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Pharma **VOICE**

THE FORUM FOR THE INDUSTRY EXECUTIVE

PORTFOLIO MANAGEMENT

Strategies

**IMPROVING PATIENT
COMPLIANCE**
with Dorothy Smith

Device and Diagnostic
MARKETING

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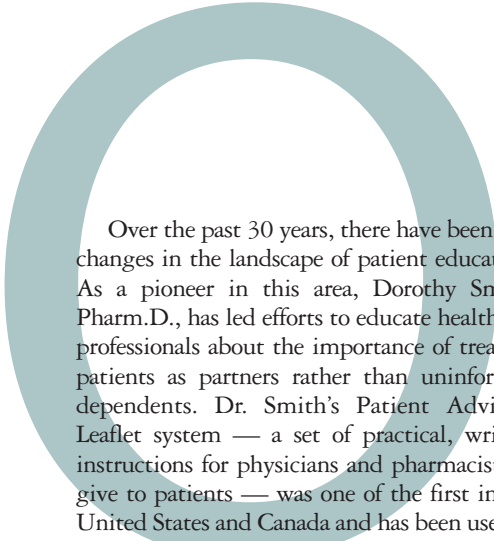
DR. DOROTHY SMITH HAS DEVOTED HER CAREER TO CONSUMER HEALTHCARE EDUCATION.

She began by shaking up the role of the pharmacist by pushing for patient-counseling programs. Today, she continues to work tirelessly to ensure that consumers are informed and involved in decisions that affect their health.

BY KIM RIBBINK



EDUCATION, THE BEST MEDICINE



Over the past 30 years, there have been vast changes in the landscape of patient education. As a pioneer in this area, Dorothy Smith, Pharm.D., has led efforts to educate healthcare professionals about the importance of treating patients as partners rather than uninformed dependents. Dr. Smith's Patient Advisory Leaflet system — a set of practical, written instructions for physicians and pharmacists to give to patients — was one of the first in the United States and Canada and has been used in more than 9,000 community and chain pharmacies in both countries.

From her earliest interests in science, Dr. Smith has been eager to explore ways to help patients understand the drugs they had been prescribed. But in the late 1960s, as a young graduate of pharmacy, no such programs existed.

"During my training, I was taught not to counsel," she says. "My old dispensing notes from university told pharmacists that if patients ever asked a question, we were supposed to refer them to their doctor. Prescriptions were written in Latin so patients didn't even know the names of the medications they were taking."

To better understand the challenge of patient noncompliance, Dr. Smith took the teachings of her parents to heart: to understand a problem look at it from the other person's point of view.

"I realized, even back then, that I wanted to counsel patients," she says.

Ever since, Dr. Smith has been finding ways to do just that. Today, she runs her own patient-education company, Consumer Health Information Corporation, which works with pharmaceutical and medical-device companies to ensure that patients know how to use their medications safely and wisely. The company, which was founded in 1983, also works with healthcare providers to help them counsel their patients to better manage their medication and with patients and consumers to motivate them to make appropriate decisions about healthcare and medication use.

"There were no ready-made jobs in patient education in either the United States or Canada," she explains. "And this was my dream — to devote all of my time to patient education to help people learn how to take better control of their meds at home."

A LADY "FARMER"

Growing up, Dr. Smith's interests were varied. She was interested in athletics, travel, cooking, fashion design, piano, religion, and science.

"I loved science and as soon as I met with our local pharmacist, I knew this was the career I wanted," she says.

But as Dr. Smith came up against the barriers placed between pharmacist and patient, she began to look at ways to overcome the obstacles. During her residency at the University Hospital, University of Saskatchewan, she persuaded the directors of the program to let her undertake a research project in clinical pharmacy, whereby she would take a drug history from a newly admitted patient and develop a system to communicate this information to the medical and nursing staff. And before patients were discharged, she would counsel them on how to take their medications properly.

Her first experience in patient counseling might have been enough to dissuade a less determined individual.

