

Hippocrates

Doing something about the Internet pharmacy

Buying and selling goods and services of every description over the Internet has within little more than five years become a far greater business than was ever predicted. It has grown too fast for ethical standards to be devised, accepted and effectively enforced. That has been the case whatever the form of commerce concerned, but the gap is especially problematical where the retail supply of drugs is concerned; for drug retailing is not merely a trade, but a profession which at its best accepts that the need to protect the purchaser from risk and to guide him in the proper use of a medicine must weigh more heavily than considerations of income and profit.

From the start it was to be expected that drug sales over the Internet, while in various respects offering improved possibilities for drug supply, could open the door to abuse. The essential difficulty is that the various mechanisms, both voluntary and compulsory, which have been devised to keep retail pharmacy on the straight, narrow and honourable path have grown up almost entirely within national frontiers, and that their development has been anything but consistent. While bodies like the World Health Organization and the International Pharmaceutical Federation have drawn up detailed charters of the retail pharmacist's duties, the national laws and codes of behaviour which might put those standards into effect still range from the exemplary to the pathetic, and in much of the world are still lacking completely. Anyone, whether seller or buyer, who regards them as a mere inconvenience, can readily set even the most watertight regime aside by merely stepping across a national border. The step need not even be physical; postal pharmacy, conducted from some of the most unlikely spots on earth, rendered the safeguards porous years ago, and the Internet makes it all that much easier and quicker. Both forms of business have grown to the point where mere spot-checks on the mails by customs officers have no significant ability to detect most of the abuses which occur. Again: the object must be to prevent such abuses and not to impede what could be and often is a perfectly legitimate form of trade. If a patient (or his health insurer) can submit a prescription to an Internet pharmacy abroad and thereby obtain a legitimate drug at a fraction of the price which he would pay downtown, then good luck to them. Without some effective set of standards, however, there is no certainty that the drug which the user receives will be of good quality or even genuine; there will be no real opportunity to counsel the incautious or ill-informed; and if an Internet source – which may be a shack run by a racketeer – proves willing to provide dangerous or restricted drugs without any prescription at all to those sufficiently foolish or impetuous to demand them, there will be nothing to stop it doing so.

One might have hoped that measures within the European Community, which in some respects is well-advanced in developing supranational controls on the drug business, would set a good standard, and the issue has been hammered out at length in Brussels; but the Internet extends well beyond the Community's frontiers, and even within those frontiers the extent to which community pharmacy functions properly is highly variable – one can find plenty of addresses where toxic antibiotics are sold over the counter to any comer without question and where patient counselling is still at best a fiction. Until those things have been put straight there is no great prospect of tackling the Internet.

One's other hope – the USA – has done rather better to counter inter-state abuses and to some extent improper imports from abroad as well. Back in 1999 the National Association of Boards of Pharmacy introduced a system of Verified Internet Pharmacy Practice Sites (VIPPS) after it had become clear that there was growing concern in the general public at some of the improper practices which had been documented [1]. Sites maintaining proper standards, as verified by inspection, can display the VIPPS emblem on their home pages. There have also been nation-wide initiatives to inform the public, to extend official FDA inspection to Internet-based suppliers, and to step up customs controls and the confiscation of drugs passing through the mail which have not been approved at the Federal level or prove to be mislabelled [2].

No single measure is going to put Internet pharmacy straight. Certainly a massive public information effort is needed, to ensure that people are rendered better capable of protecting themselves and at least made fully aware of the risks which they can run if they use the Internet primarily as a means of evading regulations which have been passed in their own best interests. At the same time global standards will need to be defined, and a basis found for the well-publicised prosecution of a number of notorious sources of supply. But – as in other fields of drug control – it will be an uphill battle to protect those people who not particularly appreciate protection, and to outpace the temptations to improper commerce presented by the ever lucrative sale of medicines.

References

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Pacifiers, dummies and all that

The objects which North American mothers call “pacifiers” and English nannies more bluntly call “dummies” are currently producing more risk literature than one would think possible [1–11]. The *Lancet*, *Paediatrics*, the *Canadian Medical Association Journal* and other worthy journals have all devoted space to these humble objects which, for many years (and perhaps quite wrongly) were considered to do no greater injury than to produce somewhat prominent front teeth among the infants who sucked all too assiduously on them.

It was Neifert's group [1] who in 1995 prominently propounded the belief that pacifiers produced “nipple confusion” and led to early weaning. However, others had raised similar suspicions, and as early as 1989 the WHO/UNICEF Baby Friendly Hospital Initiative condemned the use of pacifiers for the same reason [2]. These views were however based primarily on field observation, and they failed to take into account the very substantial factors which affect the adoption and duration of breast feeding and which vary from country to country and one ethnic and population group to another.

