Special Edition

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insight

The magazine of the **Pharmacists' Defence Association**

- *Poor Working Environments*
- *No Rest Breaks*
- *Bad Law*
- *Custodial Sentences*

Enough is Enough!

The PDA plan

Chairmans Letter

Prison sentence for dispensing error

Mark Koziol, Chairman, The PDA

In April 2009 Elizabeth Lee appeared at the Old Bailey to be handed a three month suspended prison sentence and twelve months probation for putting a label intended for prednisolone onto a packet of propranolol instead.

The elderly lady who took a single dose of the wrong tablets, died of natural causes several days after the dispensing error was spotted and rectified. In handing down the sentence the judge explained ;

> "Mrs Lee, you bear no factual or legal responsibility for Mrs Sheller's death and you are not being punished for that.
>
> You are being punished for an offence under the 1968 Act which carries a maximum sentence of 2 years in prison. The maximum is for the very worst case re misleading labelling. Your offence is very, very far from being the worst. It is nevertheless extremely serious as the public is entitled to the highest standard of care. That is why the offence exists."

There is a great deal about the detail of this case from which the profession must learn, however, because of Mrs Lee's appeal arrangements, it is not appropriate to provide a full analysis – that is yet to come.

This case raises concerns for all pharmacists but it also raises important public interest concerns.

Inappropriate use of the criminal sanction will lead to defensive practice; less innovation, fewer professional decisions and will harm new service provision. Surveys show that 40% of pharmacists may no longer be making error log reports for fear of incriminating themselves. At a recent meeting, MP's learned that some pre-reg's were now reconsidering their career choice.

All of these developments are bad news for the profession and the public.

The PDA's campaign to decriminalise workplace errors by pharmacists has been at pains to explain that the profession is not seeking to shirk its responsibilities in the event of a mistake. If a criminally negligent act is committed, then pharmacists should expect the application of criminal law. However, an innocent mistake is not a criminal act and this is true whether you are a pharmacist, doctor or plumber.

The public deserve to know that if they are harmed through a mistake, then there should be redress, but such redress is readily available in the form of civil action for compensation and professional disciplinary proceedings.

By putting the public interest argument first, we have been demanding a legislative environment that does not stifle practice, but one which fosters professionalism.

We have been consistently briefing senior government officials and others both in parliament and elsewhere and we have been gathering support.

We are therefore relieved that the MHRA has committed to consider changes to the 1968 Medicines Act, but this could take two years. It is therefore to the credit of the DoH Chief Pharmacist Keith Ridge, that he has agreed to take the lead on a PDA proposal which is to seek an accommodation with the Crown Prosecution Service so as to ensure that in the interim, while we wait for the law change, pharmacists making genuine mistakes in the workplace are not prosecuted for offences under the Medicines Act, but are instead, handed over to the RPSGB for professional investigation.

This is a huge step forward in our campaign, as it means that decriminalisation is in sight and in the interim a pragmatic solution is now to be discussed by the government and the CPS.

We will continue to press for an early and positive conclusion to these discussions.

There's more!

At a recent meeting in Westminster to discuss this matter, shadow minister for health Earl Howe called on the major pharmacy multiples to address the issue of pharmacists' working conditions. He accused Tesco, where Elizabeth Lee was working as a locum, of not accepting its share of the blame. He said:

> "The risk to the public comes not from dodgy pharmacists, but from potentially dangerous working practices. Tesco seems to be noticeably reticent in admitting that they may have had some contribution to the error that occurred."
>
> "When a pharmacist is made to work regular 10-hour shifts, you cannot put the entire blame on that one individual. Supermarkets and major pharmacy employers cannot wash their hands of the health and safety implications which their pharmacists are subject to."

We are now ramping up our campaign and are speaking to more influential politicians about the broader issues involved in pharmacy practice.

We demand a working environment and practices that are more conducive to patient safety. These are not new themes from the PDA, but, what is different now is that the events of the last three months have created some unique circumstances and a momentum which we can use to make significant progress.

We owe it to ourselves as pharmacists and as a profession we owe it to the public.

