, and also the types of reports that we get.

Lately there's been a lot of interest on the part of students about vaccination-related errors. In pharmacy schools they are taught how to administer vaccinations. And that of course becomes part of their professional life when they go into community pharmacy in particular, or ambulatory care pharmacy. And here in Pennsylvania, for example, pharmacists have the authority and there's an add-on to their license if they're certified to be able to administer vaccines. So there's a big demand now for information about vaccination-related errors, and I've been doing some of that and others that I work with have been doing the same. So any topic that people feel is interesting, we're happy to help where we can.

Speaking of vaccination-related errors: Pharmacists today are probably busier than ever with their role in distributing COVID-19 vaccines. What has been the impact on patient safety?

Giving vaccinations has been one of the most important public health functions that we've ever done in pharmacy. Reporting medication errors is an important public health issue as well. We're giving about 25% or 30% of the vaccinations in the United States now; pretty much every state is doing it and it has made it very easy for people to be able to access vaccinations in their community pharmacy where pharmacists are very available. There was a little bit of a problem when we first started with all the COVID-19 vaccinations: You had to make an appointment and that became problematic because *everyone* wanted to get vaccinated. Well, not everyone, many people wanted to get vaccinated—but not enough, I would say. Today it's very accessible and easy. And in many cases it's covered by insurance or, in this case with the COVID vaccines, it's free, it's covered by the government. So that's really been a big public health improvement that pharmacists and pharmacies have made available.

Absolutely. So what has been one of the biggest challenges in ISMP's work?

In our work we just want to do everything, and we don't have the funding to do it, you know? It's like any other nonprofit organization, you always want to do more. And we have a terrific staff: We're multidisciplinary—nurses, pharmacists. We have a medical director who's a physician. For example, right now, we'd love to start doing videos of the errors that we have reported to us. We would love to make that information more accessible, and a lot of people enjoy things like podcasts or short videos that demonstrate exactly what the concern is and show how to prevent the issue. So we've been looking into that. We have actually had some cooperation from the School of Pharmacy, Temple University, and they have been making some funding available to us. And we do have about six videos now on our website and we're going to be doing a little bit more of that as well. We're also thinking about podcasts.

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But we have had a really, really good impact, not just on practice-related issues but on product-related issues as well—regulated products. We do a lot with the U.S. Food and Drug Administration and they have a whole group that focuses on medication error prevention. It's called the Division of Medication Error Prevention and Analysis and we have a regular meeting with them once a month and then every day, pretty much, we're in touch with them about specific issues. I've been in touch with them several times about our concern related to the new pediatric COVID vaccine and what our concern is: We're worried that it's going to get mixed up with the adult vaccine, and many other vaccines that have an age-related component to the dosing, they're mixed up, and now I think we're going to be seeing that and we want to take some steps in advance to get that information out there.

Sure. That's related to my next question: What have been some of your biggest successes in in your work?

Being able to turn around the reports that we get from the field. We're very fortunate in that our style of reporting is a bit different than most of the other types of reporting. It is very important to have large databases so you get a really good feel for how often something is happening, how serious the problem is. We know what the usage is of individual products—we can get that information. And if we have a pretty good feel for how often something is happening, we can relate that to how often the product is being used. That's important, and we need large databases to do that.

But our work is really getting the stories from the nurses, the doctors, the pharmacists that are out there in the field, and they're very, very willing out of altruism, pure altruism, to tell us the story, make information available: photographs, screenshots on their computer if it's a drug name mix-up that they chose the wrong item, it could be almost anything. That has been really important to our ability to get information out there to the wide audience, both nationally and internationally. That is a big thing, and also working with the FDA. We've been able to effect product changes on the level of thousands of product labeling changes over the years.

One change alone, that goes into an FDA guidance or a United States Pharmacopeia [USP] standard that industry is required to follow can affect thousands of injectable drugs. Those numbers

are very, very high and we have had great success with these—just individual reports of “Boy, if somebody doesn’t do something, there could be a serious error with this.” We make that available to the public, to FDA, to USP, to the industry, to the individual companies. They get copies of the reports; all the identifying information is redacted so nobody knows where it comes from. So those two issues are probably the most important things for us.

You touched on this with your concerns about the pediatric COVID-19 vaccines, but considering the current state of medication errors and then looking ahead, what are some of the major issues that we need to address?

We’ve always tried to focus on a group of drugs that we named high-alert drugs [www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf] and the reason is these are drugs that may not be involved in a lot of errors necessarily but when an error happens, it’s much more likely that a patient would be injured or it could even be fatal. So we’ve tried to focus on those drugs and we have them listed on our website. We are developing one now for community pharmacies as well. And that’s an important area for us to be involved with, making that information more available and getting people focused on these activities.

The other errors that happen that don’t involve high-alert drugs are also important, and certainly getting information out about medication errors and vaccination errors so that people have this information and our recommendations on how to prevent it, which generally are pretty simple to implement. In some cases, we do recommend technology—that’s important.

Michael Cohen is founder and president at the Institute for Safe Medication Practices (ISMP). He is active in many patient safety initiatives, including as co-editor of the ISMP consumer website, chairperson of the International Medication Safety Network, former member of the U.S. Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee and Nonprescription Drugs Advisory Committee, and a current consultant to the FDA. Cohen has been widely recognized for his advocacy and expertise in medication safety, receiving the John M. Eisenberg Patient Safety and Quality Award from the National Quality Forum and The Joint Commission, and the Harvey A. K. Whitney Award from the American Society of Health-System Pharmacists. In 2006, the John D. and Catherine T. MacArthur Foundation recognized him as a MacArthur Fellow.

Cohen is a graduate of Temple University School of Pharmacy, where he received both a bachelor’s in pharmacy (1968) and Master of Science in pharmacy (1984). He was awarded honorary Doctor of Science degrees by Thomas Jefferson University, the University of the Sciences in Philadelphia, and Long Island University, and he also has a Doctor of Public Service from University of Maryland. Cohen served as director of pharmacy at Quakertown Community Hospital in Quakertown, Pennsylvania, and assistant director at Temple University Hospital prior to founding ISMP.

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