ISSUE



could do when they returned to their workplaces was to thoroughly read FDA guidance documents and enforcement letters in great detail, because they provide insight into the FDA's current points of view.

Michael A. Sauers from the FDA Office of Prescription Drug Promotion followed with an excellent presentation that provided additional regulatory details and demonstrated how to apply the concepts from Lucy's presentation to the real business and regulatory world. He showed examples of print and television advertisements - plus other marketing materials such as websites and patient and physician testimonials - that had resulted in enforcement letters from the FDA.

He gave the audience time to review each example and to identify why the FDA found the promotion in violation. These examples helped to explain to a novice in this field why drug promotions that appear in magazines are often several pages long, and demonstrated the complex nature of drug promotions and the challenges the FDA faces in enforcement. When examining the presentation of risk for a drug, for example, factors including the location, font, spacing, and ordering of the text are important; so are other subtle details, such as the appearance of the models or actors used in the promotion persons used in promotions must be representative of the target population for the drug. Similarly, patient testimonials or imagery used in a promotion must be consistent with the average experience of the patients for whom the drug is indicated.

Finally, Mr. Sauers discussed the challenges that face the FDA in the review of drug advertising and promotion. Because of the high demand for review of promotional materials, the FDA takes a risk-based approach based on several factors – including the severity of the disease, the newest approved drugs, drug warnings, and intended audience of the promotion – to their review.

This workshop brought the audience together with industry and regulatory experts in the advertising and promotion field, allowing for direct interaction with the FDA. Those attending this morning workshop received a solid introductory foundation in prescription drug advertising and promotion. •

Session Report: "My Big Break"



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As a DIA first-timer and student interested in the pharmaceutical industry, I had expected to attend a session on professional development at some point during the DIA 2012 Annual Meeting. However, little did I know that I would attend a session as a "foreign species" not because I was

a clueless first-timer student but because I am a man. What possessed me to choose My Big Break: Women at the Top in the Biotechnology Sector (Session 147) of all available sessions, since it was obviously geared towards another audience? Ironically, the lessons and insight I gained from this seminar were ultimately much more profound and impactful than those from other sessions. The topics covered in this session were universal, applicable to both sexes, and reinforced the idea that the trials and tribulations one goes through in the path of professional development are generally the same for men and women.

This session was chaired by C. Latham Mitchel, MD (Erudita Biotechnological, LLC), and featured panelists Leslie Williams, MBA, RN (ImmusanT); Carole Sable, MD (Merck & Co. Inc.); and Yvonne Greenstreet, MD (Pfizer Inc).

The first question asked the panelists what their "big break" was. When I heard this question, I sat up in full attention. You can imagine my curiosity, as a student eagerly waiting for how I might expedite my own "big break." While I heard commonly

used phrases – always strive for excellence and growth, and never give up - what particularly caught my attention was when one of the panelists simply said that you can work extremely hard and strive for excellence and growth, but at the end of the day luck always plays an immense role. This refreshing, realistic outlook put a whole new perspective on professional development. She advised us that sometimes things don't go your way, no matter how hard you work; be a smart player in the career game, with a diversified playbook, and learn that you must sometimes move onto another strategy to push forward.

Another piece of particularly profound advice was that everyone's first "big break" happens when a person discovers their passion and uncompromisingly strives toward it. This involves many things, including going out of your comfort zone to see your passion come to life. While I definitely believe this is true, I also think that one must tie passion to practicality, which goes back to the earlier statement that sometimes things just don't work out – you may be passionate about something, but you also have to accept failure when it comes and learn to move on. Truly successful people have all failed at some point. It's how they rose up from that failure that defined them. In this sense, failure may have been their "big break."

The second topic was the importance of mentorship in career development. What struck me about this conversation was how these women came to realize later which mentors they benefitted from the most.

Every panelist echoed the same sentiment: It wasn't the person they identified with or opened up to, but rather the person who was critical and expected a lot, who gave them more responsibility than they themselves thought they could handle and took a risk on them. These mentors subtly guide you in the right direction by asking the right questions and letting you make a few mistakes to learn from along the way. The key point was that proper direction from their mentors stretched each panelist beyond their comfort zone; they were forced to adjust and learn on the go, a valuable trait in the pharmaceutical industry.

The session's final topic centered on the role and importance of gender, especially to women, in the pharmaceutical industry. This topic has particularly fascinated and at the same time confounded me. While much progress has been made in this realm, there is still room for improvement. I think we can all agree that women are just as intelligent and equally qualified. Does this disparity come from something much deeper? Is it cultural or societal? I think of my personal family experiences: I have had conversations with female family members about their career paths, and why they chose to do what they do. Not one decided to go down a scientific or technical path; all chose teaching

or other healthcare fields instead. Is this because women are raised with an imbedded mindset that certain jobs are not feminine? If so, is this mindset based on certain biological and psychosocial perceived norms? It pains me to think that the answers to these questions are yes, since I know many women with brilliant scientific minds who would thrive in the pharmaceutical industry. My only hope is that we can overcome these perceived norms and perhaps even redefine what is feminine.

Overall, this session truly opened my eyes to the struggles that all people, not just women, face as they work to lift themselves to the top of the biotechnology industry. My only hope is that, as we progress into this modern age, the struggles that we face are not based on gender, and we can provide everyone with the same level playing field on which they can draw up their own personal game plans.

