Message from the 2008-2009 Co-Chief Fellows
John Noh and Katie Picone

As Co-Chief Fellows we are excited to see the new Fellowship year off to a great start. The new class clearly demonstrates enthusiasm and passion for their new positions and for the Fellowship program.

We have started off the year establishing our new Fellowship committee chairs. We clearly have great leadership in the program and we thank everyone who expressed interest in the positions. The midyear, recruiting and teaching committees have already begun working hard, with classes starting shortly and university and organizational visits already planned for the near future.

And of course, our program is focused on developing our community both within the Fellowship class and with alumni, Rutgers and the outside community. The Community Development Committee has set up events such as the Susan G. Komen Race for the Cure in NYC and Habitat for Humanity. We look forward to the participation and eagerness from the Fellows and alumni during these very noteworthy events.

This year we will continue to build on the success of the Professional Development Days and strive to exceed the standards set in recent years. We have invited a dynamic group of speakers, all with diverse industry backgrounds, to come and share their experiences with the group, as well as widely recognized external trainers who will provide invaluable opportunities to enhance professional development. There will be plenty of exciting and enjoyable opportunities this year and we encourage everyone to take advantage of them all. Let’s maintain the high energy and outstanding work that has kicked off the year.

Mark Kaldas and Shalini Vohra

Message from the Editors:
Dear Readers:
It is our pleasure to bring you all this year’s first issue of the fellowship chronicles. As always, this newsletter is meant to keep you up to date with the most current information and happenings in the fellowship program. This edition will provide highlights of past events from all of our very energetic fellowship committees. We would also like to give a special thanks to all those who have contributed to this issue, and we look forward to bringing you the latest news throughout the upcoming year.

Mark Kaldas and Shalini Vohra

RUTGERS
Ernest Mario School of Pharmacy
The Fellowship Chronicles
Official Newsletter of the Rutgers Institute for Pharmaceutical Industry Fellowships

2008-2009 Committee Chairs

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She said, “I don’t know anything about soccer, I’m just here to see David Beckham”

Mark I. Kaldas, PharmD, MS, MBA

There is no substitute for real tailgating. The hypnotizing aroma of fresh hamburgers grilling, and not on propane – nah, coals are the only way to go. The beer was flowing, there were an endless supply of homemade’ cookies, chips and dip, brownies, and some weird guy brought licorice (hint: his name is Mark Kaldas).

The new incoming fellow class of 2008-2009 and returning fellows decided to combine the world’s most popular sport with one of the most popular American sporting traditions … tailgating. Approximately 35 new and returning fellows made the trek to Giant’s Stadium to watch the New York Red Bulls play the Los Angeles Galaxy in a professional soccer match. The guys were really excited to see a competitive game between two evenly matched teams, and the women went to see David Beckham take off his shirt.

The culprits responsible for organizing this event were Craig Trusley and Matthew Brammer. Craig bought the tickets and quickly engineered a spreadsheet that delegated responsibility to volunteers for the gathering, and Matthew used his culinary background to work the grill.

Pre-game activities included: a competitive game involving a Frisbee and two trashcans, kicking a soccer ball around, enjoying each other’s stories and laughter, and several applications of sunscreen. The 6-hour pre-game tailgate seemed to fly by except for those with red hair. These fair-skinned individuals continued to sweat profusely, drink all the bottled water, and develop a nice lobster-red color.

As we started making our way to the stadium it was reported that they sold over 46,000 tickets to the game – the 7th largest crowd in history for a soccer game at Giant’s Stadium. Our seats were located behind the home team’s goal, but we had a great view of the field and players. We even participated in doing “the wave” a few times throughout the game. Craig arranged that the half-time scoreboard would display “Welcome RPIF Fellows” and when it did, we all cheered. Everyone around us knew who we were, even Beckham gave us a thumbs up”!

The guys really enjoyed talking strategy, appreciating the hard play, and whining about all the missed shots on goal. All the ladies finally got to see what they came for. Yes, David took off his shirt at the end of the game. There were more camera flashes around the stadium when that happened than when the teams actually scored (4 goals total). We finally shuffled out of the stadium and back at the tailgate Matt began grilling kielbasa sausages and hotdogs for a post-game gathering.

