Johnson & Johnson Medical Pty Ltd

Submission to Senate Community Affairs Reference Committee

Inquiry into Regulatory Standards for the Approval of Medical Devices

29 July 2011

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Organisation

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Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognise their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfil their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens - support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Johnson & Johnson

1. About Johnson & Johnson Medical

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson.

Johnson & Johnson Medical Pty Ltd (Johnson & Johnson Medical) is part of the Johnson & Johnson Family of Companies, one of the world's most comprehensive health care organisations, which was formed in the USA in 1886. In Australia, we have been caring for our customers since 1931. Across our organisation we embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Our Management Approach

Johnson & Johnson has been privileged to play a role in helping millions of people around the world be well and stay well through more than 125 years of change. As the science of human health and well-being has grown, Johnson & Johnson has been able to grow along with it. Our products, services, ideas and giving now touch the lives of at least one billion people every day.

Johnson & Johnson Medical in Australia

In Australia, Johnson & Johnson Medical is one company made up of a number of specialist divisions and currently employs over 600 Australians. This diversified structure allows Johnson & Johnson Medical to meet a broad range of patient and surgeon needs, whilst retaining the specialist knowledge and focus that comes from the ability to concentrate our efforts into the one field.

Advanced Sterilization Products is a leading developer of innovative instrument sterilisation, high level disinfection, and cleaning technologies dedicated to protecting patients, healthcare workers, and the environment with products that focus as much on safety as they do on efficacy and cost-effectiveness.

The Biosense Webster business provides diagnostic and therapeutic products for the treatment of cardiac arrhythmias. The field, known as electrophysiology, has seen many changes in the last 10 years and Biosense Webster has delivered technological advances to enable these changes.

Codman is part of DePuy and develops a wide range of diagnostic and therapeutic products for the treatment of central nervous system disorders. Our focus is on intractable pain management, paediatric and adult hydrocephalus and neuro critical care.

Cordis

The Cordis portfolio includes providing physicians with breakthrough treatment solutions for peripheral vascular disease and obstructive diseases, and cardiovascular technologies such as sheaths, catheters, balloons and wires.

DePuy

The DePuy companies span the orthopaedic and neurological care area – from early intervention through joint replacement and spinal fusion. The DePuy business includes four speciality areas: DePuy Orthopaedics, DePuy Spine, DePuy Mitek and Codman. DePuy Orthopaedics is one of the leading innovators in orthopaedic devices and supplies, including hip, knee, extremity, trauma, cement and operating room products.

DePuy Spine

DePuy Spine's products are used by orthopaedic and spinal surgeons in surgical and non-surgical therapies to treat patients with conditions resulting from degenerative diseases, deformities, trauma, and sports-related injuries. These include rod, screw and hook systems, plates and screws, ventral cervical stabilisation systems and cable systems.

DePuy Mitek

DePuy Mitek develops medical devices for surgery, with a focus on sports medicine and reconstruction. DePuy Mitek's portfolio extends to a wide array of innovative products for anterior cruciate ligament, meniscus repair, and cartilage repair surgery in the knee.

ETHICON

Ethicon is a leading developer of suture products and is one of the most recognisable and well-respected innovators in the hospital environment. The division has a long history of innovation in providing products, including sutures, topical adhesives, surgical meshes and wound drains, that enhance patient care. Ethicon offers breast and body aesthetics through Mentor, increasing our efforts in the plastic surgery area. We also offer new technologies to further address the unmet needs of ear, nose, and throat patients through the Acclarent brand.

Ethicon Endo-Surgery

Ethicon Endo-Surgery develops advanced medical devices for minimally invasive and open surgical procedures. Products include surgical stapling, trocars and access products, ligation devices, advanced energy ultrasonic cutting and coagulation devices, breast biopsy systems and devices for restrictive bariatric procedures.

LIFESCAN

For more than two decades, LifeScan has been committed to improving the quality of life for people living with diabetes. LifeScan pioneered the modern era of blood glucose monitoring with the introduction of OneTouch® Technology and this brand offers solutions to help people manage their diabetes.

Ethicon Women's Health & Urology

Women's Health and Urology is dedicated to providing innovative, minimally invasive treatments for common urologic and women's health conditions – female stress urinary incontinence, pelvic floor repair, enlarged prostate, post-surgical adhesions, heavy periods, and benign uterine conditions, such as fibroids and polyps.

Industry Membership

Johnson & Johnson Medical is an active member of the Medical Technology Association of Australia (MTAA), the national peak industry body representing companies in the medical technology industry. We support the industry Code of Practice through which the (Medical Technology Association of Australia – MTAA) aims to facilitate ethical interactions with healthcare professionals and others within the medical technology industry.

Our experience in the Australian Healthcare Environment

Johnson & Johnson Medical is a major provider to the Australian healthcare system through the provision of products and the development and implementation of support services for the medical community. Johnson & Johnson Medical works across both public and private sectors, providing the company with a solid understanding of the Australian healthcare sector.

At present Johnson & Johnson Medical has:

- 1,383 inclusions in the Australian Register of Therapeutic Goods (ARTG) across all classes of medical devices;

- Experience with Medical Services Advisory Committee (MSAC) regarding diagnostic and surgical procedures, including cardiac, endovascular, neurovascular, spinal and orthopaedic technologies; and

- 1,183 products on the Private Health Insurance - Prosthesis List. This represents around 10% of all items on the Prosthesis List, and includes the following product categories:

    - Hip Clinical Advisory Group (CAG) products;
    - Knee Clinical Advisory Group(CAG) products;
    - Spinal Clinical Advisory Group (CAG) products;
    - Special Orthopaedic Clinical Advisory Group (CAG) products;
    - Cardiac Clinical Advisory Group (CAG) products;
    - Vascular Clinical Advisory Group (CAG) products;
    - Urogenital Clinical Advisory Group (CAG) products;
    - Cardiothoracic Clinical Advisory Group (CAG) products;
    - Neurosurgical non- Clinical Advisory Group (non-CAG) products;
    - Plastics and reconstructive non Clinical Advisory Group (non-CAG) products; and
    - General and miscellaneous non Clinical Advisory Group (non-CAG) products.

The diversity of our activities gives Johnson & Johnson Medical considerable experience with the Australian medical devices regulatory environment.

2. Outline

Johnson & Johnson Medical is a provider to the Australian healthcare system through the provision of innovative products and the development and implementation of support services for the medical community. Johnson & Johnson Medical works across both public and private sectors, providing the company with a solid understanding of the Australian healthcare sector and its medical device regulatory environment.

Johnson & Johnson Medical has contributed to and endorses the submission made by the Medical Technology Association of Australia (MTAA) in response to the Terms of Reference established by the Senate Community Affairs Committee (Committee). We wish to provide further material to the Committee in this submission in specific areas which we believe we can assist through our experience. A number of the views expressed in this submission have already been covered in Johnson & Johnson Medical's submission to the Review of Health Technology Assessment (HTA) in Australia and other Johnson & Johnson Family of Companies' submissions to regulators and policymakers.

Regulatory Principles

Johnson & Johnson Medical believes that any possible changes to the Australian regulatory framework should take account of the principles of best practice regulation both within Australia and internationally. As a general principle, any regulatory burden needs to be commensurate with the benefits being sought and the outcomes delivered. If the appropriate balance is not achieved then there may be a range of unintended consequences. These may include unnecessary delays in Australian patients accessing new medical technology or in some cases being denied access all together.

It is our position that the key challenges to be addressed are how local regulatory practice interacts with international regulatory practice and the consequences (both benefits and burdens) of the overall regulatory framework that is implemented.

Terms of Reference and Limits of our Submission

The Terms of Reference established by the Committee are wide ranging and cover many areas of the regulation of medical devices in Australia. We note that the Committee intends to pay particular attention to devices with high revision rates, and focus on joint replacements. In this submission, Johnson & Johnson Medical has sought to put forward a substantive response to these Terms of Reference in order to make a meaningful contribution to the deliberations of the Committee. There are however some limitations as to the areas that we are able to cover in this submission.
As the Committee will be aware, in August 2010, DePuy Orthopaedics Inc. (DePuy), a company in the Johnson & Johnson Family of Companies, issued a worldwide voluntary recall of its ASR XL Acetabular System and DePuy ASR Hip Resurfacing System (ASR Hip System products).

The ASR Hip System products were implanted in patients in Australia, and have (and continue to have) an on-going impact to those patients. DePuy and Johnson & Johnson Medical regret the impact this recall has had on patients, their families and surgeons. In our response to this recall, our first priority is for the care and wellbeing of all ASR patients. We want to make sure that ASR patients are well informed and receive the appropriate support during this difficult time. Johnson & Johnson Medical is keen to ensure that no ASR patient suffers financial detriment relating to the recall. To this end, Crawford & Company (Australia) Pty Limited, an independent third-party claims processor, has been engaged to evaluate patient claims and reimburse them for the eligible expenses they incur in the course of their treatment arising from the ASR recall.

As at the date of this submission, we are providing support to over 3,000 ASR patients in Australia who have registered with Crawford & Company (Australia) Pty Limited and seek to do the same with any ASR patients who have not yet registered. We are committed to addressing reasonable and customary costs of testing and treatment for reasons related to the recall, including revision surgery if necessary.

Some ASR patients are pursuing legal action through the Courts. In Australia, there is presently a representative action in the Federal Court that has been brought against Johnson & Johnson Medical. We respect any patient's decision to take legal action. As matters before the Courts are appropriately dealt with in the courts, we do not propose to address matters in this submission (ASR related or otherwise) that are contemplated or currently before the Courts.

That said, we remain willing to share what information we can, and assist the Senate Committee to the extent we are able, without transgressing on matters that are properly to be heard by the Courts in accordance with their procedures.

Submissions

To the specific Terms of Reference:

(a) Role of the Therapeutic Goods Administration (TGA)

The role of the Therapeutic Goods Administration (TGA) is to ensure the quality, safety and performance of medical devices supplied in Australia and is based on a benefit/risk management approach designed to ensure public health and safety. We endorse this role for the Therapeutic Goods Administration (TGA) and acknowledge their ongoing work in this area.

We submit that:

- The TGA should adopt the role of a designating authority for Conformity Assessment Bodies which can demonstrate competence to evaluate all devices, including those which incorporate a medicine or material of animal, human or microbial origin.
- Complete alignment of classification rules between the Australian regulations and the European Medical Device Directive would enable third party conformity assessment to be implemented;
- The TGA should retain its role as a Competent Authority in determining which applications for inclusion in the Australian Register of Therapeutic Goods are accepted based on the conformity assessment evidence issued by third party Conformity Assessment bodies; and
- It is appropriate that following the recommendations of the Health Technology Assessment (HTA) Review in 2010, there has been clarification of the roles and functions of the Therapeutic Goods Administration (TGA)**,** Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC). We support the enhancement to the clarification of these roles and functions in this way

(b) Cost effectiveness of subsidised devices

The issue of cost effectiveness is an issue for both the Australian public and private health care sectors. Many of the issues in regard to the demonstration of cost effectiveness were canvassed in Government's recent Review of Health Technology Assessment (HTA), of which Johnson & Johnson Medical put forward a submission.

In assessing cost effectiveness, there is a significant role to be played by Health Technology Assessment (HTA) founded on conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients or "Evidence-Based Medicine". These are necessarily complex processes in which overall success is predicated on appropriate levels of involvement and contribution from a range of stakeholders. Importantly, any assessment of cost effectiveness needs to take into account the totality of budget impacts across the entire health care system, and not just be isolated to one single payor.

We submit that:

- All Australians, across both public and private healthcare systems, should have timely access to safe and clinically effective treatment as recommended by their clinician;
- Despite the complexity that is inherent in the use of Evidence-Based Medicine, that complexity should not be utilised as a barrier to restrict or delay access to new technologies in the Australian health care system, both public and private;
- In considering the priorities for Evidence-Based Medicine, consideration should be given to diseases and conditions that are recognised as imposing a high clinical and economic burden on patients and society, rather than being limited to high-cost intervention;
- Based on international experience, there are clear benefits to be gained from broader stakeholder input in the Health Technology Assessment (HTA) process. This input should come from a range of stakeholders including clinicians, hospitals, payors, patients and industry;
- When considering health care expenditure, government should not only be concerned with its own level of expenditure, but the total level of resources that healthcare is consuming within the Australian economy;
- The implementation of any recommendation around Health Technology Assessment (HTA) should be appropriately resourced to ensure the best possible outcomes;
- Regulations governing Health Technology Assessment (HTA) processes should be fair and adhere to principles of best practice regulation and not impose costs that are unnecessary to realise the regulatory objectives; and
- It is appropriate that following the recommendations of the Health Technology Assessment (HTA) Review in 2010, there has been clarification of the roles and functions of the Therapeutic Goods Administration (TGA), Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC). We support the enhancement to the clarification of these roles and functions in this way.

(c) Effectiveness and accuracy of the Prostheses List and Billing Codes

We support the submission made by the Medical Technology Association of Australia (MTAA) in this respect.

(d) Processes in place to ensure that approved products continue to meet Australian standards

In addressing the processes in place to ensure that approved products continue to meet Australian standards, there are a number of key matters that need to be taken into account. The first is the question as to what are "Australian Standards", and are they relevant to regulatory review of medical devices?

Secondly, the current regulatory practice that governs regulatory devices once included on the Australian Register of Therapeutic Goods (ARTG) should be considered. The current regulatory approach is based on a risk management. This approach is designed to ensure public safety and health with pre-market reviews directed towards higher risk devices and a robust post market surveillance system covering all devices. We support post-market monitoring of devices as it currently stands in the regulations. The Therapeutic Goods Administration (TGA) has a comprehensive strategy for on-going monitoring and vigilance for medical devices based on the Global Harmonisation Task Force Model.

We submit that:

- At present, a manufacturer establishes compliance to the current international standards – by means of testing which must be conducted by accredited independent laboratories. The regulatory review consists of examination of the independent test data and reports. As a result, the relevant compliance standards, are the international standards which are accepted by all established and reputable international regulatory jurisdictions (including Australia);

- In recognition of the resources available to the Therapeutic Goods Administration (TGA) and the resources available through internationally recognised bodies, the Therapeutic Goods Administration (TGA) should maximise the opportunity to access these international resources in order to leverage the expertise embodied in international reviews; and

- With respect to post market monitoring of devices, there is a need for any regulator to ensure that any new arrangements are superior in terms of long term clinical benefit and patient outcomes, reducing overall costs or yielding additional public benefit that exceeds any additional costs.

(e) Approval processes for devices that are remanufactured for multiple use

Johnson & Johnson Medical does not support the reprocessing of single use devices by third-party businesses. Third-party reprocessing raises serious patient safety, ethical and legal concerns, which need to be considered closely by all parties. Attached to this submission are three detailed submissions covering separate elements of this issue.

We understand the Therapeutic Goods Administration (TGA) is currently considering an application from a third-party reprocessor in respect of the registration of a number of reprocessed devices on the Australian Register of Therapeutic Goods. This has raised a series

of concerns within the medical technology industry including the impact on patient safety. To date, these issues have not received any significant public scrutiny since the enabling legislation was passed in 2004. We would request the Committee carefully consider the wider range of issues surrounding the third-party reprocessing of single use devices.

We submit that in considering the potential negative impacts third-party reprocessed single use devices may have on Australian patients, the Committee consider:

- The role informed patient consent plays in providing patients with the choice of whether a third-party reprocessed single use device is utilised on them during a procedure;
- The prohibitions that several European countries have in place regarding the third-party reprocessing of single use devices;
- The increasing level of evidence emerging out of the United States regarding adverse events related to the use of third-party reprocessed single use devices including injury to patients; and
- The evidence presented regarding the residual contamination of third-party reprocessed single use devices and the risk that introduces in regard to potential cross infection.

(f) and (g) Processes of notification of high revision rates or possible faulty devices, effectiveness and action and The effectiveness of the current regime in place to ensure prostheses with high revision rates are identified and action taken once these devices are identified

The regulations require a manufacturer to report adverse events to the Therapeutic Goods Administration (TGA)[1]. Such a requirement is present in all GHTF markets according to common guidance as to what should be reported, and to reporting timelines. However, such an approach has its limitations – for instance, there may be under-reporting because manufacturers may not be informed by users of adverse events and occasionally, over-reporting of trivial incidents (which may mask significant trends). In respect of these matters, we support the submission made by the Medical Technology Association of Australia (MTAA).

[1] See Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002.*

In particular, Johnson & Johnson Medical recognises the importance of identifying factors conducive to achieving successful health outcomes which result in improved standards and significant cost savings through reduced revision surgery. Clinical studies and registries are useful sources of information that provide data points which may assist in the overall assessment of the safety and effectiveness of products and procedures over a defined time period.

Specifically, registries can provide useful generalised metrics but have limitations that need to be recognised.

We submit that:

- In considering the governance of registries that the Committee consider examples such as the operation of Australian and international registries and recognise the benefits that a broad range of stakeholder involvement may bring to delivering better outcomes in the operation of a registry. We acknowledge that a consultative committee to the Australian Orthopaedic Association National Joint Replacement Registry has been formed including stakeholders from the industry. However, we would like to see broader implementation (including patients, administrators and industry) in the governance of the registry itself;

- With specific regard to joint replacements, registries should work collaboratively with all stakeholders including sponsors, to identify the factors that impact the outcomes of joint replacement procedures so that improvements can be made. These may include new product developments or the provision of appropriate training for improvements in surgical technique; and

- In order to maximise the benefits of a registry, industry and other stakeholders should be part of the group that peer reviews the interpretation of the registry's data.

(h) Effectiveness of the implemented recommendations of the Health Technology Assessment (HTA) (HTA)

We support the submissions made by the Medical Technology Association of Australia (MTAA) in this respect.

3. Principles of Best Practice Regulation

In considering any changes to legislation or regulations there is a need to take into account the principles of best practice regulation, which are set out in this section. In summary, any regulatory burden needs to be commensurate with the benefits that are being sought and the outcomes delivered. If this balance is not achieved, then there may be negative regulatory impacts. In the case of medical technology these may lead to delays for new technologies or in some cases new technologies not being made available in Australia. This would result in negative impacts upon Australian patients as they would be denied access to the latest developments in medical technology that would be available in other countries around the world.

Regulation is necessary to help achieve the government's objectives in relation to access to innovative health technology. All regulation imposes costs on various parties, including taxpayers, health technology companies, health service providers, patients, and the wider community. For health technology suppliers such as Johnson and Johnson Medical, the current regulatory regime potentially imposes a variety of costs by:

- Imposing significant administration costs;
- Requiring adjustment to R&D activity and production processes in ways that potentially add to costs; and
- Making some technological pursuits commercially unviable or less attractive.

