



WORLD ASSOCIATION OF SOCIETIES OF PATHOLOGY AND LABORATORY MEDICINE

**Minutes
Of
The Bureau of the World Association of Societies of Pathology
And
Laboratory Medicine**

The World Pathology Foundation

**27 May 2005
The Crown Plaza Hotel
Istanbul, Turkey**

Schedule of Events

26 May 2005	0900 – 1800	Registration
26 May 2005	1930 – 2200	President's Dinner ¹ (Dr. Melo; Dr. Mochan Kuzey)
27 May 2005	0900 – 1000	Opening Ceremony
27 May 2005	1000 – 1100	Keynote Lecture
27 May 2005	1100 – 1130	Coffee Break
27 May 2005	11:30 – 1700	Bureau Meeting
27 May 2005	1930 – 2130	Welcome Reception
28 May 2005	1200 – 1300	Lunch Seminar (Dr. Oellerich)
28 May 2005	1300 – 1730	House of Representatives
28 May 2005	1730 – 1830	World Pathology Foundation
28 May 2005	2000 – 2400	Gala Dinner and Auction
29 May 2005	0800 – 1200	New Bureau Meeting
29 May 2005	1300 – 1400	Closing Ceremony
29 May 2005	1400 – 1500	Farewell Party
29 May 2005	1530 – 1900	Bureau Meeting

¹ Bosphorus by Boat



Attendees:

Dr. David Davies	Australia
Dr. Alfred Hartmann	U.S.A
Dr. Gamze Mocan Kuzey	Turkey
Dr. Ikunosuke Sakurabayashi	Japan
Dr. Mário Flávio Alcântara	Brazil
Dr. Michael Oellerich	Germany
Dr. Oh HunKwon	Korea
Dr. Mikio Mori	Japan
Dr. Paul Raslavicus	U.S.A
Dr. Raj Dash	U.S.A
Dr. Robby Bacchus	U.K.
Dr. Utz Merten	Germany
Dr. Henry Travers	U.S.A.
Dr. Barrie Murphy	U.K.
Dr. Manfred Böhm	Austria
Dr. Gonec Ciliv	Turkey
Murilo Melo	Brazil
WASPALM Representative CLSI	

Guests

Gulenay Azar Kahramar Secretary to Dr. Mocan Kuzey	Turkey
Dr. Looi Lai Meng President, 24 th World Congress	Maylasia

Administrators

Dr. Masami Murakami	Japan
Mr. Susumu Kanda	Japan
Dr. I. Sakurabayashi	Japan

Review of Rio de Janiero Minutes and Review of Status of Assigned Tasks

TASK	ASSIGNED	STATUS
1. Develop a license/contract for use of the web site	Unassigned	Incomplete
2. Establish and manage a COWSA forum on the web site	Hartmann	Incomplete
3. Take steps necessary to maximize return on depository funds	Oellerich	Incomplete
4. Develop a license/contract for use of the web site	Unassigned	Incomplete
5. Secure directors insurance	Travers	Incomplete
6. Establish publication links with societies publishing journals	Travers	Incomplete
7. Develop a relationship statement between WASPALM and WPF	Travers/Murphy	Incomplete

Review of Secretariat/Committee Appointments

See minutes for 29 May 2005.



Report of the Administrative Secretariat Dr. Masami Murakami, Executive Director

Replacement of Executive Director of Administrative Office

Effective as from April 1, 2005, Dr. Murakami Masami took over the office of Executive Director, Administrative Office from Dr. I. Sakurabayashi, according to the Agreement between Japanese Society of Laboratory Medicine (JSLM) and WASPaLM signed on May 26, 2004.

Corporate sponsors

In compliance with our request solicited in March to 33 corporate sponsors in Japan, 13 sponsors kindly paid contribution of total US\$20,000 in March/April 2005. Due date is the end of May.

2002	38 sponsors	\$54,000
2003	37	\$53,000
2004	33	\$47,000
2005	13	\$ 20,000 (as of May 9, 2005)

2004 Financial Audit

On March 9, 2005, Dr. T. Kawai conducted financial audit for the calendar year of 2004 without any problems. Balance as of December 31, 2004 was US\$ 694,935.65, which increased US\$26,445.45 against of US\$668,490.20 as of the end of 2003.

Others

Reorganization suggested by Dr. Marilene Melo of April 21, 2004 was seriously reviewed. However it was recommended that the existing organization should be maintained for a time, because of the balance between productivity anticipated and investment as well as a complicated command structure of Administrative Office located in Japan.

Review of Electronic Bureau Actions

WASPALM withdrew from the Global Health Network

WASPALM web site hosting: decision pending Bureau meeting

Report of WASPaLM Officers

President (Dr. Melo)

Since my report to the Bureau in Rio de Janeiro, there has been a considerable increase of communication with the Constituent Societies mainly concerning information of 23rd World Congress, requests of representatives attendance to House of Delegates, nominating their members to make part in the WASPaLM Secretariats and Committees for the New Directory Board 2005 – 2007. For several times we asked for the Constituent Societies to send us subjects and pictures of their Societies to be used in our Bulletin. The communication with Bureau Members was participative, productive and also rewarding. Everybody has contributed for WASPaLM enlargement.

