

SCRIBE

THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

President's Message

By Elizabeth B. Andrews

Where is ISPE in Risk Management?

Occasionally, a policy shift catches our attention. The new US Food and Drug Administration (FDA) medication "Risk Management" initiative currently has the pharmaceutical industry's full attention. Why is this topic fresh on my mind? I have recently been living this new initiative by participating in FDA's first advisory committee meeting devoted explicitly to an open discussion of Risk Management. The example was a new medication that my company recently launched to treat a functional bowel disorder. That advisory committee meeting promises to be the first of many such public occasions to discuss the safety profiles of newly marketed medicines. We're not the only company affected; apparently the annual Drug Information Association meeting in June was dominated by corridor discussions of Risk Management.

Given the high visibility of the topic and its import to our field, should IPSE be playing a more active role? I think so.

Background

Many ISPE members are familiar with the FDA's May, 1999 report [Managing the Risks from Medical Product Use: Creating a Risk Management Framework](#), one of the



first major initiatives of FDA Commissioner Jane Henney. Prompted in part by recent withdrawals

of newly approved drugs for safety reasons and heightened public awareness of the magnitude of serious drug reactions, the report presents a wide array of options to evaluate safety and reduce risks.

The FDA did not simply create a report to gather dust on bookshelves. The FDA is following through on many of the report's recommendations. Upon detection of safety signals about medications approved in the last few years, FDA is asking pharmaceutical companies to articulate their Risk Management plans. These plans go beyond the standard commitments by manufacturer to make changes to the product prescribing information, communicate those changes (e.g., Dear Doctor Letters), and conduct drug safety studies. The plans are likely to be more aggressive, and include strategies to improve appropriate medication use and reduce risks (e.g., required patient leaflets, restricted medication distribution, mandatory

education), and plans to measure the success of those strategies. The plans may not stop there; if the agreed strategies do not result in measurable changes in prescribing behavior and lowered risks of serious adverse events, the manufacturer may be asked to specify in advance the additional action they might take to further reduce risks.

Given this apparent shift, we should take the opportunity to put the new Risk Management paradigm into perspective, and to consider what opportunities there may be for ISPE to shape policy and provide guidance to our members in tools and methods they may need in new areas of research.

Are the Risk Management concepts new?

Not really. Those who develop new medicines and those who regulate their safe use have long assumed responsibility for managing risks to assure that benefits of treatment outweigh risks within the context of the underlying condition being treated. In fact, the 1999 CIOMS IV report that preceded the FDA report presents a comprehensive approach to benefit-risk evaluation. The FDA report builds on that CIOMS report. And in fact there are a few historical examples, such as Accutane and Seldane, for which aggressive communication efforts were

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taken to improve appropriate product use, and surveys conducted to measure the effectiveness of these efforts to change behavior. Our annual meetings have included wonderful presentations and debates about these types of programs.

So what is new?

- A more systematic and open public review of risk assessment for new products,
- Earlier and more proactive approach to addressing safety issues, including more aggressive intervention strategies,
- Apparent attempts to establish quantitative targets for “appropriate prescribing” and “acceptable risk,” and
- Greater use of behavioral and survey research methods to

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evaluate the effectiveness of risk management interventions. The methods are not new to epidemiologists, but extensive application of these methods to Risk Management is. Market research methods have been used extensively to evaluate the impact of product advertising on sales, but these same methods have been used only occasionally in pharmacoepidemiology.

Is this process targeting the right medicines? Does the new initiative disproportionately single out new medicines? What about the older prescription and over-the-counter drugs that may be less safe, to say nothing of the non-regulated remedies so widely used and so inadequately studied? What about the concurrent push to move more products to over-the-counter status?

Opportunities for ISPE?

Is there a role for ISPE in the **policy considerations**?

- With so much attention directed toward risks, are we overlooking the benefits in the risk-benefit evaluation of medicines? While an evaluation of benefits is implicit in risk assessment, the CIOMS IV report compels us to consider benefits explicitly. Increasingly those benefits must be viewed broadly, including clinical benefits as well as impact on disease burden and quality of life. ISPE members are positioned well to conduct those benefit evaluations.
- Could ISPE help to develop a framework for identifying risk management targets (e.g., priority drugs) based on criteria relating to public health impact not just the most recently approved drugs?

If there were a policy opportunity for ISPE, what shape would it take? I might suggest a small working group to collaborate

with FDA on these topics. But would FDA find such an approach helpful? Where would it lead? Who would come forward to lead such an effort and participate (realizing, of course, that we are all volunteers)? I would recommend this approach if the chances for making a meaningful contribution were high. Further discussion is clearly needed before moving ahead.