If the costs imposed by regulation are inappropriate or excessive to achieve the regulatory objective, the regime can unnecessarily limit the scope for innovation, undermine entrepreneurial drive and reduce productivity and competition.[2] For patients in Australia, inappropriate or excessive Health Technology Assessment (HTA) regulation can lead to:

- Delayed access to, or even non-supply of, new medical technologies that are clinically effective and affordable;
- The use of less preferred medical technology in some situations where society (and the individual concerned) would be better off had the preferred technology been used; and
- Cost and risk associated with travel overseas to gain access to such technologies and treatments.

[2] Australian Government Regulation Taskforce 2005, *Taskforce Issues Paper*, Canberra.

The Federal Government should ensure Australia's regulatory environment is both appropriate, in the sense that it is necessary to achieve the government's objectives in relation to access to affordable health technology, and efficient, in the sense that the regulatory objective cannot be achieved in a lower cost way. This has been acknowledged by the Federal Government which indicated that it would carry this principle to new and existing legislation/regulation.

Since the Competition Principles Agreement was signed in 1995, many organisations and committees committed to the observance of best practice regulation and governance. These include the OECD, the Productivity Commission, the Council of Australian Governments, the Taskforce on Reducing Regulatory Burdens on Business, and the Department of Finance and Deregulation's Office of Best Practice Regulation. They have continued to advocate periodic review of regulations or regulatory requirements to identify and address areas that are inappropriate or excessive to what is required to achieve the regulatory objective. These organisations have at various times and in various reports, provided guidance to assist policymakers and regulators to identify and address aspects of regulation that are unnecessarily burdensome, complex, redundant, duplicative or stifling of incentives to innovate. We have summarised some of this guidance below:

- **Retention of regulatory requirements that are redundant, do not contribute to the policy objective or are detrimental to the policy objective (or other policy objectives)** – this includes situations where the regulatory requirement no longer applies or has been superseded by other regulations, is not enforced, is duplicated by another regulatory agency or area of regulation, remains even though government policy in the area has changed, and/or conflicts with other policy objectives of government;

- **Excessive regulatory coverage** – this occurs when regulation captures more activity than warranted by the regulatory objective. Excessive coverage is more likely to occur in situations where there is a lack of clarity about the policy intent or objective of the regulation;

- **Excessive complexity or over-engineering of the regulatory system** - so that regulatory objective is achieved at a higher cost than an alternative arrangement such as self-regulation or co-regulation;

- **Excessive specificity in Australia's regulatory regime -** for example despite Australia having a leading healthcare system worldwide, with a leading regulatory body in the Therapeutic Goods Administration (TGA) there has been a failure to harmonize Australia's regulatory regime with other best practice regimes in other jurisdictions and failure to effectively coordinate with regulators in other jurisdictions to minimise unnecessary duplication of regulatory effort;

- **Differences within the regulatory system in methodology used to assess compliance in a particular area -** which gives rise to the potential for conflicting signals to regulated firms as to whether a practice/technology is compliant;

- **Differences in definitions and reporting requirements within the same regulatory system -** which prevent regulated parties from addressing all regulatory responsibilities using a common information source; and

- **Excessive or unnecessary reporting or recording burdens -** including due to excessive red tape, regulator failure to implement best practice information and communication systems, poor coordination across regulatory agencies and/or duplicated reporting obligations;

  Unreasonable delays in the regulatory process - for example by precluding concurrent assessment, poor ex-ante disclosure of information required from regulated firms and/or inappropriate standards for evidence.

In summary, there are a range of issues in regard to best practice regulation that need to be taken into account when considering the regulation of medical technology in Australia. As this submission sets out, within the Australian context, these issues are not restricted to Australian regulatory practice, but also take into account the international regulation of medical technology. How local regulatory practice interacts with international regulatory practice and the overall regulatory burden is a key challenge in the design and function of the Australian regulatory system.

Submission

- That when considering any changes to the Australian regulatory system governing medical devices that the Senate Community Affairs Committee takes into account of the Principles of Best Practice Regulation.

4. Terms of Reference - the role of the Therapeutics Goods Administration in regulating the quality of devices available in Australia

The role of the Therapeutic Goods Administration (TGA) is to ensure the quality, safety and performance of medical devices supplied in Australia and is based on a benefit/risk management approach designed to ensure public health and safety. We endorse this role for the TGA and acknowledge their on-going work in this area.

In this section of our submission, we outline some of the key considerations for the Committee in relation to the role of Therapeutic Goods Administration (TGA) in regulating medical devices, including:

- Australia's position in the global context of medical devices regulation;
- The current regulatory practice; and
- Recommendations

Australia in the Global Context

The Australian medical technology market accounts for approximately 2% of the global market and more than 95% of products are imported (MTAA, 2009)[3]. The Australian regulatory system is consistent with other major global health authorities and the principles of the Global Harmonization Task Force.

Therapeutic Goods Administration (TGA) currently accepts pre-existing CE certification by European Notified Bodies (EU NB). These bodies are independent organisations, accredited by European national regulatory agencies to perform premarket assessment and manufacturing audit of medical technology. In addition, the European, Canadian and Japanese regulatory frameworks all employ third parties to conduct regulatory assessments or audits, with the government agency acting as a designated authority to ensure integrity of these assessments.

Current Regulatory Practice

Australia has established a direct alignment with the European medical device directive which has enabled the Therapeutic Goods Administration (TGA) to establish bilateral regulatory agreements (Aus-EU Mutual Recognition Agreement certificates). These agreements accept the assessments of the European Notified Bodies (EU NB) for medical devices manufactured in the EU and reduce the need to conduct duplicate assessments.

The Therapeutic Goods Administration (TGA) currently conducts Level 2 Application Audits on Class III devices that are not manufactured within the European Community.

[3] MTAA (2009) *About the Industry* http://www.mtaa.org.au/pages/page3.asp

This is despite these products having undergone the identical design dossier review by a recognised European Notified Body (EU NB). In addition, all medical devices containing a medicine or material of animal, human or microbial origin are required to undergo full conformity assessment by the Therapeutic Goods Administration (TGA).

Upon considering the context in which the Australian regulatory system interacts with the international (and particularly European) systems we would suggest that it is appropriate for the Therapeutic Goods Administration (TGA) to consider utilising external resources to supplement its own relevant expertise. We also suggest that the Therapeutic Goods Administration (TGA) broaden existing and establish new mutual recognition agreements with other highly regulated countries such as Canada and Japan as well as Europe. This will allow the Therapeutic Goods Administration (TGA) to approve products based on the third party conformity assessments such as provided by European Notified Bodies (EU NB), for all classes of medical devices supplied in Australia where there are no unique risks or differences in clinical practice can be identified. The benefits of accessing expertise through the international regulatory system would include reducing unnecessary duplication of regulatory effort and hence reduce regulatory burden as well as accelerating availability of new products and technology to Australian patients without compromising safety.

Submissions:

- The Therapeutic Goods Administration (TGA) should adopt the role of a designating authority for Conformity Assessment Bodies which can demonstrate competence to evaluate all devices, including those which incorporate a medicine or material of animal, human or microbial origin. Complete alignment of classification rules between the Australian regulations and the European Medical Device Directive would enable third party conformity assessment to be implemented;
- The Therapeutic Goods Administration (TGA) should retain its role as a Competent Authority in determining which applications for inclusion in the Australian Register of Therapeutic Goods are accepted based on the conformity assessment evidence issued by third party Conformity Assessment bodies; and
- It is appropriate that following the recommendations of the Health Technology Assessment (HTA) Review in 2010, there has been clarification of the roles and functions of the Therapeutic Goods Administration (TGA), Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC). We support the enhancement to the clarification of these roles and functions in this way.

5. Terms of Reference - the cost effectiveness of subsidised devices

In the Australian private healthcare system, private health insurers pay mandatory benefits for a range of prostheses listed on the Prostheses List that are provided as part of an episode of hospital treatment where a Medicare benefit is payable for the associated surgical procedure. In the public healthcare system, devices are supplied under agreements or tender arrangements, that is, the devices are purchased by the government's health authority (hospital) directly from the supplier. Insurance may be applicable if a privately insured patient admitted to a public hospital elects to be treated as a private patient. The public hospital is then paid a benefit from a health insurer.

Cost effectiveness is an issue for both the Australian public and private health care sectors. Many of the issues in regard to the demonstration of cost effectiveness were canvassed in the Government's recent Review of Health Technology Assessment (HTA), of which Johnson & Johnson Medical put forward a submission. In assessing cost effectiveness, there is a significant role to be played by Health Technology Assessment (HTA) founded on conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients or "Evidence-Based Medicine". These are necessarily complex processes where overall success is predicated on appropriate levels of involvement and contribution from a range of stakeholders. Importantly, any assessment of cost effectiveness needs to take into account the totality of budget impacts across the entire health care system, and not just be isolated to one single payor. For example, the utilisation of medical technology within the private health care sector may accrue savings to the Pharmaceutical Benefits Scheme. These savings need to be captured in any complete analysis of cost effectiveness.

In addressing this Term of Reference we considered the methods of calculating cost effectiveness and the role of Health Technology Assessment (HTA). We have outlined below the key principles of Health Technology Assessment (HTA) including the interrelationship with Evidence-Based Medicine.

We have also made submissions concerning the use of Health Technology Assessment (HTA) (HTA) and Evidence- Based Medicine in the Australian Regulatory system.

The Role of Health Technology Assessment (HTA) in Cost Effectiveness

The International Network of Agencies for Health Technology Assessment (HTA) defines Health Technology Assessment (HTA) to be:

> *"a multidisciplinary field of policy analysis [studying] the medical, economic, social and ethical implications of development, diffusion and use of medical technology".*

Like many other governments throughout the world, Australia has embraced Health Technology Assessment (HTA) as an integral part of health policy development. When Health Technology Assessment (HTA) is performed within the framework of Evidence-Based Medicine, such evaluations have the potential to guide government policy makers, regulators, clinicians, healthcare providers, payors, and patients regarding the appropriate uptake and diffusion of new and existing medical technologies. Evaluations can cover all impacts of a health technology including its clinical, ethical, equity, social, legal and financial impacts.

The approach to Health Technology Assessment (HTA) and the costs included in Health Technology Assessment (HTA) should reflect society's investment in healthcare benefit rather than treat (new) technologies as cost centres.

Health Technology Assessment (HTA) can encourage innovation if the assessments are properly conducted and consider a wide range of costs and benefits associated with a new technology, rather than focus solely on acquisition costs.

It should be noted, however, that Health Technology Assessment (HTA) is not the same as Evidence-Based Medicine. According to Sackett et al (1996), Evidence-Based Medicine may be defined as:

> *"Evidence-Based Medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."*

Properly developed and applied, Evidence-Based Medicine can:

- Stimulate the development of high quality information about treatments and devices;
- Enhance consistent and informed healthcare decision-making by physicians, patients, caregivers and payors;
- Support patient access to appropriate technologies;
- Help establish the value of medicines, medical devices, diagnostics and other health services;
- Provide the basis for optimal use of healthcare resources; and
- Promote a more quality-focused and cost effective healthcare system which delivers superior patient outcomes.

Johnson & Johnson Medical supports Evidence-Based Medicine that seeks to achieve the above objectives. Evidence-Based Medicine should not be used as a barrier to restrict or delay access to new technologies.

Individual patient needs should supersede short-term cost considerations, especially for the use of new treatments that potentially address unmet medical need and that may change the paradigm of therapy.

Priorities for Evidence-Based Medicine should address diseases and conditions that are recognised as imposing a high clinical and economic burden on patients and society, rather than being limited to high-cost interventions.

Regulations governing Health Technology Assessment (HTA) processes should be fair and adhere to principles of best practice regulation and not impose costs that are unnecessary to realise the regulatory objectives.

Health Technology Assessment (HTA) should be used to:

- Inform and guide decision making; the data used in Health Technology Assessment (HTA) should adhere to principles such as transparency, consistency, reliability, the most appropriate evidence to the question at hand, with a view to aid rational decision making;

- Where Health Technology Assessment (HTA) is a formal requirement for reimbursement, it should expedite access for patients to innovative technologies and procedures. Health Technology Assessment (HTA) should not be used covertly as a justification for rationing, restricting coverage or cost containment;

- Provide information for decision making from a holistic (non-silo) perspective, and recommendations should be followed by implementation; and

- Achieve better health outcomes and enable choices to be made between healthcare options at the individual patient level.

Authorities should accept that effectiveness is not equivalent to efficacy, and should aim to improve real-life practice, so that there is consistency between efficacy and effectiveness. Where there is a high degree of uncertainty, there should be a favourable decision with a recommendation for additional data collection.

Health Technology Assessment (HTA) recommendations should be appropriately resourced and implemented to ensure the best possible outcomes. Although based on objective analysis, Health Technology Assessment (HTA) is embedded in the political environment, and social and cultural factors, as well as public opinion, can all influence aspects of the Health Technology Assessment (HTA) process.

Consistent with Drummond's[4] key principles for an optimal Health Technology Assessment (HTA) system, Johnson & Johnson Medical supports the following principles:

Totality of outcomes and costs

To ensure appropriate evidence-based decision making, an assessment of the benefits and value of a healthcare technology should consider:

- The full range of treatment options;
- The totality of healthcare costs (e.g. including drugs, hospitalisations or relapses); and
- All healthcare outcomes, including direct and indirect benefits to patients and society such as improved quality of life, patient functionality and workplace productivity.

Aside from the economic analyses, other parameters that should be considered are:

- Unmet medical need;
- Clinical judgement;
- Budget impact;
- Prevalence and severity of the condition;
- Patient-reported outcomes and preferences;
- Public health impact (i.e. does the technology address a public health priority);
- Equity of access;
- Societal impact (particularly on the family members and direct caregivers of patients); and
- Ethical considerations.

Medical technology costs should not be judged in isolation or in silos for budget setting and budget holding. The Australian healthcare system does not take total benefits and costs into account when assessing access to medical technology, both within sectors and across sectors.

For example, when examining the impact of medical technology on Commonwealth expenditure, consideration is not given to reductions in expenditure within the Pharmaceutical Benefits Scheme or Medicare.

[4] Drummond et al (2008) 'Key principles for the improved conduct of health technology assessments for resource allocation decision' *International Journal of Technology Assessment in Health Care* 24(3):244 – 258

Across sectors, there may be cost savings accruing between the private and public sectors. Again, if access to a particular medical technology was reimbursed and available to private sector patients, then this may reduce expenditure both under the Pharmaceutical Benefits Scheme and Medicare. At present these holistic assessments are not undertaken, leading not only to a silo mentality, but also to the non-realisation of cost savings within the overall expenditure on the healthcare system. The Government should be concerned with its own levels of expenditure, as well as the total resources that healthcare is consuming within the Australian economy.

Accountability and audit

- There should be a process to monitor the implementation of the recommendations made by the Health Technology Assessment (HTA) agencies; and

- A process should also exist or be put in place to monitor the impact of the recommendation on health indicators affected and the healthcare budget.

Completeness and consistency

- The appropriate evidence to demonstrate clinical efficacy/effectiveness of a medical technology should be provided. Evidence-Based Medicine should be based on a synthesis of all relevant data available including randomised controlled trials, observational studies, clinical expert opinion and decision modelling, weighted by the quality of the studies. Although randomised controlled trials are considered the gold standard, the majority of medical devices have short life cycles, so demonstrating efficacy in randomised controlled trials is not feasible. This is due to the investment, time and resources required to deliver health outcomes information. By the time the research is completed, the evidence is invalid or out of date for assessment. For the purpose of evaluating the benefits and value of technologies in clinical practice, other factors such as patient compliance, ease of use, convenience and other relevant attributes should also be taken into account;

- 'Evidence-based' methods should be applied consistently; otherwise the results of the synthesis can be misinterpreted. This leads to substantial variation in the validity of decisions and recommendations;

- Health outcomes research should use well-established standards for high-quality research and include disclosure of the strengths and limitations of the data and results; and

- Consistent data collection methods and interpretation should also be used to avoid undue reporting burdens on health providers, sponsors and others.

Access to appropriate technologies

- All Australians should have timely access to safe and clinically effective treatment as recommended by their clinician. As Australia's healthcare system is characterised by a blend of public and private sectors, better health outcomes for all Australians can only be achieved if choice and value is delivered to all stakeholders;

- Evidence-Based Medicine needs to accommodate innovation that is improving incrementally to new generations of technologies;

- Applications of Evidence-Based Medicine that focus solely on cost effectiveness target the "average" patient and may overlook individual differences. Clinical effectiveness may vary between individuals, hospitals and clinicians and this should be taken into account; and

- The lack of data, or a specified type of data does not automatically mean that an intervention is ineffective or that a patient should be denied access to it. Data requirements need to be flexible reflecting the prevalence of the condition, strength of data for existing treatments, and unmet needs in the current therapeutic context.

Multiple stakeholder input

- Health outcomes research and its applications, like all other areas of scientific enquiry, can be best advanced through a pluralistic approach;

- There should be the opportunity for all stakeholders to request a dialogue session with the assessment authority to present their views, feedback and objections;

- Guidelines for the evaluation of health economic data should concentrate on universal principles such as data integrity and methods consistency. The adoption of the conclusions from such guidelines should be voluntary in nature and should be subject to appropriate review in order to keep pace with rapidly advancing clinical practice and innovations; and

- International experience has demonstrated the clear benefits of broader stakeholder input into the Health Technology Assessment (HTA) process. For example, the National Institute for Clinical Excellence (NICE) in the UK allows all stakeholders (patients, clinicians, hospitals, payors, industry) the opportunity to participate and contribute to the Health Technology Assessment (HTA) process, in the scoping of the assessment, submission of evidence, comment on draft reports, and access to the rationale for recommendations. If this approach was adopted in Australia, then the Health Technology Assessment (HTA) agency would gain an understanding of the technology being assessed. At the same time, the sponsor would be in a better position to prepare for the Health Technology Assessment (HTA) requirements in terms of evidence requirements prior to lodgement of a formal submission.

Transparency and communication

All stakeholders should have reasonable access to the Health Technology Assessment (HTA) process at all key stages. This ideally requires:

- Timely notification of plans to assess a specific technology or procedure;
- Identification of study questions;
- Criteria for the review of evidence and explicit value judgements. The criteria used in the decision-making process should be clearly stated and the evidence base underpinning decisions should be made publicly available, with the exception of data submitted either as academic- or commercial-in-confidence;
- Clearly defined assessment process with open dialogue between the assessors and providers of information;
- Interaction with stakeholders (including sponsors, clinicians, healthcare providers, patient groups and other interested parties) during the review process. Decisions should not be made without input from specialists in the therapy area on the full range of benefits delivered;
- Availability of the draft report of findings;
- Opportunity for public comment on draft reports (including the draft final report);
- Dissemination of the final report of findings; and
- Justification of the rationale for the decision.