Three great projects were approved by voting at the Bureau in Rio de Janeiro and they are satisfactorily in process. They are:

Bulletin: WASPaLM interrupted the Bulletin publication in 1997 and now we have re-started it again. We already have the first Bulletin edition in our website, which can be printed by Constituent Societies and the second one is being finished. The President's Messages strongly recommended the Constituent Societies to be further close to popular Press media in order to better inform the population about the importance of Laboratorial exams and also benefit themselves from preventive medicine to improve the quality of life worldwide. We feel that Constituent Societies are closer to WASPaLM after the Bulletin.

Website: Dr. Raj Dash searched for American and Indian organizations to redesign and update our website but the prices were not appropriate. Vinicius Biasoli has prepared an experimental version of the website. WASPaLM will be the owner of it and will also control all the website process, being therefore independent of Control Lab and any other company. Raj Dash has already been exchanging information with him concerning technical matters.

Accreditation in Latin America: There has been a great number of e-mails exchanged among Robby Bacchus, Mário Flávio, Wilson Scholnik and I. We are having several meetings concerning this matter in my laboratory. It was made a research on accreditation trying to find out about Latin America situation. During the Latin American Congress held in La Paz Bolivia 16-20 November/2004 the WASPaLM Document Position Statement: Accreditation of Clinical Diagnostic Laboratories was distributed to local newspapers and TV as well as to all Latin American Societies. During this Congress Ecuatorian Society and Peruvian Society became WASPaLM Associate Societies. We decided to make one workshop each semester in each different country. The first one will be held in Uruguay this coming June.

A questionnaire to study the real situation on Laboratories in Uruguay and its practice is being prepared. Each country will organize the workshop such as invite health authorities; find out the best place for the event, and all necessary procedures. WASPaLM will send the professors to give lectures.

PAHO

Dr. Arturo Terres, President of FEMPAC, (Mexican Federation of Clinical Pathology) was nominated to attend PAHO *Pan American Health Organization*, as WASPaLM Representative.

Former Constituent Societies

I have been writing to those Constituent Societies, which belonged to WASPaLM inviting them to return to WASPaLM. These Societies were searched in the Directory 1999-2001.

We gained the interest of Israel Association of Pathologists.

New Societies:	In 2003	In 2005
Constituent Societies	23	26
Associate Societies	03	05
Corresponding Societies	02	02
T O T A L	28	33

A great job of Robby Bacchus was carried out in India aiming to enhance the importance of Pathology in clinical decision process, on quality standards, on our professional development and on Laboratory Accreditation in an event, which gathered 340 participants. WASPaLM accomplished its mission; promote the teaching and practice of all aspects of Pathology/Laboratory Medicine.

WASPALM is well known in Latin America and there is great interest of national associations to belong to WASPaLM. They feel it is a pride and also a necessity to belong to WASPaLM.

The financial situation of South American Clinical Pathologists is becoming more difficult and less comfortable.

In Brazil a fusion process of big laboratories with invasion of North American capital, started in 2003 with purchase of medium laboratories in debts. Small laboratories are shutting down at the moment because of strong concurrence.

On the other hand, countries such as Japan, Korea as well as in Europe it seems that the economic situation is stable as last year. Tjaart Erasmus prepared a very detailed report about the present situation in Africa. Approximately half of the pathologists are in private pathology practice and half are employed by the state. The state has consolidated all public laboratory services into a National Health Laboratory Service, which is still in process of restructuring and re-organization. This is the only body that trains pathologists.

The private pathology laboratories employ approximately 8000 people and most of the laboratories are accredited to the South African National Accreditation System (SANAS), which conforms to ISO/IECI 7025 standard.

In the United States Paul Raslavicus sent a very detailed report, which should be carefully studied.

Now, we are in one of the most important events promoted by WASPaLM. We are holding the 23rd World Congress thanks to the competence and strong work of Prof. Dr Gamze Mocan Kuzey, Prof. Dr. Arzu Sungur, Dr. Yücel Güngen; Dr. Oya Bayindir and Dr. Ozdem Ang, We are sure that with diligent and high level scientific program, top professors this Directory is really carrying out WASPaLM mission.

Dr. Melo informed the Bureau of the offer from Prof. Enrico De Simone representing the Italian Association of Clinical Pathology and Molecular Medicine and the Italian Society for Laboratory Medicine for the 26th World Congress to be held in Italy in 2011.

Action Item #1: The Bureau received the proposal from Prof. Simone and agreed to present it to the House of Representatives and seek their advice and recommendation prior to taking formal action.

Secretary-Treasurer (Dr. Travers)

**ASSETS AND LIABILITIES
APRIL 30, 2005**

Item	Category	Amount	Comments
Assets			
	Cash on Hand	\$857,647	General + Cash Account
	Computer equip	\$3,000	
	Accts Receivable	\$7,600	Constituent Societies Duesd
	TOTAL	<u>\$868,247</u>	
Liabilities			
	Accounts Payable	\$6056	
	2005 World Congress	\$42,000	Estimated
	TOTAL	<u>\$48,056</u>	
	Net Worth	<u>\$820,191</u>	