This magazine describes our campaign so far and describes its planned trajectory, we earnestly invite you to join us in this important task.

Visit our website **www.the-pda.org**

The Campaign

At the PDA, we seek to extract many pharmacists from difficult situations that they have already found themselves in, however, we believe that it is much better to prevent our members from getting into these situations in the first place.

If we are to avoid what happened to Elizabeth Lee from ever happening again, then it will be important to take the wider view. Only then will it be possible for us to develop a plan that can be both proactive and reactive.

The whole profession is shocked about the prospects of a custodial sentence being given to a pharmacist for making a single dispensing error. To this end the PDA has robustly stated its opposition to the criminal sanction being used to punish pharmacists for making mistakes in the workplace. We believe that pharmacists should be treated no differently than are other healthcare practitioners. In those cases, once any criminal behaviour has been excluded from initial police investigations – such as gross negligence manslaughter, assault or Health and Safety offences - then the entire matter is handed to the professional regulator so that their investigation can take over.

Not so in pharmacy however, where once an investigation has excluded serious offences, the Crown Prosecution Service have used lesser offences in the 1968 Medicines Act as a sort of 'default prosecution mechanism'.

Equally we have stated that pharmacists should not have to face a hostile legislative framework that leads to defensive practice as this will not be in the public interest.

Prevention is much better than cure

These are relatively straightforward arguments and ones that are also being used by the RPSGB. We are pleased that after much intensive lobbying an early result has already been realised and the commitment of the government to make the necessary changes to the law has been secured. However, we must ensure that we do not merely address the reactive nature of what has occurred by being interested in only the narrow view. We must not waste an excellent opportunity to take action across a much wider front so as to deliver changes in pharmacy practice for the benefit of patients and pharmacists.

This may be a harder campaign to pursue, but it is a campaign to which the PDA commits.

Taking the wider view to secure more benefits

What happened to Elizabeth Lee happened because she made an error at work. Consequently, as well as keeping up the pressure for decriminalisation, the PDA will be pressing for practical safety improvements in the dispensing process and working environments for pharmacists that are more conducive to patient safety. We must put an end to the practice of pharmacies being so short staffed and under-resourced that they are a disaster waiting to happen. We must create a legislative environment that encourages innovation, professional decision making and greater participation in a national error reporting programme.

By focusing on patient safety, we can link this campaign to other examples of questionable legislation such as the current Responsible Pharmacist regulations and in particular, to Remote Supervision - the plan to operate a pharmacy in the absence of the pharmacist. As pharmacists we know that this idea is neither in the professions nor in the public's interest. If we undertake this exercise properly, then this could lead to significant improvements in pharmacy practice that will be good for the profession and the public alike.

"we can link this campaign to other examples of questionable legislation such as remote supervision"

We appeal for the support of all pharmacists

What we do know is that if we are to be successful, then we will not only need to organise a sophisticated and sustained campaign, but we will also need to work with numerous pharmacy and non pharmacy organisations – in this respect, already much has been done and a degree of success has been achieved. Most importantly, when it becomes necessary, we will need to enlist the support of pharmacists at specific junctures of the campaign. Whether this be for writing letters to constituency MP's or elsewhere, by putting pressure on the RPSGB or by signing petitions, your involvement will be pivotal to the overall success.

We hope that you can support our campaign and we outline our plans;

The two elements of the Plan

1. DECRIMINALISATION

Two priorities exist;

a) Amending the law.

The Medicines Act is currently subject to a substantial and wide ranging review, which is being undertaken by MHRA. This represents an opportunity for substantial change and is our best chance to effect some wider changes which will be even more beneficial than addressing decriminalisation issue only. The good news is that we already know that the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA) is sympathetic to the decriminalisation concept. However, because of the two year delay before the MHRA review completes its journey through Parliament, it will be necessary to keep this issue alive for that period. Consequently, it will be important to ensure that pharmacy can keep the pressure on in the longer term. What we must avoid is a concentrated burst of short term noisy publicity stunts – what we are committing to at the PDA is an intelligent and sustained campaign. This will involve the use of continual briefings of the relevant politicians and others and also participation in any relevant regulatory consultations. We are already working with partners on this matter. We are aware also that other pharmacy organisations have tactics in place and where appropriate we will seek to support these so as to maximise their effect. When we come to call on members to participate at specific junctures we will provide several bullet point arguments and ask that members pick only some of the points from the list and turn them into personalised letters. We feel that this approach will be much more effective than the use of mass produced standardised letters which are merely signed and mailed by pharmacists as this approach could damage campaign credibility.

