Offline: The scandal of device regulation in the UK

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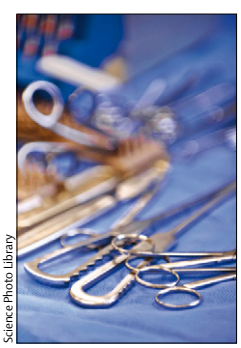
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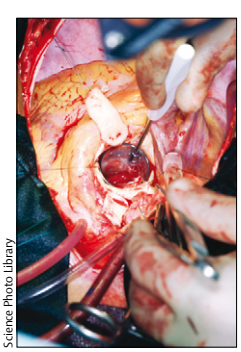
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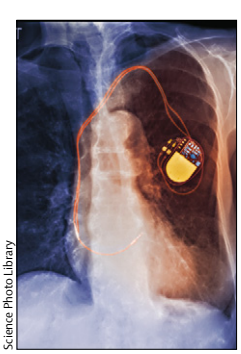
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July 7, 2011: 19 members of the UK's Committee on the Safety of Devices (CSD), together with representatives from the Medicines and Healthcare products Regulatory Agency (MHRA) and industry, gather in London to hear a disturbing presentation by Brian Toft, Professor of Patient Safety at Coventry University. Prof Toft had contacted MHRA to express concern about the CE marking process—the method by which medical devices are approved. His presentation was entitled "The Current Regulatory System: Fit for Purpose?" His answer was "no for the people that just do the paperwork and move on, hiding under the CE marking". This devastating appraisal of the severe failings of device regulation in Britain came after 2 years of intense discussion by the CSD—about devices that include heart valves, hip prostheses, surgical instruments, implantable defibrillators, and silicone-gel breast implants. Examination of the work of this Committee reveals long-standing concerns about weaknesses and gaps in the UK regulatory system. MHRA has been well aware of the risks of serious device failures for some time. But it has barely begun to address these concerns. The PIP breast implant scandal is an inevitable result of MHRA's paralysis and inability to correct the failings of a severely flawed system.

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Prof Toft argued that "some people think that if a device is CE marked it must be safe to use". This is a grave error. There was considerable "evidence that devices produced are not always up to standard". The CE mark does not guarantee safety; it may well not be "sufficiently robust" to indicate the quality or suitability of a product. In one study at Barts and London Hospital, for example, 15% of surgical instruments "had potential problems" and "did not appear to meet appropriate standards". As documented in the minutes of the July 7 CSD meeting, "The CE marking provide[s] [a] smoke-screen for faulty and dangerous devices that place patients and surgeons at risk." The minutes continue: "This is not just a UK problem, this is a worldwide global problem that needs to be dealt with." The Chairman of the Committee, Dr John Perrins, commented with disarming honesty: "It is very frustrating when clearly things don't seem to work in the way we would wish and there have been many examples of problems like this throughout the life of the CSD." The Committee went on to agree that "substantial progress" had to be made "in tightening up the process" of ensuring device safety. Part of the problem lies with European directives on medical devices—directives that are not expected to change until 2016. But part of the problem also lies with the complexity and fragmentation of the regulatory process in the UK.

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How is a medical device regulated in the UK? The MHRA is the "competent authority" for device safety and reports directly to the Secretary of State. However, the assessment of devices is performed not by the MHRA, but by around 70 Notified Bodies across Europe, including the UK. Their task is to determine the safety and effectiveness of a device and to issue a certificate of conformity (a CE mark). In other words, device regulation in the UK is outsourced to third-party organisations that the CSD knows to be of variable quality and which may be operating to different standards. The MHRA periodically audits Notified Bodies, but does not itself, unlike for medicines, scrutinise safety and effectiveness data. In the UK, devices reach patients "without the reassurance of adequate clinical trials to demonstrate their safety and efficacy". The operating principle at the MHRA seems to be: do nothing until something goes wrong. The MHRA recognises that it is failing in its duty of care to the public. In the July 7 meeting, the CSD admitted that "we need to be more specific about skills, expertise, [and] length of time involved in that particular technology" for any given Notified Body. There needed to be "greater central oversight of NB designation and monitoring". The CSD also noted that manufacturers were failing to provide sufficient information about devices to patients. Overall, the safety of medical devices is a low priority for the MHRA, with serious consequences for patient safety.

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The MHRA's mission is "to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe". The MHRA is, by its own admission, unable to fulfil this mission.

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