

The British In Vitro Diagnostics Association

BIVDA



Review 2001



The Difference Diagnostics Can Make

The prevention of disease and the provision of reliable information to doctors and patients play an important role in the improvement of British health services

The last year has seen the initials BIVDA begin to feature in the sequence of events to which MPs and members of the House of Lords gravitate. The organisation has become a key player in the application of science and technology in the area of disease detection. There is now a commitment at government level to improve the health services of this country. In this year of delivery, more activity is required, and anticipated, from BIVDA to help in the realisation of, amongst other things, the Cancer Plan and the NHS Plan.

The prevention of disease and the provision of reliable information to doctors and patients play an important role in the improvement of British health services. Together with ring fencing of budgets, this will have an important political impact on the role of BIVDA.

I look forward to increased interactions with BIVDA and its excellent staff in the coming year.

Dr. Ian Gibson MP
Chairman of the Select Committee on Science and Technology



In my recently-appointed role as director general I am pleased to be able to introduce the third BIVDA Annual Review. The annual review is intended to provide an overview of BIVDA's activities during 2001 with detailed reports on meetings held during the year and on the activities of the working parties and to give an impression of the association for those who are not familiar with its aims. This report is also an opportunity to thank everyone involved in maintaining the success of the association during the past year, the membership for their participation and the evolving relationships with professional or public bodies and in particular the continuing support shown to BIVDA by Dr Ian Gibson MP. John Menzies, the current chairman of the association, has contributed his vision for the objectives of BIVDA during 2002 - a year which coincides with the tenth anniversary of the formation of BIVDA.

During the lifetime of BIVDA the IVD industry has seen many changes and this trend is continuing with still further company mergers and acquisitions. The use of in vitro diagnostics is also changing as point of care diagnostics becomes an increasingly important market sector, while

the use of genetic testing for diagnosis and prediction of disease will feature heavily in the future.

There have also been many changes within the BIVDA organisation during 2001 with the departure of Cecilia Brown, Caroline Czermak and Eon Hare. However new people will be recruited to assist in meeting the goals for the association during the coming year. Alan Bartholomew has been appointed as office manager and brings with him a strong background in finance to assist the treasurer in managing the funds effectively. Alan will also be responsible for running the office on a daily basis with the assistance of an office administration assistant. The office administration assistant, who is in the process of being recruited, will be the first contact point for members and enquiries to the office where they will co-ordinate meetings, seminars and working party activities.

We look forward to a challenging year in 2002 with the implementation of the executive committee's updated strategy while continuing to provide the service and activities valued by our members. We also want to develop further our relationships

with other organisations including other trade associations such as ABHI and Gambica where many of our functions overlap with those required in their industry sectors. Finally, and above all, we will continue to promote the UK IVD industry so that we will no longer be *"the best kept secret in British healthcare"*.

Doris-Ann Williams
Director General BIVDA



Alan Bartholomew
Office Manager

We will no longer be
*"the best kept secret in
British healthcare"*



The British In Vitro Diagnostics Association

The BIVDA mission is to promote the role of diagnostics in healthcare and support the industry through representation and professional services.

As part of this mission BIVDA organised many successful events during 2001 and the challenge is now to build on this success and ensure that BIVDA is even more widely recognised as the first point of contact, particularly by the press, for all queries and information relating to IVDs.

The Diagnostics Club, on whose board I represent BIVDA, was incorporated in May 1991 to facilitate technology transfer from academia to industry in order to address the well-recognised and historic failure in the UK to commercialise highly innovative research. Valerie and Tony Owen (SciTech) took over the day-to-day management of the club ten

years ago and successfully built up a large membership of companies, academic institutions and individuals involved in medical, veterinary, environmental and agronomic activities, based in UK and overseas. A review process is currently under way to identify with the membership new opportunities and activities for the club.

Following the publication in December 1999 of the Foresight Healthcare Panel report in which their vision of diagnosis by 2020 was addressed, BIVDA and ABHI submitted a coordinated response to the DTI Consultation on the Foresight Programme carried out in April/May. The questions raised included the benefits to and impact on our associations, suggested improvements to and main aim of the programme, and thus the areas of focus in the future. Our response stressed the need for government to demonstrate commitment in taking up and implementing the panel recommendations, underlining the relevance of Foresight work (e.g. establishment of the National Health Diagnostics Advisory Group). It also stressed the focus that should be brought to bear on barriers to innovation. We pressed strongly for the continuation of a broadly defined healthcare sector as used in the last phase of Foresight.

2001 has been a year of considerable change. As chairman, Andy Anderson has worked tirelessly to find and employ a new director general for BIVDA. John Menzies follows him as the new chairman and has the challenge to lead, not only a new executive committee but also, a new secretariat under the recently appointed director general Doris-Ann Williams. Doris-Ann has already initiated a far reaching membership survey into attitudes towards the overall services provided by BIVDA, and in particular looking at a fresh approach to the all-important market audit in terms of data collection, management and reporting.

The executive committee has arranged a strategy meeting, which will take place early in the year and will set the scene for a demanding but exciting year 2002 for BIVDA. I look forward to working with the new team and with the membership in the next twelve months.



Kit Madden OBE
President BIVDA

The challenge is now to build on this success and ensure that BIVDA is even more widely recognised as the first point of contact

Objectives for 2002

I expect 2002 to be a year in which we refine and re-adjust our overall objectives and aims for BIVDA and try to bring the association in line with what is taking place in the IVD marketplace, particularly within the UK.

I would like to continue to build on some of the ongoing plans that have been in place for the past two to three years, but at the same time have a critical appraisal of all of the activities that we undertake on behalf of the membership to ensure that we are focussed on the right agenda items and are structured accordingly. We have made some good progress in bringing our messages forward with parliamentarians and I feel we should continue to use this communication channel during 2002 and beyond. We also need a BIVDA voice within the media and we will be exploring ways to do this early on this year.

BIVDA has been very active in supporting the membership with day-to-day enquiries and providing information and guidance on topics such as regulatory affairs and procurement, to name two examples. I see this as a very important part of BIVDA's activities and we will continue to develop our abilities in this area.

One of the foremost objectives in my mind is the active provision of UK market data that can be used by the BIVDA membership to assist in decision-making and also to enable BIVDA to fulfil our obligations to EDMA in this respect. During early 2002 we expect to be able to introduce a novel (and secure) approach to data collection that will benefit those companies submitting data.

I also want to recognise the time and effort spent by many individuals in participating in BIVDA working parties. I see the working parties as the "engine room" of the organisation and the forum for membership involvement. They enable BIVDA to get its messages and ideas out into the wider community. It is therefore very important that working parties have the direct support and involvement of the BIVDA executive and that ultimately these working parties are

aligned to the main strategies that we develop. This will be one of the internal objectives for 2002.

Early in 2002 the executive committee will be issuing an updated strategic plan and objectives that will take us through 2002 and 2003.