Whether we were there to see the game or Beckham, everyone agreed they had a great time. New friendships were made, camaraderie was forged, and established friendships were strengthened. What a perfect way to spend a hot, sunny Saturday! It left everyone wanting more, and we are all anticipating the next fellowship outing.

“The grocery store label caused alarm that they might not be homemade, but they were delicious just the same.

“Matt has no formal training in the culinary arts but his hamburgers were killer.

“Beckham never gave us the time of day. This is a complete lie and Mark should be shot.

For comments and/or suggestions please don’t contact Mark. But if you must, you can write to Mark I. Kaldas at mkaldas@its.jnj.com or call him at 215-325-5322. Please note that he will screen his e-mails and phone calls. The chances of a reply are slim to none.
"The realization of my American dream through the Rutgers fellowship program"
Enoch Kahiga Kariuki, Pharm.D.

I was born and raised in Loitoktok, a small town on the border of Kenya and Tanzania. My grandfather, like many African men of his time, did not believe in the value of educating girls. Denied of the opportunity to go to school, my mother was relegated to the duties of raising her younger brothers and sisters. At twenty three, she found herself uneducated, and a single mother raising two sons. What she lacked in formal education, she made up for with sharp entrepreneurial skills. She started retail and transport business and with hard work did very well. However, every time she needed to sign a document, she had to find someone to read and translate it to her. Frustrated by this experience, she decided that her sons would have the best education she could afford. She enrolled my younger brother and I in one of Kenya’s most highly ranked private schools. The cost was prohibitive, but she was not going to let that get in the way of her plans. Attending the private school prepared me very well for the national primary school exam. I was ranked among the top students in my region and earned myself an admission to Alliance High School. This is one of Kenya’s most prestigious high schools.

While at Alliance, I met the “cream of the crop” from across the nation. An abundance of alumni from Alliance were enrolled in top universities across the world and fortunately they often came back to share their experiences with those currently enrolled in the school. It was during these presentations that my desire to study in the United States was born. I sat for my SAT exams and performed well enough that I was offered scholarships to four American universities. The Fredrick Douglass Honors Program at Texas Southern University offered me a full scholarship, and I enrolled there in the fall of 2001. After enrolling at Texas Southern, I obtained a weekend job as a nurse’s aide taking care of Alzheimer’s patients. Using the money I saved from my weekend job, I paid for my younger brother to take his SAT exams. He soon joined me at Texas Southern University, also on a full scholarship.

At Texas Southern University, I began my journey as a Computer Science major. However, in 2001 the “dot com” bust was just unraveling and I wasn’t enjoying the programming classes as much. Though tough at times, I enjoyed my work at the nursing home and thought that I might be interested in pursuing a career in the healthcare field. My brother and I decided to pursue a career in pharmacy together.

In my third year of pharmacy school, I attended the ASHP Mid-year meeting. At the meeting, I was first exposed to the Rutgers Pharmaceutical Industry Fellowship program. While researching the program, I met Eardie Houston, a graduate of the Rutgers program currently working as a Medical Science Liaison in Texas. Having no industry experience, I was initially apprehensive. However, Eardie encouraged me to apply to the program and provided a lot of information about her experiences as a fellow. During the 2007 ASHP Mid-year meeting I interviewed with several companies. I was offered and accepted a fellowship position in R&D Strategy and Analytics with Bristol-Myers Squibb. In May of 2008, I packed all my belongings into a U-haul truck and drove half-way across the country to begin my year as a fellow with the Rutgers/BMS fellowship program. My experience so far has been rewarding and intellectually challenging. The R&D Strategy & Analytics team at BMS has made me feel welcome. They continuously offer me opportunities to learn through challenging projects but are always there to lend a helping hand. The Rutgers component has been great in providing an academic component to my learning experience.

Two months ago and after seven years, I finally got to see my mother again. I had always wanted to go home, but couldn’t afford to. We stayed in touch through constantly calling, writing letters, and sending pictures. On graduation day she could barely contain herself. To see her two sons graduate as pharmacists was more than she ever planned for. I gave a hug, and thanked her for all the sacrifices that she made. I can’t wait to go back to Kenya next summer. I haven’t seen my youngest brother and sister for more than seven years.

