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Saint Rose Magazine

Time to celebrate!



SAVE THE DATE FOR REUNION 2009!

THE COLLEGE OF SAINT ROSE
ALUMNI ASSOCIATION WILL
HONOR ALL ALUMNI WITH
GRADUATION YEARS ENDING IN
'4' OR '9' ON JUNE 5-7, 2009.



Join hundreds of Saint Rose alumni at Reunion 2009 to relive your memories and revive your Saint Rose spirit!

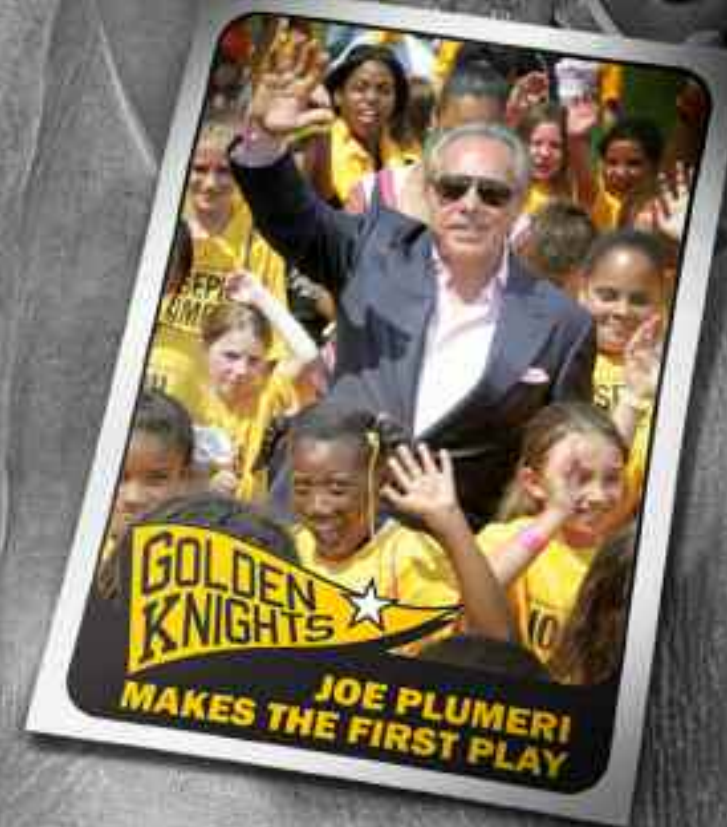
Reunion 2009 offers Saint Rose graduates like you an opportunity to reconnect with classmates, reunite with campus, and reminisce about their days at Saint Rose! Don't miss this opportunity to be involved with your best Saint Rose Reunion yet!

If you have any questions about Reunion Weekend or are interested in planning your class reunion, contact us at 518-454-5105 or email alumni@strose.edu. For more information, visit www.strose.edu/reunion.

Reunion 2009



www.strose.edu/reunion



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Teaching and Research

A Place to Nurture
Talent & Passion
for the Arts

Alumni Spotlight

Frances C. Akelewicz, Class of 1975

Founder, president, principal consultant of Practical Solutions and its affiliate A Squared Associates LLC, Yardley, Pa.



Fran Akelewicz provides risk analysis, product validation and design control. Her areas of expertise include Six Sigma, GLP and GCP credentials—on top of her B.S. in biology from The College of Saint Rose and two master's degrees—include national certification in Regulatory Affairs and Quality Engineering. Put another way: Fran Akelewicz helps extend and improve lives.

Fortune 100 companies hire her firms as they develop a drug or medical device or if these products fail. Akelewicz's success with clients and contributions to her field recently earned her a place on the Medical Device and Diagnostic Industry's 2008 list of "100 notable people." Here, she discusses the Saint Rose biology laboratories, her admiration for Nancy Drew and some of those acronyms:

MS. AKELEWICZ, YOUR WORK TENDS TO BE OBSCURE BUT IT AFFECTS MILLIONS OF PEOPLE. HOW DO YOU EXPLAIN YOUR FIELD?

I usually say that I get involved in the development of medical products and at looking at them in terms of what can go wrong, so it doesn't go wrong. I'm a Nancy Drew who can come in and say, 'hmm, you know if this happens, then that happens to the patient.' When we have the finished product, we compare results to what the regulations say we're supposed to have done.

The FDA periodically inspects a firm—sometimes the company will say 'Could you help us correct what the government pointed out?' From the start, I'm already thinking about the medical complications that can result. I love solving mysteries.

YOU ARE ALSO CALLED IN WHEN A DRUG OR DEVICE FAILS. PLEASE GIVE AN EXAMPLE.

We had a product sold internationally, a dialysis catheter that we wanted permission from the FDA to sell in the United States. We had a lot of information on its use, and I noticed a pattern in the complaints. It turns out almost 100 percent of the people who complained used it for too long.

We ended up issuing an alert to medical practitioners and partnered with the Diabetes Foundation to remind them what the labeling actually said. We added a black box warning telling you how long to use it for. We finally got permission to bring it into the States.