Minutes of the Bureau
INCOME-EXPENSE STATEMENT
September 2004 – 7 May 2005

Item	Category	Amount	Comments	2005 Budget
Income				
	Dues	\$4,710		\$9,500
	Corporate Sponsorships	\$6,000		\$50,000
	Interest	\$478		\$1,000
	Other	\$0	Istanbul World Congress	\$5,000
	Other	\$10,970	Busan World Congress	\$10,970
	TOTAL	\$22,158		\$78,470
Expenses				
	Travel	\$30,981		\$41,000
	Bureau: Room Charges	\$5,290 ¹		\$3,500
	Bureau: Food	\$0.00		\$1,500
	Bureau: Miscellaneous	\$0.00		\$1,000
	Legal/Accounting	\$4,969		\$5,000
	Bank Fees	\$159		\$400
	Dues/Memberships	\$375.00		\$375
	Secretariats			
	<i>Informatics</i>	\$353	Approx. \$4000 remains in budget	\$500
	<i>Countries in Need</i>	\$11,236 ²		\$0
	Administrative Office	\$2,000		\$6,000
	Treasurer's Office	\$100		\$1,000
	World Pathology Found	\$0		\$500
	Secretary for President	\$0		\$12,000
	TOTAL	\$55,463		\$72,775
	EXCESS INCOME	(\$15,688)		\$5,695

Notes:

¹Dr. Melo's expenses for Rio; includes room and meals

²These funds had been previously transferred to the Royal College and do not come from current income.

**2005 BUDGET
Revisions from September 2004 to 27 May 2005**

Item	Category	Amount
Income		
	Dues	\$9,500
	Corporate Sponsorships	\$40,000
	Interest	\$1,000
	Other ¹	\$10,970
	23 rd World Congress	\$5,000
	TOTAL	\$66,470.00
 Expenses		
	Travel ²	\$41,000
	Bureau: Room Charges	\$3,500
	Bureau: Food	\$0
	Bureau: Miscellaneous	\$1,000
	Legal/Accounting	\$5,000
	Bank Fees	\$400
	Dues/Memberships	\$375
	Secretariats	
	<i>Informatics</i>	\$500
	<i>Countries in Need</i>	\$0
	Administrative Office	\$6,000
	Secretary to the President ³	\$12,000
	Treasurer's Office	\$1,000
	World Pathology Foundation	\$500.00
	TOTAL	\$72,775
	EXCESS INCOME	(\$4,805)

Notes:

¹Income from Busan World Congress deposited in December 2004

²Travel expenses for Mrs. McClatchey will need a budget variance of approximately \$3,500.

³Authorized by the Bureau October 2004

New Member Society: Association of Practicing Pathologists (India)

Election of Officers and Directors

Dr. Travers certified the election of the following officers and directors:

Past President	Mikio Mori	Japan
President	Marilene Melo	Brazil
President Elect	Henry Travers	United States
Secretary-treasurer	Michael Oellerich	Germany
Director-at-Large (Africa)	Tjaart Erasmus	South Africa
Director-at-Large(North America)	Paul Raslavicus	United States
Director-at-Large (South America)	Mario Flavio Alcantara	Brazil
Director-at-Large (Asia)	Oh Hun Kwon	Korea
Director-at-Large (Australia)	David Davies	Australia
Director-at-Large (Europe)	Manfred Boehm	Germany
Director-at-Large	Robbie Bacchus	UK
Director-at-Large	Gamze Mocan Kuzey	Turkey
Director-at-Large	Gonenc Ciliz	Turkey

Incorporation and ByLaws Changes

Dr. Travers presented the revised bylaws to the Bureau for final review. He informed the Bureau of the incorporation of WASPaLM under the laws of the State of Illinois in the United States and costs of that incorporation (insurance, accounting fees, registered agent). These costs are estimated at approximately \$15,000 annually. The Bureau discussed the reality of insurable risk and the necessity for insurance, the major part of the estimated \$15,000 cost.

Action Item #2: The Bureau approved without change the document entitled “Final Draft of the Bylaws of the World Association of Societies of Pathology and Laboratory Medicine” for presentation to the House of Representatives.

Action Item #3: The Bureau authorized its members to solicit, based upon requirements drafted by Sidley and Austin, proposals for liability and directors insurance in their several countries.

Past president (Dr. Mori)

New WASPaLM Directory will be compiled immediately after this meeting with the help of Dr. M. Murakami and Mr. S. Kanda to be scheduled for the completion by the end of October and the distribution in November 2005. Since we have to update all information in each area, I would like to ask for everyone's cooperation to provide me with relevant information at your earliest convenience. Dade Bering Limited has kindly accepted to continue to be the sponsor for printing costs of the Directory.

Reports of Directors at Large

Asia (Dr. Kwon)

The first Asian Congress of Clinical Pathology (Laboratory Medicine) was held in Medan, Indonesia (November 30-December 1, 2004) under the auspices of the Asian Society of Clinical Pathology / Laboratory Medicine (ASCPaLM). ASCPaLM has 5

member countries; Indonesia, Mongolia, Japan, Korea, and Taiwan. The second and the third Congresses will be held in Japan (2006) and Mongolia (2008), respectively.

The society opens its door to any Asian societies related to laboratory medicine, but not to anatomical pathology societies. The society name, ASCPaLM is a temporary name which may be changed when necessary.