"When I introduced myself to one patient as a pharmacist, his response was 'a lady farmer?'" Dr. Smith says. "I knew I had a challenge on my hands. My reaction must have amused him, because when he was being discharged from the hospital, he presented me with a breadboard he had made in occupational therapy and wished me good luck in my career."

After lecturing for a while at the University of Alberta, Dr. Smith returned to school to get her doctorate, studying at the University of Cincinnati, where she was offered a full scholarship in medicine. But pharmacy was where she wanted to be and where she knew she could make a difference. She had witnessed patients die because they did not know how to take medications correctly, thus fueling her determination to make patient counseling a reality.

Steps to a Healthier Patient

ACCORDING DR. DOROTHY SMITH, FOUNDER AND PRESIDENT OF CONSUMER HEALTH INFORMATION CORPORATION, THERE ARE STEPS THAT NEED TO BE FOLLOWED TO ENSURE THAT PATIENTS UNDERSTAND THE PURPOSE OF THE MEDICATION, HOW TO TAKE THE MEDICATION, AND HOW TO MONITOR PROGRESS.

The first step is to develop a patient-compliance strategy for a specific medication, identifying potential literacy and other problems that patients might encounter.

The next step is to develop the content, ensuring that it meets patient comprehension tests.

"Each step of a description must be understandable," Dr. Smith says. "For instance, in a discussion of how a medication works, the consumer must be able to understand each point leading up to the concluding statement."

Risks must be translated into symptoms that patients will be able to recognize. As an example, Dr. Smith notes that it is not enough to say that a medication can cause a serious liver disease such as hepatitis.

"The patient also needs to be told the warning signs of hepatitis in patient language — for example, 'Call your doctor if you become unusually tired, lose your

appetite, or develop nausea and/or vomiting, develop a yellow color to your skin or eyes, or dark colored urine or pale stools,'" she says.

Another important aspect is ensuring that the visuals reinforce the words.

"Many companies run into problems with patient comprehension because they develop the design before they know the content," she warns. "The design is critical to patient comprehension and must follow patient-education guidelines. Colors have to be carefully selected because there is research that shows people with diabetes who have had laser therapy for retinopathy may have difficulty telling the difference between blue and green."

Thereafter, Dr. Smith notes that one-on-one patient counseling sessions are important to help patients understand and use the information and to guide them on why and how to change their lifestyle.

WE LOOK FOR STAFF WHO CAN THINK OUTSIDE THE BOX and figure out every way that a patient could 'misinterpret' a statement.

Dr. Smith accepted a position at the University of British Columbia to help set up the first clinical pharmacy program. At the same time, she interviewed and counseled patients in the Family Practice Department of Vancouver General Hospital. While working at the University of British Columbia, she began a project to translate medical terminology into patient-friendly instructions. Though she received a summer research grant to hire a pharmacy student to help with the project, the two barely scratched the service.

"By the end of the summer, we had finished the drugs from A to C, and I was left with D to Z," Dr. Smith notes. "It took me seven years to finish the project."

Subsequently, at the University of Toronto and Sunnybrook Medical Center, Dr. Smith was given an opportunity to set up an Ambulatory Patient Pharmacy with private counseling rooms.

This was exactly the setting Dr. Smith had long hoped for. But as with most innovative ideas, there are always detractors. The head of the Medical Advisory Committee (MAC) tried to shut down the program, claiming that patients didn't need pharmacist counseling. And he might well have achieved that goal had he not made an embarrassing mistake during a

presentation at a MAC meeting.

To make his point, he cited his experience in prescribing tetracycline, which included the patient instruction of taking the

broad-spectrum antibiotic with milk.

"But milk interacts with tetracycline, and the other physicians at the meeting voted unanimously that the counseling program be continued and expanded; and it's still going today," Dr. Smith says.

This was not the only obstacle Dr. Smith had to overcome in her quest to provide patients with the information that she believed, and still advocates, necessary to manage their healthcare.

When the Sunnybrook patient-counseling program came under threat of closure because of funding concerns, Dr. Smith proposed charging patients 50 cents a visit. The committee warned her that she would lose many of her patients. In truth, her patient roster tripled.