John Menzies
Chairman BIVDA
Ortho-Clinical Diagnostics





Mary Coakley,
Interim Manager, BIVDA

A Year of Change

The past year has seen significant change at BIVDA. In the early part of 2001 the decision of the director general, Cecilia Brown, to resign and her subsequent departure from BIVDA in April occupied a lot of the executive and secretariat's time. It was unfortunate that BIVDA had to lose such an energetic and enthusiastic person but it became important that everyone should remain focused on looking forward rather than backwards.

Although every effort was made to obtain a replacement as soon as possible, these things take time and the executive committee had to find a way of providing continuity to the functions of the director general. As an interim solution they made the decision to employ two people working part-time to cover some of those functions. Sue Spencer, who had recently become an independent consultant and had long been associated with BIVDA through the Regulatory Affairs Working Party, was contracted to cover regulatory affairs and membership support. Mary Coakley, who was already involved in working for BIVDA on the annual review and the website, was assigned to oversee the

functions of the secretariat and to cover the promotional activities of BIVDA. Mary was chosen because of her history of involvement with BIVDA including many years as part of the executive committee and as a member of the P & PR Steering Group. These arrangements proved to be very successful in providing effective coverage for the core activities of BIVDA during the transition period.

Further change came in September with the departure from the secretariat of Caroline Czermak. Caroline had been organising the IVD seminars for many years and had taken BIVDA through ISO9002 certification. Her cheerful presence and attention to detail will be missed by all members especially those who were in regular contact with BIVDA or attended the IVD or training seminars.

Finally, in December, Eon Hare who had been part of the secretariat for over three years, left. Eon was well known by members especially those who attended the working party meetings which he co-ordinated. Eon was a familiar face to many at exhibitions and the BIVDA symposia.

On the positive side, BIVDA was fortunate to

able to recruit a new director general, Doris-Ann Williams who has had over twenty years of experience in the diagnostics market place. Doris-Ann brings with her a wealth of knowledge of diagnostics and a wide range of skills, which will enable her to reorganise the secretariat and to take BIVDA successfully forward into the 21st century.

Parliamentary Activities

The objectives of the parliamentary campaign were to increase the awareness of MPs and their advisors interested in healthcare issues, of the benefits of increased investment in IVDs in terms of health economics and quality of life.

The initiatives, which were successful in 2001, included four quarterly bulletins of 'Diagnostics in Healthcare' and a parliamentary reception held in July at which agreement was obtained for a meeting with the public health minister. Increased contacts were made with patient groups and a conference "Diagnostics - the Best Kept Secret in Healthcare" was jointly organised with the Patients Association. The conference was highly successful with over 100 delegates attending (see report on page 8).

Meetings, Conferences and Exhibitions

BIVDA attended the major diagnostics exhibitions during 2001 including the Association of Clinical Biochemists' "Focus 2001" and the Institute of Biomedical Sciences Congress. We also exhibited at Primary Care 2001, the British Medical Association Annual Representatives Meeting (BMA ARM) and the British Medical Association Local Medical Committees Meeting.



BIVDA stand at the BMA ARM meeting in Bournemouth

BIVDA organised a seminar at the BMA ARM conference, which was entitled: "So you thought that there was nothing wrong with the patient?". The topics of early diagnosis and screening were covered by a number of speakers and the seminar was attended by over 30 delegates

BIVDA also had a presence at the Royal College of Pathology and the British Pharmaceutical Society conferences and at a conference on theranostics/predictive medicine. BIVDA also sponsored and presented at a meeting of the Men's Health Forum.

Reports of the meetings were published in the BIVDA Newsletter and in the members section of the BIVDA website as part of the P & PR Group minutes.

Regulatory Issues

In addition to the activities of the Regulatory Affairs Working Party (*see report on page 15*) and the invaluable support for members provided by Sue Spencer, there were two IVD seminars organised during 2001. The IVD seminars continue to be as well attended and as popular as they have been in previous years. It is planned to keep the seminars going and to ensure they remain current and relevant by expanding the topics to include not only the IVD directive but other topical regulatory issues.

Working Parties

The working parties (WPs) continue to be the backbone of the activities at BIVDA. There is a natural degree of flux in the amount of activity from the various working parties, as issues become more or less important dependent on what is happening in the market place or in the media. The list of people interested in each working party reflects the members with a vested interest in that particular topic. In all cases those who have registered an interest are included in all circulated information, are informed of every meeting and its agenda and are sent copies of the minutes of each meeting.

However, the actual activities of the working parties tend to be driven by a small group and most importantly the chairman. We would like to thank all those chairmen and women who have been active in driving their WPs and who have dedicated their time and thoughts to pursuing matters that benefit others as well as themselves.

This year we have seen the setting up of several new working parties and the conclusion of others. Although it is not unexpected for certain groups to become less

active it is important to have continuity of approach for important issues that require long term and/or continuous action and for this reason there will be a renewed campaign in 2002 to encourage members to take a more active role in the working parties. Working party activities are regularly reported in BIVDA News and summary reports for the year are included later in this review.

Communication

The BIVDA newsletter, *BIVDA News*, continued to be published throughout the year. There were five issues during 2001 containing a mixture of information on BIVDA events, working party activities, a regulatory update, communications from members, and a comprehensive list of upcoming events of interest to all members. The newsletter now has a colourful new design and the content will be reviewed during 2002 to ensure it remains in keeping with what the members need.





Parliamentary Bulletin

Other forms of communication in 2001 included the placement of advertisements promoting the value of diagnostics in several publications including The House Magazine (circulated to all MPs) and the National Association of Primary Care’s Annual Review. There were articles from BIVDA published in BMS Gazette, ACB News, MLW, Diabetes Today and the NAPC Review. This year there were also four issues of the BIVDA Parliamentary Bulletin *Diagnostics in Healthcare* covering the topics: (1) General Diagnostics, (2) Heart Disease, (3) Cancer and (4) Diabetes. These bulletins have been used as part of the parliamentary campaign to lobby MPs and patient groups on the value of diagnostics.

Working with EDMA

This year saw some very positive co-operation between BIVDA and EDMA as well as some difficulties. On the positive side, the PR Group at EDMA awarded BIVDA a matched funding grant for their parliamentary campaign as it was deemed to be an appropriate investment as part of their drive to promote diagnostics in Europe. John Place (Director General EDMA) attended the highly praised Conference

“Diagnostics - The Best Kept Secret In Healthcare” held in November 2001, which was part-funded by EDMA.

The difficulties arose with the market audit data collection. Every year BIVDA provides EDMA with an estimate of the total UK diagnostics market which is used to compile their overview of the European IVD market. This year BIVDA had severe difficulties in collecting the data needed to generate this estimate. Indeed it proved impossible for the UK to submit an estimate for the year 2000 due to the lack of data submissions from member companies. In the end, for the purposes of their report, EDMA made a estimate of the UK figures based on the data from previous years. EDMA were very concerned by having to do this, as the UK has in the past been one of the best countries when it came to submitting accurate and timely data. BIVDA is addressing this problem in the UK and is also working with EDMA to find ways to make it easier for members to submit their figures so to improve the quality of the data, which will be of benefit to all members.