PLEASE DISCUSS THE SAINT ROSE SCIENCE PROGRAM AND THE INFLUENCE ON YOUR WORK.

(Professors) Sister Margaret Keeshan and Sally Fox were great influences. I have a very close friend I partnered with for lab work. I remember during a genetics class, the two of us looking at fruit flies we had cross mated. Dr. Fox heard the 'oohs' and 'aaahs' and came out of her office with a big smile and said 'Over the years I've had some interesting students, but I've never seen two students so excited by fruit flies.' I loved the research and the dissection work on tissue. We designed experiments, even in genetics!

Saint Rose is not a big place. You're not lost in the student body, and there's a theme of caring for one another, the things you learn, the work you will do and the foundation of your faith in God. As I move around the industry, I see some folks who are very strictly ethical and I've seen folks rationalize things. I know I have a very strong foundation in ethics and values thanks to my parents and Saint Rose.

SPEAKING OF ETHICS, AN AREA THE COLLEGE IS EMPHASIZING, PLEASE DISCUSS QUESTIONS RAISED BY NEW MEDICAL DEVICES AND PHARMACEUTICALS.

This is an area fraught with much discussion and challenge. Should we use stem cells? Just how far should science go? Clone organs, clone people? I believe this discussion should be held. One guiding principle I have followed is 'If God wants you to discover/know this, you will learn it,'—which is then balanced by free will. The question then becomes "Should what I learned be used?" I believe very strongly in stem cell research and participate as I can. However, how the results of the research are used must be carefully deployed. Can we cure horrible diseases, potentially yes, but do we have the right to clone people?

I actually left a firm over an ethical issue that was finally resolved, I believe appropriately, but I never felt comfortable there after that experience.

YOU HAD A VIBRANT 25-YEAR CAREER WITH STERLING DRUG AND OTHER COMPANIES BEFORE STARTING YOUR OWN BUSINESSES, PRACTICAL SOLUTIONS WHICH CONSULTS WITH DRUG AND MEDICAL-DEVICE MAKERS; AND A SQUARED, WHICH PROVIDES TEMPORARY STAFFING. PLEASE SHARE LESSONS YOU LEARNED ON YOUR JOURNEY FROM EMPLOYEE TO ENTREPRENEUR.

The biggest lesson is to really pay attention. Listen hard to other people. It isn't just the act of listening it's also watching body language. And, don't be afraid to ask questions, ask them in a learning mode and with respect, and you'll find that the majority of folks will be very patient.

Also, coming from the corporate world, there's a belief that once you start out on your own you'll have more free time. You will probably work more. I average 65 hours a week...Sometimes when I am "off" I can get calls from clients wherever I am. Someone said it this way, 'As a corporate employee, you work long hours and you have no control. As an entrepreneur, you work long hours and you have complete control.'

A PRIMER PLEASE! WHAT DO SOME OF THESE TERMS MEAN?

Six Sigma: A level of control, usually in manufacturing. A state of Six Sigma means there is a probability that less than 3 parts per million will be defective.

GLP: Good Laboratory Practices, regulations that apply to animal studies.

GCP: Good Clinical Practices, regulations to protect the human participant.

ISO: International Organization for Standardization, standards that apply to medical devices.

CQA: A national certification in engineering practices.

ARE MEDICAL DEVICES AND NEW DRUGS GENERALLY SAFE?

Good heavens yes. There's a tendency to focus on the bad stories. The regulations of the FDA and in several other countries around the world are well written and adhered to very well...If you think about it, folks in their middle years today are far more active than our parents were and certainly

our grandparents. A lot of it is diet and nutrition, but it's also because of the medicines and the hips we can have replaced and the cardiac stents adding years to peoples' lives.

YOU WERE THE FIRST WOMAN TO HOLD A QUALITY ASSURANCE MANUFACTURING ROLE AT STERLING DRUG, AND THE FIRST WOMAN PROMOTED TO WORLD HEADQUARTERS IN STERLING DRUG QA FROM A MANUFACTURING PLANT. GENDER HAS NOT HELD YOU BACK, BUT HAS IT PRESENTED SOME CHALLENGES?

It has at times. The pharmaceutical and device industries are still very male dominated at the top. I ask myself why? I recently was having a conversation with my goddaughter and said to her, "I don't mean to sound pompous, but you get to do a lot of things now without thinking about it because I and some of my friends did it first."

I would have thought by this time that there would be more women in the board room. A lot more women are going into the sciences, but when you get into the executive suite you see women who need more degrees and credentials than the men, and I have to wonder to this day whether women are earning less. I'm hoping as soon as the next five years to walk into the board room and see more women at the table.

WHAT DO YOU ENJOY OUTSIDE WORK?

Near and dear to my heart is Quilts for Kids (www.quiltsforkids.org). We make quilts for children in shelters or hospitals. They can't take their stuffed animals into the surgical suite. We use materials hospitals have agreed can go with them. I am on the board and also help do the sewing. Many of the fabrics are donated by manufacturers. One of our goals is that none of this stuff ends up in a landfill.

