

SCRIBE

THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMOLOGY

President's Message

By Thomas M. MacDonald

Highlights

- Risk Management: Workshop Summary
- Educational Activities at ISPE
- Philly 2003
- ISPE Fellow



We Need You!

ISPE needs your help! The strategic planning process has swung into action and this has revealed that there is a lot of work to do! Over the years, many of you have worked hard for the society and kept it vital and dynamic. We would now like to invite and encourage you and all other ISPE members to seriously consider activating or reactivating your interest in serving the society. ISPE is in need of those who are prepared to give a long-term commitment to ensure the health of the society.

ISPE has many committees. Some of these committees are more 'active' than others. Some provide vital functions and others provide advice and guidance. The strategic planning process has highlighted that we need many of these committees strengthened significantly if we are to take the society 'To Infinity and Beyond' (to quote Buzz Light Year).



Are you as dynamic as Buzz Light Year?

Many of our committees have been handed very significant tasks by the Strategic Planning Task Force. We now need your help to staff these committees,



to meet the objectives and to take ISPE to new horizons.

Make no bones about it, this will involve you in hard work for which your

only reward will be praise from the board and the satisfaction of a job well done for ISPE. We are a society of volunteers. Will you volunteer? Are you up to the task?

Here are some of the jobs that we have to offer at ISPE:



*Education Committee:
Can you help with Pharmacoepidemiology teaching?*

The Education Committee needs enthusiastic committed members to drive along the many tasks we have set it. Some of the tasks are: organising courses, teaching, developing curricula, and working with the website team to put teaching material from our own courses online. We also need to make available all the other programs and courses and

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Deadline for
Spring 2003 Issue
April 28th 2003

Risk Management: What are we driving, Where are we going and How will we know when we get there? A Summary of the 2002 ICPE Workshop

By Elizabeth Andrews

INTRODUCTION

This workshop might be remembered because of the overflow crowd, or the fainting of an audience member while **Paul Seligman** was presenting a regulatory perspective, but we hope it will be remembered for the substantive discussion about therapeutic risk management that was begun at the 18th ICPE in Edinburgh.

Speakers included: **Elizabeth B Andrews**, PhD, MPH and **Alicia Gilsenan**, PhD, BSPHarm of RTI Health

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Solution; **Allen A Mitchell**, MD, of the Slone Epidemiology Center, Boston University Schools of Public Health & Medicine; **Paul Seligman**, MD, MPH, Director of Pharmacoeconomy and Statistical Sciences, Food & Drug Administration; and **Suzanne F Cook**, PhD, of GlaxoSmithKline

In the United States (US) and Europe, regulatory authorities are now encouraging and in some instances requiring risk management programs - systematic programs and measures to ensure that medications are used in ways that maximize benefits and minimize risks to the patients receiving them. One definition of risk management is: 'an endeavour applied to the use of therapeutic agents in conditions of general use that seeks to assure that the benefits to patients outweigh the risks'. A variety of interventions have been implemented with the aim of improving prescribing and compliance and reducing the likelihood of errors. To date, there is little available information on:

- The success of these interventions in reducing risk;
- The degree to which such measures can be integrated into the different healthcare systems.

Presenters described policy and research challenges of therapeutic risk management from different perspectives, and subsequent discussion primarily related to issues of public policy and practical implementation.

Risk Management programs in the US

All New Drug Applications (NDAs) for marketing approval in the US after 1 October 2002 may voluntarily include a risk management plan. The Food and Drug Administration (FDA) is also preparing three guidance documents on good risk assessment, good risk management and

good pharmacovigilance practices, which are due to be completed by September 2004.

Alicia Gilsenan provided an overview of the current state of risk management programs in the US. Some of the interventions that have been employed in these programmes are shown in Table 1. However, by instituting such programs, we are creating policy in the absence of data, as the evaluation of risk management programmes has been fairly limited to date. The effectiveness of interventions in actually changing the behaviour of physicians, pharmacists and patients has rarely been measured. Data on secular trends in prescribing from large managed care databases have shown that some educational interventions were ineffective in altering prescribing behaviour in some noteworthy examples, like cisapride, the effectiveness of patient information leaflets has been evaluated by examining whether patients received and read the information, but few studies have been designed to measure the impact of these tools in terms of reducing patient risk. Academic detailing has been shown to be effective, but this intervention has rarely been employed systematically in the US.