Website

The website had a new look and revitalised image at the beginning of the year 2001. The content was updated by Andy Bufton during Christmas 2000. As a result of his efforts the number of people visiting the site increased about three fold. The number of visitors to the site remains high. However with the staff changes that occurred at BIVDA during 2001 there was little time for any further development of the site. Issues such as the style, content and quality of material on the website and its editorial control are being reviewed and 2002 will see a push to make the website more interactive and useful to members as well as an invaluable source of information on diagnostics for all.

New Executive Committee

Following a postal vote the new executive committee for 2001/2002 was announced at the AGM in October 2001. Newly elected members were Judi Jackson (DPC UK), Paul Weinberger (Roche) and Yvonne Parker (PerkinElmer). Re-elected were John Menzies (Ortho-Clinical) and Phil Wood (IL UK).

Ian Davidson was also elected but has since resigned.

Andy Anderson (Quidel), Andy Bufton (Abbott) and Geoff Gower (DAKO) have all retired from the committee. BIVDA would like to thank them for their support and contributions. Andy Anderson is thanked especially for his past year as chairman during which time he faced the major challenge of finding a replacement director general, which he did as promised before he resigned in October.

Andy Bufton, who has spent almost ten years on the executive committee, including two years as chairman, must be thanked for his long service and fortitude. His support and major contribution to BIVDA has been invaluable and BIVDA remains truly grateful for this. Andy will remain as chairman of the P & PR Steering Group so that he can continue his tenacious interest in steering the campaign to promote the value of diagnostics.

Geoff Gower, who has been treasurer for the past three years, has been moved by his company to a position abroad and we wish him well in his new role.

John Menzies as chairman elect for 2000/2001 has, with the support of the new committee, taken over as chairman and the new committee has elected Bill Cunningham (CDx) as treasurer (a position he has held in the past) and elected Clem Fitzgerald (Randox) as the new vice chairman (chairman elect for 2003/4).

The executive committee meets fully at least four times per year. Sub-committees, comprising members of the executive will be set up to progress particular issues and they will meet as and when needed.

BIVDA COMMITTEE 2001/2002

President

Kit Madden

Director General

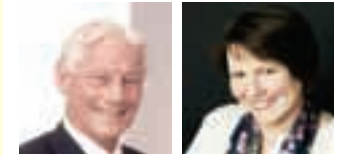
Doris-Ann Williams

Elected Committee Members

John Menzies	Chairman	Ortho-Clinical Diagnostics
Bill Cunningham	Treasurer	CDx
Clement Fitzgerald	Chairman Elect	Randox Laboratories
Brian Fishwick		Beckman Coulter
Colin Foster		Bayer
Judi Jackson		DPC UK
Yvonne Parker		PerkinElmer
Paul Weinberger		Roche
Phil Wood		IL (UK)
George Zajicek		Axis-Shield

EDMA Representative

Willie Burns Ortho-Clinical Diagnostics



Kit Madden



Doris-Ann Williams



John Menzies



Bill Cunningham



Clem Fitzgerald



Brian Fishwick



Colin Foster



Judi Jackson



Yvonne Parker



Paul Weinberger



Willie Burns



Phil Wood



George Zajicek



Ian Davidson MP (far left) with members of the Parliamentary Working Group, (left to right) Andy Bufton, Cecilia Brown, Yvonne Parker, Doris-Ann Williams, Mary Coakley and John Menzies, and John Place (EDMA)

“Diagnostics - The Best Kept Secret In Healthcare”

Organised jointly with the Patients Association, the primary aim of this conference in November 2001 was to raise understanding of the benefits realisable with increased use of diagnostics and identify the roadblocks, which government needs to address.

The message from David Taylor, a trustee of the Patients Association, was that patients are suffering as a result of inadequate use of diagnostic tests and patient groups are demanding greater access to in vitro diagnostics. This includes the provision of controversial testing areas, such as genomic risk profiling and screening for diseases for which there are not yet effective treatments.

The role of genomics and the impact on healthcare was covered in more detail by Dr John Archer, from Cambridge University. He commented that all genetic tests are not the same; some are diagnostic and will clearly indicate whether a disease is present, whether or not there are symptoms. Some tests are predictive and are more important in terms of action and preventative care.

These will provide information and give individuals choices. Finally, another important group are the theranostic tests, which will enable drugs to be targeted at people with a specific gene mutation.

The area of prediction is still the cause for greatest public concern and this was highlighted by Anne Campbell, MP for Cambridge, who pointed out that she did not want to know that she was going to get Alzheimer’s in ten years time. Clearly, this is an area for industry to take a proactive role. Each person has the right to understand what information is available. And they need to be educated in order to decide how and if they want to use that information. It is postulated that, as we become more comfortable with genetic



Dr John Archer, (Cambridge University), Doris-Ann Williams, Andy Bufton, Mike Stone and Dr David Taylor (The Patients’ Association)

testing, we as a society will become more comfortable in taking action that will prolong healthy life.

David Taylor answered the points raised by some of the MPs by stating that we should not forget the overall potential of diagnostics to quantify risk, identify disease earlier and allow better treatment. The promise of diagnostics is not just in single point mutation genetic disorders but in areas such as coronary heart disease, arthritis and diseases that the population as a whole are likely to experience. He also identified some of the problems restricting the use of diagnostics, which include evidence-based retrospection, inadequate economic evaluation and inflexible “silo” budgeting.

His final comment was that we can afford to keep up with new medical technology but it requires political and public will in order to prompt the investment needed.

How can Government Help?

Finally, on behalf of the member companies of BIVDA, Andy Bufton clarified the extent of the problem. In vitro diagnostics constitutes only 5% of medical sales and

only 1% of UK healthcare spending. The average in the EU is 18 Euros per person, with the UK spending less than 10 Euros. However, diagnostic information may form 60-70% of the electronic patient record (EPR).

The single primary concern is that hospital pathology laboratories are still viewed as an overhead by most UK trusts. This is one of the major reasons why the full potential of diagnostics is not being fulfilled. For example to implement proven new tests e.g. Troponin's, each trust demands its own specific business case. The UK has the slowest uptake and use of new tests in Western Europe. Government needs to recognise that earlier diagnosis and more effective treatment can be achieved by the timely use of in vitro diagnostics.

Yvonne Parker
PerkinElmer

Reports on this BIVDA conference have also appeared in ACB News (December 2001) and in Clinica (Issue 984, 19th November 2001).



