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In Conversation with… Michael Cohen, RPh, MS, ScD (hon)

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Robert Wachter, Editor, AHRQ WebM&M: Tell us a little bit about your background and how you got into pharmacy.

Dr. Michael Cohen: My father worked as a store clerk in a drug store, and he used to take me there on Saturdays. When I was about 10, I started doing odd jobs there, like delivering prescriptions on my bicycle. I decided then that I wanted to be a pharmacist. I went to pharmacy school at TempleUniversity, and after I graduated, I began to work at TempleUniversityHospital. My first job was very unusual. At the time, in 1968, most pharmacists worked in a basement pharmacy—you were a voice on the phone to the doctors and nurses and not much more. But I had taken Temple's first course in clinical pharmacy, and my boss gave me a job on a 56-bed men's surgical ward, full-time.

I was constantly going in and out of the unit and talking with the nurses and the doctors. And they would come into the pharmacy to look at our books or have a cup of coffee, and they began to ask us questions. Soon, they began to trust me more and more and knew that I would never report them if something went wrong, so they began telling me stories about problems. Of course, some things I could see for myself. After a while, I realized some of the stories were real gems. So, I talked to the director of pharmacy, who fortunately was the editor of the journal*Hospital Pharmacy*, and he asked me if I wanted to start a column about the things that I was learning about medication errors. And that's what we did. It really took off—we started getting reports from all over; people would see us at meetings or call us or send us a written report. What really makes the program work so well, it's not just receiving the report, but also advocacy for safe practices and products. We follow up on the report with the practitioner, and we can contact the FDA, JCAHO, or even product vendors if broader product issues arise.

These publications, and a book we wrote called *Medication Errors* (1)*, generated a lot of letters from administrators and providers who were very upset. They worried that people were going to be so scared about errors that they were never going to come into hospitals for care. It was kind of ridiculous, but that was the way it was back then. By 1990, we realized this was becoming a full-time operation. We were getting calls to come out and give talks. We were doing a lot with the FDA. I started seeing the writing on

the wall. I couldn't work as a hospital pharmacist and do this type of work full-time as well.

So we chartered our small enterprise as a non-profit organization called the Institute for Safe Medication Practices. And it really took hold. We launched a newsletter, hired full-time staff, and developed our high-alert drug list. By late 1999, when the IOM report came out, ISMP was well entrenched as an organization, and it's grown much larger since then. Today, we have 23 full-time people, almost all nurses and pharmacists, plus a physician medical director. And the entire focus is on medication error prevention and related matters, like cultural issues to support safe practices.

RW: Being in the Philadelphia area, you are working near one of the most profitable industries in the world—the pharmaceutical industry. What sort of tension has that created? There's all this money around you, and a lot of the people doing research in the field get dollars from the industry. How have you dealt with that?

MC: Credibility is extremely important to us, and a lot of trust has been built in the ISMP program. We would never do anything where we were advertising or helping in the marketing of a specific product. However, we do some product testing. That's a totally separate division of ISMP, with its own staff. I'm not involved in it at all. It's called Med-E.R.R.S. (Medical Error Recognition and Revision Strategies, Inc.). For example, if drug companies are coming out with a new product, they may want to look at the drug name to make sure that there's not a chance that it might be confused with something else. The companies come to Med-E.R.R.S. and ask for an analysis of the potential for error with the name, label, or device design.

RW: It strikes me that you really developed the first important health care error reporting system in the United States. It sounds like it organically grew from you being interested in this on your ward to getting reports from elsewhere in the hospitals, in the country, elsewhere in the world, and all of a sudden it became this big thing. As patient safety has become a bigger issue, people are struggling with how to develop an error reporting system that works. Can you share some of the lessons that you have learned through your work that are relevant to other error reporting systems?

MC: Absolutely. First of all, you're right, we started in March of 1975, which actually predates the Aviation Safety Reporting System, and I don't know of any other system that's been around that long. There is certainly evidence that our system has had a great impact. Many of the Joint Commission's National Patient Safety Goals have grown out of our reports and recommendations, and hundreds of product changes and medications taken off the market have as well.

What has worked? First, never identifying an individual or a location. They know we're not going to identify them. We're never going to call a state board or anything like that. And we have no authority to make them do anything. It's really all about trust. Second, giving people many different ways to contact us—I don't care if they call us, see me at a meeting, use our reporting form in the mail, or send me an e-mail. Third, when people take the time to tell us their stories, we get the word out. And when we write, we're not writing to the doctors, we're not writing to the nurses, we're not writing to hospital administrators, we're writing to the entire medical community. We try to make it easy to read, so almost anyone can understand the message, even unit clerks.

Lastly, and most importantly, they see their material actually being put to use. They see the changes. So they see great value in the program. They see it being put into use by other organizations. And that's what makes this work. Nothing beats a system in which people can just pick up a phone and tell you something and know that you'll follow up on it and work to change things, so that what they saw is no longer a problem.

RW: Talk a little bit about your connection to outside organizations. When you see a report of something that you think is worrisome or a pattern of something, are you just publishing it in your materials and then making sure that JCAHO or FDA see it, or do you have a pipeline into these organizations?