CASE STUDIES

Three case studies of risk management programmes in place in the US provided an insight into the factors involved in implementing and evaluating effective risk management programmes. **Allen Mitchell** of the Slone Epidemiology Center presented the isotrenoin and thalidomide examples, and **Suzanne Cook** from GlaxoSmithKline gave an overview of the plans for the alosetron risk management program.

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Isotretinoin (Accutane®)

Isotretinoin is approved to treat a serious form of acne, which does not respond to other treatments. Although isotretinoin is very effective in treating cystic acne, its use carries a high risk of birth defects. In 1988, Hoffman-La Roche, the manufacturers, introduced the Accutane® Pregnancy Prevention Program (PPP), an intensive physician and patient education programme. The multicomponent PPP was aimed at female patients and their physicians. The Slone Epidemiology Center (SEC) of Boston University School of Public Health designed and conducted the Accutane® Survey to evaluate the effectiveness of the PPP. The aims of the Survey included assessing compliance with the PPP and awareness of risks among patients receiving Accutane®. Physician and patient behaviors were also evaluated, with the outcome of primary interest being the rate of pregnancy among women taking Accutane. Initial results from the survey¹ identified the need for better compliance with certain measures, and compliance improved following changes to the packaging and patient information.

Regarding the main outcome measure, SEC's analysis of the data from 1989-2000 showed that there were 1,087 pregnancies among 387,698 women: a rate of 2.7 pregnancies per 1000 courses of Accutane®. This is a very low rate – but is it low enough? And is it the direct result of the PPP? There were a number of limitations to the Accutane® Survey. There was no comparison of results before and after the risk management interventions and no clear definition of success. The Survey itself was an intervention and since enrollment was voluntary, it may not have been representative of all

women taking Accutane®. In April, 2002, a new risk management programme for Accutane® was introduced: the System to Manage Accutane® Related Teratogenicity (SMART).²

Thalidomide (Thalomid®)

The SEC also designed and implemented an evaluation of the risk management programme for thalidomide, which is marketed as Thalomid® by Celgene Corp, for the treatment of erythema nodosum leprosum (painful skin sores associated with leprosy). When the drug was approved for this indication in 1998 it was subjected to unprecedented regulatory requirements, for obvious reasons. Thalidomide was available by prescription only from physicians and pharmacies registered in the System for Thalidomide Education and Prescribing Safety (STEPS). STEPS is a mandatory, restricted distribution programme designed to prevent foetal exposure to thalidomide.³ Initially (from introduction to July 2001), STEPS required:

- Pregnancy testing and birth control measures
- Physician and patient education
- Registration of patients, physicians, and pharmacies
- Patient informed consent forms.
- Patient participation in the SEC Thalomid Survey

An additional, FDA-mandated requirement was for the SEC Survey staff to intervene if patients or physicians were found to be non-compliant.

In July 2001, a second phase of STEPS was introduced. Among the changes, physicians and patients were screened for compliance in advance of approval to dispense the drug, and participation in the Survey was no longer mandatory.

In both phases, the SEC Survey was designed to monitor compliance with STEPS, and specifically to identify pregnancy rates, outcomes, and risk factors. Survey data from phase 1 (October 1998, to June 2001) identified no pregnancies among 11,444 women were enrolled in the STEPS survey, of whom 1,533 were of child bearing potential.

Alosetron (Lotronex®)

Alosetron (Lotronex®) has been associated with reports of serious intestinal adverse events, including severe constipation and ischaemic colitis. It was voluntarily withdrawn from the market in November 2000. GlaxoSmithKline, in consultation with the US FDA, has developed a new, comprehensive risk management program for Lotronex®. This follows the FDA's decision, in June 2002, to approve a risk management program for the drug for women with severe diarrhoea-predominant irritable bowel syndrome.⁴ The risk management programme for Lotronex® involves the active participation of the physician, the patient and the pharmacist.⁴ It includes:

- Changes in the labelling for Lotronex® - including black box warnings in the physicians' package insert;
- Physician attestation – the physician will place a qualification sticker on all Lotronex® prescriptions;
- Distribution of a Medication Guide for Lotronex® - providing safety information for patients;
- Physician-Patient agreement document – discusses the treatment decision to use Lotronex®, highlights the possible risks and actions patients should take should adverse events occur.