Dealing with uncertainty

Uncertainty should be addressed in an environment of partnership between the Health Technology Assessment (HTA) agencies and sponsors. This may involve submission of new data. The partnership environment should continue when additional data becomes available and draw on the evidence as it becomes available. There should be cooperation between the relevant stakeholders to maintain such data and draw on them. Reimbursement or coverage with evidence generation can be a valid way forward and allows flexibilities for all parties without compromising access.

Transferable evidence

It is recognised that clinical evidence is the most transferable between markets or countries. Health Technology Assessment (HTA) can contribute most by providing a core review of clinical evidence. However, it also needs to consider differences in clinical practice between countries. Current standards of care are unlikely to be homogeneous for all conditions reviewed.

It is also recognised that economic evidence is less transferable between markets or countries. Standards of care differ and therefore 'comparator' interventions may not be the same in each market, whilst economic dynamics of the healthcare market vary widely from country to country. Therefore, what may not be considered economically viable in one market could benefit another.

Core components that can be transferred could include systematic reviews of efficacy data and evidence of safety.

Country specific components could include:

- Clinical interpretation against local practice;
- Demographics and unmet need;
- Health policy agenda;
- Local comparators;
- Costs used in economic models;
- Cost effectiveness thresholds;
- Ethical considerations;
- Organisational consequences;
- Local resource use;
- Treatment patterns; and
- The structure of an economic model.

We submit that:

- All Australians, across both public and private healthcare systems, should have timely access to safe and clinically effective treatment as recommended by their clinician;
- Despite the complexity that is inherent in the use of Evidence-Based Medicine, that complexity should not be utilised as a barrier to restrict or delay access to new technologies in the Australian health care system, both public and private;
- In considering the priorities for Evidence-Based Medicine, consideration should be given to diseases and conditions that are recognised as imposing a high clinical and economic burden on patients and society, rather than being limited to high-cost intervention;
- Based on international experience, there are clear benefits to be gained from broader stakeholder input in the Health Technology Assessment (HTA) process. This input should come from a range of stakeholders including clinicians, hospitals, payors, patients and industry;
- When considering health care expenditure, government should not only be concerned with its own level of expenditure, but the total level of resources that healthcare is consuming within the Australian economy;
- The implementation of any recommendation around Health Technology Assessment (HTA) should be appropriately resourced to ensure the best possible outcomes;
- Regulations governing Health Technology Assessment (HTA) processes should be fair and adhere to principles of best practice regulation and not impose costs that are unnecessary to realise the regulatory objectives; and
- It is appropriate that following the recommendations of the Health Technology Assessment (HTA) Review in 2010, there has been clarification of the roles and functions of the Therapeutic Goods Administration (TGA)**,** Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC). We support the enhancement to the clarification of these roles and functions in this way.

6. Terms of Reference - the effectiveness and accuracy of billing codes and Prostheses List

Johnson & Johnson Medical supports the submission made by the Medical Technology Association of Australia (MTAA) in regard to this matter.

7. Terms of Reference - the process in place to ensure that approved products continue to meet Australian standards

In addressing the processes in place to ensure that approved products continue to meet Australian standards, there are a number of key matters that need to be taken into account. The first is the question as to what are "Australian Standards", and are they relevant to regulatory review of medical devices.

Secondly the current regulatory practice that governs regulatory devices once included on the Australian Register of Therapeutic Goods (ARTG). The current regulatory approach is based on a risk management. This approach is designed to ensure public safety and health with pre-market reviews directed towards higher risk devices and a robust post market surveillance system covering all devices. We support post-market monitoring of devices as it currently stands in the regulations. The Therapeutic Goods Administration (TGA) has a comprehensive strategy for on-going monitoring and vigilance for medical devices based on the Global Harmonisation Task Force Model.

International Standards

Although there are differences in administrative and review process, one of the successes of the Global Harmonization Task Force process has been extensive convergence of consensus standardisation in support of regulatory assessment. There is a large body of international (ISO and IEC) and European standards which are recognised in all major regulatory jurisdictions. There is active cooperation under the Vienna agreement for joint development of standards between ISO/IEC and Europe. The Therapeutic Goods Administration (TGA) formally gazettes a number of these international standards for use in Australian regulatory review and informally accepts almost all other international standards.

Australian standards although based on international norms are in some cases out of date. This follows the disengagement of Standards Australia from most international standards committees in the early 2000s.

Regulatory review is based upon external product testing data. The manufacturer establishes compliance to the current international standards – by means of testing which must be conducted by accredited independent laboratories. The regulatory review consists of examination of the independent test data and reports.

In summary, the issue is not compliance with Australian standards, but rather compliance with the international standards which are accepted by all sophisticated international regulatory jurisdictions, including Australia. We submit it is not feasible for a market the size of Australia to have a unique set of regulations which exceed international standards of equivalent overseas markets. This reinforces the position set out in our response to Terms of Reference (6) that the Therapeutic Goods Administration (TGA) needs to find a way to leverage the expertise embodied in international reviews conducted against the international, state of the art consensus standards.

Current Regulatory Practice

Once a medical device is included in the Australian Register of Therapeutic Goods and therefore approved, the device must continue to meet all of the safety and performance criteria that were required for the approval.

Section 22 of the Australian Regulatory Guidelines for Medical Devices details an extensive framework of ongoing responsibilities for the sponsor, manufacturer and Therapeutic Goods Administration (TGA) in monitoring and reporting the performance of medical devices in clinical use. Johnson & Johnson Medical supports the approach to post-market safety and performance monitoring and vigilance outlined in the guideline.

The current regulatory framework is based on a risk management approach designed to ensure public health and safety with pre-market review directed toward higher risk devices and a robust post-market surveillance system covering all devices.

It is a condition of inclusion for all high risk devices for the sponsor to provide three consecutive annual reports to the Therapeutic Goods Administration (TGA) following inclusion of the device in the Australian Register of Therapeutic Goods. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year. Complaints received by the manufacturer relating to the use of the device, including its supply under a different name, in other countries where the device is available must also be included.

In principle, Johnson & Johnson Medical supports post-market monitoring of products but the regulator should ensure that the new arrangement is superior (reduces overall costs or generates additional public benefits that exceed additional costs)

Registries are an important source of information in assisting companies in the monitoring of the performance of a procedure or product.

Submissions:

- At present, a manufacturer establishes compliance to the current international standards – by means of testing which must be conducted by accredited independent laboratories. The regulatory review consists of examination of the independent test data and reports. As a result, the relevant compliance standards, are the international standards which are accepted by all established and reputable international regulatory jurisdictions;

- In recognition of the resources available to the Therapeutic Goods Administration (TGA) and the resources available through internationally recognised bodies, the Therapeutic Goods Administration (TGA) should maximise the opportunity to access these international resources in order to leverage the expertise embodied in international reviews; and

- With respect to post market monitoring of devices, there is a need for any regulator to ensure that any new arrangements are superior in terms of reducing overall costs or yields additional public benefit that exceeds additional costs.

8. Terms of Reference - the safety standards and approval processes for devices that are remanufactured for multiple use

Johnson & Johnson Medical does not support the reprocessing of single use devices by third-party businesses. Third-party reprocessing raises serious patient safety, ethical and legal concerns, which need to be considered closely by all parties. Attached to this submission are three detailed submissions covering separate elements of this issue.

We understand the Therapeutic Goods Administration (TGA) is currently considering an application from a third-party reprocessor in respect of the registration of a number of reprocessed devices on the Australian Register of Therapeutic Goods. This has raised a series of concerns within the medical technology industry including the impact on patient safety. To date, these issues have not received any significant public scrutiny since the enabling legislation was passed in 2004. We would request the Committee carefully consider the wider range of issues surrounding the third-party reprocessing of single use devices.

Third-Party Reprocessing – Background

Single use medical devices used in surgical and diagnostic procedures are designed to ensure that patients receive the safest care possible with the least amount of risk. Each single use medical device is designed to be used once on a patient then discarded. Unlike devices that are designed for reuse, single use devices are designed for a single purpose for clear medical reasons. The reprocessed single use devices are used on a multiple number of patients.

The single use design has been created so that the device is sufficiently intricate, and made of a suitable material, so that it can perform complex clinical procedures. It is not designed to withstand the physical rigours of disassembly, sterilisation and remanufacture.

The single use medical devices include endoscopes, used in minimally invasive procedures, surgical instruments such as staplers, and devices for far more complex and invasive procedures such as electrophysiology catheters, which are placed into the heart. The single use devices should not be confused with purpose-built reusable devices such as certain surgical instruments, which are manufactured to be reused. They are normally made from durable surgical steels and designed so they can withstand the robust processes of disassembly and re-sterilisation.

The reuse of medical devices was once widespread within Australian hospitals, until the evident risks of infection and injury from the physical failure of worn-out devices led to calls from professional bodies and industry groups for the practice to be halted.

Third-party businesses have developed a market for reprocessing single use devices in the United States and other countries where regulations allow the reprocessing to occur. In Australia, the Therapeutic Goods Administration (TGA) has not to date approved applications for reprocessing, but it may receive further applications in future.

The reprocessing of devices involves several stages after usage: disassembly, cleaning and sterilisation, remanufacture, repackaging and transport. While these stages are typical of reusable devices, they are not suitable for single use devices.

Cleaning and sterilisation can be difficult in single use devices when they are not designed to be disassembled, leading to potential contamination. The assembly process can damage or weaken the performance of intricate devices and affect their durability.

The third-party reprocessors do not have full details of the device design, including manufacturer changes to the original design. This can create substantial technical challenges and affect compliance with critical regulatory safeguards, including materials safety and assessment of risk.

A range of studies and international experience shows that reprocessing introduces risks of cross-infection, the spread of transmissible diseases, device failure and patient injury[5]. More research is required to investigate each of these safety concerns thoroughly.

Reprocessing also raises questions of ethical responsibilities and legal liabilities which need to be considered. Typically patients are not informed that reprocessed devices are to be used or their consent requested. Surgeons and other clinicians also are not normally aware if a device they are about to use is reprocessed.

With financial pressures on hospitals, reprocessing appears to offer economic benefits due to its apparent lower cost. Such a cost-analysis, however, is simplistic as it ignores the associated costs to hospitals of internal management, regulatory compliance and potential legal liabilities.

The claimed environmental benefits of reprocessing also require further analysis. A full life-cycle analysis of reprocessing would give a more accurate assessment of its environmental impact. Quantifying disposal rates is a limited measure of sustainability.

In assessing regulation around the reprocessing of single use devices, close attention needs to be paid to the primary concerns of patient safety, risk and consent. These pose key questions:

Are reprocessed single use devices safe? Should patients be informed and their consent gained when using the devices? If evidence emerges of a health risk, do healthcare providers and facilities have a duty to notify affected patients? Who is responsible if a device fails or causes injury?

Third-Party Reprocessing – Current Status

Reprocessing is now subject to full Therapeutic Goods Administration (TGA) regulation, with third-party reprocessors required to meet the same regulatory requirements as the manufacturers of new single use devices. We understand that Australian hospitals have applied for Therapeutic Goods Administration (TGA) approval for reprocessing but none have been successful.

[5] European Commission. *Report on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC*. 2010 Brussels.

The United Kingdom and several European countries prohibit reprocessing. Most recently, the European Commission has accepted a formal opinion from its independent scientific advisory body, the Scientific Committee on Emerging and Newly Identified Health Risk, that the practice is unsafe.

In the United States commercial third-party reprocessing has been allowed since 2004, and is subject to the regulatory oversight of the Federal Drugs Administration. The Federal Drugs Administration's Adverse Events Reporting System and peer review literature shows emerging evidence of the risks of failure, injuries and adverse events from reprocessed single use devices. Six years on there is emerging evidence in the Federal Drugs Administration Manufacturer and User Facility Device Experience Adverse Events Report and in peer review literature of:[6]

- A substantial number of adverse event reports being submitted to Federal Drugs Administration for reprocessed single use devices;
- Patterns of suboptimal device performance with manifest clinical risk;
- Repeated instances of specific modes of failure associated with reprocessing, and
- A number of very serious injuries associated with reprocessed devices.

Johnson & Johnson Medical opposes the third-party reprocessing of single use devices based on the current available evidence. Our complete position on this issue is set out in the three detailed papers that accompany this submission in the Appendix:

- Johnson & Johnson Position Paper on the Reprocessing of Single Use Devices;
- Re-use of Singe Use Devices in Australia: Safety and Performance Imperatives and Challenges to Regulatory Compliance; and
- A patient's right to know and right to informed consent: Ethical and legal considerations concerning the use of reprocessed single use medical devices.

[6] Johnson & Johnson Medical, " Challenges to Regulatory Compliance" paper 10 March 2011

Submissions:

In considering the potential negative impacts third-party reprocessed single use devices may have on Australian patients, the Committee consider:

- The role informed patient consent plays in providing patients with the choice of whether a third-party reprocessed single use device is utilised on them during a procedure;
- The prohibitions that several European countries have in place regarding the third-party reprocessing of single use devices;
- The increasing level of evidence emerging out of the United States regarding adverse events related to the use of third-party reprocessed single use devices including injury to patients; and
- The evidence presented regarding the residual contamination of third-party reprocessed single use devices and the risk that introduces in regard to potential cross infection.

9. Terms of Reference -the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices & the effectiveness of the current regime in place to ensure prostheses with high revision rates are identified and action taken once these devices are identified

The regulations require a manufacturer to report adverse events to the Therapeutic Goods Administration (TGA)[7]. Such a requirement is present in all Global Harmonisation Task Force (GHTF) markets according to common guidance as to what should be reported, and to reporting timelines. However, such an approach has its limitations – for instance, there may be under-reporting because manufacturers may not be informed by users of adverse events and occasionally, over-reporting of trivial incidents (which may mask significant trends). In respect of these matters, we support the submission made by the Medical Technology Association of Australia (MTAA).

In particular, Johnson & Johnson Medical recognises the importance of identifying factors conducive to achieving successful health outcomes which result in improved standards and significant cost savings through reduced revision surgery. Clinical studies and registries are useful sources of information that provide data points which may assist in the overall assessment of the safety and effectiveness of products and procedures over a defined time period.

Specifically, registries can provide useful but generic real world evidence but have limitations that need to be recognised, such as:

- Registries generally only measure the number of procedures undertaken – a registry will generally consider revisions as an end point. It may not take into account or consider other effectiveness end points (such as patient reported outcome measures) or any other benefits that might accrue to stakeholders, including reduced length of stay, surgeon training and support, surgical efficiency or instrumentation management. These factors should be included in the overall assessment of a device or procedure;

- Registry data can be skewed by different products with different application techniques at the same or different centres. Registry data rarely accounts for such differences in the data analysis;

- Registry results can be very sensitive to intensity bias. Some interventions such as unicompartmental knee arthroplasty (UKA) and hip resurfacing arthroplasty are recognised as having an association between procedure volume and outcome. The Swedish Knee Registry and New Zealand Joint Registry have shown this for UKA. Analysis of registry data should allow for the effect of surgical volumes, both by the surgeon and by the institution when making comparisons between products;

[7] See Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002.*

- Registry results can be very sensitive to learning curve effects if products are compared at different points on their users' learning curves and is linked to intensity bias noted above;
- Most registries do not independently evaluate the root cause of revision procedures or the reason for failure. The Swedish registry has central evaluation of all revision procedures but the findings are not in the public domain. This is potentially an additional limiting factor when evaluating new technology, alongside the procedure volume and learning curve issues; and
- Simple comparisons using registry safety data alone are not suitable for evaluating products that present a different risk/benefit profile.

We would submit that registries should work in close collaboration with all stakeholders including sponsors and in government. This would consist in identification of the factors that impact the outcomes of joint replacement procedures so issues can be properly identified and improvements can be made. These improvements may include monitoring new product developments or the collaboration in the provision of appropriate and enhanced training.

We would submit that if the registry data were to be used to measure the success or otherwise of a procedure, it is important that the following be in place:

- Industry and other stakeholders be part of the group that peer-reviews the interpretation of registry results;
- Clear and transparent evidence that bias as noted above have been accounted for and their effects minimised in the data analysis;
- Technologies should be reviewed at appropriate and comparable points on their life-cycles. Products that are at an early point in their adoption curves can only be compared to other products at the same stage of adoption;
- The final evaluation should be conducted taking into account available clinical effectiveness evidence from other credible sources; and
- Industry should have access to information on individual hospitals using its products to better be able to operate post-marketing surveillance.

By way of illustration of a model which could be considered for governance and data access, we would suggest the Committee consider an assessment of other national joint arthroplasty registers. We set out below an example, for the Committee's reference, a summary of the United Kingdom National Joint Registry (NJR).

United Kingdom National Joint Registry

The United Kingdom National Joint Registry (NJR) is overseen by a Steering Committee which is made up of members and representatives from a range of stakeholder groups.

Members of the United Kingdom National Joint Registry (NJR) Steering Committee include:

- Chair (1);
- Orthopaedic surgical profession (3);
- Industry - Orthopaedic Implant Suppliers (2);
- Public Health and Epidemiology (1);
- Practitioner with special interest in orthopaedics (1);
- NHS trust management (1);
- Independent healthcare sector member (1); and
- Patient representative (1)

The United Kingdom National Joint Registry (NJR) Steering Committee responsibilities include:

- Setting the United Kingdom National Joint Registry's (NJR's) work programme and monitoring its progress;

- Providing advice to Ministers, orthopaedic units, hospitals and implant suppliers where the information shows concerns about the concerns of certain prostheses;

- Setting the cost of the levy, based on the contractual costs of running the Registry and the work programme agreed;

- Providing an annual report to Ministers on the performance of the United Kingdom National Joint Registry (NJR) and following Ministerial agreement, to make publicly available;

- Establishing and monitoring codes of conduct for the contractor dealing with orthopaedic units within NHS trusts and independent healthcare providers, as well as the orthopaedic implant industry; and

- Facilitating, where appropriate, the use of United Kingdom National Joint Registry (NJR) data for research purposes.

Industry representatives are represented on the Implant Performance Committee that is responsible for the outlier evaluation process, but are not on the Implant Scrutiny panel for obvious conflict of interest reasons.

Data access

The United Kingdom National Joint Registry (NJR) validates the collection of data, and analyses it to provide performance information on joint replacements and on outcomes for hospitals and individual surgeons. The analysed data can then be transmitted to stakeholders with due regard for patient and clinician confidentiality.

The details of the type of data collected by the United Kingdom National Joint Registry (NJR) is set out in Attachment A, a data collection sheet. The United Kingdom National Joint Registry (NJR) data collection process enables a comprehensive analysis of procedural outcomes to be undertaken and a wider range of any contributing factors to trends observed to be identified and analysed.

