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FEATURE

Commentary: The risk of over-regulation

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Regulatory bodies are expected to protect the public from the danger of inappropriately tested treatments—a shield against the vested interest of drug and device companies to sell products irrespective of their safety and effectiveness. The idea of the greedy industrialist focused on short term advantage and endangering lives with low quality components used to save manufacturing costs is familiar to the public and seems to justify stringent regulatory processes. But one person is forgotten in this equation—the doctor.

The doctor is directly accountable to the patient and is expected to have the competency and motivation to select appropriate devices and drugs. The personal ethical responsibility of every doctor towards his or her patient may get diluted in the impersonal setting of large hospitals run by governments or private health providers. Doctors have largely ceased to be independent professionals and became employees forced to follow rules aimed at maximising profit and containment of expenses. The medical industry is the main source of sponsorship for clinical trials and the main supporter of postgraduate medical education. This creates links with industry that have been overemphasised, depicting doctors like car dealers with a vested interest to "sell" products. The net result has been a shift of power in the decision making process about providing and regulating healthcare from the medical profession to administrative bodies. But have patients truly benefited from these changes and should we continue in this direction and strengthen the power of regulatory bodies policing the introduction and monitoring of new devices across Europe?

Lessons from interventional cardiology

Interventional cardiology, a young subspecialty in which progress is strictly linked to technical development, is a goldmine of examples warning against the potential risks of over-regulation and showing that even the strictest regulatory process does not offer the full protection expected. We now know that coronary angioplasty saves the lives of patients with acute myocardial infarction and selected patients with acute coronary syndrome. But when Gruentzig and colleagues first described the technique in 1977,[1] it was not mature enough to be used for these challenging indications. Possibly the most widely applied "surgical" procedure in the world would have died in its infancy if powerful regulatory bodies had demanded demonstrations of equivalency or superiority to the other mechanical revascularisation technique available, coronary bypass surgery. It took more than 30 years and numerous trials of balloon angioplasty, bare metal stents, drug eluting stents versus surgery to have sufficient evidence for the representatives of the cardiology and cardiothoracic surgical associations to agree on common guidelines defining the relative merits and indications of the two strategies.[2]

Many new techniques introduced nowadays, when more stringent regulatory processes are in place, risk being stopped before progressing to show their full potential and find their true indications. For a new transcatheter device to treat mitral insufficiency, the MitraClip, the Food and Drug Administation requested a randomised comparison with valve surgery, a mature technique benefiting from more than 30 years of experience. The result was not convincing enough for the FDA to grant approval. In Europe, where the device received a CE mark, doctors have used it not to replace reconstructive mitral valve surgery but to provide alternatives to the failure of medical therapy in inoperable patients and those with severe heart failure and secondary insufficiency—probably a more logical application for this technique than the comparison with surgery requested by the FDA. Even though the device is manufactured in the United States, it is available there only for restrictive compassionate use applications forcing patients to go abroad for treatment.

Happy medium

Critics of the current European system argue that the system leads to inconsistency because of the variable attitudes of notified bodies and national regulators. Patients should enjoy the same protection everywhere in the world, and the standardisation recommended by Fraser and colleagues is desirable.[3] The number of drug eluting stents approved in Europe is 10 times greater than in the US, and many of those approved offer no advantage over bare metal stents for restenosis prevention or have much worse results than other drug eluting

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stents. This can be corrected by doctors, who can choose only well proved devices for their patients. Medical societies such as the European Society of Cardiology are also helping in the selection process, producing guidelines that recommend only devices with sufficient evidence.[2] Unfortunately, stents and other devices are increasingly selected by hospital managers based on their cost rather than performance.

Although there is room for improvement, uniformly increasing the hurdles in the regulatory process risks raising costs without any real increase in patient safety. The approval process must acknowledge the varying requirements of different types of devices. It is illogical to have similar requirements for a new thrombectomy catheter which is more trackable and aspirates larger particles of thrombus than previous devices and for a stent using a new drug and eluted by a novel fully biodegradable polymer. In the second situation clinical outcome measures are required. Number of patients should not be the only qualifying aspect of registration trials. We cannot expect that a trial in a selected subgroup of patients will apply to the wider population treated in clinical practice. Allcomers studies—started as the personal initiative of few enlightened European investigators[4-7]—should become a strict requirement for approval of truly new stents.

If a stringent scrutiny is applied to preregistration mechanical testing and clinical studies, unforeseen surprises are unlikely with wider clinical applications. But doctors and regulators still have a commitment to their patients to ensure that a sufficiently large and prolonged follow-up is available. The European Society of Cardiology's EurObservational research programme[8] is an ambitious project to monitor cardiac interventions, similar to the successful initiatives in Sweden.[9] Sponsorship of such registries for device surveillance and recommendation to the various national health authorities to enforce and police their applications are likely to be more effective ways of protecting patients than doubling the European Medicines Agency's offices, employees, and consultants to extend its competency over devices.

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