Dr. Smith's belief that patients are willing to pay for counseling was further validated during her three-year tenure at the American Pharmaceutical Association. Dr. Smith worked with Lou Harris Polls on a national telephone survey.

"The results of the survey revealed that many would pay up to \$30 for a counseling

session," she says. "This survey has been repeated since then with similar results."

PUTTING KNOWLEDGE INTO PRACTICE

Effective patient counseling is one of the most difficult things to do, Dr. Smith contends. It requires not only having an intricate knowledge of the medications and their side effects, but also being able to predict the types of mistakes patients might make. She began looking for an opportunity to put her wealth of experience gained from teaching in academic settings, writing medication instructions, and counseling into wider practice.



DR. DOROTHY SMITH

A Tireless Pioneer

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, DR. DOROTHY SMITH, FOUNDER AND PRESIDENT OF CONSUMER HEALTH INFORMATION CORPORATION, TALKS ABOUT WHAT MAKES HER TICK, THE CHALLENGES IN ADDRESSING PATIENT EDUCATION, AND THE THRILL OF MAKING A DIFFERENCE.

IN YOUR PERSPECTIVE, WHAT ARE SOME OF THE MOST PRESSING CHALLENGES FACING THE HEALTHCARE INDUSTRY?

Consumers still do not know how to manage their prescription and nonprescription medications. For example, at least 50% of all prescription drugs are not taken correctly and consequently people are suffering needless medical complications. This is hurting pharmaceutical companies. Poor patient retention is one of the primary reasons direct-to-consumer ads are not as effective as they could be. Of every 100 consumers who read a DTC advertisement, seven people

will receive a prescription, six will get the prescription filled, but only one person will make it to the fourth or fifth refill. Pharmaceutical companies need to focus on patient retention as well as patient acquisition.

Why not develop a patient-compliance strategy for the product that begins with Phase III clinical trials, is integrated at launch throughout the DTC campaign and all the patient-education programs that health professionals distribute, and then designed so that patients on chronic medications are given the type of information they need at different times during the treatment?

OVER THE YEARS, YOU AND YOUR COMPANY HAVE WON AWARDS FOR THE WORK YOU'VE DONE IN THE FIELD OF PATIENT ADVOCACY. WHAT DO THESE ACCOLADES MEAN TO YOU?

For so many years, I felt as though I were the only one in the world in patient education. So when my peers acknowledge that my dream job

"My experience in clinical practice taught me the patient is the most important person in the drug-therapy cycle, and the patient holds the ultimate power," Dr. Smith says. "If the patient is not convinced of the benefits of a medication or is afraid to take a medication as prescribed, the time and money spent putting the drug through clinical trials and getting it to market are wasted."

Consumer Health Information's founding mission was to change patients' understanding of medications. Before long, the company's work expanded to helping pharmaceutical and medical-device companies develop "how to use" instructions, disease management materials for clinical trials, and "patient" package inserts. The company transforms complex, medically oriented information about the risks associated with a medication into straightforward, patient-friendly language that meets both legal and regulatory requirements.

"Health literacy and patient comprehension are more than just translating adverse drug effects into layman terms," she says. "Patients need to be given information that will help them recognize early warning signs, and, when appropriate, practical information on how to manage the side effect."

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Through its proprietary DocuSource methodology, Consumer Health Information's pharmaceutical programs include sophisticated drug information literature searches, evaluation of the study design to make sure the findings are valid, and documentation for the company to use internally and to present to the FDA.

"DocuSource enables us to provide the pharma companies with the type of documentation and rationale they need, because it is essential that the written medication information be fully explained from a medical, behavior modification, patient compliance, and health literacy standpoint."

To achieve these far-reaching goals, Dr. Smith looks for staff who understand the problems associated with turning patient-education problems into practical solutions.

"We look for staff who can think outside the box and who can determine every way that a patient could misinterpret a statement," she says. "We have to take complex medical information and simplify it so that it can be understood by the average patient."

TACKLING THE CHALLENGES

Despite improvements in patient education, the industry still faces many challenges in

helping consumers manage their health and remain compliant.

