The Society of Industrial Pharmacy Students: A New Organization at the University of Houston

Dear Editor,

Pharmacy students at the University of Houston are taking advantage of a unique organization devoted to raising interest in the field of industrial pharmacy and managed care. The organization is SIPS—the Society of Industrial Pharmacy Students—which came into being in 1998, the brainchild of a few pharmacy students who desired more information about the business side of pharmaceutical care. The mission of SIPS is to create an environment and provide opportunities for students and the pharmaceutical industry to interact and collaborate on mutually beneficial projects. The organization’s goal is to provide students with detailed information regarding career opportunities within the pharmaceutical industry.

For the past 5 years, the officers of this very active organization have invited eminent individuals from across the country to visit the University of Houston and expound upon their life experiences to SIPS members. Over the years, SIPS has expanded its focus from providing a platform to learn about pharmaceutical companies to also learn about the areas of managed care and drug distribution. Some of the past speakers have been from companies such as Pfizer, Eli Lilly and Company, Merck, Pharmacia-Upjohn, Wyeth, AstraZeneca, Cardinal Health, McKesson, and Kelsey-Seybold Clinics.

The SIPS organization was the first at the College of Pharmacy to devote its efforts specifically to understanding issues facing the pharmaceutical industry and to delve into the effects managed care has on a pharmacist’s professional responsibilities and growth. Special attention is given to recognizing that pharmacy is undergoing a controversial evolution and plays a pivotal role as drug and health care costs rise at exponential double-digit rates.

The University of Houston College of Pharmacy has an advanced pharmacy management program consisting of 4 semesters of didactic coursework devoted to bringing students “up to speed” on issues that affect the current pharmacy environment. The College also has a very active masters program in pharmacy administration. The addition of a joint PharmD/MS program that the College plans to offer further indicates that the progressive growth of managed care anticipated within pharmacy is recognized by academicians.

Why was it necessary to form such an organization? First, the lack of a strong industry presence on most pharmacy campuses, compounded by the lack of exposure to career opportunities within the pharmaceutical industry, triggered the need for a greater understanding of this growing area of pharmacy. Students in pharmacy schools across the country spend up to 6 years preparing to be pharmacists, with little interaction with prospective employers in the pharmaceutical industry. Most students opt to select traditional community (retail) or institutional (hospital) careers because of their constant exposure to them in their pharmacy training. The SIPS organization felt that students’ exposure to the pharmaceutical industry would intersect them in lucrative positions available in managed care.

Another main focus of the organization has been to clarify opportunities offered by the pharmaceutical industry. A misconception that SIPS tackled was that the pharmaceutical industry only offers sales representative jobs that utilize very little of the students’ pharmacy education. In addition, students posed the question of why they should struggle in industry if all they had to do was dispense medications in a retail pharmacy and be more highly compensated for their time. Many students also believed that the pharmaceutical industry only offered better positions if students furthered their education and became research scientists. Since drug discovery and pharmaceutical research is traditionally not highly emphasized in most pharmacy schools, students are not even aware of what research entails. Thus, the SIPS organization addressed these misconceptions. The SIPS organization not only provides this industry exposure but is also a platform for communication between the students and the pharmaceutical industry.

The SIPS organization also strives to help students understand the fundamental reasons for rising health care costs and the importance of managed care in this process. It addresses this issue by inviting pharmacists from managed care environments to visit the University of Houston. As health care costs increase and baby boomers age, managed care plays a vital role in the evolution of health care. It does so by taking on more responsibility and reining in costs in order to provide a broader range of services to a greater population of people. PricewaterhouseCoopers published a report in April 2002 that investigated what fuels the rising cost of health care. Several reasons for an increase in costs were identified, including drug and provider costs and inflated legal expenses. The report also projected the impact managed care will have over the next 5 years in controlling costs. These are some of the topics that are discussed by presenters at the SIPS monthly presentation seminars.

Other SIPS seminar topics include the role of the pharmacist in managed care, protocol development, drug approval by pharmacy and therapeutic committees, the pharmacist’s role in drug protocol development, and promotion of evidence-based medicine. By participating in formulary selection and guideline implementation, pharmacists can have a profound influence on patient outcomes and health care costs.

What are SIPS students doing to further prepare themselves for entry into the field of managed care? As Society members, students can explore the various opportunities available to them via informal meetings and lunches with pharmaceutical companies. Students who want to learn about the business side of pharmacy now have a formal process in which to be mentored by fellow pharmacists in the industry. The SIPS organization is now collaborating with managed care and industry to develop company partners for future collaborative efforts that further the goals of SIPS members.