Addressing the audience, Professor Alan Shenkin, President, Association of Clinical Biochemists



Expressing a viewpoint, Dr Ian Banks, President, The Men's Health Forum



Andy Bufton

Securing our Future Health: Taking a Long-term View¹

“The NHS is the public service most valued by the British people”. So began the NHS Plan², published in July 2000, which showed the need for radical change in the delivery of health services. It was underpinned by the decision taken in March 2000 to commit to a sustained increase in NHS spending, with the expressed aim, over time, of bringing health spending up to the EU average. Against that background, in March 2001, the chancellor of the exchequer set up the Wanless Review to examine technological, demographic and medical trends. Its purpose is to identify the key factors determining the financial and other resources required to ensure that the NHS provides a publicly funded, comprehensive, high quality service on the basis of clinical need, and not ability to pay. Wanless is to report to the chancellor by April 2002, to inform decision-makers in the next public spending review.

“Securing our Future Health: Taking a Long-Term View - Interim Report” is a 220 page report reflecting the evidence taken from stakeholder workshops, a conference, international visits and a number of

submissions from interested parties. I presented on “Trends in Diagnostics” at one of the stakeholder workshops under the auspices of the ABPI, and found the review process very thorough and balanced. The report itself also provides questions to assist the consultation process, which has taken place in the period since publication.

Although the laboratory professions are not cited in the list of stakeholders, the role of diagnostic services and particularly genetic testing in prevention and treatment of risk is recognised in the report. ‘Screening for a wider range of diseases will become available as the National Screening Committee develops its work’ it states, and ‘...pharmaco-genetic (testing)... offers the potential to target drugs more effectively and create individualised drug therapies for patients...’. Data shows that the per capita spend on diagnostic testing in the UK is half of that in Germany and France in the area of viral disease, and less than a third in the area of cancer. Uptake of, and access to, new technology is also very slow, whereas there is a public expectation for diagnostics technology to be available for use in the GP surgery, making diagnosis quicker and waits shorter³.

Issues of ethics, public acceptability and reaction to receiving results of screening programmes are seen as key factors influencing the trends in this area. The extent of the impact will depend on healthcare professionals being able to absorb new areas of knowledge and adjust practice accordingly. It will depend on whether the health system is able to adjust to new screening programmes, and whether patients react by demanding more health services following the use of pre-disposition tests or resisting testing because of fears about the results or the use of the data.

Remote monitoring and testing are amongst those potentially beneficial technologies dependant on information and communication technology (ICT). The report identifies that developing NHS ICT is a critical factor. Annual spending per employee on ICT in the NHS is one third of that in other government areas, and a ninth of that employed in the financial sector. Current plans commit to a £1 billion investment in modernising NHS information systems over the period to 2005⁴.

Staffing the NHS is naturally a key issue. The UK does not have enough doctors and

nurses, although there is an 8% unemployment rate amongst doctors across Europe. Technology is likely to make it possible for many more diagnostic and treatment services to be provided by primary care, and the report expects substantial changes in the roles and responsibilities of healthcare professionals. GPs have traditionally provided continuity of care and ensured that specialist services are used appropriately. The report recognises that maintaining these benefits in a potentially more fragmented system will be a key challenge over the next decade. There is little in the report concerning professional and technical staff, except to point out a 62% growth over the last 20 years (compared with 55% increase in medical staff and 30% administrative and clerical, with nurses about even). For most NHS staff, roles have changed over time, with a rise in team working in primary care, more emphasis on health promotion and disease prevention, and moving of services from secondary to primary care.

The next two decades are expected to realise an acceleration of these changes, which might be said to have yet to impact the laboratory professionals to any marked

degree. Perhaps the difficulties experienced in recruitment, motivation and retention of laboratory staff are, in some part, due to a lack of integration with the broad changes taking place in healthcare strategy, reinforced by a funding system based in secondary care overheads rather than as a strategic health resource. The Wanless Report provides interesting reading for anyone associated with healthcare provision, and is indeed, by definition, the 'writing on the wall'.

Andy Bufton

Abbott Diagnostics

1. *Securing our Future Health: Taking a Long-Term View, Interim report, Derek Wanless, November 2001. Public Enquiry Unit, HM Treasury, London*
2. *The NHS Plan - A plan for investment, a plan for reform, Dept. of Health 2000, The Stationery Office, London*
3. *McKinsey (2001) Expectations of the 2020 UK Healthcare system. Health Trends Review: Proceedings of a conference held at the Barbican Centre, London on 18 and 19 October 2001, November 2001, HM Treasury, London*
4. *Building the Information Core - Implementing the NHS Plan, NHS Information Strategy, Dept. of Health (2001), The Stationery Office, London*

Data shows that the per capita spend on diagnostic testing in the UK is half of that in Germany and France in the area of viral disease, and less than a third in the area of cancer.



The Public and Professional Relations Steering Group

During 2001 the P & PR Steering Group has continued to expand its network of contacts amongst organisations representing patients and particular healthcare interests, and, through the parliamentary group, the 'corridors of power'. We have been involved in the conferences of the BMA, NHS Information Technology, the Institute of Healthcare Managers, National Association of Primary Care, NICE, and both the ACB and the IBMS conferences. In conjunction with the Patients Association, and sponsored by Dr. Ian Gibson MP, BIVDA held a major conference for a wide ranging audience in Portcullis House, which is reported in detail on page 8.

BIVDA has also played a significant role in the European Diagnostics Manufacturers Association (EDMA) Public Relations Working Party, securing European funding to support UK efforts.

The dynamics of the UK healthcare system, with the advancing implementation of the NHS Plan, not only provides our diagnostics

industry with the opportunity to take a central role in the provision of health, but also puts the UK in the spotlight of those interested in health reform across Europe. The Public and Professional Relations Steering Group continues to invite anyone who shares the vision of patient-centred health, utilising the proven benefits of the timely and accurate use of diagnostics, to join it or its working parties in the coming year.

I would like to thank the many enthusiasts from industry, the healthcare professions, patient support groups, and government bodies who have made the work of this group so rewarding during the year 2001.



Andy Bufton
(Chair)
Abbott Diagnostics

DISEASE CAMPAIGNS

Osteoporosis

Osteoporosis remains a major public health problem. The cost of treating and managing fractures in the UK exceeds £900 million per

year and with an ageing population this figure is expected to rise sharply over the next few years. Osteoporosis can be easily prevented if found early enough and the BIVDA working party has produced a position paper and associated diagnostic paradigm for finding those patients most at risk from the condition.

Although well received, we have reached a point where only a major change in the way the primary care sector screens for risk and manages patients with low bone density will enable us to develop our ideas further. We plan therefore to organise a meeting to discuss diagnostic strategies for osteoporosis in 2002 and to galvanise the healthcare community into using new diagnostic technologies for measuring bone health and to improve the management of this condition.