MC: The FDA, as the main drug regulator, is obviously very important. I'm on the FDA's Drug Safety and Risk Management Committee, which gives me some input there. Over the years, I've developed relationships with FDA personnel. We actually do a video with them every month called FDA Patient Safety News. We're also very much in tune with the United States Pharmacopoeia (USP). I should mention that our reporting system is done in conjunction with the USP. The Pharmacopeia itself is an official compendium, and therefore its directives must be followed by FDA as far as labeling issues, packaging issues, and even nomenclature issues. So that's obviously been a big help. I'm on the IOM Committee on Identifying and Preventing Medication Errors. We've also developed relationships with the drug companies—we know how to get through to usually the right people, and propose the kinds of changes we like to see for over-the-counter or prescription drugs. Sometimes it works, sometimes it doesn't. And of course our staff is involved with just about every major patient safety organization, NQF, JCAHO, the USP Safe Medication Use Expert Committee. Right now, we have active projects with the Association of Operating Room Nurses (AORN), the Medical Group Management Association (MGMA), and the American Hospital Association (AHA). So we're all over the place. ISMP also works with ECRI, a Pennsylvania-based health services research organization, which has a contract with the state's Patient Safety Authority. We help the Authority to prioritize and analyze medication error data submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS), the state's mandatory medical error reporting program and also help produce their Patient Safety Advisories to suggest steps to avoid future adverse events.

RW: A lot of discussion in the patient safety world is about how to change the culture of physicians and nurses, and relatively less about the evolution of the field of pharmacy. Talk about where you think the field is and where it's going. It is a field we should be encouraging young people to pursue?

MC: Oh, absolutely, the choices are vast now in pharmacy—in regulatory, in industry, in hospital, in clinical, dispensing in the community, plus lots of management opportunities. I think it's a great field. Where else can folks get a job immediately after graduating and make $100,000 right away? But it's not just the financial rewards; I think there's great satisfaction in it. Today, the students' rotations are so diverse—we have students at ISMP throughout the year. They're on rounds with the medical students all year long. They have a lot of electives, in many ways similar to what the medical students do in their senior year. I have personally seen a change, just in working with the committees that I'm on. On these committees, I see the doctors—who never would have mentioned pharmacists in the past—now really looking to pharmacists to help keep their patients safe. And nurses feel the same way. I think the role of pharmacists has really changed for the better in the last few years.

RW: These days, people talk about culture and making sure that everyone is sufficiently assertive and engaged and that care is interdisciplinary. Do you think pharmacists are being trained the right way?

MC: I think we could do a lot better. I walk into some community pharmacies, and the management just hasn't caught up to the safety issues. But many of the large chains are beginning to see the light as far as medication errors are handled. I think we need more focus on the State Boards. They still seem not to get it. We still have pharmacists being punished in many different ways, yet they still overlook that the pharmacy that they worked in was bad. Or that, it's not just that one pharmacist needs to learn a particular lesson, every pharmacist in the state or the country needs to learn it. So we have a lot more work to do at that level.

RW: Twenty or thirty years out, what does the role of the pharmacist look like in a completely computerized environment?

MC: Well, people have pointed out that with bar coding, smart pumps, and computerized prescribing, all of which ISMP has fully supported, medication errors may disappear 10, 20, 30 years from now. I guess that's possible, but I cannot really envision it. The technology will change the role of the pharmacist, to a greater focus on drug information provision, clinical presence, and drug development with the pharmaceutical industry. With medication management therapy, we're starting to see for the first time pharmacists being able to be reimbursed for talking to a patient, educating them, and monitoring their therapy. Ultimately, groups of patients will be counseled by a pharmacist in their community pharmacy. Doctors, obviously, may still make mistakes; even if they get warnings, mistakes can get through. Pharmacists will be responsible for order screening. I think pharmacy has a very bright future.

RW: I can't leave you without talking about the MacArthur Award. First of all, did you know you were in contention, and how did you find out?

MC: No, you don't know that you're in contention at all. I was in New Zealand to give a talk, and because of the time change I couldn't sleep. The phone rang, and it was a gentleman who asked me if I ever heard of the MacArthur Foundation, which I had. Anyway, he told me that he wanted to interview me because they're considering someone for the award. After about two or three questions, I started realizing he was talking about me and finally he said, "Do you know who we're talking about?" I just was quiet, and he said, "We're talking about you." And he also told me I probably would never talk to him again. And I didn't. It was all very mysterious.

RW: Did you think it was a prank phone call for a second?

MC: No. I was pretty sure it was real because he said they were considering someone else. The MacArthur Foundation—I mean nobody is going to cook up something like that.

RW: I have friends who would do that to me.

MC: Oh really? My friends aren't that clever.

References

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1. DavisNM, Cohen MR. *Medication Errors: Causes and Prevention*. Philadelphia: George F. Stickley Co.; 1981.

* A new edition of the book, edited by Michael R. Cohen, was published in 1999 by the American Pharmaceutical Association under the title Medication Errors. A third edition will be published later in 2006.