For the investigation of higher than expected revision rates (outliers) of both implants and surgeons, the United Kingdom National Joint Registry (NJR) has established a process for assessment, documentation and notification of the relevant stakeholders. This involves the determination of agreed statistical methodology and reporting timeframes. This process is outlined in Attachment B.

Clinicians have online access to their own data. This access allows them to carry out analyses.

Personal patient information is only available to the individual patient and their surgeon. Patients are able to see their own records off-line in accordance with the UK privacy legislation.

Suppliers are able to access anonymised patient level data on their own products updated on a monthly basis. This dataset also contains surgeon and surgical unit reference numbers to allow centre or surgeon effects to be identified for further investigation.

The analyses of individual surgeons' data is only available to surgeons and their employing orthopaedic hospitals (where the surgeon has given consent).

Anonymised data is made available for research purposes but the data is aggregated in such a way that it is not possible to identify an individual surgeon or patient.

The United Kingdom National Joint Registry (NJR) states that it is seeking to deliver direct benefits to patients by[8]:

- Improving patient awareness of the outcomes of hip, knee and ankle replacements;
- Finding out how long the different joint replacements last; and
- Helping to identify individual patients who have received an implant if there is a need for urgent clinical review.

[8] http://www-new.njrcentre.org.uk/njrcentre/Patients/IntroductiontotheNJR/tabid/89/Default.aspx

The Committee could consider the United Kingdom National Joint Registry (NJR) in terms of joint registry governance. Industry is able to access real time data for the sponsor's own products compared to the overall product class. The data should facilitate post marketing surveillance and internal review of data on new products and identify and assess training effectiveness and learning curves of surgeons. Data on newly introduced products can be evaluated on a monthly basis to ensure any clusters or poor performance can be identified and evaluated in a timely manner.

Submissions

- In considering the governance of registries that the Committee consider examples such as the operation of Australian and international registries and recognise the benefits that a broad range of stakeholder involvement may bring to delivering better outcomes in the operation of a registry. We acknowledge that a consultative committee to the Australian Orthopaedic Association National Joint Replacement Registry has been formed including stakeholders from the industry. However, we would like to see broader implementation (including patients, administrators and industry) in the governance of the registry itself;

- With specific regard to joint replacements, registries should work collaboratively with all stakeholders including sponsors, to identify the factors that impact the outcomes of joint replacement procedures so that improvements can be made. These may include new product developments or the provision of appropriate training for improvements in surgical technique; and

- In order to maximise the benefits of a registry, industry and other stakeholders should be part of the group that peer reviews the interpretation of the registry's data.

10. Terms of Reference - the effectiveness of the implemented recommendations of the Health Technology Assessment (HTA)

Johnson & Johnson Medical supports the submission made by the Medical Technology Association of Australia (MTAA) in regard to this matter.

11. Conclusion

Johnson & Johnson Medical supports the continuing efforts to enhance the regulatory standards for the approval of medical devices in Australia.

We are committed to working with Government and stakeholders to enable enhanced access to high quality healthcare for Australians.

In this spirit, we thank the Senate Community Affairs Reference Committee for the opportunity to make this submission. We are pleased to submit this document for the Committee's consideration.

APPENDIX

Johnson & Johnson Medical Pty Ltd

Submission to Senate Community Affairs Reference Committee

Reuse of single use medical devices in Australia
A position statement from Johnson & Johnson Medical

29 July 2011

Johnson & Johnson Medical Pty Ltd
1-5 Khartoum Road, North Ryde, NSW 2113 Australia

Executive Summary

Single use medical devices used in surgical and diagnostic procedures are designed to ensure that patients receive the safest care possible with the least amount of risk.

Each single use medical device is designed to be used once on a patient then discarded. Unlike devices that are designed for reuse, single use devices are designed for a single purpose for clear medical reasons. The reprocessed single use devices are used on a multiple number of patients.

The single use design has been created so that the device is sufficiently intricate, and made of a suitable material, so that it can perform complex clinical procedures. It is not designed to withstand the physical rigours of disassembly, sterilisation and remanufacture.

The devices include endoscopes, used in minimally invasive procedures, surgical instruments such as staplers, and devices for far more complex and invasive procedures such as electrophysiology catheters, which are placed into the heart.

Third-party businesses have developed a market for reprocessing single use devices in the United States and other countries where regulations allow third-party reprocessing to occur. In Australia, the Therapeutic Goods Administration (TGA) has not to date approved applications for reprocessing, but it may receive further applications in future.

This position statement argues that Johnson & Johnson Medical does not support third-party reprocessing of single use devices by third-party businesses. Third-party reprocessing raises serious patient safety, ethical and legal concerns, which need to be considered closely by all parties.

The reprocessing of devices involves several stages after usage: disassembly, cleaning and sterilisation, assembly, repackaging and transport. While these stages are typical of reusable devices, they are not suitable for single use devices.

A range of studies and international experience shows that reprocessing introduces risks of cross-infection, the spread of transmissible diseases, device failure and patient injury. More research is required to investigate each of these safety concerns thoroughly.

Cleaning and sterilisation can be difficult in single use devices when they are not designed to be disassembled, leading to potential contamination. The assembly process can damage or weaken the performance of intricate devices and affect their durability.

The third-party reprocessors do not have full details of the device design, including manufacturer changes to the original design. This can create substantial technical challenges and affect compliance with critical regulatory safeguards, including materials safety and assessment of risk.

Reprocessing also raises questions of ethical responsibilities and legal liabilities which need to be considered. Typically patients are not informed that reprocessed devices are to be used or their consent requested. Surgeons and other clinicians also are not normally aware if a device they are about to use is reprocessed.

The single use devices should not be confused with purpose-built reusable devices such as certain surgical instruments, which are manufactured to be reusable. These are normally made from durable surgical steels and designed so they can withstand the robust processes of disassembly and re-sterilisation.

The reuse of medical devices was once widespread within Australian hospitals, until the evident risks of infection and injury from the physical failure of worn-out devices led to calls from professional bodies and industry groups for the practice to be halted.

Reprocessing is now subject to full Therapeutic Goods Administration (TGA) regulation, with third-party reprocessors required to meet the same regulatory requirements as the manufacturers of new single use devices. Australian hospitals have applied for Therapeutic Goods Administration (TGA) approval for reprocessing but none have been successful.

The United Kingdom and several European countries prohibit reprocessing. Most recently, the European Commission has accepted a formal opinion from its independent scientific advisory body, the Scientific Committee on Emerging and Newly Identified Health Risk, that the practice is unsafe.

In the United States commercial reprocessing is allowed, and is subject to the regulatory oversight of the Federal Drugs Administration. The FDA's adverse events database and peer review literature shows emerging evidence of the risks of failure, injuries and adverse events from reprocessed single use devices. More research, however, is needed to allow for more definitive conclusions.

With financial pressures on hospitals, reprocessing appears to offer economic benefits due to its apparent lower cost. Such a cost-analysis, however, is simplistic as it ignores the associated costs to hospitals of internal management, regulatory compliance and potential legal liabilities.

The claimed environmental benefits of reprocessing also require further analysis. A full life-cycle analysis of reprocessing would give a more accurate assessment of its environmental impact. Quantifying disposal rates is a limited measure of sustainability.

The Therapeutic Goods Administration (TGA) is likely to receive future applications from commercial reprocessing businesses to reprocess single use devices. To gain approval the reprocessors will need to demonstrate adequate compliance, which could require significant oversight of the devices by the Therapeutic Goods Administration (TGA) to allay clinical and community concerns.

In assessing regulation around the reprocessing of single use devices, close attention needs to be paid to the primary concerns of patient safety, risk and consent. These pose key questions:

Are third-party reprocessed single use devices safe? Should patients be informed and their consent gained when using the devices? If evidence emerges of a health risk, do healthcare providers and facilities have a duty to notify affected patients? Who is responsible if a device fails or causes injury?

This paper outlines the research, evidence, international experience and regulatory approaches to aid in the consideration of the issues.

Contents

Definitions

Reprocessing	Cleaning, testing, disinfecting, re-sterilising, labelling, and packaging single use devices that have already been used on a patient with the aim of restoring that device so that it may be used again with the same guaranteed quality, safety and functionality as the original product.
Resterilisation	Repackaging and re-sterilisation of medical devices that have become non-sterile, but have not yet been used.
Reusable device	A medical device that has been designed and manufactured to be disassembled, cleaned, resterilised and reassembled so that it can be used in patients many times.
Single use device	A medical device (instrument, device or machine) that has been manufactured to be used in humans and has been marked by the original manufacturer for single use only.
Third-party reprocessors	The third-party businesses that conduct the reprocessing of single use devices so that they may be used multiple times in patients.

1. Introduction

Single use devices are medical devices that have been designed to be used on one patient a single time. Prior to their development, medical devices were commonly reused in patients; some devices today are still designed and manufactured to be reused safely.

The emergence of blood-transmitted diseases in the early 1980s led to a shift away from devices being reused and the development of single use devices.[2] The types of materials used in their manufacture changed from glass, metal and rubber, which could be readily reprocessed by steam sterilisation, to plastics and other materials.

The new synthetic materials have high performance values and together with other technological advances enabled the medical devices to become more intricate and delicate, which allows greater access and less tissue damage during more invasive surgeries. Lumens, for example, became smaller and the mechanisms more complicated.

The new devices were considered difficult, if not impossible, to clean or sterilise to adequate standards as plastics are less resistant to the physical or chemical treatments and the high temperatures that are typically used during steam sterilisation.[2, 11, 13] They were consequently defined as “single use” only.[2]

The single use devices improved patient safety for both medical and practical reasons. The reusable devices are subject to strict requirements for cleaning, disinfecting and sterilizing, in particular the stringent requirements of AS/NZS 4187:2003.[11] Consequently the reusable devices must be made of robust materials and undergo a range of processes to meet the Australian standard.

The reuse of medical devices means that health care facilities must have the necessary sterilisation equipment, skills, close management and care to meet the standards. Not all facilities have the required equipment or necessarily the capability to properly sterilise devices, particularly complex devices [15]. Trocars, for instance, which allow access to the abdominal cavity for laproscopic surgery, are difficult to sterilise. Single use trocars eliminate the need for sterilization, decreasing the risk of infection and the risk of transmissible diseases caused by inadequate cleaning, such as HIV.[15]

Today the medical devices that are most often designed as reusable are certain common surgical instruments. These are manufactured from durable materials – mainly surgical steels, and designed in such a way that they can be easily disassembled, completely cleaned and resterilised. The devices that meet the rigorous standards for cleaning and resterilisation must be robust and are therefore costly.

Overall, the advent of single use devices has been driven by two medical imperatives:

- The need to eliminate the risk of cross-infection associated with reusable devices used in surgical procedures on multiple patients, and

- The need for designs, particularly for invasive devices such as complex catheters and endoscopes, which are smaller, more intricate and delicate to allow for improved invasive access with minimal tissue trauma.

The reprocessing of single use devices by third-party businesses is a new and developing industry, which has only been researched to a limited extent.[1] The reprocessing of single use devices occurs most frequently due to increasing financial pressures in hospitals.[2, 3]

Third-party reprocessors have argued that reprocessed single use devices offer economic benefits for hospitals due to the lower cost of a reprocessed device versus a new single use device. The industry has also claimed that reprocessed devices may be safer than original devices because each device must be inspected before use.[8] These claims are not supported by evidence.

During the last decade, a range of overseas studies into reprocessing of single use devices and experience to date have pointed to the potential risks involved to patients of infection and the potential failure of a device that has been used multiple times.

In 2010 the European Commission's independent scientific advisory body, the Scientific Committee on Emerging and Newly Identified Health Risk, raised multiple risks surrounding reprocessing single use devices, including potential for infection, device failure and contamination. The committee called for research to be undertaken to evaluate and validate functional performance of reprocessed single use devices [2].

In Australia the reprocessing of medical devices is regulated by the Therapeutic Goods Administration (TGA). This followed an Expert Panel Report in 1994 by the National Health and Medical Research Council (NHMRC) that either a blanket ban on reprocessing should be put in place or the practice regulated by the Therapeutic Goods Administration (TGA).[40, 41]

Subsequent changes to the Therapeutic Goods Act in 2002 require third-party reprocessors to meet the same regulatory requirements as those applying to the manufacturers of new devices. They must fully meet Therapeutic Goods Administration (TGA) Safety and Performance standards before they may legally supply reprocessed single use devices; they are also subject to Therapeutic Goods Administration (TGA) assessment of design and manufacturing controls.

Since the legislative changes, several hospitals have applied to the Therapeutic Goods Administration (TGA) seeking approval to reprocess single use devices but none have been successful. It is likely that applications for approval of reprocess single use devices will continue to be submitted to the Therapeutic Goods Administration (TGA).

2. Patient safety

The potential risks to patient safety resulting from the use of reprocessed single use devices can be summarised as:[12]

- The potential for cross infection due to the inability to clean and decontaminate the device;
- The potential for chemical burns or allergic reactions due to the residues used in chemical decontamination; and
- Possible device failure due to alteration of component materials.

The nature of these risks, and how they arise, are described in a range of research reports and studies discussed below.

2.1 Cross-infection

Single use devices are often manufactured so that it is either difficult or impossible to dismantle them.[27]. This increases the risk of cross-infection as proper cleaning and sterilising of the devices requires them to be dismantled.[12]

Devices that have narrow lumens are particularly vulnerable as they are made of synthetic materials that are heat sensitive. Materials that cannot withstand high heat cannot undergo steam sterilisation, posing the risk of viable microorganisms being transferred between patients.[12]

Unsterile reprocessed single use devices have led to cross-infection and deaths, according to some reports.[28]

Despite rigorous cleaning and sterilisation, one study published in 2001 showed that viruses remained on 30 per cent of single-use cardiac catheters that had been reprocessed [29].

A German study found that reprocessed single use devices failed to be decontaminated even when the existing regulatory standards for cleaning, disinfection and sterilisation were met.[4] This study also found that reprocessing procedures may result in material changes, which add to the degradation and reduced functional integrity of single use devices.

Another concern is the build-up of abnormal proteins associated with prion diseases such as Creutzfeldt-Jacob Disease (CJD) and the variant Creutzfeldt-Jacob Disease (vCJD). These abnormal proteins are resistant to all conventional methods of decontamination and sterilisation, thus presenting a very real risk of transmission in reprocessed single use devices.

In the United Kingdom reprocessing of single use devices is prohibited. The UK Medicines and Healthcare Regulatory Agency (MHRA) strongly discourages reprocessing because of the risk of transmission of vCJD between patients.

The British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group Endoscopy and vCJD Subgroup estimated that 60 people were exposed to potentially contaminated health care instruments in 2007.[7]

The working group recommends using single use accessories wherever possible, and certainly for all high-risk patient groups.[7]

The risk of transmitting hepatitis is also an issue. A 1994 study of an outbreak of hepatitis C in a NSW hospital found a possible link between the use of a reprocessed single use device and the infection. The study found a transmission could have occurred through the laryngeal mask used in the administration of the anaesthetic.[33]

2.2 Allergic reactions, chemical burns and toxic shock

Some single use devices are made of materials that may absorb the chemicals used in the disinfection process, such as glutealaldehyde. These chemicals may leach out during use of the device that has been reprocessed, posing a risk of chemical burns or allergic reactions occurring in both the patient and the clinician.[12]

During sterilisation, gram-negative bacteria are killed; however, endotoxins can build up. Endotoxins are not made inactive through sterilisation and can lead to life-threatening toxic shock.[12]

Further, the remains of bacteria, viruses, proteins, or blood cells after the sterilisation process may act as pyrogens and therefore induce an inflammatory immune response.[31-33]

2.3 Device failure

During clinical use, devices undergo a certain amount of stress. Manufacturers of reusable devices take this into account in their manufacturing process. Manufacturers of single use devices do not. As a result, fatigue-induced failure may occur in reprocessed single use devices[12]. Reprocessed single use device devices may appear to be acceptable visually, but then fail during the operative procedure.[12]

Some instruments pose a significant threat if they fail during surgery. For example, the failure of trocars, the instruments used to provide access during minimally invasive surgery, can lead to puncturing of blood vessels and significant bleeding.[12]

An evaluation of 27 reprocessed devices by the Cordis Miami Chemical and Physical Quality Assurance Laboratory in the US found deficiencies in product functionality after reprocessing [37]. For example, balloon catheters were found to have the following defects: the trackability of balloon catheters was affected; the balloons could not be prepared in accordance with the instructions for use; and the movability of the guiding wire of the balloon catheter was reduced.[37]

The Cordis study found that 26 per cent of the reprocessed devices showed contamination with blood or proteinaceous material, 50 per cent showed residual contrast media and 63 per cent showed packaging errors.[37] They further noted that the manufacturer's lot number was not included with the repackaged device.

Poor labelling of reprocessed single use devices can lead to problems in the case of product recall. In cases where regulations require the tracing of products or monitoring of reprocessing frequency, accurate labelling is essential to assess compliance.

2.4 Case study findings

While the research described above indicates the risks to patient safety posed by reprocessing, further research is needed to properly identify and quantify the risks throughout each stage of reprocessing.

Johnson & Johnson Medical commissioned four research studies into a range of single use devices that had been reprocessed to supplement existing research.[46] The case studies investigated device functionality, sterility and the adequacy of packaging at the end stage of reprocessing i.e., when the reprocessed device was ready for use at a health care facility.

The research found evidence of contamination by residues in the devices, the presence of blood, and reduced functionality, damaged packaging, mislabelling and missing instructions. The case studies, detailed at Attachment A, can be summarised as follows:

- **Case study 1.** The research analysed catheters. Blood residue was found on the set screw and anchor pin slot of the catheter and white and/or green residue. No instructions for use were included; however, general safety instructions were provided;

- **Case study 2.** Five single use devices that had been reprocessed were analysed, including an electrophysiology catheter, an endoscopic linear cutter and an ultrasonic scalpel. Several instruments were contaminated with a brown/red substance and a possible adhesive bond was found on the scalpel handle. A red fibre was found in the internal mechanism of the scalpel and the shears were no longer fully patent. The original manufacturer's name on the label of the electrophysiology catheter was incorrect and the description did not comply with the specification of the type of catheter;

- **Case study 3.** The ARL study of 40 ultrasonic scalpels found a red or brown protein-based residue in 70 per cent of the instruments and the presence of blood in 30 per cent; and

- **Case study 4**. The Exova study of 50 ultrasonic scalpels found a red or brown protein-based residue in 62 per cent of the instruments and the presence of blood in 30 per cent.

3. Informed consent and legal liability

In a health care environment, informed consent is the process where patients consent to, or refuse, a medical intervention based on information provided by a health care professional regarding the nature and potential risks of the proposed intervention.[42]

By definition informed consent cannot be given unless patients have sufficient information to assess whether they should proceed with a recommended treatment. If they are given no information, or inadequate information, they cannot actively participate in the decision-making process.