"It troubles me that I have been working in this area for almost 30 years and patients still are not receiving adequate counseling or high-quality written instructions every time they receive a prescription," she says. "Patients are still suffering needless medical complications from improper medication use."

While all prescriptions come with package inserts, the Food and Drug Administration has gone so far as to call most instructions useless.

"The FDA has stressed the need for pharma companies to make sure patients can understand how to take the drug, in language people can understand," Dr. Smith says.

Among Dr. Smith's goals going forward is to develop an electronic version of patient medication instructions that can be used in community pharmacies in the United States and Canada. Also, she wants to develop a consumer line of publications and tools that will help patients and caregivers learn how to manage medications safely. These might include compliance tools such as a progress log that patients can take to their physicians to assist with diagnosing a problem.

The answers to many of the problems, Dr. Smith believes, lie in making consumers aware of the risks to their health if they are not given the counseling they need to manage their medications wisely and safely.

is helping to advance the profession, it is just a really good warm and fuzzy feeling, and one that gives me that extra boost to get back to work on Monday and tackle another problem confronting patients.

There is so much left to be done. I know we can't solve all the world's problems in patient compliance, but we can try our best and if we are lucky, we can improve some of the quality of life of some patients by helping them get the full benefit from their medicines.

HOW DO YOU SEEK TO LEAD AND INSPIRE OTHERS?

I guess I am the eternal optimist and

always ready to take on a challenge. This has resulted in our company getting involved in so many different and unique programs.

Being a pharmacist, I am a very organized person and believe that this is the key to our team being able to accomplish so much.

We have a detailed procedure manual that everyone uses so that our company can run like clockwork, and we don't get bogged down with trying to figure out how to handle some office administration procedure. This frees up everyone's time to work on projects.

Then again, I have never had a 10-year plan and have learned how to lead in faith. That's worked well for the company and makes the days more exciting because often the doors that open are ones we would never have envisioned.

WHO ARE THE INDIVIDUALS WHO HAVE HELPED LEAD YOU TO WHERE YOU ARE TODAY AND HELPED FORM YOUR OUTLOOK ON WORK AND LIFE?

My parents always taught me that if I recognized a problem not to sit back and wait for someone to fix it, but to go fix it myself. They also taught me that whatever career I decided on was fine as long as I was helping people. My father died in the prime of his life, and my mother became a strong supporter and was there to encourage me when I started the company and when the going was tough. She had a strong business sense and more common sense than anyone I have ever met. My patients have also been a huge influence on the business decisions I've made.

The Journal of the American Pharmaceutical Association published a study in 2001 — Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model — showing that improper use of medication cost the country \$177.41 billion a year, including: 9.6 million hospital admissions, costing \$121.52 billion; 18.7 million emergency room visits, costing \$5.76 billion; 3.5 million nursing home admissions, costing \$32.78 billion; 126.8 million physician visits, costing \$13.83 billion; and, 83.7 million additional prescriptions, costing \$3.52 billion.

“Why not reimburse health professionals for the time they need to counsel patients out of this \$177.41 billion?” Dr. Smith asks. “Patient response to medications will improve; direct and indirect costs will decrease; patient retention will increase; and when all is said and done, patients will receive more benefit from their

MY DREAM WAS

to devote all of my time to patient education to help people learn how to take better control of their meds at home.

reach out to patients is through its consumer newsletter, Taking Control of Your Medicines. In the wake of September 11, Dr. Smith says it occurred to her that, with many patients unable to get to their homes, it made sense for people to carry around small amounts of their medication at all times.

“I wrote a newsletter right away and we sent it out to national consumer and professional health organizations, universities, chain drugstores, and pharma companies, urging all of them to forward the newsletter,” she says. “Within hours, we were receiving requests from companies all over the country to post the newsletter on their Websites. Chain drug

medications and pharma companies will have increased ROI.”

Dr. Smith says her company is expanding its programs and ideas to improve patient compliance. One way it seeks to

stores ran with the idea and offered this as a free service to their patients and absorbed the cost of preparing a second prescription vial with the medication.”