To whom much is given, much is expected. Every morning as I drive into the expansive Lawrenceville BMS site, I am reminded of how lucky I am. The compound is far removed from the small town of Loitoktok that I grew up in. Every year thousands of children die of preventable diseases in Africa. AIDS is rampaging across the continent killing millions; I have lost several friends and relatives to the disease. I want to use the learning opportunity that I have through the fellowship program to equip myself with the necessary skills and experience to be able to go back home and do the little that I can to make things better.
President’s Emergency Plan for AIDS Relief
By Nina Gutman, PharmD and Ripal Shah, PharmD

During our time at the FDA, we had the wonderful opportunity to meet and learn from Monica Zeballas, PharmD. Dr. Zeballas is a Project Manager in the Division of Antiviral Products (DAVP). This She has sole regulatory oversight of the President’s Emergency Plan for AIDS Relief (PEPFAR) initiative within her Division. This initiative, “to meet a severe and urgent crisis abroad…a work of mercy beyond all current international efforts…” was announced by President George W. Bush during his State of the Union Address on January 28, 2003. Congress committed $15 billion over five years towards a comprehensive approach to combat the pandemic disease of HIV/AIDS. To ensure accountability and results of this initiative, President Bush created the position of Global AIDS Coordinator. To implement this plan, the coordinator would collaborate with seven departments and agencies, including the Department of Health and Human Services which incorporates the FDA, CDC and NIH. The goals set forth from this initiative were 1) to prevent 7 million new infections, 2) to treat 2 million HIV-infected people with antiretroviral therapy (ART) and 3) to care for 10 million people infected and affected by HIV/AIDS, including orphans and other vulnerable children. Fifteen countries that account for more than 50% of global HIV/AIDS cases including: Botswana, Cote d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia were selected as the primary focus under this initiative.

Treatment of HIV/AIDS with pharmacologic agents that have been demonstrated as safe and effective is an important component of the PEPFAR initiative. In October 2006 the FDA issued a Guidance for Industry prepared by the DAVP in cooperation with the Office of Regulatory Policy. This guidance encouraged the development of single entities, fixed dose combinations (FDCs), co-packaged products of previously approved antiretroviral therapies, and encouraged the submission of generic applications.

Products submitted under the PEPFAR initiative are subject to User Fee Requirements but can be granted a waiver under the barrier-to-innovation category. Most applications are granted fast track and priority review designation which provides for the review of an application within 6 months. The Agency may grant the applicant tentative approval or approval of the FDC or co-packaged product based on the patents and exclusivities of the products in question. The applications submitted for tentative approval contain only manufacturing and bioequivalence data as the safety and efficacy has been established from the individual reference listed drugs. By providing a tentative approval or approval action on an application, the FDA has put its seal of approval on the product so that PEPFAR contractors may now be able to purchase these products. Susan Denser, a reporter for PBS, stated “A year worth of treatment for one person used to cost thousands of dollars, but the US program can now purchase a typical combination drug treatment for as low as $90 per person per year.” It is important to recognize that products granted tentative approval cannot be marketed in the United States because of existing patents and/or exclusivity.

Between its inception in 2003 and March 2008, PEPFAR has helped to bring lifesaving ART medications to more than 1.6 million people with HIV/AIDS in the 15 focus countries. The success of PEPFAR spurred its reauthorization by President George W. Bush on July 30, 2008. Under this new legislation, the financial commitment has increased to $48 billion. This funding will directly combat the fight against HIV/AIDS, tuberculosis and malaria. The goals for this bill are ambitious and set over the next 10 years. The new legislation calls for 1) the prevention of 12 million new infections, 2) treatment of 3 million HIV-infected people, and 3) care for 12 million people already infected and affected by HIV/AIDS, including orphans and other vulnerable children. “Working on this initiative has been both a rewarding and challenging experience,” Dr. Zeballas tells us, “but when you see the numbers, and the grand progress we have made in the past 5 years, the day to day challenges all feel completely worth it!”