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The goals of the risk management programme include ensuring that physicians and patients are fully informed of the risks and benefits of Lotronex®; that only patients in whom the benefits of the drug exceed the risks receive the drug; and that only qualified physicians prescribe it.

Multiple approaches will be used to monitor the Lotronex® risk management programme. GlaxoSmithKline will study prescribing patterns to ensure appropriate prescribing. In addition, the company will use information from databases to follow the use of Lotronex®. Patients will be surveyed to assess their knowledge and understanding of the risks, benefits and warning signs for adverse events. Serious gastrointestinal adverse events and risk factors for such events will also be monitored.

CHALLENGES

A number of challenges and unanswered questions were identified by **Paul Seligman** of the FDA, the other speakers, and members of the audience.

Implementation

When setting up a risk management program, we need to define the nature of the risk and when it is appropriate to invoke such a program. We have to determine the tools and

interventions to be used. It is important that there is appropriate linkage between the goals of the program and the tools that are used to manage risk. The roles and responsibilities of the various partners (industry, regulators, healthcare providers/payers and consumers) also need to be clearly defined. In the US, for example, the FDA's role includes providing guidance documents and supporting the validation of regulatory risk management tools. The FDA is also involved in post-marketing surveillance for adverse events, but the agency does not regulate how drugs are actually used in clinical practice. The challenge is how to engage all the appropriate partners in devising and implementing risk management programmes. These include the larger public health community, medical practitioners and patients. How do we make involvement in risk management worthwhile for health care practitioners? Can we require patients to participate in risk management programmes if this is a research activity?

Evaluation

Evaluating risk management programmes is a major challenge. As discussed above, risk management involves the simultaneous application of multiple tools to address different audiences. It is therefore difficult to identify the impact of the various

components of the risk management process and evaluate their effectiveness. We need to clearly define the criteria that will be used to assess the success or failure of a program. Baselines, targets and outcomes must be established for each risk management program. Who should evaluate these programmes? The SEC has used independent Advisory Boards to assist with evaluating the Accutane® and thalidomide programmes, for example. When can a risk management programme be reduced in scope and how is that decision to be reached? Once a manufacturer says, "I do", is that forever? Who is responsible for risk management once a drug is no longer covered by patent protection?

Integration

We also need to consider the implications of risk management interventions and evaluations for the health care system and how these will vary in different countries. Is risk management a US obsession? A balance needs to be struck between the ideal scenario and what is practical and feasible. We need interventions that are likely to be accepted by patients and providers and which can be integrated into a coherent healthcare system.

CONCLUSIONS

We face a number of challenges in order to establish effective, systematic risk management programs. Research is needed to identify which interventions are, or are not, effective. Information is required on how decisions about benefit/risk and prescribing are made. Finally, we need to determine how risk management programs should be evaluated and who should do this. Pharmacoepidemiologists have a key role to play in developing effective risk management programs, which can maximize benefits and minimize risks for patients.

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Table 1 Risk management interventions

- Changes in product information
- Letters to healthcare professionals
- Academic detailing
- Medication guide/patient information leaflets
- Patient informed consent/agreement
- Required physician training
- Physician and/or patient registries (voluntary or mandatory)
- Restrictions on drug distribution
- Pharmacy controls (e.g. limited quantity of drug)
- Special packaging/sticker programme



Royal College of Physicians of Edinburgh *in association with*
The International Society of Pharmacoepidemiology (ISPE) and
The International Society for Pharmacoeconomics and Outcomes Research
(ISPOR)

Symposium on:
Drug Treatment: Maximising Benefit and Minimising Risk
Edinburgh, 14 April 2003

Venue: Royal College of Physicians of Edinburgh

The College has joined forces with two major international societies to bring together a number of key individuals in risk assessment and outcomes evaluation of treatment with modern medicines. There will be speakers representing clinical medicine, academia and the pharmaceutical industry including:

- Professor Stephen Evans (London, UK)
- Dr Jacques LeLorier (Montreal, Canada)
- Professor Ian Ford (Glasgow, UK)
- Professor Milton Weinstein (Boston, USA)
- Dr Susana Perez Gutthann (Barcelona, Spain)
- Professor Tony Avery (Nottingham, UK)
- Dr Mac Armstrong (Edinburgh, UK)
- Professor James Raftery (Birmingham, UK)

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Educational Activities at ISPE

By Jacques LeLorier

The Education Committee recognizes the value ISPE members place on continuing education, and pursues opportunities to meet identified needs. Perhaps our best effort is the *Introductory Course to Pharmacoepidemiology*, which is offered the first day of the Society's annual meeting.