Andy Anderson
(Chair)
Crawford Medical



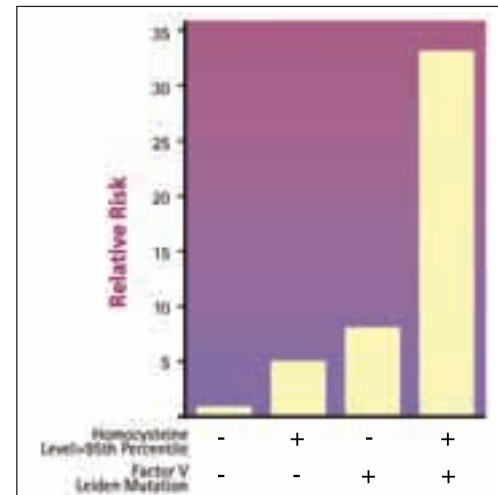
Heart Disease

The fourth in the series of BIVDA position papers focussing on coronary heart disease (CHD) was published early in 2001. The position paper stressed the huge drain that CHD represents to the UK economy, costing around £10 billion pa, or around a quarter of the annual NHS budget. Although CHD accounts for over 40% of deaths, mortality is

beginning to decline as we recognise risk factors associated with the development of cardiovascular disease and how to address them. In its white paper entitled "Saving Lives: Our Healthier Nation" the government has set itself a goal of reducing mortality and morbidity from CHD by two fifths by 2010.

It is BIVDA's contention that the multifactorial nature of CHD lends itself to screening for conventional and newer risk factors, with the use of algorithms to quantify overall risk. As well as conventional CHD risk factors, newer markers, such as low level CRP, homocysteine and improved indicators of lipid status rather than the traditional total cholesterol, are now being used to improve early identification of risk. The interaction of risk markers is important. Figure I shows how risk is multiplicative if plasma homocysteine levels are raised and an individual has the Factor V Leiden mutation.

Figure I



The association, and the working party in particular, will continue to seek to encourage the government and healthcare professionals to increase the use of diagnostic tests for CHD risk, particularly in primary healthcare. Education of the whole population is key in this task and ultimately tests will be developed for use by the general public as responsibility for health shifts to the individual. The group will continue to develop these themes over the coming year, and will also seek to address immediate care diagnostics in acute coronary care.



George Zajieck
(Chair)
Axis-Shield

Diabetes

Many important issues relating to diabetes received prominence in 2001. These included the ongoing development of the National Service Framework for Diabetes, with members of the working party consulting with government officials concerning both the evidence-base upon which it relies, and its implementation. There were issues

associated with SIGN and NICE guidelines, and the ever-present matters of regulatory changes and the workings of the drug tariff.

A key example of the benefits of the appropriate use of diagnostics, supported this year by the publication of a number of important journal articles, diabetes is often to the fore in presentations carried out by BIVDA members. With a significant number of the population undiagnosed, and the potential to make improvements in quality of life and long term budgetary savings by early detection and treatment, Diabetes offers the government a perfect example of the expectations raised by the NHS Plan. The Diabetes Working Party will endeavour to see that the role of in vitro diagnostics is fully appreciated by healthcare decision makers, and embraced by those responsible for implementation of the 21st century health service.



Andy Bufton
(Chair)
Abbott Diagnostics

Parliamentary Group

Following on from 2000, the BIVDA Parliamentary Group (PG) has continued a high level of activity, focusing on the primary objective to increase the awareness of governmental bodies regarding the clinical and cost utility of in vitro diagnostics.

During 2001, members of the PG have held a number of briefing meetings at Westminster with MPs from all political parties. The message has been well received and meetings have been held on more than one occasion based on requests for continued dialogue. As a result of these meetings, researchers have approached BIVDA for material on diagnostics related to specific areas of healthcare. Further to those meetings, BIVDA was recently invited to an inaugural meeting of the Cross Party Health Forum to be held in January 2002.

2001 was a year of consolidation, to build on the success of 2000. Many of the initiatives were repeated. For example, the quarterly diagnostics newsletter was mailed to a database of 150 MPs with an identified interest in healthcare, a reception was held in the House in June and in keeping with the

strategy to foster stronger relationships with patients' groups, a conference was held at Portcullis House in November.

Clarity of message to the government is an important pre-requisite if BIVDA is to achieve the goals and objectives of its member companies. In formulating healthcare policy, the needs of patients' groups are thoroughly researched. The PG therefore identified that, as a group, it needed to understand the priorities of those groups and identify opportunities for joint activities.

More than 20 patient groups were targeted in the initial phase and members of the PG had meetings with representatives of those groups. This initiative was supported by EDMA matched funding and was an extremely successful part of the PG agenda for 2001. In particular, the PG focused on two main groups: the Patients Association, which has developed a very strong media presence and governmental links and the Men's Health Forum which has a particular interest in prostate cancer screening and chlamydia.

The November conference "Diagnostics - The Best Kept Secret In Healthcare" at Portcullis

House was well attended, with over 100 delegates representing the professions, several patient groups, DoH, DTI, MDA, ACB, IBMS, media, member companies and also 15 MPs, some of whom were members of the Select Committee on Health (*see report on page 8*).

Key Message for the 2002 Campaign

The BIVDA PG will continue to maintain the level of dialogue with MPs. BIVDA has been invited to submit a subject for investigation by the Health Select Committee related to the uptake of diagnostics. The key messages for the forthcoming year, can be summarised thus:

- Managing the introduction of new tests at local level should be changed to that of a nationally driven strategic health resource
- Clear cases can be made for greater use of appropriate in vitro diagnostics, which can be shown to be cost-effective when appropriate



health economics questions are asked.

Yvonne Parker
(Chair)
PerkinElmer

Market Audit Working Party

There are a number of reasons why accurate data on the UK consumption of clinical in vitro diagnostic products should be gathered and made generally available. Perhaps of the greatest significance here is the need to be able to back up arguments presented to healthcare decision makers about the value of diagnostic tests and the extent to which they are being used or adopted.

We all know that the expenditure on IVD reagents and systems is a tiny proportion of healthcare costs, but we should be able to demonstrate correlations between the adoption of new tests and improved outcomes. We cannot do that unless we can measure relevant parameters such as tests performed or kits purchased or sold. In addition to this, there is value to member companies themselves of good market data independently obtained, and there may be value to our customers as well, who are not always aware of how testing trends in their laboratories reflect national trends towards or away from particular tests. Apart from these arguments, an industry that is not confidently able to present statistics on its own size and composition can hardly expect to receive

serious attention or help from government.

In some countries published statistics are readily available, but this is not the case in the UK. BIVDA has consolidated detailed sales data from member companies for some years now, using the services of an independent auditor to maintain company confidentiality. This data has been made available as six-monthly reports to member companies, enabling them to see market sizes and trends at any level of detail from the UK total sales of IVD products to sales of a specific test. The Market Audit Working Party (MAWP) has also examined the raw statistics and estimated the value of sales for companies who have not contributed to the survey, in order to produce estimates of the total market and of major segments (e.g. immunochemistry, haematology, clinical chemistry). These estimates are submitted to EDMA and form part of the European statistics that are published bi-annually.