Since 1998, the SIPS organization has hosted many events, including arranging industry field trips, promoting representation at conferences, inviting eminent speakers for presentation, developing career workshops, and endorsing the overall posi-
Dear Editor,

I read with great interest the article by Meyer and colleagues in the March/April, 2003 issue of the Journal. I am very concerned that the authors may not have used complete information and may have made inappropriate assumptions in their research. My concerns are as follows:

1. While the Evidence for Interferon Dose Effect: European-North American Comparative Efficacy (EVIDENCE) trial showed a 12% greater number of relapse-free patients for interferon beta-1a (Rebif—referred to as IB1a2 by the authors) versus Interferon beta-1a (Avenex—referred to as IB1a1 by the authors) at 24 weeks, the data showed a 1% greater number of relapse-free patients favoring IB1a1 at 48 weeks. Inferring long-term clinical effectiveness, especially with a lifelong disease like multiple sclerosis, from short-term study findings can be fraught with difficulty.

2. No consideration is given by the authors to the costs of treating the increased number of side effects attributable to use of IB1a2 versus IB1a1 as demonstrated in the EVIDENCE trial. These include higher frequency of occurrence of injection site disorders, liver abnormalities (including elevated ALT and AST), and white blood cell abnormalities (including leukopenia).

3. In estimating the incremental cost to a plan of adopting IB1a2, the authors deduct administrative costs related to managing multiple products on formulary. The assumption is that IB1a2 is adopted in place of other approved products, not in addition to these products. As such, the savings in question are attributable to the plan’s decision to adopt an exclusive formulary, not to IB1a2 per se. Similar savings would accrue to the plan if exclusive status were awarded to IB1a1 or to any other approved product. The true incremental cost to a health plan of placing a new patient on IB1a2 versus other products in a nonexclusive formulary setting is therefore significantly higher than the $.05 PMPM cited by the authors.

4. Incidence of neutralizing antibodies was much higher in IB1a2-treated patients than IB1a1-treated patients. While the clinical significance of antibodies has not been completely elucidated, many clinicians are now testing for neutralizing antibodies and discontinuing interferon beta therapy when the antibody titer increases to greater than 20.

5. IB1a1 is the only interferon beta product to have shown positive effects on brain atrophy in clinical trials. These findings may correlate to better long-term treatment success.

In conclusion, pharmacoeconomic modeling is based upon certain assumptions, and the pharmacy-budget impact analysis in the article by Drs. Meyer, Phipps, Cooper, and Wright did not properly represent the known clinical evidence for the treatment of multiple sclerosis or common practices used in drug benefit administration.

Sujit S. Sansgiry, PhD
Assistant Professor and Faculty Co-advisor for SIPS
Amy Sorensen
PharmD candidate and SIPS Secretary, 2002-2003
University of Houston College of Pharmacy
Houston, Texas
E-mail: SSansgiry@uh.edu

DISCLOSURES
There was no specific funding for the preparation of this letter. Dr. Rich has served as a consultant to Biogen, Inc; Berlex, and Teva.

REFERENCES
The Authors Respond

Dear Editor,

We appreciate Dr. Rich’s careful review of our manuscript, which appeared in the March/April 2003 issue of JMCP.

As we clearly outlined in the introduction, our objective was to suggest a method for using administrative claims to evaluate potential direct population costs of pipeline therapies prior to the availability of full cost-effectiveness analyses. This analysis was undertaken before the launch of the product in order to provide preliminary information to those with direct responsibility for the pharmacy budget alone. The study was published after the drug was approved.

The majority of Dr. Rich’s points (points 1, 2, 4, and 5) focus on costs related to clinical outcomes, side effects, and patient functioning that would be included in a full cost-effectiveness or budget impact analyses. These types of analyses are critically important to evaluate the true value of therapies, but formulary dossiers containing the information may not be available until after the drug is marketed. However, payers frequently require customized proactive information prior to marketing to anticipate potential blockbuster drugs and possible cost-containment strategies. The proposed claims analysis is an attempt to bridge that early information gap.

When more information becomes available through detailed cost-effectiveness and completed phase III and IV studies, the true budget impact on both the pharmacy and medical budgets would indeed take precedent over preliminary assessments. For instance, the 63-week extension of the EVIDENCE study demonstrated a 17% reduction in relapse rates for 44 µg tiw interferon beta-1a (Rebif-IB1a2) compared to 36 µg cw interferon beta-1a (Avonex-IB1a1), indicating a sustained impact on relapse over time. With regard to side-effect management, a statistically significant higher rate of flu-like symptoms were also reported in the IB1a1 group (53.4%) compared to the IB1a2 group (44.8%). Information from the trial shows that neutralizing antibodies are not related to clinical impact on relapse rates; therefore, the influence of neutralizing antibodies is still unclear.