Australia (Dr. Davies)

1 Royal College of Pathologists of Australasia - activities 2005

These were outlined in the issue of 2nd January 2005 of the College fortnightly newsletter "Pathology Today" as comprising:

Meetings for College Governance: 3 x Council Meetings, 10 x Executive Committee Meetings, 2 x Meeting of the Executive Committee with Chairmen of Advisory Committees for the different disciplines of Pathology

Meetings on different aspects of professional practice: 15 x Major Committee meetings – Quality Assurance and Scientific Education, pathology professional Activities Committee, Board of Censors (Examiners), Board of Education, 18 x Advisory Committee meetings, 10 x Sub Committee/Working Party meetings

Educational Activities: 1 x Conference (Pathology Update), 8 x Other Education events/workshops, 2 x Visiting Professor tours, 3 x Sets of examinations (all disciplines)

Publications: 25 x Publications of Pathology Today, 6 x Publications of the journal 'Pathology', 6 x Publications of Common Sense Pathology, 12 x General Publications including Annual Report, Information Book, Trainee Handbook, Pathology Update Registration and discipline program books, 4 x Publications of 'PathWay' magazine for the medical profession and public.

2 Professional practice

2.1 Laboratory accreditation

As previously advised from 1st July 2005 it will be mandatory for this to comply with ISO standard 15189 instead of 17025. The National Pathology Accreditation Advisory Council (Australia) has recently issued for comment a document entitled "GUIDELINES FOR QUALITY MANAGEMENT IN MEDICAL LABORATORIES", which provides a good overview. Although intended primarily for use in Australia the information it contains is likely to be of interest to pathologists and managers of laboratories in other jurisdictions. Compared with ISO 17025, 15189 places much greater emphasis on the performance of laboratories in its interaction with medical practitioners who order and use laboratory tests. For example G7 Advisory services refers to Section 4.7 of ISO 15189:2003 that has no equivalent in ISO 17025: 1999. This will require laboratory professional staff provide advice on choice of examinations and use of services, documentation of meetings of professional staff with clinical staff regarding use of laboratory services and of consultation on scientific

matters. Participation by professional staff in clinical rounds also is an issue.

Adoption of this standard will require an enhanced role for the clinical pathologist/laboratory physician.

The document can be viewed on:

[http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-
npaac-publication.htm](http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-
npaac-publication.htm)

2.2 Registration of Laboratory Tests and Instruments as “In vitro diagnostic Devices” (IVD)

As a consequence of a decision of the Australian Council of Health Ministers the Therapeutic Goods Administration (TGA) (the Australian equivalent of the FDA) is to extend its regulatory role from therapeutic agents to “In vitro diagnostic Devices” (IVD). Delineation of these is still not clear but it would appear to have a broad scope covering not only laboratory instruments but also diagnostic kits including so called “in house” kits, which are test systems devised within laboratories rather than purchased commercially. One of the stated purposes of this is “global harmonisation” with standards of other jurisdictions although what is proposed seems to be more stringent than elsewhere. The intention is to classify IVDs by a risk rating. If the “device” is involved with a test with implications for the public health as a whole e.g. testing for blood borne viruses such as HIV and hepatitis B and C it will be assigned the highest rating, category IV. Lower ratings apply if the risk is limited only to an individual and will be assigned according to the perceived magnitude of the risk. The criteria for this are yet to be established. This development has generated major concerns by establishing yet another regulatory layer on what already is one of the most highly regulated environments for pathology practice. TGA has agreed to allow accreditation by NATA/RCPA for low risk in house testing. It is also encouraging that RCPA has been invited to participate in this process. The scope and magnitude of the task to be undertaken in a relatively short period of time continues to cause concern.

2.3 Genetic testing and related issues

RCPA has noted that following two public hearings held between 19 and 26 January 2005 in Munich, the Opposition Division of the European Patent Office (EPO) has rejected the main points of the claims of two European patents on BRCA1 granted to Myriad Genetics. The first patent relates to the BRCA1 gene and its applications, while the second concerns BRCA1 gene mutations associated with breast and/or ovarian cancer susceptibility. This follows full revocation of the first BRCA1 patent in May 2004. The Institut Curie, the Assistance Publique-Hôpitaux de Paris, the Institut Gustave- Roussy, and other European opponents, have since 2001, been fighting these patents and wide-ranging claims of Myriad Genetics on this issue.

These developments are likely to have international implications.

Transport of Pathology Specimens

Advice from the (Australian) Civil Aviation Safety Authority (CASA) has drawn attention to the interpretation of regulatory agencies' rules and regulations that continue to generate questions for laboratories. Concerns are increased as a result of the significant fines for violations, which impact on both shipper and carrier. When sending specimens to a reference laboratory the laboratory where the specimen originates is considered the shipper. The shipper is responsible for understanding and following all regulations for shipping infectious substances. International Civil Aviation Organisation (ICAO) and the International Air Transport Association (IATA) established 2 categories of specimens, Diagnostic Specimens and Infectious Substances. Each specimen type requires specific packaging and handling procedures that are designed to protect anyone who comes in contact with the package. The shipper (your send-out staff) must decide which category applies to each specimen. Once the infectious status of a specimen is determined, proper packaging, labelling, and documentation must be prepared. The transport by air of infectious substances and diagnostic specimens is required to conform to international regulations. These regulations have also been adopted now to regulate the surface transport of infectious substances within Australia. It is recommended that laboratories should aim to adopt the general principles of packing specimens as defined by the IATA Dangerous Goods Regulations for all modes of transport.

While these provisions apply now for transport of specimens by "common carriers" e.g. airlines and overnight road transport it has now been foreshadowed that increased security against infectious hazards will have to be adopted by for transport of specimens by pathology practice courier services.