Informed consent places considerable onus on the health professional or institution concerned to fully inform a patient about the risks involved in a procedure. Across the health care sector it is sometimes described as 'the most important legal doctrine in patients' rights'.[43]

Ethically, the trust at the foundation of the doctor-patient relationship includes the expectation that patients have a right to make their own decisions concerning their own medical treatment. This understanding is at the basis of the legal notion of informed consent.

The ethical and legal aspects of informed consent raise the question of whether informed consent would need to be gained if reprocessing of single use devices was to occur in Australia.

A research paper on the ethical and legal aspects of reprocessing found the potential risks raised many health, ethical and legal issues. "The depth and complexity of these issues underline the need for a patient's right to know and right to give informed consent in this matter."[43]

A health care provider who ignored a duty to warn and failed to inform a patient of the use of a reprocessed single use device could conflict with both ethical and legal expectations. The paper concluded it was theoretically likely that doctors and health care institutions would be exposed to liability, especially where no disclosure was made to patients regarding the use of reprocessed devices.[43]

In Europe, the principle of the informed patient has led to the increasing importance of medical information being transparent and supplied to the patient prior to a medical procedure. This trend suggests that given the potential safety issues, a patient should be informed if a reprocessed single use device is to be used, and their potential risks and benefits explained.[7]

While patients give informed consent to undergo a procedure, it is not common practice to inform patients that a reprocessed single use device is to be used.[3] One regulatory study said this could be considered equivalent to a clinical trial being conducted when no informed consent was gained and when patient benefit was questionable .7]

In Canada, a healthcare provider is legally required to disclose the risk information that a reasonable person in the patient's position would want to know. This means that a patient who is harmed through the use of a reprocessed single use device might argue that he or she ought to have been informed that a reprocessed device was to be used.[3]

The legal questions that need to be clarified include:[3]

- Who is responsible if a patient is harmed by using a reprocessed single use device?
- Should patients be informed, and provide consent, that a reprocessed single use device will be used as part of their treatment?
- If new evidence emerges that reprocessed single use devices pose a health risk, do health care facilities and providers have a duty to trace affected patients and notify them of this risk?
- Is it fair practice that a patient is charged by their private health insurance for a new device, but is then sold a second-hand device?

In Australia, the legal and ethical issues regarding informed consent have not been considered or debated by professional and regulatory bodies. They require further attention so as to minimise liability and maintain the primary goal of ensuring patient safety and trust.

4. International regulation

Regulatory authorities overseas vary in their approach to the reprocessing of single use devices. Some authorities have banned the practice on the basis the risks outweigh any perceived benefits; others have approved reprocessing to varying degrees.

4.1 United Kingdom

The United Kingdom prohibits the reprocessing of single use devices due to serious concerns about the risk of cross- contamination with Creutzfeldt-Jacob disease (CJD), known as mad cow disease in the 1980s, and the variant Creutzfeldt-Jacob Disease (vCJD).[8, 9]

CJD is an infection caused by prions, which are disease-causing agents that are not bacterial, fungal or viral. Prions have been held responsible for a number of degenerative brain diseases, including CJD. Prions normally occur in proteins that are harmless; however, the normal protein can turn into a rogue agent, which co-ops other normal proteins to become rogue prions.

Prion contamination poses a serious danger in reprocessed single use devices as they cannot be eliminated through sterilisation. If prions are transferred from a patient to a single use device, they cannot then be rendered inactive through subsequent decontamination procedures using heat or chemicals.

The UK Medicines and Healthcare Regulatory Agency (MHRA) strongly discourages reprocessing because of the risk of transmission of vCJD between patients. The European Union's advisory committee has also expressed specific concerns about the transmission of prions,[2] as discussed below.

Several British medical working groups recommend the use of single use accessories, particularly for high-risk patients, due to contamination and cross-infection risks.[7]

In addition to possible prion contamination, UK and regulatory authorities are concerned by the potential reduced efficacy of reprocessed single use devices, which may threaten patient safety through iatrogenic harm.

Market research conducted in the UK found that when choosing to use a single use device, clinicians take into account concerns about the risk of infection and the risk of injury. Most clinicians preferred the use of single use devices on themselves and their family if they were patients, rather than reprocessed single use devices.[23]

4.2 Europe

The reprocessing of single use devices is not approved in many European countries and prohibited in several others. Some European Union members have introduced varying degrees of regulation; others have no regulations or bans.

The EU has no uniform policy governing the reprocessing of single use devices.[16]

Most recently, however, the European Commission sought a formal opinion from its independent scientific advisory body, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), about the risks involved in the reprocessing of single use devices.

The SCENIHR's 2010 report raised multiple concerns about the hazards involved in reprocessing single use devices and identified three major hazards:

- Remaining contamination;
- The persistence of chemical substances used during the reprocessing process; and the
- Alterations in the performance of a single use device due to the reprocessing.

The advisory body recommended that not all single use devices were suited for reprocessing. It expressed specific concern about the potential contamination with transmissible agents such as prions, for which elimination and inactivation is not possible. The committee was also concerned that reprocessing was not compatible with the materials generally used for a single use device.[2]

The SCENIHR noted that while the number of documented incidents was very small, the reporting of incidents could be incomplete. There might be a 'grey' area related to adverse events, for instance, where it was difficult to recognise and attribute the cause of the event. For example, a surgical procedure could be prolonged due to the stiffness of a cardiac catheter that had been reprocessed or hospital days could be prolonged.[24]

The SCENIHR recommended that more research be undertaken to identify and reduce potential hazards associated with reprocessing. It recommended that the whole reprocessing cycle be evaluated and validated, starting with the collection of single use devices after their first use up until the final sterilization and delivery step, including its functional performance.

The European Commission accepted the formal advice of the SCENIHR about the hazards and unsuitability of single use devices for reprocessing.[2] In accepting the advice, the commission said:

> *"Although clinical data is limited, the SCENIHR opinion identifies several potential hazards of re-using single use devices that may lead to a risk for patients. The opinion concludes that certain design features make a single use device unsuitable for reprocessing. Major hazards can arise from inadequate cleaning, disinfection and/or sterilization, resulting in contamination and possibly causing toxic reactions or infections. Chemicals used for disinfection may also affect the performance of the device. Areas of particular concern are the potential contamination with agents that cause transmissible spongiform encephalopathies (TSEs) and the risk of using reprocessed single use devices in invasive medical procedures. Other hazards mentioned in the opinion include poor traceability of a reprocessed single use device and loss of documentation such as the instructions for use."*

4.3 United States

The United States has allowed the commercial reprocessing of single use devices since 2004, under the regulatory oversight of the FDA. The FDA monitors reports of adverse events involving reprocessed single use devices and regularly inspects third-party reprocessors.[20]

Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) all reprocessed single use devices, and their third-party reprocessors, are required to be identified.[18]

Reprocessed single use devices are recorded in all reports of adverse events within the Manufacturer and User Facility Device Experience (MAUDE) database. Between 2003 and 2006, the database recorded 434 reports of events where reprocessed single use devices were identified.[20] The reprocessed devices were assessed to be a causal factor in 15 per cent, or 65, of the adverse events.[20]

Johnson & Johnson Medical recently conducted a review of the latest MAUDE data, as no formal review had been conducted since 2006, and found the number of adverse events associated with reprocessed single use devices had increased by more than ten-fold since 2006 to around 750 events.[44].

Most reports related to malfunction of surgical instruments, particularly electrocautery devices, staplers, harmonic scalpels and arthroscopic shavers and similar devices. Several reports described serious injuries arising from excessive tissue adhesion to harmonic scalpels.

The recent data review together with peer review literature revealed emerging evidence of adverse events associated with reprocessed single use device:[44]

- A substantial number of adverse event reports being submitted to the FDA for reprocessed single use devices;
- Patterns of suboptimal device performance with manifest clinical risk;
- Repeated instances of specific modes of failure associated with reprocessing; and
- A number of serious injuries associated with reprocessed devices.

Note that the recent review is based on the summary records in the MAUDE database and not on primary clinical records. Interpretation of the data also requires caution. Adverse events are generally considered under-reported, with the FDA estimating that reporting to MAUDE reflects only one to ten per cent of actual events.[45].

The FDA holds the position that available data show that single use devices can be reprocessed with a reasonable assurance of safety and effectiveness.[20] The FDA holds the view that reprocessed single use devices that meet the FDA's regulatory requirements are as safe and effective as a new device.[20]

The FDA assigns a risk category to devices based upon the level of risk posed and the controls necessary to ensure safety and effectiveness.[20]

- Class I devices (low-risk, e.g. elastic bandages) are exempt from pre-market submission requirements set for in Section 501(k) of the FDA (pre-market notification).[20]

- For Class II devices (medium-risk, e.g. powered bone drills), the manufacturer is required to submit a premarket notification report that provides evidence that the device is substantially equivalent to a device already on the market.[20]

- For Class III devices (high-risk, e.g. balloon angioplasty catheters), manufacturers must submit a pre-market approval which includes clinical data demonstrating that the device is effective and safe. [20]

The FDA's inspections of reprocessors between 2005 to 2008 found that seven out of ten (70 per cent) had problems in reporting requiring corrective action.[20] Six of the reprocessing businesses took actions considered adequate to address the identified deficiencies. The seventh was still undergoing inspection and resolving the identified deficiencies, including failure to investigate reported problems with reprocessed single use devices and failure to report problems to the FDA within the required timeframe.[20]

In 2008, the US Government Accountability Office reported that neither existing FDA data or studies performed by others were sufficient to draw definitive conclusions about the safety of reprocessed devices.[20] No head-to-head studies have compared the safety and effectiveness of reprocessed single use devices versus the similar original devices.[20]

However, the FDA's position is that the cost of conducting such studies would not be an efficient use of resources given that the limited evidence available does not indicate that reprocessed single use devices present a patient safety risk.[20]

Key stakeholders have raised important concerns about the FDA's position on the reprocessing of single use devices. The Centre for Patient Advocacy expressed concerns that: [6]

- Single use devices are intricate in their design, and are not manufactured in a way that allows them to be easily cleaned, refurbished or re-sterilised;

- The devices are made from materials and component parts that may not safely be reused;

- The majority of patients are unaware of reprocessing and the risks that imposes during their surgery; and

- More than 70 per cent of surgeons, nurses and patients do not support the reprocessing of single use devices.

Similar concerns are held by the Society of Gastrointestinal Nurses in the United States.[7]

The Centre for Patient Advocacy recommended that the reprocessed single use devices must be held to the same rigorous safety and efficacy standards as the original single use device, and the burden for demonstrating this should fall on the reprocessor.[6]

The centre concluded that strict FDA oversight is required to minimize risks to patients and help ensure patient safety.[6] A randomised clinical trial of new versus refurbished external fixation devices sold in the US as a single use device had 65 per cent of their eligible patients (n=274) refuse participation. This shows that most patients are risk averse when given a choice between single use device and reprocessed devices.[21]

4.4 Canada, Japan and New Zealand

Canada currently has no guidelines on the reprocessing of single use devices, although a national Scientific Advisory Panel on Reprocessing of Medical Devices made some recommendations in 2007.[22]

Certain provinces have banned reuse of single critical use devices and other provinces have said that hospitals should use a licensed reprocessor.

In Japan, single use devices are required to be labelled “single use” and the instructions for use must contain “reuse is prohibited”.[25]

Hospitals in New Zealand follow the Australian and New Zealand standards (AS/NZS 4187:2003) on the cleaning, disinfecting and sterilisation of reusable medical devices and surgical equipment.[11] There is no specific regulations dealing with the reprocessing of single use devices.

Although it is recommended that used single use devices be discarded, local hospital policies and procedures apply. A survey showed that hospitals had only limited auditing of compliance to policies and procedures for the reuse of single use devices.[16]

5. Regulation in Australia

The reprocessing of single use devices in Australia is regulated by the Therapeutic Goods Administration following changes to the Therapeutic Goods Act in 2002.

Initially, Australian hospitals commonly reprocessed medical devices in facilities that were unregulated. However, concerns were raised about high reusage rates of devices in multiple patients; in one case, electrophysiology catheters were being reused in the hearts of more than 100 patients. Professional bodies and industry groups called for reprocessing to be stopped due to the risks of cross infection, patient injury and device failure.

A subsequent investigation by an NHMRC Expert Panel recommended that the reprocessing of single use medical devices should be regulated or banned.[40, 41]. In response, in-hospital reprocessing was discontinued by a State Commonwealth agreement.

Legislative changes in 2002 introduced a definition of "refurbishment" to the Therapeutic Goods Act, which included any or all practices of disassembly, cleaning, reassembly, disinfection and sterilisation of medical devices and their supply in Australia.

Under this definition, any organisation which refurbishes single use medical devices is treated in the same way as a manufacturer of new medical devices. The organisation must meet the same regulatory requirements to gain approval for the legal supply of new or reprocessed medical devices, including Therapeutic Goods Administration (TGA) assessment of design and manufacturing controls and Therapeutic Goods Administration (TGA) Safety and Performance standards.

Since these legislative changes, several hospitals have applied to the Therapeutic Goods Administration (TGA) seeking approval to reprocess single use devices but none have been successful.

Under the Therapeutic Goods Administration's (TGA's) regulatory requirements, it is difficult for third-party reprocessors to gain adequate compliance for a reprocessed single use device. These are:

- *Compliance with the Therapeutic Goods Administration's (TGA's) own Essential Principles* - In particular it is difficult to meet requirements relating to risk management, materials performance and cleanliness and sterilisation;

- *The ability to maintain current design documentation*-Given the lack of access to original manufacturer design files and in particular lack of knowledge of significant design changes, reprocessors may not be aware of critical design changes;

- *Requirements to notify Therapeutic Goods Administration (TGA) of significant changes in design* -For higher risk devices (such as electrophysiology cardiac catheters) notification and Therapeutic Goods Administration (TGA) regulatory review is required prior to commencement of supply of modified designs; and

- *Requirement to maintain a valid Declaration of Conformity* -Manufacturers are required to maintain a legal declaration that devices supplied continue to meet all regulatory requirements.

If any of these requirements are not fully met, a third-party reprocessor would be unable to meet the requirements of the Act and therefore would have no grounds for regulatory approval of the reprocessed single use devices.

6. Who benefits from reprocessing?

Commercial reprocessors often argue that reprocessed single use devices offer cost savings to hospitals as they are cheaper than new single use devices. However, it is questionable whether these savings would be passed on to patients or health insurers.

Typically any financial benefits from using reprocessed single use devices are realised by the healthcare provider and the third-party reprocessor, not the patient.[10]

For example, if a cheaper reprocessed single use device was used in the treatment of a patient at a private hospital, would the hospital notify the private health insurer of the lower cost to ensure the price of the reprocessed device was reimbursed rather than the price of the new device.

If the private hospital did not notify the insurer, then the hospital would gain the cost saving rather than the insurer. The insurer also would have no ongoing financial benefits to pass on to patients through lower health insurance premiums, so that patients reaped no savings.

It should be remembered that third-part reprocessors are participating in a growing industry.

The US market for reprocessed cardiovascular, laparoscopic, orthopaedic, arthroscopic and gastrointestinal devices was valued at more than $140 million in 2008.[5] This is estimated to rise significantly to an estimated $250 million by 2013 as health care facilities seek to cut costs. [5]

6.1 Economic benefits

As hospitals around the world are under increasing pressure to lower healthcare spending, the claimed economic benefit of reprocessing single use devices is often cited as a reason for reprocessing.[5] Various studies show that reprocessing single use devices is cheaper than using a single use device.[3, 13]

However, the analysis of economic benefits is often inadequate as it is based upon a comparison of the cost of reprocessing versus the price of a new single use device. This type of analysis does not take into account other significant costs to hospitals such as internal costs, regulatory compliance costs and the penalty costs of adverse events such as device failure or contamination.[13]

Recent research by D. Hailey at the University of Calgary in Canada suggests that while there are savings on *the device*, this saving is offset by the costs of these adverse effects.[3]

Intervention	Cost per patient				Break-even values
	Device cost	Cleaning cost	Expected cost of adverse events	Total cost of intervention	
Catheter for angioplasty, base case					
• single use	$250	$0	$0	$250	
• reuse	$48	$29	$0	$77	
Catheter for angioplasty, break-even value for probability of adverse events					Break-even value of probability of adverse event is 12.6 per 1,000
• single use	$250	$0	$0	$250	
• reuse	$48	$29	$206	$250	
Laparoscopic cholecystectomy for base case values					
• single use	$1,233	$0	$0	$1,233	
• reuse	$246	$15	$0	$262	
Laparoscopic cholecystectomy break-even value for probability of adverse events					Break-even value of probability of adverse event is 445 per 1,000
• single use	$1,233	$0	$0	$1,233	
• reuse	$246	$15	$973	$1,235	

Table 1. Comparative Cost Analysis[3]

As the analysis in Table 1 shows, the break-even value for angioplasty indicates that the cost per patient is the same in the reuse of a catheter as it is in the single use if the probability of an adverse event due to the reuse strategy is 12.6 per 1,000 procedures. For laparoscopic cholecystectomy this is 445 per 1,000.[3]

The research suggested that reuse would generate system-wide savings for laparoscopic cholesystectomies, but not angioplasty.[3] However, comprehensive information on the adverse effects caused by reprocessing single use devices is not available.

Hailey concluded that his findings did not support the reprocessing of single use devices in Canada, stating:

> *"The findings of our assessment do not provide support for the reuse of single use devices in the context of Canadian healthcare. Policy options might include taking steps to eliminate reuse of single use devices, restricting the practice to particular types of device or permitting reuse only after reprocessing by a third party organization of acceptable quality. Implementation of any policy changes will require continuing dialogue between the different levels of government and institutions, particularly as the ultimate decision on single use device reuse rests with the hospital sector."*

A Belgian study suggested that for angiography catheters, reprocessing is slightly more expensive than buying new catheters, although the differences are small.[27]

When the catheters are reprocessed in batches, reprocessing is cheaper than buying new, but again the price difference is small.[27] This study took into account one death per 5,000 patients. A similar result was seen for cholangiography catheters: no advantage was gained from re-processing.[27]

In the case of electrodes for pacemakers, reprocessing was never found to be financially advantageous, even when taking the benefits of bulk reprocessing into account.[27]

6.2 Environmental benefits

The sustainability of products and services is increasing in importance in the private and public sectors worldwide. Many large organisations provide public sustainability reports on the impact of their operations, including companies in the health care sector.

There is limited evidence as to the environmental benefits of health care providers using reprocessed single use medical devices rather than single use devices, particularly in Australia where reprocessing (versus reusing) has not occurred.

Broadly, however, the environmental impacts of using *single use devices* only once would include: the use of raw materials and energy to manufacture each new device, transportation of the devices from the manufacturer to the user, and the disposal of waste after use.