At the appropriate moment we will also deploy PDA locum membership group member Graeme Stafford's petition which has now attracted more than 12,000 signatures.

b) Altering the application of the law

Following on from the deaths of babies at the Bristol Royal Infirmary in the 90's, and other healthcare scandals, the Home Office sent a directive to all UK Chief of Police Officers suggesting that they should investigate any deaths involving healthcare practitioners as potential gross negligence manslaughter offences. Sadly, in pharmacy, having first 'got their teeth' into a pharmacist in an initial manslaughter investigation only to draw a blank, the police are still able to keep the prosecution of a pharmacist alive by turning to the Medicines Act. This has generally been the pattern which has led to all police instigated Medicines Act prosecutions in the last decade. This has led to pharmacists being treated unfairly, inconsistently and entirely unnecessarily by the criminal justice system.

The Crown Prosecution Service

The PDA campaign has sought a reversal in this default policy and this will need to be done by reaching an agreement with the Crown Prosecution Service. It is not feasible, to seek a complete change to the original Home Office directive, but we have called for a new interim protocol for the Crown Prosecution Service (CPS) which needs to be put in place urgently whilst the Medicines Act is in the process of being amended. The proposed interim protocol will need to ensure that once any Criminal Negligence Manslaughter proceedings have been excluded (as in the Elizabeth Lee case) then no further criminal proceedings under the 1968 Medicines Act are continued. Instead, we are asking that the Police hand the entire matter to the RPSGB so that it can be handled as a professional disciplinary matter. This is consistent with what happens with other healthcare professions in similar situations. We are pleased that the Crown Prosecution Service has now agreed to consider new and more appropriate protocols. We are encouraged that in June 2009 the Department of Health and the MHRA have agreed to lead these discussions with the CPS. These developments are very helpful and we will continue to express the importance and press for an early resolution to this specific matter.

"We are asking that in future, the Police hand these matters to the RPSGB"

2. A FOCUS ON PATIENT SAFETY

We believe that at the current time, working environments and their impact upon patient safety stand a much better chance of being taken seriously by the relevant authorities.

Furthermore, the patient safety argument will be an excellent way to involve patients and members of the public. In our current dealings with the national media over this case, it is clear that they are far more positive about a patient safety issue approach than they are about a decriminalisation debate as some of them see the sole prospect of decriminalisation as a potential dilution of public protection.

By contrast, a campaign which focuses on patient safety is relatively risk free. The arguments are good news for pharmacists and patients alike as the list of matters that are relevant to this include; proper staffing levels, rest breaks, manufacturers packaging, bar code checking devices, the greater clinical input of the pharmacist, remote supervision and

Responsible Pharmacist.

Staffing levels and rest breaks

We are tired of hearing about the large number of occasions where pharmacists are working under pressure with either insufficient numbers of staff or staff that are inadequately trained. Furthermore, we also know that many pharmacists are required to work for long periods without breaks simply because the employers do not want to run the expense of providing pharmacist cover.

We have brought these concerns to the attention of parliament and we are gathering support from key influencers.

Lack of rest breaks in pharmacy have now become a matter of such concern in parliament that senior politicians have suggested that this practice is bad for pharmacists and the public alike. We believe that the modern retail pharmacy working environment which militates against rest breaks has effectively brought the profession into disrepute.

What is now needed is concerted action across the entire profession and also a nationally agreed approach to developing appropriate staffing systems and rest break policies.