3 Workforce

As advised in my report to the bureau in November 2004 previously a review of the pathology workforce in Australia by the Australian Medical Workforce Advisory Committee (AMWAC) found a substantial shortage of pathologists. It recommended an increase of 100 in the annual number to the current "base workforce of Australian pathologists of 1,250. Following the Pathology Agreement between the Commonwealth and the RCPA in 2004, 10 new pathology training positions worth \$75,000 each were awarded this year. These 10 registrars have already commenced their training around the country. Three of the six states have also contributed an additional 12 positions. The College continues to lobby other State governments to contribute, particularly the largest state, New South Wales. . Although the new training positions provide urgently needed Trainees, the funding falls short of actual requirements with another 79

positions needed across Australia. The Chief Executive Officer of the RCPA highlighted the critical situation in the national press in an article in the Weekend Australian on 2-3 April 2005.

Similar difficulties exist with pathology workforce in New Zealand and are aggravated by migration to Australia. The RCPA (NZ) Workforce Analysis found that in 2003 that there were 210 active pathologists (of all disciplines) for a population of approximately 4 million, i.e. 1 pathologist to approximately 19,000 population. From the AMWAC report the Australian ratio is 1 pathologist to 15,500 population. For New Zealand to achieve a comparable level to Australia another 48 pathologists are needed. The shortage is particularly severe in Anatomical Pathology and is critical in Forensic pathology. Measures to address them by the NZ government and its agencies are not as advanced as those in Australia.

4 Raising the profile of Pathology

The RCPA has established a number of activities for this purpose. The Annual Pathology Update, which has the national Government as a major sponsor, serves as a focus for some of these. Pathology Week precedes this with promotional display in their hospitals, laboratories or collection centres. The College has discipline specific brochures and posters available. In addition, a special initiative will be a combined brochure produced by the RCPA and the various scientific associations explaining and promoting pathology.

The College has an active program to raise the profile of pathology including a targeted media strategy, publication of "PathWay" magazine, (a magazine targeted at medical students and other doctors) and a strategy in schools and the general community. This is distributed in Australia and New Zealand and issues generally have a "theme" with the one currently in preparation focussing on medical Microbiologists.

5 Promotion of Electronic Imaging in Pathology

During 2004 the College was successful in attracting a grant of more than \$A250,000 to acquire equipment to establish "wide field" (whole section) digital imaging with the Virtual Microscope. The project is being managed jointly with RCPA QAP (Quality Assurance Programs) Pty Ltd. The "ScanScope" was commissioned in August 2004 and a large image bank has now been accumulated. Demonstrations were provided at the XXVth International Congress of the IAP in October 2004 and again at Pathology Update 2005 where they attracted much interest. The guest speakers at Pathology Update 2005 included Professor Ulysses Bayliss a world leader in this technology who is a practicing pathologist and the images were used for a number of workshops. A pilot program is now under way for its introduction in External Quality Assurance in Anatomical pathology to be followed by its use in other disciplines of pathology. A parallel development is

the promotion of the “InView” electronic training modules for cytopathology, which were also featured at pathology Update 2005.

6 Pathology update 2005 – a template for the 2009 International Congress

Pathology Update 2005 was held over the weekend of 11-14 March 2005 again at the Sydney Convention and Exhibition Centre Darling Harbour the intended venue for the 2009 International Congress when it is intended that it will be combined with Pathology Update for that year.

Attendance this year was a record with 961 registrants. Though most were from Australia New Zealand was well represented and a number of attendees were also from countries in South East Asia. The conference was well supported by exhibitors and attracted Major sponsorship form the Australian Government Department of Health and Aging. There were 3 distinguished overseas guest speakers whose contributions were complemented by those of experts from Australia and New Zealand. The Professional Day on Friday 11 March providing attendees with an opportunity to hear from government, to hear about risk management in Pathology and about developments in Quality Assurance. The remaining 2 days had multiple sessions including workshops covering Anatomical Pathology, Cytology, Chemical Pathology, Forensic Pathology, Immunopathology and Medical Microbiology. As always the conference infrastructure provided by the Convention centre was of a high standard. Audiovisual support was impeccable and 100% reliable and the Convention Centre staff were as helpful as always and their kitchens produced many thousands of meals, morning teas and cocktails.

North America (Dr. Raslavicus)

Since my report to the Bureau in Rio de Janeiro, there have been a number of issues within medicine and within our specialty that have drawn the attention of the media, the government and of all pathologists. They are highlighted in this report.

Medical Liability Reform

For many years the medical profession in the United States has suffered increasing financial burdens in civil actions alleging medical malpractice. Within the last decade the jury judgments and out of court settlements have reached in some cases the multimillion dollar range and premiums for obtaining insurance have become prohibitively expensive for some specialties. This situation has resulted in the unavailability in some cases of appropriate specialists, especially in high risk fields such as obstetrics and neurosurgery. Whenever important diagnostic errors have occurred anatomic pathologists have also not been immune from this malpractice epidemic.

Now that President Bush and his party have significant majorities in both Houses of Congress, the passage of significant malpractice legislation has

significantly increased its chances. The major goal of proposed legislation is to limit non economic damages to a maximum of \$ 250.000 dollars.