The environmental impact of using *reprocessed single use devices* would include: a reduced amount of raw materials and a reduced amount of waste as the reprocessed devices are used multiple times, and, hence, would provide environmental benefits.

Taking into account the full life cycle of reprocessing, however, shows there could also be negative environmental impacts, including:

- Extra transportation from user to the third-party reprocessor to user multiple times,
- The use of water and energy for the heating and cleaning required in disinfection and sterilisation, and
- The use of chemical products and their disposal, and the re-packaging of the reprocessed devices.

Transportation might appear to be a relatively small contributor to environmental impact; however, if the reprocessing of single use devices was to occur in Australia, a current proposal says the reprocessing would occur in the United States. Transporting each device over such a long distance, and to do so multiple times, is likely to substantially increase the energy use and carbon emissions associated with device usage.

The other impacts of reprocessing need to be properly assessed and quantified: the level of water use, energy use, and chemical use to clean, disinfect and sterilise the single use devices each time they are reprocessed, as well as chemical disposal.

Some argue that the disposal of chemical sterilisation agents used in single use device reprocessing have similar harmful impacts on the environment to those associated with device manufacturing and waste disposal.[37]

Further studies need to be done in order to make an informed judgement on whether it is better environmentally to reprocess single use devices.

7. Conclusion

The potential reprocessing of medical devices that were designed to be used once raises a range concerns for patients, clinicians, health care facilities, regulators and governments.

Of primary concern is the health and safety of patients. Many international studies have identified serious safety risks in the reprocessing of single use devices. Potential contamination could cause infections and transmit diseases. Patients could sustain injuries or their procedure could be adversely affected as a result of the failure or poor functioning of a reprocessed device.

Some risks have been researched and monitored to a degree, such as the tracking of data in the FDA's MAUDE adverse events database in the United States, where the reprocessing of single use devices is allowed to occur. Internationally, regulators and advisory bodies have expressed caution about allowing reprocessing due to the risks involved.

There is no global consensus from regulatory authorities on the issue. Some countries have determined that the risks of reprocessing outweigh any perceived benefits and banned the practice. Others allow it to a degree, while many have not investigated the issue and have no position.

A consistent theme is that a far greater level of research is needed to confirm the safety and integrity of reprocessed single use devices. This position is supported by Johnson & Johnson Medical, which itself has done some research into the contamination and functionality of reprocessed devices.

The ethical and legal issues surrounding the reprocessing of single use devices is another area of concern for all parties involved in health care. Patient safety and trust needs to be maintained as a central part of the doctor-patient relationship.

In assessing whether reprocessing of single use devices should take place, the ethical and legal aspects of informing patients, and the potential legal liabilities in the event of patient trauma, all need to be debated thoroughly and resolved.

Another question is the potential benefits offered by any new process or procedure emerging in the health care system.

The financial benefits of using cheaper reprocessed devices initially appears attractive, particularly to hospitals under financial pressure. However, an analysis of financial benefits needs to look beyond simple cost savings on device purchase and include all the costs involved, from staff time and management, to compliance costs and potential legal liabilities.

Environmental benefits of reprocessed single use devices should be assessed on *all* the environmental impacts throughout the reprocessing cycle, and not on some aspects of device manufacture and disposal. While sustainability is important, however, ultimately patient safety and minimising risk would need to be the overriding priorities in public policy.

The regulatory framework that governs the reprocessing of single use devices is a final issue. Third-party reprocessors must meet the regulatory requirements of the Therapeutic Goods Administration. This raises particular challenges under current regulations. It would place a responsibility on the Therapeutic Goods Administration (TGA) to assure the community that approved reprocessed single use devices would adequately comply with existing standards.

On the basis of current evidence, the third-party reprocessing of single use devices should not be supported due to the potential negative impacts on patients, the lack of sufficient research to validate the safety of the practice, and the significant ethical, legal and regulatory issues involved.

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ATTACHMENT A - case studies of the integrity of reprocessed single use devices, conducted for Johnson & Johnson Medical

Case study 1

This case pertains to a BiosenseWebster EP Catheter, a Celsisus Thermocouple, D curve, 7F, Redel 10 pin connector. It was reprocessed by a German third-party reprocessing company for a German hospital and was labelled as being sterile and ready for use.

Following reprocessing it was sent to BiosenseWebster for analysis. Visual inspection of the product packaging showed damage to the outer box corners. The product was sealed at both ends with labels and was packaged in a straight box configuration. The product was on a mounting card inside a sealed pouch appeared intact. The outer box and inner pouch labels referred to the correct product type and there were the German third-party reprocessing company's Lot and Serial Numbers. There were no instructions for use included in the sealed package; however, there was a general safety instruction and warning insert, which included a statement to see accompanying documents. There were no accompanying documents. The product appeared intact.

Following analysis, it was found to have blood residue on the set screw (Figure 1) and anchor pin slot, and white and or green residue.

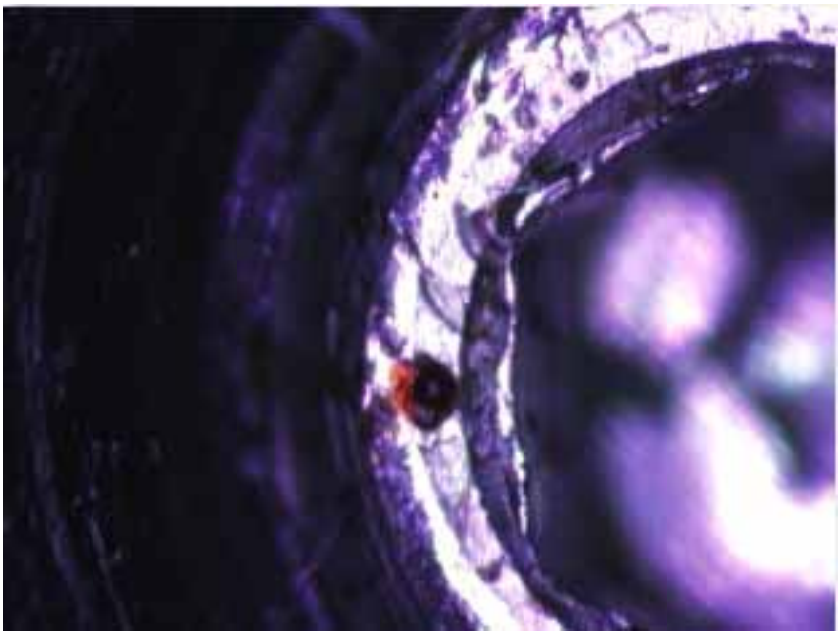

Figure 1: Blood contamination on set screw

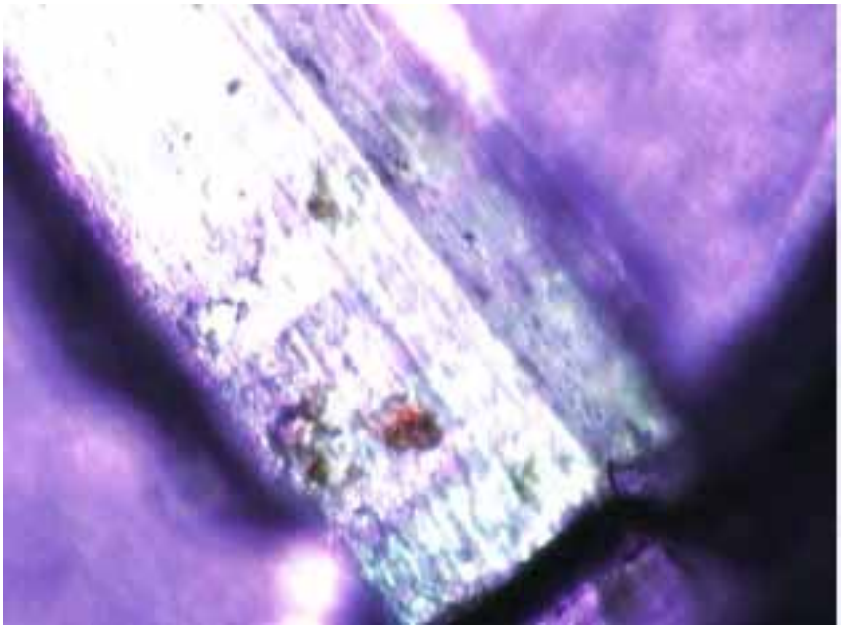

Figure 2: Blood contamination on the anchor pin slot

Case study 2

In this case study, five instruments were sent to a German laboratory to examine the reprocessing of an Endopath ETS-35 Endoscopic Linear Cutter, an Ultrasonic Harmonic Scalpel CS-14C, an Ultrasonic LCS ultrasonic cutting instrument LCS 6S, a THR D-Kurve ablation catheter, and a Posteroseptal-D electrophysiology catheter [38].

Reprocessing was completed by a German third-party reprocessing company. All instruments were supplied in sealed cartons or were double packaged in sterile bags. The sterile packaging was undamaged.

The Endopath ETS-35 Endoscopic Linear Cutter was contaminated with a brown/red substance on the mounting of the internal mechanism to the external tube, along the entire length of the plastic guide for the internal push rod, on the internal push rod (Figure 3) and on the anvil of the jaw section.

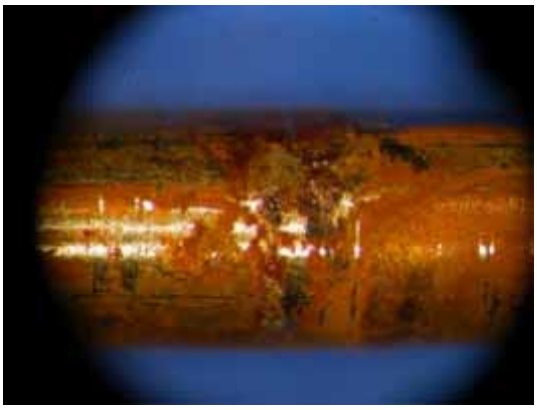

Figure 3: Contamination of the internal push rod

The Ultrasonic Harmonic Scalpel CS-14C had brown/red contamination on the jaw area below the plastic pad. A possible adhesive bond was seen on various parts of the handle. The internal push rod was covered with isolated drops of water along its entire length. There was brown/black discolouration of the joint area. A red fibre was found in the internal mechanism, and the fully automatic opening o f the shears was no longer fully patent (Figure 4).

Figure 4: Automatic opening of the shears is incomplete

On the Ultrasonic LCS ultrasonic cutting instrument LCS 6S there was a shiny transparent layer where the two halves of the plastic handle come into contact with each other, a brown/red discolouration around the joint of the instruments pincers, various small white deposits on the instruments casing and very noticeable brown/red discolouration in front of a welded area on the activation mechanism of the internal push rod.

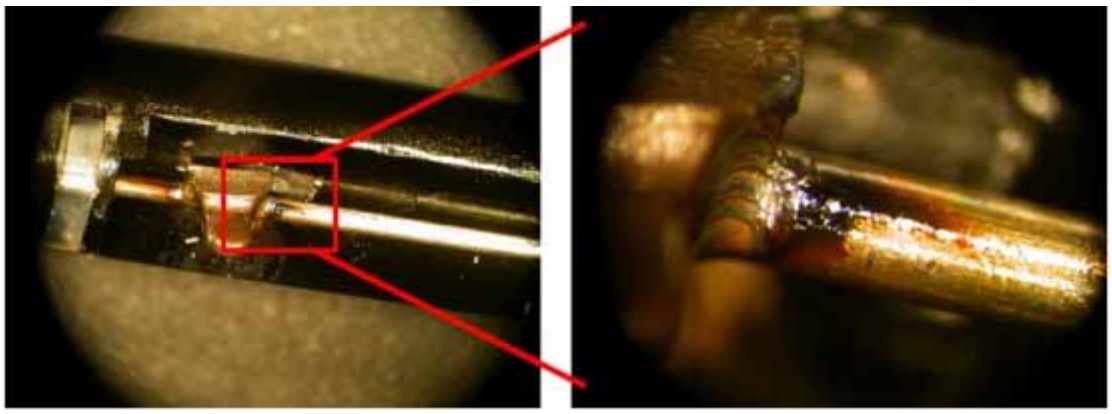

Figure 5: Contamination of area around the activation mechanism on the internal thrust rod

The THR D-Kurve ablation catheter was found to have electrodes embedded into the front of the catheter, with the connections covered in adhesive, some of which was non-uniform in structure.

Small cavities, filled with air bubbles had hardened on the surface after having partially opened up, with red areas clearly visible in the resulting hollows.

There were also traces of mechanical effects: longitudinal, concave recesses running perpendicular to each other.

Figure 6: Air bubbles and contamination in the adhesive used to secure the electrode

Finally, the Posteroseptal-D electrophysiology catheter was mislabelled with the original manufacturer's name being incorrect. The description did not comply with the specification of the type of catheter, and was missing a lot number.

Case study 3

In the ARL case study, out of a sample of 40 ACE36P ultrasonic scalpels reprocessed a third-party reprocessor, 70% tested positive for red or brown protein-based residue and 30% tested positive for the presence of blood (Figure 7).

Case study 4

In the Exova case study, out of a sample of 50 ACE36P ultrasonic scalpels reprocessed by a third-party reprocessor, 62% tested positive for red or brown protein-based residue and 30% tested positive for the presence of blood.

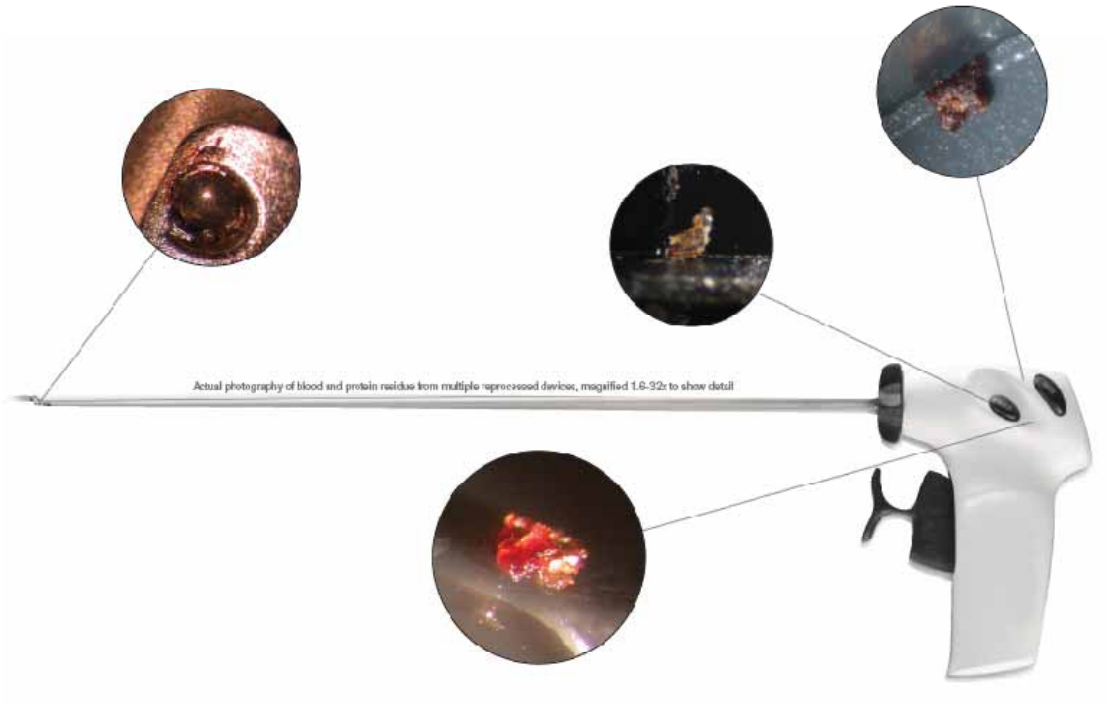

Figure 7: Photographs of blood and protein residue on an ultrasonic scalpel

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Johnson & Johnson Medical Pty Ltd

Submission to Senate Community Affairs Reference Committee

Reuse of single use medical devices in Australia: safety and performance imperatives and challenges to regulatory compliance

29 July 2011

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Executive Summary

Regulatory decisions relating to third-party reprocessing of single use medical devices will impact the safety of Australian patients. It is essential that these decisions are made with awareness of the reasons for the existing legislation, breadth of implications and the approaches used in other jurisdictions. This paper has been developed to provide a coherent overview of the current data on reprocessing of single use medical devices relevant to the Australian context.

Development of Australian Regulations

Single use medical devices are designed to be used once and then discarded. This approach eliminates risk of cross infection and allows design of devices, many of which are small and intricate, to achieve clinical performance with minimum trauma to the patient. Such devices are easily damaged by attempts to clean reassemble and sterilize, with risk to the patient on their subsequent reuse.

Reprocessing of single use medical devices was once widespread and unregulated in Australia, with examples of highly invasive devices such as cardiac catheters being reused in large numbers of patients, with clear risks of cross infection and patient injury from worn out devices.

Following concerns from professional groups, industry and the general public about inadequate safety of reprocessed devices, the *Therapeutic Goods Act* was amended in 2002 to make reprocessing of single use medical devices subject to full Therapeutic Goods Administration (TGA) regulation. Since Therapeutic Goods Administration (TGA) regulation was imposed, hospitals have ceased reprocessing. Several hospitals have subsequently applied for Therapeutic Goods Administration (TGA) approval for reprocessing but none have been successful. It is likely that Therapeutic Goods Administration (TGA) will continue to receive applications for approval of reprocessed single use medical devices not only from hospitals, but from companies based outside of Australia who are in the business of reprocessing single use medical devices.

International Experience

Reprocessing of single use medical devices is banned in most of Europe, and the European Commission has recently accepted a formal opinion from its Scientific Committee on Emerging and Newly Identified Health Risk that the practice is unsafe.

The only marketplace where commercial reprocessing is undertaken is the USA where the practice has been FDA regulated since 2004. Six years on there is emerging evidence in the FDA MAUDE adverse events database and in peer review literature of:

- A substantial number of adverse event reports being submitted to FDA for reprocessed single use medical devices,
- Patterns of suboptimal device performance with manifest clinical risk,
- Repeated instances of specific modes of failure associated with reprocessing, and
- A number of serious injuries associated with reprocessed devices.

Inability of Reprocessors to provide Assurance of Safety

Disassembly, cleaning, reassembly and resterilization of devices which were never designed to withstand such processes presents formidable technical challenges and there are examples in recent United States postmarket experience of safety and performance being compromised in reprocessed single use medical devices.

Lack of reprocessor access to original manufacturer design files prevents effective compliance with a number of critical regulatory safeguards including requirements for materials safety, control of design, and risk assessment.