Finally, in 2001, Kramer, Barr, Dagenais and their colleagues from Canada [11] published a randomized controlled trial which had been carried out over a 20-month period in a Montreal maternity hospital. It involved 281 healthy women with single births who had expressed the intention of breastfeeding their babies. One group entered an “experimental postpartum breastfeeding programme” in which a breastfeeding consultant advised them to avoid the use of a pacifier to calm a restless (“fussing”) baby. The

other women did not receive this advice; instead they underwent an interview where all the various means of calming a baby were discussed, including the use of pacifiers, with no preference being expressed. In both groups the infant's behaviour was recorded by the mother for three consecutive days at the fourth, sixth and ninth weeks. At the twelfth week, a blinded interviewer met each woman and asked about the continuation or discontinuation of breast feeding.

In all respects the women in the two groups were comparable. There was a fair proportion of dropouts in both groups (with only some 57% completing the survey at the ninth week), the dropout rate being higher among young women, single mothers and smokers. There was however no difference between the two groups in the proportion ceasing to breastfeed by the 12th week (18.3% and 18.9%, respectively), in the proportion receiving supplementary feeding, or in the incidence of crying and "fussing" at any of the study points.

What does this study show? Certainly it does not suggest that pacifiers or dummies have any effect at all on the duration of breastfeeding, but as Erica Weir has pointed out in a thoughtful commentary [12], there was no information on the cultural or ethnic background of the mothers. More significant are perhaps the findings obtained when the same authors went on to determine whether pacifier use was a predictor of early weaning from the breast. It turned out that among infants reported to be given a pacifier daily, 25% were weaned before the third month; whereas, of infants not given a pacifier, only 12.9% were weaned by the third month of life. In that respect – and these findings run parallel to the suspicions and results of other authors [6] – it could simply be that the use of a pacifier is an expression of breastfeeding difficulties or of a low motivation to breastfeed rather than the cause of early weaning. If that is the case, as Weir points out, it may be good to keep an eye open for women who are regularly giving their babies a pacifier – it may indicate that they need additional encouragement and support to go on breastfeeding. One suspects that more work will be done to clarify the picture.

References

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Handling the aggressive patient

Patients who, for one reason or another, are physically aggressive represent a danger to their surroundings, health care staff and themselves. A sensible comment on the issue by an anonymous contributor to our London contemporary *THS* relates the degree of special care which they get – or fail to get – to the tightening of budgets and the need to set priorities in systems like Britain's National Health Service. Two cases serve as examples:

“... Elsie Hardcastle is a difficult patient. She comes from an abusive family and spent much of her childhood in one home or another. She gets very angry. She was first admitted to an acute mental health unit when she was seventeen. She had been living rough in the Midlands and started to shoplift to fuel her growing drug habit. A court diversion scheme had routed her in the direction of the NHS. She was very depressed on admission, but this resolved itself quite quickly and she was discharged back to her family home, where she hoped to be reconciled with her mother. It did not work, and soon she was back on the streets. She drifted from one relationship to another. She was an angry person and often got involved in fights and disputes. If there was a demonstration going, she was up for it. She was convicted of a number of minor offences.

She had no contact with mental health services until one day she seriously injured another woman in a fight. She was convicted of a serious assault and sent to prison. She was a difficult prisoner and started to self-harm and attack prison officers. Eventually she was diagnosed as having a personality disorder and transferred to an NHS forensic unit. She continued to self-abuse and attack staff. She was very angry. Eventually the clinical teams could cope with her no longer. She was charged and convicted of assaults against NHS staff and returned to gaol. She fared little better in prison and got to the end of her sentence, much to the relief of the Prison Service who were at their wits' end at finding staff to monitor her. As she was still a danger to herself and others, she was readmitted to the NHS and a new clinical team. On admission, she was angry and violent and had four staff with her throughout the day. The injury toll among staff continued to rise. The possibility of putting her in a semi-permanent restraint was discussed by the clinical team, but rejected on principle. Elsie is a patient, not a prisoner.

In another forensic unit many miles away a young man has AIDS. He too is angry. He is determined to spread his disease to others. Anybody will do. He is a big powerful man who, at every opportunity, bites, spits or spreads blood or faeces in places that others will come into contact with it. The risk of transfer is small, but real. He too has four staff with him throughout the day who are in protective clothing at all times. This is a rather special form of barrier nursing. Whether the patient can ever return to a normal ward environment and thus expose other patients to risk is a much-discussed question. Does he have to stay in solitary confinement all his life? It's unthinkable, but what are the practical alternatives?