We developed a resource pack in 2006 that provides pharmacists with the practical tools to handle these two matters. However, at the time it received neither support from the RPSGB nor any interest from any of the pharmacy bodies – not so now! The PDA's ideas on how to secure and manage staffing levels and rest breaks were the main development considered by a pan pharmacy conference at the RPSGB's workplace pressure conference which was held in April 2009. This conference involved representatives from all sectors of the profession, employers, employees, the RPSGB, academics and others. We have updated this resource tool and urge all in pharmacy to use it, as it will help to alleviate the workplace pressures. Pharmacists wanting a copy can download it from www.the-pda.org.

Error log reporting

Research estimates that there are approximately 20,000 dispensing errors in just England and Wales per month – that is almost 250,000 in a year in the community setting. And yet, the NPSA receives only 3,500 dispensing error reports from community pharmacy per year!

A significant proportion of these are reports which have been initially processed by some employers and they seem only to be reporting the low level incidents. This severely limits what the NPSA can achieve.

The PDA has always advocated the need to learn from mistakes, this can only be done however, if these mistakes can be reported centrally and studied nationally so that the whole profession can learn.

What appears to be the pattern on the ground is that most employers use this information internally. Others use the information gathered to exact discipline upon the pharmacists involved. Worse still, PDA has dealt with cases where the RPSGB inspectors have trawled through error logs, for purposes of taking down the particulars of pharmacists involved in errors and this information is then used in Fitness to Practice investigations.

To add to all these problems, one natural consequence of the Elizabeth Lee case is that as it stands currently, pharmacists may consider that an error log entry is tantamount to providing incriminating information which could lead to a criminal prosecution.

Consequently, we are unsurprised at the results of an RPSGB survey which show that more than 40% of pharmacists may now no longer make error log entries.

The PDA position on this however is based on the experience of knowing that in many civil and professional cases, we have been able to extract our members from sanctions because we have been able to show that a contemporaneous written record of an incident was made at the time, whereas the complainant and/or claimant had no such written record. In the case of when errors are fully admitted, you need only to study the judges remarks in the Elizabeth Lee case to know that despite the draconian sentence that he handed down, he gave her credit for doing all of the right things once the error had been discovered. He recognised that she made an error log report and had she not done so, he may well have treated her even more harshly.

As a result, we urge all pharmacists to participate in error log reporting and we call upon all employers to re-double their efforts to use these logs to improve practice and not as a disciplinary tool. In cases where discipline is used, we will stand four square behind members and support them. We also urgently call on all employers to send their data to the NPSA – as patently, they are not doing this currently.

We have also written to the RPSGB and have challenged them on their use of error logs to support Fitness to Practice investigations. They deny that they do so, but our experiences show that this has been a practice used.

The PDA e-error log

Although we recommend that error reports are made in the pharmacy, we know that this will not always happen. It is equally frustrating that the NPSA receive such a low percentage of error notifications. We believe that it is necessary to provide additional options for purposes of recording errors.

The PDA is shortly to release its own version of an e-error log, which pharmacists will be able to access on-line so as to record their error report. Entries made in this way, will be protected by legal privilege and will not be accessible to the prosecution side as evidence in all but the most exceptional of circumstances.

It is important to note, that whilst this system will produce a protected confidential error log, if it is used without any entry being made in the employers systems, then this may result in a potential conflict with an employer, if the requirement to make a work-place error log appears in the employers standard operating procedures. However, the PDA tool could be a useful

adjunct enabling pharmacists to leave a much more detailed error log with the PDA, than they might contemplate with a workplace log. It will also be useful to those who find themselves in a pharmacy where there appears to be no readily accessible error log system in place.

The other plus point, is that any errors reported on the PDA e-error-log system will be anonymised and sent on to the NPSA so as to support the national learning experience.

It is important to note, that when any error occurs, pharmacists should consider what learning results and what changes should be put in place in the pharmacy to prevent a repetition.

Use of technology to improve the accuracy check.

If a tin of tomato's is purchased in Tesco's then bar code scanning technology is probably used at the checkout. However, in the pharmacy, where medicines capable of curing or harming patients are supplied, such technology is rarely used to support the pharmacy operation.