Design changes made by the original manufacturer will not always be apparent and changes which make the device unsafe to be reprocessed may be undetected. This means that currency of safety validations cannot be assured and reprocessors may unknowingly supply unsafe devices which will only be detectable when a clinical failure occurs. This is a significant concern to patient safety and ensuring that safe and effective single use medical devices are supplied and used within the Australian healthcare system.

Contents

1. Introduction

Single use medical devices are designed to be used once only on a single patient and then discarded. They include devices such as endoscopes used in minimally invasive surgical and diagnostic procedures, surgical instruments such as staplers and arthroscopy blades and electrophysiology catheters which are placed into the heart.

Single use medical devices should not be confused with intentionally reusable devices such as common surgical instruments. These are manufactured from durable materials (mainly surgical steels) and designed in such a way that they can be easily disassembled, completely cleaned and resterilised. Because of these demanding requirements reusable devices must be robust and are therefore costly. Rigorous standards apply to the cleaning and sterilisation of reusable devices, in particular the stringent requirements of *AS/NZS 4187:2003 - Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.*

The advent of single use medical devices has been driven by two imperatives:

- A need to eliminate risks of cross infection associated with reusable devices used in surgical procedures on multiple patients; and
- A need for designs particularly for invasive devices such as complex catheters and endoscopes, which are smaller, more intricate and delicate to allow for improved invasive access with minimal tissue trauma.

These needs cannot be met by devices intentionally designed for reuse.

Reuse of single use medical devices was once widespread within Australian hospitals. Devices were reprocessed in unregulated facilities with examples of invasive devices such as electrophysiology catheters being re-used in the hearts of more than 100 different patients. With such evident risks of cross infection or of serious injury from physical failure of reprocessed invasive devices, there were increasing calls from professional bodies[9], industry groups[10] and in the media[11] for the practice to be halted. In 1994 an NHMRC Expert Panel Report recommended that there should be either a blanket ban on reprocessing or the practice should be regulated by the Therapeutic Goods Administration (TGA).[12,13]

In response, in-hospital reprocessing was discontinued by State-Commonwealth agreement and changes were made in 2002 to the *Therapeutic Goods Act* ("the Act"). This change introduced a definition of "Refurbishment" which included any or all practices of disassembly, cleaning, reassembly, disinfection and sterilisation of medical devices and their supply in Australia.

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Third-party reprocessors (organisations which refurbish devices according to this definition) are required to meet the same regulatory requirements as apply to manufacturers of new devices, including Therapeutic Goods Administration (TGA) assessment of design and manufacturing controls and requirements that reprocessed devices must fully meet Therapeutic Goods Administration (TGA) Safety and Performance standards before they may be legally supplied.

Since these changes to legislation, several hospitals have applied to the Therapeutic Goods Administration (TGA) seeking approval to reprocess single use medical devices but none have been successful.

Internationally various positions have been taken:

- Few countries in Europe allow the reprocessing of single use medical devices and several prohibit it outright;
- Reprocessing single use medical devices is unregulated in Canada and Japan (although appears to be declining in these markets); and
- The practice is regulated by the United States Food and Drug Administration (FDA) with requirements for FDA evaluation of safety data and audit of reprocessing facilities, with a small number of commercial reprocessors in operation.

The situation in Europe is particularly relevant to Australia, as the Australian regulations being aligned with GHTF, are very similar to those in Europe. More importantly, the Therapeutic Goods Administration (TGA) routinely accepts CE certification in lieu of Australian Conformity Assessment certificates for imported devices.[14]. However once a device is reprocessed, the European approval ("CE Mark") CE mark is no longer valid and it is the responsibility of the reprocessor independently to establish compliance of the reprocessed device. No CE mark has ever been awarded for a reprocessed device.

It is important to understand that any regulatory review of a reprocessed single use medical device cannot therefore rely on a pre-existing CE mark. Furthermore it is problematic that many devices bear the CE mark directly on the device (in compliance with regulatory requirements). Unless the CE mark is physically removed (a process which may in itself damage the device) the reprocessed single use medical device is effectively misbranded.

The European Commission recently sought a formal opinion from its Scientific Committee on Emerging and Newly Identified Health Risk (SCENIHR) (Attachment 2). The SCENIHR committee raised multiple concerns about the hazards involved and the unsuitability of single use medical device for reprocessing.[15] In accepting the opinion of the SCENIHR experts, the commission stated:[16]

[14] Australian Regulatory Guidelines for Medical Devices. page 98.

[15] The Safety of Reprocessed Medical Devices Marketed for Single-Use: SCENIHR opinion. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf.

[16] *Safety of reprocessed medical devices marketed for single-use - Adoption of scientific opinion.* http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1004

> *"Although clinical data is limited, the SCENIHR opinion identifies several potential hazards of re-using single use medical devices that may lead to a risk for patients. The opinion concludes that certain design features make a single use medical device unsuitable for reprocessing. Major hazards can arise from inadequate cleaning, disinfection and/or sterilization, resulting in contamination and possibly causing toxic reactions or infections. Chemicals used for disinfection may also affect the performance of the device. Areas of particular concern are the potential contamination with agents that cause transmissible spongiform encephalopathies (TSEs) and the risk of using reprocessed single use medical devices in invasive medical procedures. Other hazards mentioned in the opinion include poor traceability of a reprocessed single use medical device and loss of documentation such as the instructions for use."*

It is likely that applications for approval of third-party reprocessed single use medical devices will continue to be received by the Therapeutic Goods Administration (TGA). The purpose of this paper is to ensure that decisions that will impact Australian patients are made with the awareness of the reasons for the existing legislation, breadth of implications and the approaches used in other jurisdictions.

2. Technical Obstacles to Safety and Performance

Testing requirements

In order to meet regulatory requirements as manufacturers, third-party reprocessors will need to be able to demonstrate safety and performance of reprocessed devices. This requires extensive testing to:

- Validate adequacy of cleaning, disinfection and sterilisation,
- Ensure the device meets performance standards; and
- Ensure that the reprocessing does not compromise the physical integrity and safety of the device.

Cleaning, sterilisation and physical Integrity

Given that single use medical devices were never intended by their original designers and manufacturers to withstand the rigours of reuse, there are evident challenges to compliance with safety regulations. Specific problems include the following:

- Difficulties in effective cleaning and sterilization of devices such as catheters, endoscopes and single use surgical instruments, which have small lumens and other inaccessible cavities;
- Risks of damage to the device, where the original design requirements did not include robustness to exposure to chemically and physically aggressive cleaning and sterilization regimes; and
- Reductions in safety and performance arising from wear and tear from repeated use and from exposure to reprocessing chemicals and heating cycles. This can cause reduced materials integrity, altered handling characteristics and mechanical degradation arising from wear and fatigue.

Undetected design changes which may compromise safety

Therapeutic Goods Administration (TGA) regulations also require that there is continuing control of the product design, including a need to repeat testing every time the device design is changed. However third-party reprocessors have no access to proprietary design information of the original manufacturer and crucially have no visibility of changes to designs.

Some changes to design are not immediately apparent (for example changes to materials, to embedded software or to electrical properties). Without knowledge of changes to original product design, safety verifications current today may be invalid tomorrow and neither third-party reprocessor or end user will be aware of the change.

If such a change caused the device to become unsuitable for reprocessing (for example because a substituted material could not withstand cleaning or resterilization) and the third-party reprocessor did not detect that the change had occurred, there is a risk of undetected supply of unsafe devices.

Such a combination of safety failure and lack of awareness during manufacture is particularly dangerous, as the hazard will only be detected once there is a failure in the clinic, possibly causing injury to patient or user.

3. Regulatory Challenges

Certain Therapeutic Goods Administration (TGA) regulatory requirements present particular challenges which make it difficult to achieve an adequate compliance solution for a third-party reprocessed single use medical device. These are:

- **Compliance with Essential Principles.**

  In particular it is difficult to meet requirements relating to risk management, materials performance and cleanliness and sterilisation.

- **Ability to maintain current design documentation**

  Given the lack of access to original manufacturer design files and in particular lack of knowledge of significant design changes, third-party reprocessors may not be aware of critical design changes.

- **Requirements to notify Therapeutic Goods Administration (TGA) of significant changes in design**

  For higher risk devices (such as electrophysiology catheters) notification and Therapeutic Goods Administration (TGA) regulatory review is required prior to commencement of supply of modified designs.

- **Requirement to maintain a valid Declaration of Conformity**

  Manufacturers are required to maintain a legal declaration that devices supplied continue to meet all regulatory requirements.

  The following discussion details the specific reasons why third-party reprocessed single use medical devices cannot adequately comply with the above requirements. If any of these requirements are not fully met the reprocessor cannot meet the requirements of the Act and therefore there are no grounds for regulatory approval of the reprocessed single use medical devices.

Compliance with Essential Principles[17]

The following specific Essential Principles (EPs) contained in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* ("the Regulations") present particular compliance challenges for reprocessed single use medical devices.

EP 1	*Use of medical devices not to compromise health and safety* *A medical device is to be designed and produced in a way that ensures that:* *(a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and* *(b) any risks associated with the use of the device are:* *(i) acceptable risks when weighed against the intended benefit to the patient; and* *(ii) compatible with a high level of protection of health and safety.*
EP 2	*Design and construction of medical devices to conform with safety principles…* *(2) …in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:* *(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose,* *(b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction;…*

Compliance Challenges:

The above Essential Principles speak to requirements to conduct adequate risk assessment. Risk assessment is required to be maintained current and to be reviewed each time there is a significant change to the device design or production, or significant new postmarket experience. It is important to understand that for any given design change, the outcome of risk assessment may be very different for a single use medical device compared to a reprocessed device. In particular, changes to materials, mechanisms or electrical properties may be insignificant for a single use medical device but may present unacceptable risks if the device is to be reprocessed. Given that it is not always possible for a third-party reprocessor to detect materials changes by the original manufacturer, it is hard to envisage how requirements for adequate risk assessment can be met.

[17] Act s41CA, Regulation 2.1 and Regulations Schedule 1

Further, the technical challenges of reprocessing of devices which were never designed to be disassembled, cleaned, resterilised and withstand multiple use cycles makes compliance with Essential Principle 1(a) very difficult. As described in the review of US postmarket experience in Section 0 below, there is accumulating evidence of sub-optimal performance of reprocessed devices which compromises patient safety and a smaller number of incidences of serious injury to patients in association with reprocessed devices.

The lack of access to original manufacturer design documentation means that a reprocessor cannot be assured of possession of current information necessary for determination of risk acceptability. Therefore it is not possible, in absence of this information, to guarantee continued compliance with Essential Principles 1(b) and 2(2)(a).

It is difficult to envisage that reprocessed single use medical devices, which were originally not designed to withstand the rigours of multiple use and exposure to cleaning and resterilisation, can be considered to be of "inherently safe design" and compliant to Essential Principle 2(2)(b).

EP 7.1	Choice of materials In ensuring that the requirements of … [General Essential Principles 1-6] are met in relation to a medical device, particular attention must be given to: (a) the chemical and physical properties of the materials used in the device; and (b) the compatibility between the materials used and biological tissues, cells, body fluids and specimens;
EP 9.2	*Minimisation of risks associated with use of medical devices* *A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:* *…* *(e) any risks associated with the ageing of materials used in the device;*

Compliance Challenge:

Third-party reprocessors are not privy to the usually proprietary composition of materials used in manufacture of single use medical devices. The only alternate means of determining properties is empirical testing of the device. The key difficulty arises when an original manufacturer makes a material change, which is very likely to go undetected, as for reasons of branding the changed material is likely to be of very similar appearance to the prior material. In making such a change the original manufacturer is required to conduct a risk assessment. However that risk assessment is not required to consider ability to withstand reuse and the very real possibility exists for an undetected substitution of a material to one which is less able to withstand reprocessing. In these circumstances the third-party reprocessor is not able to maintain compliance with EP 7.1(a) or EP 9.2(e).

Furthermore, resterilization can adversely affect the chemistry of materials, particularly advanced polymers. Such effects may cause generation of leachables which directly impact biocompatibility of the material or change its properties in regard to retention of sterilant residues. Therefore a material change by the original manufacturer may lead to an undetected failure to comply with biological safety required by EP 7.1 (b).

EP 9.1	Medical devices intended to be used in combination with other devices or equipment A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that: (a) the medical device, and any other device or equipment with which it is used, operate in a safe way; and (b) the intended performance of the device, and any other device or equipment with which it is used, is not impaired.

Compliance Challenge:

Medical devices proposed for reprocessing include items such as electrophysiology catheters, electrocautery instruments, harmonic scalpels and endoscope systems. Such devices are all used in combination with other devices generally all sourced from the same manufacturer. The maintenance of interoperability of the devices within the system is achieved by integration of change controls for all components by the system manufacturer. A change in any one component is validated for continued compatibility with other system components. For example changes in design of an electrophysiology catheter which affect electrical properties may require changes to electrical outputs or software controls in associated controllers or monitors.

If the single use system component is reprocessed, the integration of change control is lost. The possibility exists for a third-party reprocessed single use medical devices to be returned to the clinic and for use with incompatible later versions of other system components. The effect would be an undetected failure to comply with EP 9.1.

Compliance with Conformity Assessment Regulations – Control of Design18

Conformity Assessment requirements of the Regulations require that all manufacturers control the design of their devices, either through the design control provisions of Clause 7.3 of ISO 13485, or through suitable alternative arrangements for lower risk Class I and IIa devices. These requirements require specifically that devices are verified to comply with their performance and safety requirements (including regulatory compliance) by means of design verification testing.

[18] Act s41DA, Regulation 3.4

Examples of such testing include: biocompatibility evaluations, validation of cleanliness and sterility and performance testing against device specific standards (which usually include requirements for physical properties and durability).

It is necessary for reprocessed devices to be tested for complete compliance in the same way as original manufacturers test their devices. When a manufacturer changes a material, component or any other aspect of the design, they are required to re-verify safety and performance by re-testing. Where the changes are substantial, the re-verification must be subjected to Therapeutic Goods Administration (TGA) review before supply of the new design in Australia.

A problem arises if the primary manufacturer makes a design change to a single use medical device which is not immediately apparent in the finished device, or a change to another device which is used in conjunction with a third-party reprocessed single use medical device (such as a controller for an electrophysiology catheter or a power source for a harmonic scalpel). Of particular concern are changes which may not affect the appearance but which impact on important properties such as:

- Pphysical performance of mechanical mechanisms such as in single use staplers, trocars and endoscopy equipment;
- Electrical properties of devices such as electrophysiology catheters;
- Device durability – which may be affected by materials changes; and
- Software or electronics changes in controllers or power sources for single use medical devices.

If the third-party reprocessor is unable to detect immediately changes of this nature it will be very difficult or impossible to comply with the design verification and validation requirements of Regulations.

Compliance with requirements for Notification of significant change

Manufacturers of higher risk devices such as electrophysiology catheters, which are subject to Therapeutic Goods Administration (TGA) review via Design Dossier Evaluation or Type Testing are required[19] to notify Therapeutic Goods Administration (TGA) in advance of any significant changes to product design. Therapeutic Goods Administration (TGA) review is required before devices affected by the change may be legally supplied in Australia. The fact of conduct of such a review is not necessarily public information available to the reprocessor.

It is evident that the inability of reprocessors to detect and manage design changes by the primary manufacturer present considerable challenges to meeting regulatory obligations designed to ensure that such changes are adequately reviewed by Therapeutic Goods Administration (TGA). It is hard to envisage a practical solution to this obstacle to ensure compliance.

[19] Act s41DA, Regulation 3.4, Regulations Schedule 3 1.6(4), 2.4(1).

Currency of Declaration of Conformity

The manufacturer must maintain a Declaration of Conformity. This is a legal document stating that the devices supplied are in compliance with the regulations (and in particular the Essential Principles) at the time of supply. For the above stated reasons it is difficult to envisage how a third-party reprocessor can confidently maintain a current Declaration of Conformity, particularly in the context of possible undetected design changes initiated by the original manufacturer.

4. Postmarket Experience in the United States

Overview

It is pertinent to review the recent United States experience (as one of the very few markets that permit reprocessing), as reflected in peer reviewed literature and in the FDA postmarket *Manufacturer and User Facility Device Experience* (MAUDE) database.

In conjunction with the introduction of the United States regulation of reprocessing, the MAUDE database was modified in 2003 to include a 'flag' indicating that a report was associated with a reprocessed single use medical device. In evidence before the US Congress Committee on Government Reform in September 2006[20], the then FDA Commissioner Daniel Schultz summarised current postmarket experience as reflected in the MAUDE database. At that early stage there were few (approx. 65) reports of significant adverse events contained in the database and no apparent evidence of serious injury to patients or users.

Given there has been no formal review of this data since 2006, Johnson & Johnson Medical has recently reviewed[21] the MAUDE database for reports pertaining to reprocessed single use medical devices captured from 2003 to date. MAUDE now contains a substantial number of reports of adverse events associated with reprocessed single use medical devices. It is emphasised that this recent review is based on the summary records in the MAUDE database and not on inspection of primary clinical records or the devices involved.

The review shows that there are a significant number of new reports of adverse events in association with reprocessed single use medical devices and that these include concerning anecdotal reports of serious injuries, and emerging trends of reduced clinical functionality of some types of reprocessed devices, leading to suboptimal clinical care and elevated patient risks from consequences such as prolonged surgery.

Interpretation of this dataset requires some caution. Post market adverse events are considerably under-reported as a general rule. The FDA estimates reporting to MAUDE reflects only 1-10% of actual events.[22] The overall quality of reports is poor with a high proportion of errors. For example inspection of a subsample of the 2995 "reuse" flagged reports showed many instances of errors, for example reports incorrectly categorised as "Malfunction" instead of "Injury" and *vice versa.*

The MAUDE database does not contain data on the number of devices of any type actually supplied and in the absence of such information (and the high rate of underreporting) it is not possible to make comparative assessment of incidence of events. Given these limitations no statistical analysis was attempted.

[20] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121067.htm

[21] The FDA MAUDE database contains over 1.6 million records. The following strategy was used to identify records relevant to reprocessed single use medical devices. MAUDE datasets were downloaded from FDA and imported into Microsoft Access for searching. All Records with the "reuse of single use" flag set to "Y" (2901 reports) were combined with all records (586) which identified the manufacturer as one of the 5 largest reprocessors . This combined data set contained 2995 records of interest. These were further filtered to extract only those which were identified as event type "Injury" (There were no patient deaths reported in this record set) giving 1,022 reports which were then each examined for accuracy and relevance.

[22] GAO, Adverse Events: Surveillance Systems for Adverse Events and Medical Errors, GAO/T-HEHS-00-61 (Washington, D.C.: Feb. 9, 2000).

These findings are supported by limited emerging peer reviewed literature on safety and performance of reprocessed devices.

The following specific trends and reports were noted.

Overall trends

After adjustment for incorrect reports, there are a substantial number (approximately 750) of recent reports of actual adverse events arising from reprocessed devices. This represents a tenfold increase in total reports since 2006.