In the last three years the number of IVD companies submitting UK sales data has declined significantly (more than is accountable for by mergers and acquisitions), and the delay in receiving submissions has lengthened. The MAWP commissioned

research during 2001 to discover why this has happened, to examine ways in which the value of the report to member companies could be increased, and to see how the extraction of data into a form for submission could be made easier. We hope to have proposals early in 2002.



John Bagshaw
(Chair)
bioMérieux UK limited

Regulatory Affairs Working Party

The IVD Directive got off to a very slow start last year, primarily because there were very few Notified Bodies available. The CE marking process is now starting to gather momentum as more and more companies start to CE mark their products. As the legislation now begins to bed in we are also experiencing the first implementation issues.

Registration

At the start of the year companies experienced difficulties in registering products in Sweden; however, this appears to have been quickly

resolved following discussions with the Competent Authority. Companies continue to have problems registering products in France according to article 10.6. This is the measure introduced in the absence of the European database for companies to copy their registration to all member states where the product is sold. Both registration problems related to the request for addition forms to be prepared, above and beyond those required by Article 10 of the Directive. The European database is being redesigned and is unlikely to be available during the coming year so we will continue to encounter these problems for some time to come.

EDMA have produced some excellent guidance to help companies through the registration process.

Common Technical Specification (CTS)

The CTS is one of the corner stones of the approval of Annex II list A products. Whilst the initial drafting of the CTS was a rapid process, the subsequent revision and approval have taken much longer than expected and the final version is still not formally published through the Article 7 Committee of the Commission. This is primarily because the CTS are a new feature

of new approach directives; as a consequence there is no clear process for approval, which leads to delays. Notified Bodies are fortunately operating to the draft CTS in the absence of the final version enabling Annex II products to be approved. As Annex II products become approved so the process of batch verification has begun.

Notified Bodies

As previously stated the IVD Directive got off to a slow start due to the shortage of designated Notified Bodies. The UK now has three Notified Bodies, two of which have broad scopes including Annex II products. These scopes are continuing to expand and can be found on the Medical Devices Agency (MDA) website. The designation process within the UK was very thorough and the process took longer than many anticipated.

Labelling

Conquering the labelling challenges presented by the IVD Directive continues to be a topic of interest to many companies. This year has seen the amendments to the European labelling standard delayed and vigorous discussions about the use of alternative means to provide instructions for use by electronic means such as CD-ROM.

Each manufacturer has to find their own solution to meeting the language requirements introduced by the majority of member states through their national transpositions.

Foot and Mouth and TSE

The incidence of transmissible spongiform encephalopathies (TSEs), which includes BSE in animals and vCJD in humans, was the subject of a Cambridge meeting in February 2001, organised by the MRC on behalf of UK public funders of TSE research (BBRSC, DoH, FSA, MAFF and MRC). The meeting was attended by Kit Madden (President of BIVDA) and the chair of the meeting was Sir John Pattison, then R&D Director of the NHS. The conclusions relating to vCJD emphasised the complexity of the disease and the extent of the work still to be done, particularly the urgent need to accelerate the development of new, non-invasive tests. The wide implications for animal health, food chain issues and human health are causing increasing concern. International requirements for regulatory documents relating to TSEs are becoming increasingly demanding and causing considerable difficulties for IVD companies involved in the manufacture and export of products

derived from animal based raw materials.

The outbreak of foot and mouth disease (FMD) in the UK has further highlighted the problem and caused many regulatory issues, which required a quick resolution to enable products to be exported. In addition to the foot and mouth crisis many countries have introduced new legislation relating to the risks raised by TSEs. This resulted in problems with the export of product to countries such as Egypt and Turkey. Members of the Regulatory Affairs Working Party (RAWP) shared information to enable best practice to be quickly established and allow shipments to move more easily.

Forthcoming Regulations

The coming year will continue to see the change and expansion of regulations. The UK will shortly publish a new statutory instrument, which will address the whole family of Medical Device Directives in one document as well as introducing the legislation for the Mutual Recognition Agreements (MRA) with the USA and Canada.

Other countries are introducing new or updating old legislation, which applies to

this industry including Canada, Japan and Australia. In addition we are seeing an increased emphasis on environmental legislation it is anticipated that this will become increasingly important in the coming years and may even become required in the same way as ISO 9000 to win tenders.

The RAWP will continue to work hard to discuss and disseminate these changes during the coming year.



Sue Spencer
(Chair)
Cascade Consulting

Point of Care Forum

As a rapidly expanding sector within diagnostics, point of care testing needs careful monitoring as distinct actions may need to be taken in the future. The Point of Care Forum has been created as a special interest group within BIVDA since there is not at present any clear objectives for a working party to pursue.

The inaugural meeting of the Point of Care Forum was held on 14th November 2001 at the new ACB offices in Tooley Street, London. This was a well-attended meeting which initiated discussions during the day among the members of BIVDA with business interests centred on point of care testing. The forum was also well attended by members of the ACB, which illustrates the raised profile of point of care testing within this profession.

The forum opened with a presentation by the former chairman of BIVDA, Andy Anderson, who discussed "Point of Care - Opportunity or Threat?" Lawrence Robinson from the Wythenshawe Hospital then went on to explain the role of a point of care co-ordinator within an NHS trust, and the

concerns that point of care testing may bring to the pathology department. Introduction of point of care technology brings the associated problems of financing new equipment, and the commercial aspect of how this could be funded was presented by David Rose (Medical Equipment Finance Ltd). Annette Thomas from WEQAS produced a comprehensive overview of running external quality assurance (EQA) on a point of care diagnostic with her presentation on maintaining quality control beyond the glucose meter.