Making patients part of the solution is critical, Dr. Smith believes. The fact that there are far more patients than healthcare professionals means the industry must find ways to engage the consumer.

“I believe I know how to convince consumers that the cost of a medication is miniscule compared with the cost of medical complications that can occur if medications are not taken correctly,” she says. “Once we have the consumers’ support, they will put pressure on the legislators who will then bring about the changes needed to ensure that everyone who receives a prescription medication is adequately counseled at every stage of treatment and that health professionals are reimbursed for their time out of the nearly \$180 billion being spent on avoidable medication complications.”

Along the Counseling Path

PROFESSIONAL AND ACADEMIC POSITIONS:

1983 – PRESENT. Founder and president, Consumer Health Information Corporation, McLean, Va.

1983 – PRESENT. Adjunct associate professor of community and family medicine, Georgetown University School of Medicine, Washington, D.C. (This was Dr. Smith’s first cross appointment; subsequently she has 32 cross appointments to schools of pharmacy across the United States.)

1991 – PRESENT. Associate clinical professor of pharmacy, School of Pharmacy, Medical College of Virginia, Richmond, Va.

1980 – 1983. Director of clinical affairs, American Pharmaceutical Association, Washington, D.C.

1978 – 1980. Associate professor of clinical pharmacy, Faculty of Pharmacy, University of Toronto, Toronto

1974 – 1978. Coordinator of ambulatory pharmacy care, Sunnybrook Medical Centre & Flemingdon Community Health Centre, Toronto

1974 – 1978. Assistant professor of clinical pharmacy, Faculty of Pharmacy, University of Toronto

1972 – 1974. Assistant professor of clinical pharmacy and coordinator of clinical under-graduate program, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver

1970 – 1972. Clinical Instructor of Pharmacy, University of Cincinnati, Cincinnati

1969 – 1970. Lecturer, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, Edmonton, Alberta

EDUCATION:

1972. Doctor of pharmacy, University of Cincinnati

1969. Residency in hospital pharmacy, University Hospital, University of Saskatchewan

1968. Bachelor of science in pharmacy (Great Distinction), University of Saskatchewan

SELECTION OF AWARDS:

2003. Paul G. Rogers/NCPIE Medication Communicator Award

2003. Robert J. DeSalvo Award, University of Cincinnati

2001. University of Cincinnati 2001 Distinguished Alumni Award, University of Cincinnati Alumni Association

2001. University of Cincinnati Master Alumni Award

1994. “First and Best,” University of Saskatchewan

1985. Honorary Life Membership in Canadian Association of Pharmacy Students and Interns (CAPSI) for outstanding contribution to the enhancement of student development within the profession of pharmacy

1970. Mead Johnson Award

1969. Intra Award, Canadian Society of Hospital Pharmacists (awarded for submission based upon residency project entitled “Pharmacist on the Ward”)

1968. Dean George A. Burbidge Memorial Award (awarded for highest standing in Canada in Pharmacy Examining Board of Canada examinations)

1967. Canadian Centennial Scholarship (academic achievement and student leadership), Canadian Pharmaceutical Association

A MODEL FOR EDUCATION

Over the years, Dr. Smith has become more adept not only at helping patients, but in teaching and inspiring future generations of pharmacists. She attributes her ability to mentor students to what she has learned from working with patients.

"I've learned to counsel patients and have taken courses in techniques of counseling and interviewing," she says. "I think that's where I learned how to get to the point, be clear, concise, straightforward, use reinforcement, and make it creative and interesting."

Much has changed since Dr. Smith began her studies, and today every school of pharmacy teaches students how to counsel patients. Consumer Health Information offers a clinical clerkship teaching site for more than 32 schools of pharmacy in the United States. The company also has a summer internship program open to students in any discipline interested in patient education.

Every state now has a regulation that mandates pharmacists offer some type of counseling to patients. But, according to Dr. Smith, often the written instructions handed out by the chain drug stores tackle only a fraction of the information patients need and don't deal with ongoing side effects and other information patients will need as they refill a prescription.