We did include administrative costs of prior authorization related to costs that plans may incur by implementing a prior-authorization program (point 3). We assumed in the base analysis that the new product would compete with existing therapies and IB1a2 would be used in place of other similar products. The model is flexible to incorporate a variety of scenarios, but we chose a share-shift analysis approach in the base case where there was some decline from the other products.

The 80% share estimate in new users was indeed aggressively set forth by the manufacturer (point 6). We specifically performed sensitivity analysis around this estimate as presented in the manuscript. However, a reduced market-share estimate would only reduce the anticipated impact of interferon beta-1b.

Christina Meyer, MHS, Manager, Predictive Modeling

Alan Wright, MD, MPH, Senior Vice President and Chief Science Officer

Deborah Cooper, PharmD, BCCP, Director, Pipeline Impact and Trends

AdvancePCS, Center for Health Improvement

Hunt Valley, Maryland

E-mail: Christina.Meyer@AdvancePCS.com

REFERENCES


Patient-Reported Utilization Patterns of Narcotic Drugs

Dear Editor,

I read the article on the above subject in the May/June 2003 issue of JMCP with interest. A perhaps far more interesting topic could be explored by the authors: the topic of “the rest of the story,” when patients choose to take themselves off of such medications. In the treatment of chronic nonmalignant pain, it is important to recognize that this category is a hodge-podge. We cannot assume that there is only one situation or pathophysiology involved. So, any commentary on the “group” needs to recognize that there will be variation in applicability.

However, with that said, it is fascinating to observe the patients with “chronic nonmalignant pain” who become fed up with taking all the pills (or patches) and simply take themselves off. They may go from high doses of very expensive medications to use of nothing more than ibuprofen. Yet, this may occur with no observable change in the underlying condition. The only thing that changes is their desires. This is a very, very revealing outcome when it happens.

Perhaps these authors would care to look at “the rest of the story.” They must certainly have some patients who eventually go off of all the narcotics. When this happens, what leads to the outcome? What evidence exists that underlying pathology changed? Or is the change simply one of choice? If so, what do we learn from this?

Obviously, there are many countries in the world that do not
have the economic situation to support the use of chronic high-grade narcotics (particularly very expensive ones). What do their citizens do? And have you ever seen an animal that needed chronic narcotics? The lessons I'm obviously implying are easily available for anyone who simply wishes to look at pain behavior across the world. However, ethnocentrism seems to lead many investigators to turn a blind eye to the rest of the world.

While full understanding of pain behavior in humans requires looking at all humans, we may still learn a great deal from examination of selected subgroups. In regard to the subgroup of patients with chronic nonmalignant pain, there is much to learn about pain from an examination of desires.

John P. Barbuto, MD
Neurology In Focus
An Outpatient Neurology Clinic at HealthSouth, Sandy, Utah
E-mail: doctorbarbuto@aol.com

REFERENCES

Common Industry Practices and OIG Compliance Guidance

Dear Editor,

I read the Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers published May 5, 2003. In my opinion, the key to the “guide” is contained in the introductory discussion under kickbacks. The OIG states that what people may regard as common industry practices (for example, relationship-building activities such as taking customers to entertainment or sporting events, dinners, or seminars) are not necessarily legal when viewed under the antikickback laws. This is a somewhat disingenuous statement, as there is a lot of discretion involved in determining these matters, and it is a very technical reading of a very vague statute.

The antikickback statute is so broadly written, everything seems illegal. We’ve raised, and now seem to celebrate with large legal fees, a generation of technocrats: compliance experts that sanctimoniously opine on what’s legal, etc., based on literal readings, without understanding or caring about the impact from a substantive or industry standpoint.

The biggest trap in the guidelines is the reliance on the so-called “one purpose” test: If one purpose of a program can be considered to be inducing referrals, then the whole program structure fails. What is it that the drug manufacturers do that isn’t based on the motivation to sell their product or induce referrals? Does anyone think the education and research programs, even divorced from sales, are charitable? If the OIG wants price competition, it seems to me that it should try to adapt its rules to common industry practices and focus on obvious abuses and outright fraud or inappropriate conduct. Doesn’t price competition require manufacturers to follow, not disregard, “common industry practices?”

Michael Tichon, Esq.
Executive Vice President and General Counsel
Healthsmart Corp., Long Beach, California
E-mail: mtichon@healthsmartcorp.com

REFERENCES