Laboratory Accreditation

In the USA, the College of American Pathologists has been the major accrediting agency of medical laboratories (both clinical labs and anatomic pathology-surgical pathology laboratories) on behalf of the government. Within the last six months several crises situations have arisen wherein several laboratories have been found deficient in their performance—despite having achieved the CAP’s accreditation requirements, even “with distinction.” This has created a political firestorm whereby opposing forces want to limit the CAP’s involvement and/or wish the individual states to take over the accreditation process. Since these attempts threaten the accreditation process by inspection by peers (not to mention the significant revenue stream of the CAP) there has been a vigorous attempt to retain supremacy in the accreditation venue. This has included appropriate government testimony, media presentations and an improved inspection process.

External Quality Assurance

Considerable concern by WHO and other organizations arose when it became known that the H2N2 virus was distributed through the quality assurance programs of the CAP and three other quality assurance sponsors. Fear was expressed that although this virus posed little threat to laboratory employees and even lower threat to the public, nevertheless, it was a virus to which a significant portion of world population is not immune. With an abundance of caution all of the specimens worldwide were destroyed. In the future pertinent organizations such as the WHO and the CDC will be appraised of contemplated shipments.

Pathologists scope of practice

Significant activities in various states of the USA have taken place wherein pharmacists have been trying to expand their scope of practice to include the ordering and interpretation of laboratory tests. The CAP has been opposed to the expansion of the authority of these non physician professionals and has been generally successful in defeating these proposals.

Further, with the migration of laboratory testing to molecular techniques and the identification of tumors by genetic aberrations, pathologists scope of practice is also challenged. This has come to the forefront with the development of techniques to detect tumors on a molecular (i.e DNA) basis as in the case of urothelial neoplasia. The distinction whether a particular laboratory procedure requires at least in part the services of a physician is quite important in the US system of payment. For those tests with direct hands on physician involvement pathologists are paid directly for their services ; without such involvement all payments are made to the hospital or the parent

laboratory and payment to the physician for his supervisory services is a matter of individual contracting.

Non pathologist physicians as providers of pathology services

With decreasing levels of payment for direct patient care services rendered by clinicians, some of them have turned to the provision of pathology services as an economic necessity. This has been achieved by assuming ownership of laboratories or engaging of pathologists as employees. The specialties affected have been primarily dermatologists, urologists and gastroenterologists. In the case of biopsy materials on their patients, they have found it economically advantageous to perform histology services or diagnostic pathology services as part of their practices. In the latter case they have hired pathologists on part time basis, and entrepreneurs have established histology laboratories to be directed by the clinical physicians. These practices have raised questions of ethics and profiteering, with possible violation of federal laws.

The CAP has been instrumental in advocating for state laws that permit only the performing physician to bill for the services rendered to patients. As of this time eight states have enacted such “direct billing” requirements.

Society status with WASPaLM

The American Society of Clinical Pathology has declined the invitation to become a Constituent Society but wishes to remain a Corresponding Member. The College of American Pathologists continues to be a dues paying Society. Invitation has been extended to the CAP to send appropriate officer representatives to the Congress in Istanbul and to participate in Bureau activities and the awarding of the Gold Headed Cane posthumously to Kenneth McClatchey, MD, DDS.

Global Workshops (Dr. Bacchus)

The third WASPaLM educational enterprise was conducted in collaboration with the Royal College of Pathologists and the Indian College of Pathologists and the British Council in New Delhi between 17th – 21st January 2005. The venue for this event was the India Prastha Apollo Hospitals which provided the supporting infrastructure for the event.

Following the meeting in Vellore in 2003, which focused mainly on cellular pathology requests from India received were to enlarge the focus of cover to encompass other disciplines of pathology. In the Indian subcontinent pathology signifies Anatomical Pathology/Histopathology, the other disciplines are categorised as clinical pathology.

Accordingly a symposium was organised to cover some of the topics of interest importance and concern defined by discussions with Indian pathologists. The symposium was inaugurated by the Minister of State for Science, Technology and



Ocean Development. Other dignitaries included the Director General of the Indian Council of Medical Research , the chairman and dean of the Indian college of pathologists, director general of the Armed Forces Medical Services. The UK Faculty was led by the President of the Royal College of Pathologists Professor Sir James Underwood. Faculty members were chosen for their experience and expertise in the varied disciplines. the format for cellular pathology consisted of didactic talks and slide seminars and were sub-speciality based encompassing topics of breast, gastrointestinal tract and gynaecological pathology and digital imaging to enhance the importance of pathology in the clinical decision process several clinico –pathological symposia were held with the visiting faculty and local clinicians. These interactive sessions generated very animated and sometimes heated, though always friendly debate. The audience was always enthusiastically receptive and the feedback in the slide seminars demonstrated an eagerness to learn and profit from the experience of the visiting faculty. Topics covered in the other disciplines include the immunological reactions to blood transfusion and the establishment of a cord blood bank quality assurance, quality standards and professional development, laboratory accreditation, the universal problem of MSRA, Molecular diagnostic methods in Microbiology, evidence based laboratory treatment options for myelomas, controlling infections and transplantation, developments in laboratory automation.

The meeting was attended by 340 participants including six from Sri Lanka. The participants came from all regions of India and several had travelled for 48 hours by train across the vast deccan plateau to participate in the event. A reception was hosted by the British High Commissioner Sir Michael and Lady Arthur for the visiting faculty and Indian participants and an end of symposium dinner was hosted by the British Council.