The *Introductory Course* is designed for people who register for the conference, but are not familiar with pharmacoepidemiology terminology and basic methods. (The conference registration fee includes attendance at the course.) Our experience suggests the course is always a success, generally with standing room only audiences. I believe some of the success is attributable to the dichotomous audience - half are there to learn about the subject matter while the other half comes to learn tricks about how to best teach the subject matter. But whatever the reason, the *Introductory Course* is part of the Society's excellent educational tradition.

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Success will depend upon the involvement of all the different partners in the health care community. At least in the US, discussions about risk management are mainly taking place between industry and regulatory agencies at present. We need to engage the wider public health community, health care providers and consumers in these discussions. ISPE can provide an important forum for discussion and communication between the various constituencies.

While this workshop stimulated an international audience to consider the broader implications of the US initiatives in Therapeutic Risk Management, more substantive discussions are clearly needed around policy, methods, and implementation. The 19th ICPE in

Several years ago, the suggestion was made to organize an advanced course as a complement to the Introductory Course. The first *Advanced Topics in Pharmacoepidemiology* was offered at the 2001 International Conference on Pharmacoepidemiology (ICPE) in Toronto. Non-ISPE members were invited to present. A nominal registration fee was charged for this course to help defray speaker expenses. The evaluations suggested the course was an unqualified success, largely due to the quality of the faculty. The second *Advanced Topics* course, which was held in at the 2002 ICPE in Edinburgh, was well received and experienced record attendance.

The Committee fine-tunes the courses based on comments and suggestions received from the participants and speakers. As we prepare for the 2003 annual meeting in Philadelphia, August 21-24, 2003, the following changes have been made.

Philadelphia is appropriately named also the *First International Conference on Therapeutic Risk Management*. Let us take these discussions to the next step!

REFERENCES

1. Mitchell AA, van Bennekom CM, Louik C: A pregnancy-prevention program in women of childbearing age receiving isotretinoin. *N Engl J Med* 1995; 333:101-106
2. FDA Talk Paper October 31, 2001. <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01113.html>
3. <http://www.fda.gov/cder/news/thalinfo/thalfaq.htm>
4. http://www.fda.gov/cder/infopage/lotonex/lotonex_qa_0602.htm

[Editor's Note: Dr. Andrews may be contacted at eandrews@rti.org]

The *Introductory Course* and *Advanced Topics* will be offered in sequence on **Thursday, August 21, 2003**. The *Introductory Course* will be presented in the morning (no admission for attendees who register for the entire conference), followed by the *Advanced Topics* (separate admission charge) in the afternoon. Lunch will be on your own. This scheduling will allow a participant to attend both courses, a change from past years when both courses were scheduled concurrently. So make your travel plans accordingly. Information about both courses will be posted on the ISPE website, www.pharmacoepi.org

Also, we will recruit faculty for the *Advanced Topics* course from outside the ISPE membership. Our objective is to bring fresh ideas to the society and also to attract to the society, and hopefully recruit as members, high quality individuals whose work belongs to the field of pharmacoepidemiology. Once at the meeting, we hope the speakers will join us for the conference and become addicted to ISPE. To keep costs down we will attempt to recruit our *Advanced Topics* faculty from somewhere between Boston and Baltimore (you can't miss them, they are just southeast of Montreal). If you have suggestions for *Advanced Topics* speakers and the specific subject you would like them to discuss, please contact me as soon as possible. (Jacques.le.lorier@umontreal.ca)

Finally, I am pleased to announce the *Introductory Course* will be offered for the first time in an extended one-day version (courses in the morning and workshops in the afternoon) during this year's Mid-Year meeting. **Judith Jones, Sean Hennessy, Nicolas Moore** and I will present the course **April 15, 2003**, at the Royal College of Physicians of Edinburgh, Edinburgh, Scotland.