There is another factor at work here, if the accuracy check in the dispensary could be supported by appropriate levels of properly trained staff and also bar code technology, then pharmacists could be primarily involved in a role that only pharmacists can undertake which is the direct 'face to face' clinical interaction with the patient. Currently, this is a scenario that is rarely seen in many pharmacies simply because of detrimental staff and resource implications. As a consequence, pharmacists are currently expected by their employers to be involved in both roles, but with little or no consideration as to feasibility. This in turn has a knock on effect, with pharmacists unable to support developments like MUR's and enhanced services because there is

no staff support available to release them.

Some, forward thinking pharmacies already make use of such technology in the dispensary and we will now be campaigning for its wider introduction to enhance patient safety and to enable more pharmacists to focus on roles for which they are uniquely qualified.

Had this approach been available in the Tesco pharmacy where Elizabeth Lee's error occurred, then this may have been avoided.

Responsible Pharmacist and Remote Supervision

The introduction of the Responsible Pharmacist provisions was all about increasing the personal accountability of the pharmacist in the pharmacy. However, these regulations have been poorly thought through and show a significant lack of insight into some of the most basic tenets of pharmacy practice, employment and health and safety legislation.

"A pharmacy without a pharmacist will never be as safe as one with a pharmacist present"

The new regulations introduce numerous new professional sanctions and also, like the current 1968 Medicines Act, some more criminal consequences. The debate around the RPSGB's Responsible Pharmacist toolkit puts this confusion into stark relief and it is clear that now that they are imminent, the Responsible Pharmacist proposals are causing significant consternation amongst pharmacists. As a consequence, far from delivering enhanced patient safety, the proposals risk causing significant upheaval and this could cause substantial problems for patients especially in the community setting.

The PDA has raised concerns about these proposals ever since they were first announced four years ago. However, when expressions of concern raised by the PDA finally reached the Houses of Parliament, Department of Health spokespersons were able to pacify the house by explaining that they were working closely with the professional body and also that the government would never push to implement the proposals faster than the rate at which the profession wanted to go. We believe that had it not been for the Society's acquiescence to these policies, the Responsible Pharmacist regulations would not have resembled the current offering, the start date would not be October 1st 2009 and the plan to operate a pharmacy in the absence of a pharmacist (remote supervision) would never have even left the drawing board.

In light of the Elizabeth Lee case, the liability and safety concerns that had previously been expressed by the PDA and had been ignored – must now be carefully reconsidered.

In 2010, the Society will become a voluntary body and it is currently seeking to champion more membership friendly policies. We believe that it is not too late to change the plan and this is why we must now exploit the new 'eager to please' mentality at Lambeth in order to persuade the Society to do a U-turn on these matters. The RPSGB can have no credibility in claiming to defend the profession from the criminal consequences of a simple dispensing error, while it is a willing partner to a Department of Health programme which brings with it brand new professional and criminal sanctions.

A pharmacy without a pharmacist will never be as safe as one with a pharmacist present. This may be an inconvenient truth for the Department of Health, and a hurdle to a cost saving for employers in the pharmacy operation, but this is a standpoint that must now be adopted by the Society. If, as a profession we can deliver a much greater face to face involvement with the patient in the pharmacy through improved staffing levels and better use of technology, then the spectre of remote supervision and the reality of pharmacists being asked to leave the pharmacy goes away.

The Department of Health will find it difficult to argue its case in support of the remote supervision regulations yet to be laid in Parliament if the profession stands united against such a proposal. We believe that the RPSGB U-turn approach described represents a good opportunity to effect a halt – especially to remote supervision. Importantly, it also represents a good outcome for the public.

The PDA will be seeking to put pressure upon the RPSGB to change its position and we will be calling on all pharmacists to invite the RPSGB to join the PDA in its unwillingness to accept such changes.

Piling the pressure upon the RPSGB

A CALL TO ACTION – what can you do?

What we have described is a formidable and comprehensive plan of action, but it is one to which we are entirely committed. However, if we are to succeed then we will need to call on the support of many pharmacists. So what is it that you can do?