An evaluation of the programme revealed that the education content was relevant and appropriate to the needs of the participants, helped to clarify what they needed to know, and enable them to modify their clinical behaviour. New Delhi is situated in the Northern India with a population of about 13 million. The road are crowded and the senses bombarded with noise, scents, sounds and apparent chaos. Old Delhi with its medieval Mughal Buildings, narrow roads and teeming bazaars. To the colonial grandeur of New Delhi still lives up to Kiplings description “such a river of life exists nowhere in the world” India not only mystifies, it enthral, enlightens and above all This symposium not only provided not only provided an update on various topics, but also enabled the opportunity of promoting education for both pathologists and clinicians it facilitated the development and forging of further professional linking’s with our Colleagues in India and to promote exchange of Knowledge and understanding of the pathology disciplines.

A decision was made by the Indian College of Pathologists to promote the WASPaLM workshops as a regular annual event and before I left Delhi I received a request from a University in south India to host the next event.

The Royal College of Pathologists
Statement of Account for Period July 2004 - June 2005
WASPALM SPCN

OPENING BALANCE AT 01/07/2004	<u>15420.53</u>
EXPENDITURE	
Total Expenditure for India Workshop	11235.70
TOTAL EXPENDITURE	<u>11235.70</u>
BALANCE CARRIED FORWARD AT 10 March 2005	<u>4,184.83</u>

Dr. Bacchus reviewed the three workshops he has produced through the Secretariat on Countries in need. Approximately £4,100 remains in the budget. The Bureau expressed support for continuing the program of Workshops for Counties in Need.

Action Item #4: The Bureau authorized an expenditure of up to £2,000 for the Secretariat for Countries in Need to conduct a workshop in Bangalore, India in February 2006.

Proposal to WASPaLM and Dr. Bacchus from Dr. Scholnik

Dr. Scholnik proposed the organization of workshops on accreditation in Latin America in several formats in a letter to Dr. Bacchus. Notwithstanding the proposal itself, it appears that a definite workshop on accreditation has already been organized. Dr. Alcantara requested WASPaLM's financial help in support of faculty attendance.

Action Item #5: The Bureau postponed further discussion of this proposal until the next meeting of the Bureau.

Review of World Congresses

Malaysia 2007

Dr. Looi Lai Meng presented the program and brochure for the 24th World Congress of pathology to be held at the Sunway Lagoon Convention Centre,

Petaling Jaya, Malaysia and hosted by the College of Pathologists, Academy of Medicine Malaysia.

Sydney 2009

See the report of the Director-at-Large for Australasia.

WHO Report (Utz Merten)

World Health Organization Executive Board 115th Session January 17th-January 19th 2005

On Sunday before the EB meeting there was an in official **NGO meeting** in WHO headquarters during which officers of WHO informed NGO of some items of the EB agenda they though interesting and for which WHO may seek support by NGO's.

The agenda listed:

Welcome by Dr Kazem Behbehani, Assistant Director-General

Introduction to the Executive Board Agenda by Dr Bill Kean, Director, Governance

Item 4.3: Responding to Health aspects of crisis By Dr D N Nabarro, Representative of the Director-General, Health Action in Crisis

Item 4.2: Achievement of health related MDG's (Millennium Development Goals): Status report by Dr A Cassels, Director, Health and Development Policy

Item 4.9: Antiretrovirals and developing countries by Dr H V Hogerzeil, Director, Medicines Policy and Standards

Item 4.13: eHealth by Dr J-C Healy, Director, Office of Assistant Director-General, External relations and Governing Bodies

This was quite general but specific questions could be forwarded and suggestions made. In future, being prepared according specific items on the Agenda, this is one way to enter discussion.

On Monday the meeting took place in WHO Head Quarters as usual, this year having more than 550 attendees - again officials and diplomats being primary actors. Agenda see WHO website (www.who.org)

During the opening session on Monday morning Dr Lee, WHO Director-General, focused on **the tsunami** and WHO response to the situation. From "Abraham Lincoln" a US carrier floating in the sea near ACEH, Indonesia a direct audio TV message was sent with speeches from an US admiral, an Indonesian official and a representative of WHO. Information handed to the delegates are attached to this report. The presentation was spectacular and impressive. WHO obviously was using the situation to foster the preparedness of governments to support their work. This was supported by a report an "Protecting health following the Asian Tsunami".

The EB decided a change of the agenda as it was agreed to place after the speech of the Secretary General a discussion concerning **Influenza pandemic**

preparedness and response. The discussion on Influenza pandemic preparedness and response indicated the necessity for national governments to act.

Further there was a discussion on the “**Achievement of the health-related Millennium Development Goals: status report**”. Attachment 3. Targets related to pathology are “reduce child mortality, improve maternal health and combat HIV/AIDS, Malaria and other diseases”. Again it was proclaimed: “Health is too important to leave it to the doctors alone” In Attachment 4 you find the “**Proposed programme budget 2006-2007**”. This may help to recognize pathology related project of WHO

On Monday noon the Dr. Merten met Dr. Vercauteren (WHO-Essential Health Technologies).

For further information (i.e. reports concerning SARS, Smallpox, Poliomyelitis and Measles) these can be copied from WHO website www.who.org

Summary:

There is few space for WASPaLM related activities but through cooperation with EHT WASPaLM could reach a permanent stronghold.