Philly 2003: Everything You Like About ICPE, And Then Some

By Sean Hennessy

Who can forget the high drama of last year's ISPE Members' Meeting, when the proposal to add risk management (RM) to ISPE's name was resoundingly pooh-poohed, while the importance of our research to RM, the value of RM in applying our research, and the importance of studying the effectiveness of RM approaches were all resoundingly endorsed. Following up on this endorsement, the ISPE Board of Directors voted to hold the *1st International Conference on Therapeutic Risk Management (ICTRM)* concurrently with the *19th International Conference on Pharmacoepidemiology*. The meeting will be held **August 21-24, 2003** at the Wyndham Franklin Plaza, Philadelphia, Pennsylvania.

As chair of the 2003 Program Committee, I can't wait to see the short- and long-term effects of this experiment. Will this year's meeting draw a broader audience, as hoped? Will the sessions dilute and distract from the core pharmacoepidemiologic content, as feared? Will the ICPE and ICTRM remain one meeting, or will ICTRM be spun off?

Whatever the case, this year's Annual Meeting (whatever it's called) promises to be everything you've always liked about ICPE, and then some. As always, the 2003 meeting will be driven primarily by submitted abstracts, workshops, and symposia, the quality of which seems to be improving steadily, if not monotonically. Given the health of ISPE as a scientific society, I have every

reason to believe that this trend will continue into 2003 and beyond. With so much good science being submitted, and because we're running two concurrent meetings, podium time will be at a premium. Poster sessions, therefore, will play a central role, which I believe is also a mark of a healthy scientific society.

The tone for the 2003 meeting will be set by keynoter **Robert M. Califf**, a thoughtful and world-renowned cardiovascular clinical trialist. We will also hear from **Samuel Shapiro**, whose sometimes iconoclastic work is familiar to us all. Naturally, the Annual Meeting will also be the schmooze-fest it's always been. What's to be learned from the ICTRM experiment? Come and judge for yourself.

ISPE Fellow (FISPE)

ISPE members are invited to apply for ISPE Fellow status. Fellows may refer to themselves in public statements, documents, and resumes as "Fellow of the International Society of Pharmacoepidemiology", add the letters FISPE after other credentials, and receive appropriate recognition by ISPE. Fellows also must pledge to support the Society's mission, vision and values, serve the Society, including mentor new members, and contribute to the Society.

QUALIFICATIONS: To be an ISPE Fellow, a candidate must be an ISPE member for at least five years, present/author at least three papers or posters at the ICPE or in *PDS*, serve at least two years on at least one committee or the Board, evidence a passion for pharmacoepidemiology in one or more elected positions, committee chairs, or other roles, and be a member in good standing.

DEADLINE: March 14, 2003

All members who feel they meet the criteria are encouraged to self-nominate this year. The Fellowship Committee will screen applications and nominate the initial Fellows for appointment to the Board. The Board will officially appoint the initial Fellows who will be honored at the 2003 annual meeting. An application form may be downloaded from the ISPE website; *Join Us module, 2003 ISPE Fellowship*.

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online teaching material for our members and (soon to be) fellows. Currently this committee consists of one hard-pressed member! He is our immediate past president, **Jacques LeLorier!** Now we all know that Jacques is a super human, like Batman! However, even the Caped Crusader needs the help of an assistant or two. Are you Robin the Boy Wonder?



Money, Money, Money...

Our Development Committee needs fund raisers. Do you think that you can help **Peter Gruer** and **Annette Stemhagen** raise some bucks? With the stock market doing poorly, ISPE is in great need of extra funds to deliver the goods to our members. Do you have ideas? Are you a hard worker? Do you have the contacts and the skills to increase our flow of donations and sponsorships?



www.can_you_html.com

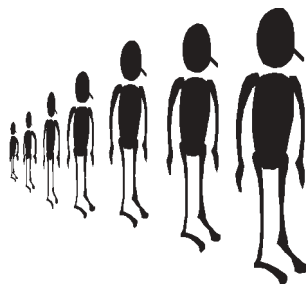
Are you a web whiz kid? Do you see yourself working with our website support contractor to spice up the content, the look and the feel of our site? Can you liaise with the Board, the executive, PAI management and the publications team to make the ISPE web site more dynamic and interesting? What can we add to our members-only site that will be so

invaluable that people will want to join ISPE to get access? Can you sort out how to capture presentations given at our annual conference and make them available on our web site? These and other tasks await the intrepid volunteers for this task. The Web Site Task Force needs a leader and several enthusiasts to make these things happen. FUCANHTML then great. FNOTBTUHVIDEAS then we need you.