One way to address this is for pharmacy counselors to employ the transtheoretical model of change, Dr. Smith says.

The transtheoretical model of change stems from the research efforts of James Prochaska, Ph.D., John Norcross, Ph.D., and Carlo DiClemente, Ph.D. Their research into how people make successful and lasting positive change in their lives resulted in a scientifically proven model. After studying thousands of successful "self-changers" (people who successfully made a change without formal therapeutic intervention), researchers identified "stages" through which self-changers pass. These stages are: precontemplation, contemplation, preparation, action, maintenance, and termination.

"This research has shown that people need different kinds of information at different stages of the prescription," Dr. Smith says. "When first prescribed a medication, the patient needs the basic information: how to take it and why to take it. Later, patients need more information about why they need to continue taking it: are they making progress, how do they decide if they need a refill, and when to call the doctor. Because of time con-

straints, pharmacists can't meet with patients during every visit. Usually, they only consult on the first visit, but that's not when patients may experience side effects."

Health literacy is the key to successful treatments, especially in light of the complex tasks patients are asked to perform — review consent documents, fill out questionnaires, follow complicated prescription instructions, monitor their response to drugs, and manage

complicated medicine administration, Dr. Smith notes.

"Patients will only remain in long-term therapy if they believe the treatment is working, so they need to know how to monitor their progress," she says. ♦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

A Winning Formula

AS A LEADING PURVEYOR OF PATIENT EDUCATION AND MEDICATION INFORMATION, CONSUMER HEALTH INFORMATION CORPORATION HAS BEEN INVOLVED IN SEVERAL HIGHLY ACCLAIMED PROJECTS.

Dr. Dorothy Smith, founder and president of the company, cites several that stand out. One was a disease-management program for a Type 2 diabetes medication and another was a DTC program for liver and kidney transplant patients.

The diabetes program, conducted for what was then Upjohn, took place a few years after Consumer Health Information was formed. Dr. Smith says the client trusted the entire project to her nascent company, even down to the printing of millions of copies of the material. The program won the gold award in the National Health Information Awards and was a finalist in the Global Awards. The client's trust paid off and Upjohn attributed a 30% increase in ROI to the program.

Consumer Health Information was asked to put its logo on the program to give it credibility and soon afterwards health professionals and patients started writing to Dr. Smith and her colleagues.

"I really felt we were helping people better manage their diabetes," she says. "To me, this is the best reward."

The second, the liver and kidney transplant project, was a multicomponent program conducted for Fujisawa Healthcare that included a transplant journal for patients to use before surgery as well as after the transplant.

"This program required a careful blending of clinical content with empathy, behavior-modification techniques, and graphic design so that it would not create unnecessary fear," Dr. Smith says. "The client has told us that the DTC program has been highly successful and has been expanded into transplant centers across the country because health professionals wanted to use the program materials in their patient-education sessions. We were also thrilled that this program won the 2003 NHIA Gold Award for the best program in the Direct Mail Consumer-Decision Making category."

Another powerful, patient-focused program that the company has worked on is a consumer pamphlet for the National Council on Patient Information and Education (NCPIE). NCPIE is a nonprofit coalition of about 200 healthcare organizations representing healthcare providers, consumers, university professors, and business groups that develop patient information.

"We hope that companies and health organizations will brand it and distribute it to patients and that it will give patients the information they need before dropping out of therapy prematurely," Dr. Smith says.

In December 2003, Dr. Smith received the 2003 Paul G. Rogers/NCPIE Medication Communicator Award for her contributions to health literacy.



FDA Says Consumers Need DTC Ads They Can Understand

The FDA “believes that FDA-approved patient labeling is a better vehicle for communicating risk information to consumers than lengthy, technical FDA-approved professional labeling.” FDA Draft Guidance, January 2004

No Need to Worry!

Join our list of blockbuster drugs – You can’t afford to wait.

Get the Maximum ROI from your DTC Ads

- Industry Leader in Patient Education
- Team of Health Professionals
- Experts in FDA-Approved “Patient-friendly” Labeling
- Experts in Patient Compliance
- Experts in Patient Retention
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