I definitely believe there is a role for ISPE in **methods development and membership education**. ISPE members must become more fluent in the language of medication benefits. In addition, we need to become more conversant in methods used in other sectors to change behavior and evaluate program effectiveness. One action might be to use ISPE resources and networks such as the Education Committee to raise awareness of these tools and methods through special workshops or symposia.

I see opportunities for ISPE to become highly engaged and visible in this new Risk Management initiative. Am I being too parochial? Is this an issue only of interest within the US and only of concern to industry? At minimum, we should have an interesting discussion in this year's Industry Council meeting!

Please share your specific recommendations for positive ISPE action with Bert Leufkens, ISPE's next President, or myself, or raise them at the annual membership meeting at ICPE in Barcelona.

See you in Barcelona!

**DEADLINE FOR
 FALL ISSUE
 OF SCRIBE:**

October 6, 2000

EXECUTIVE SECRETARY'S OBSERVATIONS

By Mark H. Epstein

As my first year with ISPE comes to a close, I thought highlighting several of our accomplishments would be of interest to you. We've made considerable progress in a few short months. And it's important to take time out to smell the flowers.

ISPE changed management firms in early 2000. Sometimes things work out for the best, and this was one of those times. We weathered the changes and achieved stability. Now ISPE is poised for growth. Kudos to **David Goldsmith** and the other members of the Management Continuity Committee for their dedication and commitment to finding a good, comfortable home for ISPE. And thanks to **Bob Wise** for suggesting the coffee at the ISPE International Office be upgraded. It was. Please stop by for a cup when you're in town.

Priority was given to improving the ISPE website. Substance was emphasized over form this year. We created a Members Only Section, which includes a searchable online membership directory, bulletin boards, and the Policy Manual. The website was used to promote the *Symposium on the Power and Perils of Health Data Used in Epidemiologic and Economic Research* (April) and the 16th ICPE as well as to encourage voting in the 2000 elections. We also added a job bank, links to sites of interest, a What's New Section, and posted current issues of the *Scribe* online. The changes had an effect. The number of hits increased from 29,000 in April to 50,000 in June, and the number of unique visitors increased from 2200 to 2900 during the same period. Next year we will improve the site design.

The transition provided the unexpected impetus for ISPE to embrace electronic abstract submission and grading for the ICPE. More than 400 abstracts from 33 countries were processed and graded without any significant problems. This

change also contributed to the shortest Mid-Year Scientific Program Committee meeting – a mere 6 hours. Of course, we also have **Sam Lesko** and **Susana Perez-Gutthann** to thank. Together they have developed a sound planning process for future ICPEs.

ISPE has a world-renown reputation for providing exceptional educational programs. The ICPE 1999, the Mid-Year Symposium, and ICPE 2000 received enthusiastic reviews. These meetings also are a source of new members and supporters. Planning is underway for next year's educational programs in the Netherlands (April) and Toronto (August). In addition to these programs, we need to know what courses and topics you would like ISPE to address. So drop us a line.

Hugh Tilson played a pivotal role in the creation of the Forum of International Professional Societies (the Society of Medical Decision Making, the International Society of Quality of Life, the International Health Economics Association, the International Society for Pharmacoconomics and Outcomes Research, the International Society for Technology Assessment in Health Care, and ISPE). The elected leaders and staff directors of each association met in January at a landmark meeting to share information and identify mutual interests. The second meeting will be held this Fall.

One of my delights this year has been the opportunity to work with a first-class group of volunteer leaders. The success of any voluntary membership society is inextricably tied to the dedication, commitment and energy of its leaders. From my initial discussions with **Keith Beard**, **Elizabeth Andrews** and **Bram Hartzema** last summer, and through

numerous committee conference calls and email exchanges, I have been impressed with the ISPE leadership. The challenge is to identify emerging leaders from the membership who can gradually assume more responsibility. ISPE faces an exciting future. Don't sit back and let the others do it; we need you. That's enough sniffing for this year.

Election 2000 Results

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Peter Gruer
Susan Sacks

Congratulations
to the
Class of 2003.

THOMAS A. LASSER: IN REMEMBRANCE

(January 18, 1956—May 23, 1999)

By Katherine L. Puder

I write this tribute to Tom Lasser on the anniversary of his passing, May 23, 1999. It is an almost impossible task to even attempt to surpass the sad, but topnotch job that Keith Beard did last year [see ISPE's SCRIBE of August 1999: 2(3), 4]. So, I will try to add some of my own thoughts to Keith's memory of Tom.

Keith was superb in describing Tom's exceptional and unique qualities as a colleague, as well as remarking about how well he undertook his responsibilities as ISPE's Chair of the Publications Committee for two years—all during the course of being treating for the agonizing disease of malignant melanoma. Undoubtedly in his heart, Tom knew there would be no cure.