This is part of the NHS few see. The costs of specialising at these levels over extended periods of time are enormous. Unless a miracle happens, these patients will remain in the care of the NHS for most, if not all, of their lives. They have no normal future like the people they see on their television screens. This is part of their anger.

It is impossible. And yet hope flickers. On a recent visit Elsie confided to a visitor that with her new clinical team she felt much better. “They are wonderful” she said. “They haven't given up on me, despite the awful things I have done to them. I love them.” The staff are gratified but remain very much on their guard.

What should the NHS do? First, it should do more to recognise, respect and admire the work of those staff that practise in such challenging environments. Second, it could do more to support research into this difficult territory. Basic research tools such as case registers are still not very much in evidence.

Indeed, some registers have been closed down in recent years as casualties of one reorganisation or another. National clinical conferences about really difficult cases hardly ever happen. Who would fund them? The numbers of patients are too small to get the pharmaceutical companies seriously engaged. The NHS might well, with great advantage, stimulate professional exchanges about how best to cope with such patients and perhaps offer advice on some of the difficult ethical questions involved in their care. Finally, the NHS needs to think about what it could offer these patients if their aggressive behaviour did moderate. Where could they go and still be safe? Little is available today.

These are exactly the sorts of questions that the Department of Health policy teams used to be good at. Complex issues that involve other parts of government and have a political dimension for high profile cases. They are too busy these days inventing new performance management tools for Ministers, but they should put these problems on the long list of questions to address. When they get time!”

When writers get it wrong

How many authors of medical textbooks or editors of Journals have stopped to consider the medical (and sometimes the legal) consequences of errors in print?

Books and overview articles in particular are there largely because they will be used as sources of reference and they tend to be trusted as if they were infallible; they will often be consulted in an emergency when no other source of information is to hand. But pens slip and decimal points slide, and one does encounter in the most highly reputed sources examples of incorrect information. It may not matter if the dose of Valium is indicated as 5 g instead of 5 mg, since the absurdity is obvious and no-one will contemplate giving a thousand tablets; the problem is the the type of error which is serious yet not palpably absurd. That admirable body The Institute for Safe Medication Practices – which functions in the USA and Canada – has made a custom of alerting doctors and others (including publishers and authors) to dangerous errors in print; particularly for users of American handbooks a visit to the Institute’s website (www.ismp.org) is rewarding, and a little disconcerting.

The Institute noted how a paper by Adams in *Pharmacotherapy* [1] listed the vincristine dose as 1.4 mg/m² to be given on days 1–5 of a CAV regimen; in fact vincristine should only be given on day 1 of the regimen. In a 1997 edition of ASHP’s the Chatelut formula for calculation of carboplatin clearance [2] was mixed up – among other errors the factor of 0.457 in the age calculation should have read 0.00457.

Cytostatics are indeed a notorious field for mistakes: in the June 16th 1997 issue of *Drug Topics* at page 28, a study by Chan et al. was described which compared docetaxel with doxorubicin in patients with metastatic breast cancer. Docetaxel was given in a 100 mg/m² infusion once every three weeks and doxorubicin a dose of 75 mg/m² at the same interval. But according to *Drug Topics* the drugs were given three times a week, which of course, would be a lethal overdose.

Nor does psychiatry escape. The Institute noted that both the 7th edition of the Lexi-Comp Drug Information Handbook for Psychiatry and the simultaneously published Psychotropic Drug Information Handbook (2000, page 137) advised that seriously agitated patients be rapidly tranquilized with haloperidol using oral doses of 100 mg or intravenous doses of 50 mg given every 30–60 minutes until a total averaging 300–600 mg had been given. All these doses are ten times too high.

And finally, the Institute put on record two serious complications attributable to an erroneous statement on the dilution of albumin which had appeared in an older edition of a textbook which was still in use in some centres; in both patients large volumes of sterile water had been used to prepare albumin solutions for plasmapheresis with due regard for avoiding hypotonicity. Both patients hemolyzed, and one died.

Whether such handbook errors are likely to have consequences at civil law is not clear; the legal literature on liability of medical authors seems to provide only a single and ancient French case report on the matter in which an author was ruled to be liable for the consequences of incorrect advice [3]; in some Swedish disciplinary cases, physicians making errors in dosage have sought to blame unclear statements in formularies [4]. Certainly, where a serious fault in treatment can be shown to have been due to an error in print, the causal connection should satisfy any court to find for an injured claimant. More important is the finding that the number of errors identified by the Institute is small when compared with the volume of material published. And encouraging is the willingness which publishers have shown to issue speedy and prominent corrections.

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