Firstly, this needs to be a sophisticated campaign which is largely about briefing, lobbying and securing the backing of powerful voices in parliament. We ask that you find a circle of friends that you can mobilise when called, to write letters, sign petitions or other. Watch out for campaign information which we will circulate at the appropriate time to notify you of specific actions that are required. In particular we need you to assist with pressure on the RPSGB so that we can persuade them to reconsider and change some of their policies – especially regarding the Responsible Pharmacist and Remote Supervision.

Campaign synopsis and tactical appraisal

1. **Creating a legislative environment that fosters beneficial practice**
   - **Amend the 1968 Medicines Act**
     - Use the MHRA review process.
     - Contribute materials to the consultation
     - Continue briefing MP's and relevant others
     - Mobilise pharmacists to support the requisite changes.
   - **Alter the application of the law**
     - Secure an interim agreement with the Crown Prosecution Service while the law is amended to ensure that 1968 Medicines Act prosecutions are not used by the CPS in genuine errors but instead such cases are handed to the RPSGB.
     - Continue briefing DoH
     - Keep pressure on to effect the interim arrangements as soon as possible.
2. **Focus on patient safety by dealing with factors which may impact upon error situations.**
   - **Staffing levels and rest breaks**
     - Exploit the RPSGB's 'new' stance on workplace pressures. Issue the PDA staffing levels and rest breaks resource pack to all pharmacists.
     - Take selective action against certain employers who openly flout the Code of Ethics, Employment legislation and Health and Safety regulations in these respects.
   - **Manufacturers packaging**
     - Share PDA data on dispensing errors with the NPSA in which the manufacturers packs have been a factor.
   - **Bar code accuracy checking systems**
     - Continue briefing parliament and relevant others.
     - Put pressure on employers
     - Harness patient groups and various pharmacy organisations
     - Mobilise the debate within the profession.
   - **Reporting of errors in error logs.**
     - Continue to support pharmacists who face any form of disciplinary or legal action because of information taken by investigators from error logs.
     - Provide pharmacists with an additional option for reporting errors electronically which provides protection through legal privilege for those using the system. Send any errors thus reported to the NPSA to support the national learning exercise.
     - Encourage pharmacists to report errors and employers to share this information with the NPSA.
   - **Responsible Pharmacist and Remote Supervision.**
     - Step up the campaign to brief parliament and relevant others as to the problems with these impending proposals.
     - Mobilise the debate in the profession and seek to put pressure on the RPSGB so that it does a U-turn on its current supportive policy towards these initiatives.
     - Seek to secure a united 'policy front' from pharmacy organisations so as to negotiate a change in approach from the Department of Health.

CUSTODIAL SENTENCE FOR A LABELING ERROR?

Pharmacy is being practiced in an increasingly hostile environment.

Who's defending your reputation?

In the last year alone, PDA has supported members in nearly 4,000 incidents where many have initially faced career threatening situations at the hands of the RPSGB, employers and now even the Police. There have been numerous instances where we have been able to secure positive outcomes. The lesson, is that whether it is community, hospital or primary care practice, a significant number of problems occur because of the poor working environments that pharmacists find themselves in.

Often, the pharmacists end up facing the full consequences, while their employer attracts little or no sanction.

This inequity must be addressed!

"The risk to the public comes not from dodgy pharmacists, but from potentially dangerous working practices. When a pharmacist is made to work regular 10-hour shifts, you cannot put the entire blame on that one individual. Supermarkets and major pharmacy employers cannot wash their hands of the health and safety implications which their pharmacists are subject to."

Earl Howe – shadow Minister for Health

If parliament gets the message then isn't it time the employers did too?
Ensure that your legal rights are protected - join the PDA without delay!

- ✓ More than £500,000 compensation already secured from employers who have treated their pharmacists unfairly or illegally
- ✓ £500,000 worth of Legal Defence Costs insurance
- ✓ £5,000,000 worth of Professional Indemnity Insurance
- ✓ Union membership option available

now more than 14,000

~~12,000~~ **pharmacists have already joined the PDA.** → have you?

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