Media Management

Public Relations is a new area for ISPE. Although we have done PR via our various committees and structures in the past, the Strategic Plan suggests that we set up a committee specifically to manage this area. Are you a good media person? Can you write a good press release? Can you schmooze the media and put a good gloss on a tricky situation? If so, then we need you!



Members: the life-blood of ISPE

The Membership Committee is arguably the most important of the committees. Without members we would have no society. If we have more members, we become more financially secure, have more

influence and we can run better events. The cost per head of providing a service to 1000 members is much less than providing it to 500. The economies of scale are thus important.

Do you know someone who should be an ISPE member? I bet you know several. How do we get them to join ISPE? Can we recruit you to the ISPE recruitment team?

This year sees the election of the first ISPE fellows. Fellows are expected to be very pro-ISPE in all matters. If you are someone who is committed to ISPE, why not see if you meet the fellowship criteria? These are available on www.pharmacoepi.org/ A word of warning! We expect ISPE fellows to pay a higher subscription and to be 'actively' involved in ISPE! Are you prepared to work hard to have the letters FISPE after your name?



ISPE: an International Society

One of our strategic goals is to become a more 'global' society. This means that we have to reach and to enthuse those interested in our discipline in all corners of the world. The Global Development Committee is tasked with this job. A particular target at the moment is Japan but we recognise that other countries are underrepresented within ISPE. Can you help to strengthen the 'I' letter of ISPE?

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Food and Drug Administration
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



**Medical Officer or Epidemiologist
Drug Effects in Pregnancy**

The Food and Drug Administration, Center for Drug Evaluation and Research, Office of the New Drugs, Pregnancy and Labeling Team, Rockville, MD is recruiting a physician **OR** epidemiologist with experience working in the area of medical/scientific research on drug effects in pregnancy. The incumbent of this position is a member of a team, which is responsible for developing regulations, guidance documents and procedures related to how drugs are labeled for use in pregnancy and lactation. The team also works with and responds to consult requests from drug review divisions related to writing the pregnancy and lactation sections of labeling; evaluating risk management programs; evaluating study protocols and analyzing data from industry sponsored pre- and post marketing clinical studies in this area; and evaluating case reports/case series of possible drug-induced adverse pregnancy outcomes.

Medical Officer

QUALIFICATIONS: **Medical Officer** candidates must have a doctor of Medicine or Doctor of Osteopathy degree from an accredited medical school. Graduates of foreign medical schools must be certified by the Education Commission for Foreign Medical Graduates (ECFMG). Candidates for Civil Service or U.S. Commissioned Corps must be U.S. citizens. Permanent U.S. residents may apply for staff fellowship appointments.

HIGHLY DESIRABLE: Strong clinical background in the area of obstetric medicine, embryology, teratology and/or epidemiology.

SALARY RANGE: Civil Service GS-14-15 (\$81,905 to \$112,863), plus a physician comparability allowance up to \$24,000 (depending on years of experience) and excellent benefits package. This is a term appointment (2 years), with the possibility of conversion to permanent appointment.

Epidemiologist

QUALIFICATIONS: **Epidemiologist** candidates must have a degree with a major study in an academic field related to the health sciences or allied sciences appropriate to the work of the position.

HIGHLY DESIRABLE: Ph.D. or DrPH in epidemiology. Strong research background related to the evaluation of pregnancy outcomes, embryology and/or teratology. In addition, the applicant should be competent in the analysis of data from clinical and epidemiologic studies, and have strong written and oral communication skills.

SALARY RANGE: GS-13-14 (\$66,229 to \$101,742)

HOW TO APPLY: Submit curriculum vitae with cover letter indicating that you are applying under source code #103060 to:

Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane, PKLN Bldg. # 9-60 (HFD -008)
Rockville, Maryland 20854
ATTENTION: Recruitment

THE FDA IS AN EQUAL OPPORTUNITY EMPLOYER WITH A SMOKE FREE ENVIRONMENT

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Publications: the currency of academic endeavour

Are you a natural born editor? Can you spot an article of significance? Can you make a dry subject a 'good read'? If so, then we need you on our Publications Committee. The chair of publications job is still up for nominations. We hope to announce this appointment in Edinburgh in April. The chair will oversee all ISPE publications and will report to the ISPE board. The responsibilities will include our newsletter 'Scribe', ISPE commentaries in *Pharmacoepidemiology & Drug Safety*, the content of the website and all other ISPE publications.