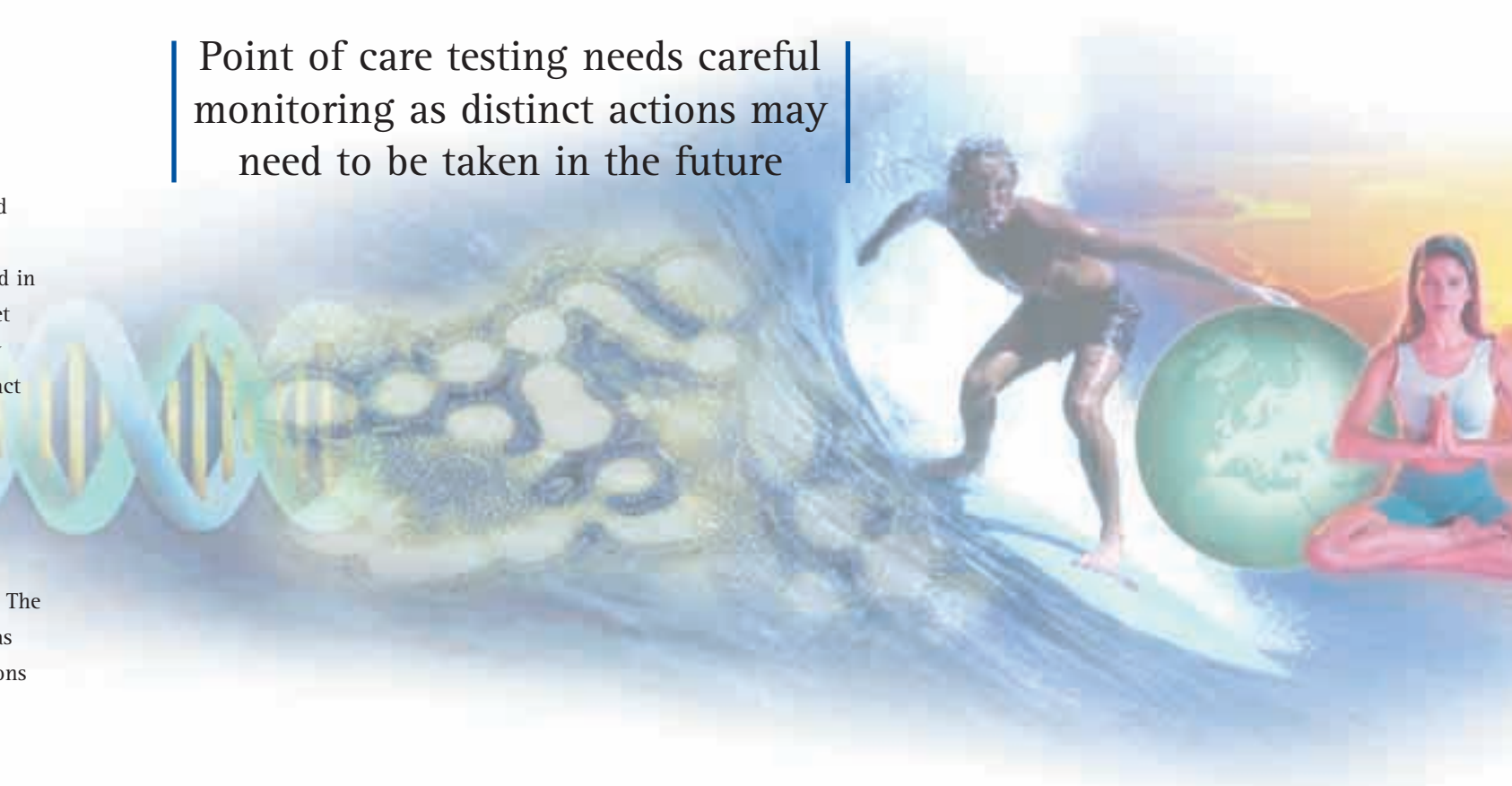
The issue of quality management was expanded further by Doug Hirst, Bradford Royal Infirmary, talking on how quality control can be managed and users trained in the hospital environment. As a high street pharmacist from Nottingham, Caryl Kelly was able to disclose her view of the impact point of care testing will have on her business in the future. The very full programme was concluded by Paul Weinberger of Roche Diagnostics with a though provoking topic "We can ask the questions, but can we find the answers?" The wide-ranging agenda for this meeting was well received, with some in-depth questions fuelling debate.

A second forum is planned for late spring 2002 and it is anticipated that the outcome of these two meetings may well provide a framework to resume a structured working party later in the year.



Bill Cunningham
(Chair)
CDx Ltd.

Point of care testing needs careful monitoring as distinct actions may need to be taken in the future



How does Membership of BIVDA Benefit a Large Company?

Beckman Coulter has been an active member of BIVDA since its inception and has seen considerable growth in the service it offers its members. Of particular significance is the recognition for the diagnostics industry it has gained from outside sources, including the various agencies within the NHS and other government departments. Additionally there has been a much more active role in European IVD regulatory issues and for all diagnostic companies wishing to provide a quality orientated service, this is becoming increasingly important.

Perhaps inevitably along with these very positive developments has come an increase in membership fees. Diagnostic companies of all sizes have budget constraints and where we spend our money must always be seen to generate 'value'. Membership fees are scaled according to company turnover. For some of the larger companies, such as Beckman Coulter who already have many of the resources offered by BIVDA available internally, justifying the relatively higher membership fees is as much an issue as it is to a smaller company that may not have the in house resources (and therefore would, on the face of

it, gain more for their lower subscription). In many respects the scaled membership fees must be seen as a protection of investment with larger companies investing more to augment their larger turnovers.

Strength in numbers is one benefit when addressing NHS or government departments to make representations for changes or concerns with upcoming legislation.

Additionally, although we may have the contacts ourselves within the NHS it is not always appropriate to be the sole name behind any direct criticisms of the NHS so having a trade association that can take these issues forward with the relevant departments will protect any delicate relationships and also add strength to the argument if BIVDA is able to say that many members have the same problems.

Working with the Purchasing and Supply Agency (PASA) is a very good example of the difference a united voice with one message can make, we have made significant inroads into standardising tenders and terms and conditions that will save both industry and the NHS considerable sums of money.

The active involvement with several working

parties that have relevance to our business has proven to be advantageous in at least two ways:-

1) When introducing a product into what is a new market segment for them, e.g. coronary heart disease. Membership of the appropriate working party enables a quicker and better insight into this sector, which means market penetration can be achieved faster and more cost effectively

2) The Parliamentary Campaign has really brought to the attention of many MPs the "difference that diagnostics can make", and we believe this will ensure that IVD is no longer the easy target for cost cutting but an area that if utilised correctly can bring cost benefits to all

In summary, like so many things in life, the more you partake of any activity the more you gain from it, so whether you are a small growing business or a larger established operation I would encourage you to be as



active a member as you can in order to maximise the opportunities that BIVDA offers.

Brian Fishwick, Beckman Coulter

How does Membership of BIVDA Benefit a Medium-sized Company?

When Randox were approached to write an article for this year's BIVDA annual review we were faced with quite a challenge, outlining the key advantages of BIVDA membership in only a few hundred words!

After several years involvement with BIVDA the benefits derived from our membership can only be described as both diverse and far-reaching. From the arrival of the monthly newsletter to feedback from BIVDA's latest lobbying results, BIVDA provides a central link to news and developments within the in vitro diagnostic industry. Randox, from their headquarters in Northern Ireland, takes full advantage of the services on offer; from marketing to regulatory affairs. BIVDA is a vital resource offering valuable information, which is only a phone call away.

With the conception of the new IVD Directive and the importance of accurate CE marking, unlimited contact with BIVDA has been essential. One to one with BIVDA and our inclusion in an industry-wide mailing list offers our regulatory affairs team information and advice that can only be described as 'excellent'. BIVDA represents our interests at national

exhibitions, which are not always core to everyday product sales but are increasingly important to raise the awareness of clinical diagnostics as an important resource. Meeting our 'cousins' in related areas of healthcare (BMA, RCP, NPA) is time consuming, expensive but vital for the future of this industry.

If persuaded to name the most beneficial aspect of our BIVDA membership it would be the formation of an industry-strong collective voice with those who, although competitors in business, are allies in our increased determination to grow and develop this industry through knowledge and awareness of the true value of diagnostic information.