Items to be followed by WASPaLM should be:

- education of young pathologists in countries in need
- expansion of external quality assessment schemes (EQAS) countries in need
- patient’s right to know that health related studies of their specimens is performed only under the responsibility of a pathologist.

58th World Health Assembly, 16-25 May 2005 (Dr. Merten)

WASLaLM representatives were Drs. Merten and Bacchus. Discussions were held with Professor A.B. Akosa, Director-General, Ghana Health Service and President of the Commonwealth Medical Association; Professor Peter Chang, MD, MPH, ScD, Director-General, Bureau of International Cooperation, Taipei, Taiwan (ROC), Senator Winston Dang (Taiwan), Chin-Shui Yu, Director of the Taiwan Medical Mission in Mzuzu, Malawi; and Dr. Gabi Vercauteren.

CIOMS

Membership renewed for 2005.

Reports of Categorical Secretariats and Committees

COWSA (Dr. Alfred Hartmann)

Alfred Hartmann MD liaison report of the “ ISO/TC 212, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems” meeting held 4-6 May, 2005 in Washington DC

Eleventh meeting of ISO/TC 212 chaired by Dr. Stinshoff(Swiss) with delegates from 25 participating countries. Working Groups 1,3,and 4 were also meeting concurrently.

New Work Item Proposals:

1. Genetic Testing-Specific requirements for quality and competence(N-149) submitted by the Japanese delegation will be postponed until the documents currently in preparation by the Organization for Economic Cooperation and Development(OECD) are available.
2. Laboratory Medicine-Estimation and reporting of measurement uncertainty of routine values(N141) was approved as an activity of WG-2 with WG-1 advising. The project will be a joint activity with CEN/TC 140 and the first meeting will be scheduled for Jan 2006. The US delegation voted against this NWIP but the vote carried for approval by a margin of 12 yes and 5 no votes.

Action item: identify CAP members with expertise in this area to sit on WG-2 to protect CAP and US interests.

3. NWIP on” Health Informatics-Structure for nomenclature, classification, and coding properties in clinical sciences” was withdrawn by the Swedish delegation to be resubmitted to ISO/TC 215.

Action item: CAP should explore whether this potential project supplements or conflicts with SNOMED and identify CAP members for Working Group participation.

Reports of Working Groups:

1. WG-1: Quality management in the clinical laboratory
 - a. change the name of the working group to “Quality and competence in the medical laboratory”
 - b. ISO 15189 will be minimally revised to conform with ISO 17025. These revisions are mainly with terminology to conform the two documents. ISO 15189 draft amendment 1 will be circulated for vote. ISO 15189 will have a major revision to be completed by 2008 along with the revision of ISO 17025. This revision is stated to address the needs of the medical laboratory and related accreditation bodies.
 - c. WG-1 will contact ILAC to develop a guidance document on the use of ISO 15189 by accreditation bodies to be jointly developed with WG-1. This document would be similar to ISO 22869 the guidance document on laboratory implementation of ISO 15189.

Action item: It is clearly evident that ISO 15189 is becoming the core document world wide for the basis of laboratory accreditation . The CAP needs to continue to develop the LAP checklist to conform with ISO 15189 if the CAP wants to maintain its leadership role in the accreditation process.

2. WG-2:Reference Systems

- a. Did not meet but the NWIP concerning measurement uncertainty was approved.

Action item: see above. CAP experts needed to be identified to work on this project.

3. WG-3: In vitro diagnostic products

- a. ISO 14971 annex on risk management for IVDs shall be circulated for DIS vote. If vote affirmative the responsibility for the document will transfer to ISO/TC 210.
- b. ISO 18113 will be divided into 5 parts . These documents address information supplied by the manufacturer for “labeling” of in vitro diagnostic medical devices.
- c. Comments were addressed on ISO 17593, Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy and this document will be submitted for final draft international standard

4. WG-4: Antimicrobial Susceptibility Testing

- a. Comments will be addressed concerning ISO 20776-1(Reference methods for in vitro testing of the susceptibility of antimicrobial agents against bacteria involved in infectious diseases) during the DIS voting.
- b. ISO 20776-2(Evaluation of performance of antimicrobial susceptibility devices) will be drafted with CEN/TC 140 and submitted for DIS vote in the fall of 2005.

The next meeting of ISO/TC212 will be held in Berlin 31 May to 2 June 2006.

Dr. Hartmann will find out if final international standards from ISO may be distributed by WASPaLM to its constituent societies.

Informatics (Dr. Dash)

- Web hosting and search service costs remain small (~US\$500 annually)
- Increased “hits” on the web site, but there is a decline in the number “hits” within the web site; this is thought due to decreased content turnover
- General issues identified in Rio de Janeiro persist: web site participation and content



- Dr. Dash presented the offer from ControlLab to rewrite and maintain the web site indefinitely at no cost to WASPaLM and the Bureau had a chance to review a concept design from ControlLab. He further had reviewed several web site service providers to assist if ControlLab ceases to provide web services.

Action Item #6: The Bureau agreed to accept the ControlLab proposal effective immediately and to consider, at the next Bureau meeting, whether any additional support from services providers other than ControlLab is required.

Adjournment

The Bureau adjourned until 29 May 2005 in Istanbul, Turkey.