However, *Scribe* will continue to need its own editor (currently **Jacques LeLorier**). *Scribe* will probably go completely on-line in the near future.

The ISPE commentaries that appear in each edition of *Pharmacoepidemiology & Drug Safety* also will need an editor. Up to now, **Ineke Neutel** (the current publications committee vice-chair) has solicited and edited these commentaries on behalf of the society but we now need a successor.

The content of the web site will need an editor also.

The editor will need a vice-chair and a team of executive editors to support him or her. We hope that such

posts will be seen as prestigious and academically worthy. We urge applications from all of our constituencies. These posts should be filled by the broad church of ISPE members and fellows.



*Academic Council,
Government/Regulatory Council,
Industry Council, Student Council*

ISPE needs counsel from its constituents. The four councils are there to provide this and to support the ISPE board in these domains. The academic council has been tasked to outline a program of study for pharmacoepidemiology and a curriculum for risk management. These are big tasks and probably best done by the four councils collaborating.

ISPE FUTURE



The strategic planning process has allowed us to glimpse the 'preferred future' of ISPE as an

organisation. These are big and sometimes difficult steps to take to move us towards this vision.



ISPE: a shared vision.

ISPE is blessed with a large number of very capable members amongst its' ranks. Whilst we have different flavours to our thoughts, ISPE members share a common view about the discipline of pharmacoepidemiology. As a society of like-minded individuals, we have the ability to infect others with our interest and enthusiasm for ISPE. If we can strengthen the current ISPE platform, it will provide a solid base for our own and future generations of 'ISPE-ites'. We need a strong base if we are to reach up to 'Infinity and Beyond'. We need you!



19th
International Conference
on
Pharmacoepidemiology
&

1st International
Conference on Therapeutic
Risk Management

21-24 August 2003

Wyndham Franklin Plaza Hotel
Philadelphia, Pennsylvania



Revolution's In the Air

The 2003 annual meeting will be a revolutionary event in ISPE's history, marking the 1st International Conference on Therapeutic Risk Management, to run simultaneously with the 19th International Conference on Pharmacoepidemiology. Come and learn about the latest advances in pharmacoepidemiology and therapeutic risk management, and of course catch up with old friends and make new ones. The Keynote Address by **Robert M. Califf, MD** promises to be insightful (and provocative), and the Special Plenary Lecture by **Samuel Shapiro, MB, BCh, FRCP(E)** will leave us with much to talk about. Come be a part of history in the making.

SPONSORSHIPS & EXHIBITS

ISPE offers organizations opportunities to support the 19th ICPE and 1st International Conference on Therapeutic Risk Management through sponsorships and by displaying their products and services to conference attendees. Contact the ISPE Office for more information. ISPE@paimgmt.com or 301-718-6500.

ISPE

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■ **12-15 April 2003.**

Mid-Year Meeting

Royal College of Physicians of Edinburgh,
Edinburgh, Scotland

April 12 ISPE Board of Directors Meeting (Noon)

April 13 ISPE Scientific Program Committee
Meeting (10:00 am)

April 14 Symposium on Drug Treatment:
Maximising Benefit & Minimising Risk

April 15 Introductory Course on
Pharmacoepidemiology: Workshop

Contact: www.pharmacoepi.org
2003 Mid-Year Meeting

■ **21-24 August 2003**

1st International Conference on Therapeutic Risk
Management & 19th International Conference on
Pharmacoepidemiology & Wyndham Franklin
Plaza, Philadelphia, Pennsylvania

Contact: www.pharmacoepi.org
2003 Annual Meeting

■ **20-23 September 2003**

Global Evidence for Local Decisions: 5th
International Conference on the Scientific Basis
of Health Services, Washington, DC.

Contact: www.icsbhs.org.

■ **TBD, August 2004**

ISPE Annual Meeting
Bordeaux, France

■ **TBD, August 2005**

ISPE Annual Meeting
Nashville, Tennessee