Like many other BIVDA members, at Randox we believe that the relationship we have with our industry representative is a two-way relationship and we should therefore not only ask what BIVDA can do for the industry but what we can do for BIVDA. It is only with the full and active support of members that BIVDA will be able to deliver results.

To help improve the effectiveness of our NHS healthcare professionals, Randox are organising a principal symposium at this year's national meeting of the Association of

Clinical Biochemists, FOCUS 2002. Entitled 'Laboratory Medicine: Benefit or Burden', the symposium will address the major problem of hospital waiting lists through the examination of the benefits of disease prevention, earlier detection and more efficient disease management - a solution that may be made possible through the full utilisation of laboratory medicine as a resource. With the NHS laboratory, policy makers, patients and the government represented the symposium provides the perfect opportunity to present the often-neglected benefits of laboratory medicine. The main objective of the symposium lends itself to the entire industry, namely lobbying government at the highest level into appreciating why pathology laboratories should be regarded as a resource and not as a cost centre



Clem Fitzgerald
Randox Laboratories Ltd.

How does Membership of BIVDA Benefit an Small Company?

Omega Diagnostics is an SME company based in Alloa, Scotland where we have been manufacturing infectious disease assay kits since 1987. We have now extended our product range to include cardiac tests under the brand name of Cardiopath and have 40 employees.

Omega joined BIVDA in 1995 as we believed, and continue to believe, as a British IVD manufacturer, that BIVDA is the right association to represent our needs and act as the voice for the IVD industry (even though the UK market accounts for only a small portion of our revenue as the majority of our sales are in export, chiefly in Asia and South America).

Being based in Scotland, and of relatively few in number, means that it is difficult to attend regular meetings and gain the whole value of what BIVDA can provide. We clearly recognise that the old maxim 'you only get out what you put in' certainly applies to belonging to a trade association and we hope to be able to participate increasingly in the future. So we were delighted when the venue chosen for the last IVD seminar held during October was

Edinburgh! Omega was able to send three delegates to benefit from the information and advice on offer whilst also taking advantage of the networking opportunities with other companies. We would certainly welcome more regional meetings as demands on time make it difficult to attend meetings held in London.

We have also been interested to hear about the way BIVDA has been raising the awareness of diagnostics at government level through the parliamentary lobbying campaign and would be keen to be involved with similar activities north of the border in the Scottish Parliament where we already have some connections.

We look forward to taking further advantage of the services BIVDA membership can offer both ourselves and other companies. In addition we would urge any company in the IVD business to join in order to maintain a strong, cohesive body of influence to represent our requirements as an industry within both the UK and the European Union.



Andrew Shepherd
Omega Diagnostics Ltd.

Income during 2000 was £282,219, a decrease of £6,027 (2%). During 2000 we received our final "Sector Challenge" funding of £43,205. This funding has contributed a total of £143,138 since 1997. BIVDA seminars contributed over £43,000 and members' subscriptions totalled nearly £187,000. The percentage of income generated by members' subscriptions has remained virtually the same at about 63% over the past two years.

BIVDA seminars, particularly on the impact of the IVD Directive, have been well attended, attracting greater interest from overseas.

In the previous report it was estimated that the planned expenditure would for the first time exceed income during 2000. In reality our income exceeded expenditure by £3,000 and BIVDA's reserves increased to £211,159.

At the time of writing the final accounts for 2001 are not available but at the end of October (ten months) income at £282,275 had already exceeded the budget (£277,488). Member subscriptions have risen to £227,303, contributing over 80% of BIVDA's funds. This has been achieved through attracting new members and through an increase in the subscription fees, which we felt more adequately reflected the value and benefits of BIVDA membership. BIVDA has met the challenge of increasing the number

of membership subscriptions during 2001. The parliamentary campaign continues to play a major role in BIVDA activities and it has to be adequately funded for it to be effective. This campaign was a large part of the expenditure for BIVDA during 2001 and is predicted to be so on into 2002/3.



Geoff Gower
Treasurer BIVDA
DAKO Ltd.

BIVDA has met the challenge of increasing the number of membership subscriptions during 2001

Profit and Loss Account for the year ended 31st December 2000

	2000	1999
	£	£
Turnover	282,219	288,246
Net Operating Expenses		
Distribution Costs	(48,384)	(50,251)
Administrative Expenses	(238,841)	(167,518)
Other Operating Income	10,019	6,669
Operating Surplus	5,013	77,146
Interest Payable	(2)	(7)
Surplus on Ordinary Activities Before Taxation	5,011	77,139
Taxation	(2,004)	(1,419)
Retained Surplus for the Year	3,007	75,720

Balance Sheet as at 31st December 2000

	2000		1999	
	£	£	£	£
Fixed Assets				
Tangible Assets		3,945		4,371
Current Assets				
Debtors	49,132		43,668	
Cash at Bank and in Hand	222,310		182,186	
	271,442		225,854	
Creditors: Amounts Falling Due Within One Year	64,228		22,073	
Net Current Assets	207,214		203,781	
Total Assets less Current Liabilities	211,159		208,152	
Capital and Reserves				
Reserve Account	211,159		208,152	
Total Members' Funds	211,159		208,152	

What is BIVDA

The British In Vitro Diagnostics Association (BIVDA) was established in London in February 1992 as the national trade association for companies with major involvement and interest in the in vitro diagnostics (IVD) industry.

BIVDA represents the interests of the IVD industry in the UK at the European Diagnostics Manufacturers Association (EDMA), which in turn represents the IVD industry in Europe.

The membership of BIVDA currently represents over 90% of the industry. These members decide the general policy of BIVDA by voting at the annual general meeting and through the election of the executive committee members. BIVDA is governed by an executive committee, which consists of ten company representatives, elected from the membership. The executive committee assumes responsibility for formulating policy together with planning activities and services. Day-to-day running of the association is handled by a full-time secretariat, based in Central London, managed by the director general.

How do We Operate?

Representation

BIVDA represents its members on a range of national and international bodies, working parties and committees. These include the council and working parties of EDMA and BSI Standards Committees. In addition, we maintain specific contacts with the Department of Trade and Industry and the Medical Devices Agency.

International Promotion

Members' commercial interests are promoted internationally through a wide range of trade missions, seminars, trade fairs and conferences.

Information Services

Information on issues relating to in vitro diagnostics is gathered, summarised and disseminated through the newsletter, *BIVDA News*, and retained for reference. In addition, members have access to our in-house library.

Public Relations

BIVDA regularly provides information on the role of in vitro diagnostics for industry-specific media, general media, exhibitions and educational material.

What are Our Aims?

BIVDA represents both manufacturers and distributors who are active in the UK. All IVD companies, irrespective of their national origin, operating in the UK are eligible to become members and to nominate individuals for election to the executive committee or to have representatives on the working parties.

Mission Statement:

“To promote the role of IVD in healthcare and to meet the needs of the UK diagnostics industry through representation and professional services.”