Still, Tom kept reaching for the stars,

always trying, constantly hoping, carrying out his responsibilities with grace, a smile, love for his family and friends. He was a gentleman who was born with grace and an elegance of style. I never once heard Tom complain.

As Ed Bortnichak put it recently: "He was an inspiration to us all." I also remember speaking to Tom's friend and colleague, Newell McElwee, shortly after Tom's death. We were both profoundly disturbed, since Tom was only 43 years old when he passed away. His death at a young age was a sad reminder to us all of how short our lives really are. It brought home to us who knew him well that we should consider our time as precious as did Tom, and use it wisely with compassion, generosity, and kindness.

I had the opportunity to meet Tom

about 10 years ago. Actually, it was our parents who "officially" introduced us, even though I knew Tom probably since the day I was born (and we all know that was only yesterday). They thought we would have a lot in common to talk about. This time, they were right! We starting speaking of pharmacoepidemiology and never, ever stopped....

Some of us who have had the experience of working in 'Corporate America,' have heard over and over again how expendable people are. Speaking for myself, however, I know that Tom can never be replaced. The loss of Tom will remain ours.

As Keith mentioned last year, a foundation been set up in his name by his loving family. Any contributions can be sent to:

The Thomas A. Lasser Foundation
The Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, New Jersey 08901
Attention: Mr. Gerold Volk,
Director of Development

As Tom's niece, Betsy, wrote in a poem at his memorial service:

"... It seems like only yesterday, we were under the apple tree when he took three apples and juggled them for me....
I know as his family in your heart he has a special place, but his most important location is in the smile on your face."

Yes, in whatever walks of life we choose, shall we always remember his bright, green eyes and that wonderful smile.

Future ISPE Meetings

- 17th ICPE
Sheraton Center
Toronto, Canada
August 23-26, 2001

Abstract Submission Deadline:
February 23, 2001

Visit the ISPE website
www.pharmacoepi.org for information
about abstract submissions and
program information.

- 18th ICPE
Edinburgh Conference Center
Edinburgh, Scotland
August 17-21, 2002

**Division Head
Pharmaceutical Outcomes Research
Department of Pharmacy Practice
School of Pharmacy
University of Colorado Health Sciences Center**

The Department of Pharmacy Practice at the University of Colorado School of Pharmacy is seeking an experienced educator and researcher (at the rank of Associate or Full Professor) to lead its newly formed Division of Pharmaceutical Outcomes Research (POR). The Division Head will be expected to have an established teaching and research program, to provide leadership and mentoring to four existing POR faculty, and to elevate the stature of the division and its work to a level of national excellence.

The School of Pharmacy is dedicated to ensuring the success of the new Pharmaceutical Outcomes Research Division, having recently committed two graduate student stipends, new state-of-the-art computing resources, and common laboratory space to the core division faculty.

Opportunities for innovation and excellence in teaching, research, and service exist within the school's Ph.D. program in Pharmaceutical Outcomes Research; its newly implemented, highly integrated entry-level Pharm.D. curriculum; and through its established collaborative arrangements with entities such as the Colorado state Medicaid program, local managed care organizations including Kaiser Permanente and Anthem Blue Cross/Blue Shield, and a network of medical centers in the Veterans Administration (VA) health system, among others. Collaboration with faculty in the School of Medicine, the Colorado Health Outcomes Program, and established campus Centers of Excellence including the Center for Health Services Research, is readily possible and expected.

To augment existing faculty and program strengths, applicants should have a Ph.D. degree in one of the following disciplines (or a closely related field):

Health Services Research, Pharmacoeconomics, Pharmacoepidemiology,
Health Care Systems, Decision Sciences, Health Policy, or Health Informatics

In addition to the degree requirement and disciplinary emphasis, previous academic administrative experience and a background in pharmacy are strongly preferred. Applications will be accepted until the position is filled. Applicants should send a letter of interest containing a statement of career goals, a current curriculum vitae and the names of three references with regular and e-mail addresses, and phone and fax numbers to:

Robert Valuck, Ph.D.
Chair, POR Division Head Search Committee
Department of Pharmacy Practice
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IN APPRECIATION

The Board of Directors, members and staff of ISPE would like to thank the following members and firms for their contributions to making the 16 ICPE an unqualified success.

Susana Perez-Gutthann,
 Chair, Scientific Program Committee
 Members, Scientific Program Committee

Josep Lluís Segú,
 Chair, Local Host Chair
 Members, Local Host Committee

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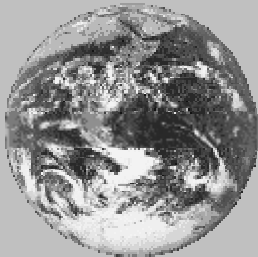


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Visit us at the 16th International conference on
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