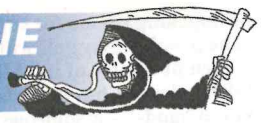
MEDICINE BALLS



Another fine mesh...

"I AM always struck not only by the scale of the suffering, but by the wider impact on the woman and her family too. The physical and emotional pain that follows these terrible complications leads to the break-up of marriages and partnerships, and the loss of jobs, homes and social lives." So observes Baroness Cumberlege in her ongoing review into the use of transvaginal artificial mesh used to repair pelvic floors. But why was the harm mesh was causing hidden for so long?

As MD and others pointed out in 1997, following the failure of the Capital hip prosthesis, a mandatory register is needed for all implants to pick up problems as quickly as possible. The fact this didn't happen for mesh is another catastrophic failure for surgeons, manufacturers, regulators and governments.

It is not just in the UK where women have suffered at the hands of over-enthusiastic surgeons swayed by magical mesh marketing. Globally, more than 100,000 women have so far sued over transvaginal mesh devices, complaining of symptoms such as persistent vaginal bleeding or discharge, chronic pelvic pain and pain during sex.

In the US, transvaginal mesh was approved by the Food and Drug Administration (FDA) in 2002 (and in the UK by NICE, the National Institute for Care and Health Excellence, in 2003); but it took until 2019 for the FDA to demand that the two remaining companies still making it (Boston Scientific and Coloplast) withdraw it from the US market as they "have not demonstrated a reasonable assurance of safety and effectiveness." Seventeen years after approval, we don't have evidence that transvaginal mesh is safe or more effective than traditional surgery.

As with any scandal, it pays to follow the money. Up to half of women will suffer from a degree of stress incontinence or prolapse at some stage, so mesh is a massive potential market. The transvaginal mesh tape (TVT) was pioneered by Swedish gynaecologist Ulf Ulmsten. After a small but promising trial of TVT in 75 women with stress incontinence published in 1996, he signed an agreement with Ethicon, a subsidiary of Johnson & Johnson, worth $1m, provided a second trial upheld the findings of the first. It was even more positive. Of 131 women, 91 percent were declared cured of stress incontinence and 7 percent were "significantly improved".

"Most encouraging was the low complication rate in 'less experienced' hands"; and Ulmsten and his co-authors concluded that "TVT can be considered a safe and effective procedure." In 1999, J&J paid Ulmsten's company Medscand a reported total of $24,525,000 "to purchase all assets associated with the TVT business". Many other companies climbed aboard. Some gynaecologists enjoyed "TVT parties" and expenses-paid conference jollies to the US.

In November 2017, US patient Ella Ebaugh was awarded $57m in damages after she was left with a mangled urethra and continual pelvic pain following mesh surgery that led to three revision surgeries to remove J&J's TVT-Secur mesh that had cut into her urethra and migrated to her bladder. The mesh is now off the market, but it was approved for human use without any human trials, relying on the dodgy US and European equivalence rules, which allow a new device to be rushed through if it is "similar" to existing ones.

This has proved hugely dangerous for hips and now mesh. Just because a device is approved for use doesn't mean it is safe. As with all implants, the success of mesh depends not just on the substance but precisely what it is used for (eg stress incontinence or prolapse repair) and the skill and judgement of the surgeon. Long-term safety data takes a long time to collect, so it is vital to have a compulsory register of all devices to detect problems promptly. Patients need to be diligently and independently monitored over a long period. This takes time, effort and money; but to not do so risks repeated harm, as the Cumberlege review has uncovered.

In 2003 when NICE approved the use of mesh, it recommended that data on the effectiveness and safety should be collected "over a period of 10 years or more". But NICE was ignored. The Medicine and Healthcare products Regulatory Agency (MHRA) "discussed the need for a national registry" but it didn't happen. When women started to report side effects, companies and surgeons downplayed these, for fear of litigation.

But women refused to be silenced. Reviews found a serious complication rate of around 10 percent. Without a registry, however, we may never know the true extent. Many women are happy with the results, but others are asking for their mesh to be removed at huge cost to the NHS. Surgeons who were honest about unknown long-term risks of mesh and used it wisely are facing less litigation than those who enthusiastically embraced it with little caution. A compulsory national registry would not only protect patients, but should also improve outcomes and reduce costs. And a public inquiry would flush out yet more of medicine's dirty little vested interests.

M.D.

CLEANED OUT...

THIRTY-FIVE years after Margaret Thatcher's government triggered the first strikes by hospital domestics against privatisation of NHS support services, cleaners at the Princess Alexandra Hospital in Harlow have voted overwhelmingly to walk out over plans to "market test" their work.

The hospital currently boasts that it is "one of the top performing trusts in the country for our low rates of MRSA and low levels of infection", and the domestic staff warn that flogging off the services to the private sector could spell "disaster" for patients. A brief flirtation with market testing at Harlow in the 1990s ended disastrously when infection rates rose, and the then contractor Mediguard was dumped after a year.

Research published this February, looking at data from 130 NHS trusts over five years to 2015, found that private providers are "cheaper but dirtier than their in-house counterparts." Staff also fear that pay and conditions will fall behind those of their colleagues, as a private contractor would not be part of any future NHS pay award and new cleaners could face worse employment terms.

However, health unions are having some success in making contractors restore staff wages to NHS rates and match last year's NHS pay rise. Strikes have already brought back NHS pay rates for OCS Group workers at Liverpool Women's Hospital and Sodexo employees in Doncaster – with further action planned elsewhere. In the last 12 months several attempts by other hospital trusts to hive off support services into "wholly owned companies" have been successfully resisted by strikes or strike threats. Privatised hospital cleaning, it seems, is no more popular now than it was under Mrs Thatcher.

The Agri Brigade

ENVIRONMENT secretary Michael Gove is still promising details of a post-Brexit farming policy for England and a proposed environmental land management (ELM) system that will reward farmers with "public money for public goods". But how can the government ensure farmers and landowners don't "game" whatever systems emerge?

Ensuring that farming and environmental subsidies aren't exploited, with little food being produced or wildlife preserved, is notoriously hard. The current EU farm subsidy, the basic payment scheme (BPS), is a case in point: it pays farmers for each acre "farmed" whether or not any food is produced. As soon as it was introduced in 2005, some farmers (particularly those with marginal land in Scotland) abandoned farming in favour of living on the subsidy – so-called "slipper farmers".

A similar problem emerged recently in the US, where farmers are compensated for falling farm-gate commodity prices resulting from the Trump administration's various international trade disputes.

The government intended to limit payments to $125,000 per "person" or legal farming "entity", but some farms have claimed millions of dollars under different trading names from the same address. Others have created "general partnerships" which claim to have large numbers of partners "actively engaged" in farming. These complex structures are created to maximise subsidies and are known in the US Department of Agriculture as "Mississippi Christmas trees". The US government has already paid farmers more than $8.5bn for the "market facilitation program" since September.

In England, Gove proposes to gradually phase out the EU's idiotic BPS (which pays UK farmers £3bn a year) from 2021 until it disappears completely by 2027. In its place he proposes ELM, which will ensure that – whatever public money is given to farmers – reward only goes to environmental improvements such as reduced greenhouse gas emissions, improved water quality or higher levels of biodiversity on farms.

However, by flagging ELM so many years in advance Gove has created the real danger that farmers will simply postpone taking part in current environmental initiatives in case they will be better rewarded for reducing their polluting behaviour under ELM (which will not be introduced until at least 2025). This almost certainly explains the very poor take-up of the current Countryside Stewardship scheme, which is seriously undersubscribed.

When ELM is eventually introduced, it must be designed not to play into the hands of farmers who game the system. Bad environmental farming practice should simply be outlawed through law, rather than farmers being compensated for, say, reducing soil erosion or water pollution through an agri-environment scheme.

ELM payments should be reserved for existing environmental excellence on farms that show good biodiversity and sound soil management. In other words, it should not repeat the mistake of previous schemes which compensate farmers who were previously engaged in destructive forms of food production more than farmers who are already doing their bit for the environment.

'Bio-Waste Spreader'