Most reports related to malfunction of surgical instruments particularly electrocautery devices, staplers, harmonic scalpels and arthroscopic shavers and similar devices.

Serious injuries

Several reports described serious injuries arising from excessive tissue adhesion to harmonic scalpels including:

- Loss of an ovary (MDR 1050257);
- Loss of ovary and fallopian tube (MDR 1496543); and
- Excessive blood loss (900cc) from damaged vessel (MDR 1233938).

These findings are consistent with the study by Weld et al. [23]of 90 new harmonic scalpels against 89 reprocessed harmonic scalpels found that new ones measure significantly better in haemostasis, tissue sticking, tissue dissection, and grasping. Additionally, reprocessed scalpels had a statistically significantly higher middle shaft temperature with the potential to cause patient harm.

Burns and punctures to heart leading to tamponade were reported following use of reprocessed electrophysiology catheters. (MDR 1707209).

An incidence of *Pseudomonas* opthalmitis leading to enucleation of the affected eye following use of a resterilised phacofragmentation instruments was reported. (MDR 1615772).

Damage to devices from reprocessing

Reprocessed shavers, burrs and other cutting instruments featured in numerous reports of fracture, shedding of metal particles or of ineffective cutting performance. This is consistent with the findings of King et al[24] who in a study of reprocessed arthroscopic shavers found all shavers examined exhibited noticeable wear with some showing severely damaged, chipped and blunted blades (see **Figure 5**). Clinical results showed menisci cut with reprocessed shavers had rougher edges than those cut with new shavers.

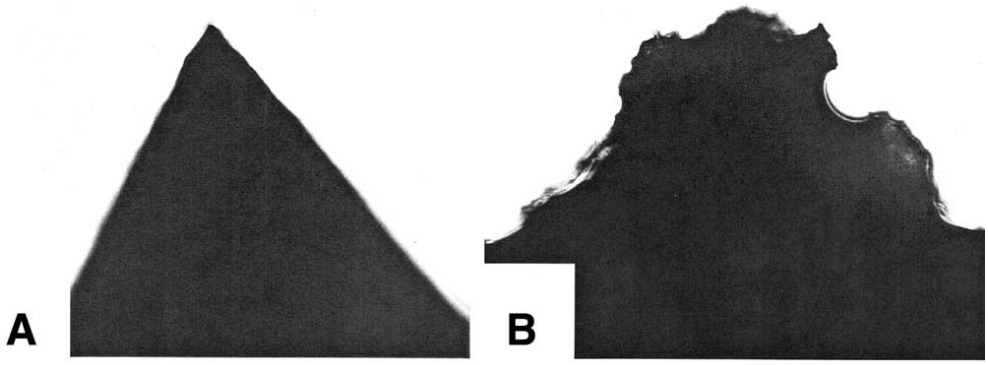
[23] Weld, K.J., et al., *Comparison of mechanical and in vivo performance of new and reprocessed harmonic scalpels.* Urology, 2006. **67**(5): p. 898-903.

[24] Jonathan S. King, M.D., Marilyn M. Pink, Ph.D., and Christopher M. Jobe, M.D. Assessment of Reprocessed Arthroscopic Shaver Blades. *Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol* 22, *No 10 (October), 2006: pp 1046-1052*

A notable feature of the reports for reprocessed devices was that the reprocessor routinely attributed observed device damage to abuse of the device by the user. For example in two longitudinal series of 19 reports of failed harmonic scalpels and 11 reports of failed arthroscopic shavers observed device damage was in every case attributed to misuse or "aggressive use". It appears that the possibility that the observed wear and tear may have arisen from multiple reuses was not contemplated.

Figure 5.

From King et al. Comparison of new arthroscopic shaver blade (A) compared to the worst case reprocessed blade (B).



Inadequate cleaning

King et al. showed 48% of arthroscopic shaver blades had detectable levels of protein and 63% had detectable levels of nucleic acid, indicating inadequate cleaning of the reprocessed blades.

A small number of MAUDE reports (e.g. MDR 782409), of reprocessed devices were visibly contaminated with biological material and dried blood indicating that necessary standards of cleaning are not always being met.

Malfunctions and inadequate performance

The following reports relate to serial failures of reprocessed devices in the same clinical facility which indicated specific recurring performance problems with the reprocessed devices in question.

- Reprocessed trocars failed to provide an adequate seal and thus preventing maintenance of pneumoperitoneum during laparoscopic surgery (MDRs 1732859, 1732833; 1782875); this is consistent with the findings of Mues et al[25] who identified leakage as a key performance difference between new and reprocessed trocars.
- A series of 4 mechanical failures of biopsy forceps impeded colonoscopy procedures. (MDR 1542833).

[25] Mues, A. C., Haramis, G., Casazza, C., Okhunov, Z., Badani, K. K. & Landman, J. 2010. Prospective Randomized Single-Blinded In Vitro and Ex Vivo Evaluation of New and Reprocessed Laparoscopic Trocars. *Journal of the American College of Surgeons,* 211**,** 738-743.

- Four ultrasonic catheters were reported to have poor image quality. One ultrasonic catheter had its tip broken as a result of fatigue from ultrasonic energy. It is noted that this device was a model for which reprocessing was later stopped (MDR 1633730).
- Seven burn injuries were reported from malfunctioning electrocautery devices, including one to a patient's liver. Two of these were attributed to insulation failures. MDR 1490558 stated the reprocessor found a manufacturing operation error during reassembly of the device

Johnson & Johnson Medical Pty Ltd

Submission to Senate Community Affairs Reference Committee

A patient's right to know and right to informed consent: Ethical and legal considerations concerning the use of reprocessed single use medical devices.

29 July 2011

Johnson & Johnson Medical Pty Ltd
1-5 Khartoum Road, North Ryde, NSW 2113 Australia

Introduction

Single use medical devices are medical devices labelled by the original manufacturer as "single use." They are intended for once-only use and then discarded. More recently, some organisations have become involved in reprocessing these medical devices to then allow their multiple re-use on a number of different patients. This paper argues that patients have a right to know when this occurs and to have a choice via an informed consent process to agree to the use of reprocessed single use medical devices in their medical procedures.

This paper presents a case based on the legal and ethical issues central to the following concern:

> *Whether patients have a right to know and should be informed that they will have a reprocessed single use medical device used in the course of their medical treatment and, as a consequence, have the right and the opportunity to give informed consent or otherwise to such use.*

The primary concern of this submission is the health, safety and well being of the patient. It is also driven by respect for the patient's autonomy as an individual and right as a consumer. Further, it is motivated by a broader professional concern wherein ignoring a duty to warn and thereby failing to inform a patient of a use of a third-party reprocessed single use medical device prior to its use may conflict with some of the ethical foundations on which the contemporary doctor-patient relationship is premised.

This concern also raises potential legal liabilities that may arise from using reprocessed single use medical devices. Notably, this might result from a failure by a health professional and/or institution to inform patients of any use of a reprocessed single use medical device and to provide relevant advice and information thereby providing the ability of the patient to give their informed consent.

1. Informed Consent

Informed consent, in a health care setting, is the process whereby patients consent to, or refuse, an intervention based on information provided by a health care professional regarding the nature and potential risks (consequence and likelihood) of the proposed intervention[i].

Consent cannot be anything other than an informed process - thus, "informed consent". It places considerable onus on the health professional or institution concerned. Indeed, across the health care sector, it is sometimes described as 'the most important legal doctrine in patients' rights.'

2. Reprocessing Risks

Reprocessing single use medical devices for reuse is a complex matter. It raises many important issues regarding risk at both societal and individual level, especially those of an ethical, health, legal, economic and environmental nature.

The depth and complexity of these issues underline the need for a patient's right to know and right to give informed consent in this matter.

A successful reprocessing of a used single use medical device must be able to clean the device thoroughly, sterilise it to acceptable standards, and ensure that the device has not been degraded in functionality.

However, many single use medical devices were never designed and manufactured with re-use in mind. That this is so is clearly evidenced by the descriptor of these products, by the manufacturer, as "single use". This means:

- Some single use medical device s are unable to be effectively dissembled, cleaned and reequipped to their original functionality. It has been widely recognised that the reuse of single use medical devices may lead to potential risks of cross infection or contamination as a consequence of inadequate cleaning and sterilisation; [ii]

- Residual organic debris may be left in the device, causing biocompatibility issues with new patients on whom the device is being used;[iii]

- Sterilising chemicals from reprocessing may cause toxic reactions when they come in contact with the device, or when the residues enter a new patient's body system; and[iv]

- Cleaning, disinfecting and sterilising processes may degrade the device material or result in the device not functioning or performing to the same standard as a new device.

Any of these known risks could potentially have catastrophic consequences for a patient's health and safety and the quality of this medical care**.**

A review of studies conducted in the past 15 years demonstrates that the safety and effectiveness of reprocessing single use medical devices remains controversial. This is notable in reviews of the clinical or physical integrity of reprocessed cardiovascular devices.[v]

Different laboratory studies have reached different conclusions. While some concluded that reprocessed single use medical devices were theoretically safe, depending on the functionality testing outcomes, many identified potential problems with device function and sterility, for example due to residual organic debris or bacterial contamination some reprocessed catheters were found to be carrying.[vi]

Little Research Done: More Research Needed

It remains a concern that the actual risk of infection, disease transmission, toxic reaction and other possible adverse clinical outcomes associated with device malfunction is not readily quantifiable, due to a lack of clinical studies on the subject.

Few studies on the use of reprocessed single use medical devices have evaluated outcomes directly related to patients. Those available are of variable quality, methodology and duration, conducted on small samples of subjects only.

Although there are some clinical studies that generally reported that reused catheters on patients were safe in terms of sterility or pyrogenicity of reused devices[vii], these reportings alone are insufficient in evaluating occurrences of known theoretical risks identified in laboratory studies.

Further, there is inadequate evidence to conclude that potential risk of harms associated with third-party reprocessed single use medical devices is being effectively controlled and addressed by hospitals that reuse single use medical devices.

There is little information on the functionality testing systems that are being used by third-party reprocessing facilities, and no survey of patient outcomes comparing reused single use medical devices with new devices.

Opportunity and Imperative for Informed Consent

Another important question concerns the criteria on which a decision to reuse a single use medical device is based ie:

> *How a decision is made to use a* reprocessed single use medical device *on a patient and what weight is given to the known theoretical risks of harm when making the decision.*

It is concerning that the answers to these questions are largely unknown.

This concern is deepened by the fact that patients may not be given an opportunity to be informed and fully included so that they may ask questions and actively participate in the decision-making process. Further, and consequently, it is of concern that these patients are denied the right to make informed choices.

The following sections in this paper illustrate the ethical and legal frameworks that give rise to the patient's right to know and to make informed decisions for themselves. They also point to a duty on the part of healthcare professionals and healthcare organisations to:

- Give their patients valid decision-making opportunities by informing them of any proposed reuse of single use medical devices;
- Provide them relevant information on the potential risks and quality assurance measures taken; and
- Provide patients with the right to informed consent to the use or otherwise of single use medical devices in their medical procedure.

3. Ethical issues

Many ethical issues are raised in using a reprocessed single use medical device where no warning or adequate information regarding the reuse is given to the patient or, importantly, the right to informed consent to that procedure.

Patient's autonomy and consent

In Australia, doctors and patients are encouraged to build a relationship based on trust, openness and communication, which enable them to work in "partnership".[viii]

It is a usual expectation in Australia that patients should be able to place trust in their doctors to provide care, to the best of their skills and abilities, throughout all stages of a medical service including investigation, diagnosis, advice and treatment.

This trust should not be misconstrued, as a surrender to the doctor of a patient's right and capacity to make their own decisions concerning their own personal medical treatment. In other words, treatments that may impact upon the individual patient's bodily integrity and wellbeing.

This understanding is long recognised by the law and is at the basis of the legal notion of informed consent.

Treatments administered without a valid consent of the patient, or in some cases, of the patient's legal guardian, constitute battery or trespass at law. In this situation, the doctor could be held liable even if the treatment had been performed in the best interests of the patient.

For a patient's consent to be valid, it should be given voluntarily by a competent adult. It should be made specifically in relation to the treatment or procedure for which the patient has formed an understanding regarding its nature, effects and any associated implication or risk.[ix]

Providing Sufficient and Relevant Information to Allow Informed Consent

The doctor's responsibility toward a patient therefore encompasses a range of ethical and legal obligations including the provision of sufficient and relevant information.

This provision would cover the condition, treatment options, benefits, risk of adverse effects or complications and alternatives to treatment, in order to enable patients to make their own decision about undergoing a procedure or treatment,[x] in other words, informed consent.

The obligation includes a proactive responsibility on the doctor's part to ensure a patient's understanding on all material issues and, importantly, even where no question has been asked by the patient.

Clearly, given the imbalance in knowledge and information between a doctor and a patient, no presumption can be made in such situations as to whether the patient has understood, or has wanted to know, a particular piece of information about the treatment before giving consent. Nonetheless, the ethical obligation merges with a duty that is imposed by law to inform patients of risks associated with the treatment.

For practical and legal purposes, the risk management aspects of informed consent are often emphasised. The courts are required to review the doctor's actions retrospectively with reference to the risk that had materialised.

A concern for the respect of patient autonomy is not readily apparent in a legal analysis focused on a failure to warn. In contrast, from an ethical perspective, the *duty to warn* should be regarded as a prerequisite for the exercise of patient autonomy "in the wider context of an appreciation of basic human rights"[xi], rather than the central focus of informed consent. [xii]

It is therefore ethically unsound to argue that doctors do not have a duty to inform of the use of a single use medical device that has been reprocessed according to the standards set by the *Therapeutic Goods Act*, solely based on that fact.

Presumption about a reprocessed single use medical device on patient's behalf

Doctors are similarly not entitled to presume that the patient's decision would be unaffected by the reuse so long as the reprocessed single use medical device is sourced from an approved manufacturer, and to proceed to effectively make that decision on the patient's behalf, without the patient's knowledge.

On the other hand, doctors have an ethical duty to ensure that the patient is assisted with all relevant information in order to make an informed and autonomous decision concerning his or her health, and in accordance with his or her individual values and preferences.

A consideration of the focus on individual autonomy indicates that where a reuse of a Therapeutics Goods Administration (TGA) approved reprocessed device is concerned. The correct step would be to inform of the procedures and processes to be followed under the Therapeutics Goods Administration (TGA) standards, and the extent to which this regulatory compliance may ensure the safety and effectiveness of the single use medical devices that have been remanufactured under those standards.

Cost saving versus patient safety

The practice of reprocessing single use medical devices may not be unethical per se if it is established that the quality of care is unaffected by the reuse and there is no unacceptable increased risk of harm to the patient. However, given the inconclusive evidence surrounding the issue of safety and efficacy of reprocessed single use medical devices, an ethical issue would seem to arise in the situation where patients are not informed that they may come in contact with a reprocessed single use medical device.

The economic benefits of reusing single use medical devices must be balanced against the patient's right to a safe healthcare environment and a right to know. Hospitals, and possibly health funds, could be exposed to serious ethical conflicts for adopting practices designed to derive economic savings at the expense of patient safety, particularly without full disclosure of the practices being followed and obtaining informed consent.[xiii]

Patient's right as a medical consumer: a matter of informed choice

Patients are entitled to exercise basic consumer rights with regard to their medical service regardless as to whether it is public or private.

In this sense, the provision of relevant treatment information comes from a respect for the patient's freedom of choice and capacity to reason and reflect on the available options in critical awareness of and to make one's own values. [xiv]

Treatment or no treatment

Patients are entitled to control certain aspects of the medical treatment/procedure they elect to receive. As J.A. Coy remarked: "*even when only one type of medical treatment exists for a given problem, at least two options are available to the patient: treatment or non treatment*." [xv]

A failure to inform patients of the use of a reprocessed single use medical device would constitute denial of the patients' right to make an informed choice, in accordance with their own assessment of value, between the options of using a new device or a reprocessed single use medical device as part of their medical treatment.

4. Legal issues

This section highlights potential legal liabilities that healthcare institutions and/or healthcare practitioners may be exposed to as a consequence of a failure to allow patients to arrive at informed consent regarding the use of a reprocessed single use medical device, including warning of any potential associated risk.

Civil action in negligence under tort

Common law imposes on doctors a duty to exercise reasonable care and skill in the provision of professional advice and treatment[xvi].Specifically, a doctor has a duty to warn his or her patient of a material risk inherent in the proposed treatment. This is a comprehensive duty and the standard of care applicable to other categories of medical negligence is not usually relevant in establishing breach from a failure to warn.[xvii]

The law recognises a fundamental difference between diagnosis and treatment, and the provision of information. Whether a doctor undertakes treatment in accordance with the appropriate standard of care is a question requiring critical input from an accepted body of professional opinion, so long as that body of opinion is not irrational or unreasonable (Section 5O Civil Liability Act NSW (2002); Section 59(2) wrongs Act Vic (1958) .

On the other hand, whether the patient has been given all the relevant information is a question of a different order. On this point, the Courts have drawn upon the ethical basis of a *duty to warn*, highlighting that all medical treatment is preceded by the patient's choice to undergo it, and that the choice would be meaningless unless it is made on the basis of relevant information and advice.

Reasonable Risk

A risk is material if, in the circumstances of the case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to the risk; alternatively if the doctor was, or should have been, reasonable aware that the particular patient would be likely to attach significance to the risk.

> *Considering the above factors, it is likely that a risk of harm associated with different types of reprocessed single use medical devices would be considered a material risk at law.*

Warning of the Risk

In brief, would a patient have preferred to eliminate material risk factors if they had been warned?

Central to this is the legal question regarding a doctor's failure to warn the patient. The patient may claim that such failure *caused* them to go ahead, unknowingly, with the option of using a reprocessed single use medical device, and then to suffer the injury as a result of the risk associated with the reprocessed device.

In a situation where the device was found to carry inherent defects, which were undetected during the reprocessing and testing processes, the doctor who used the device on the patient would be able to escape liability in relation to the injury caused by those inherent defects where that doctor had appropriately warned the patient of the risk.

Where the doctor had omitted to give such a warning, however, the doctor would still be exposed to the liability in connection with that failure to give warning. [xviii]

In Queensland and Tasmania, the legislation has codified the common law test for materiality of risk by creating a proactive and reactive obligation on medical practitioners to warn of a risk. [xix]

A doctor in these states is required to give, or arrange to give, before the patient undergoes any medical treatment or at the time of being given medical evidence, the following information about any risk of personal injury to the patient:

- Information that a reasonable person in the patient's position would, in the circumstances, require to enable the person to make a reasonably informed decision about whether to undergo the treatment or follow the advice; and

- Information that the doctor knows or ought reasonably to know the patient wants to be given before making the decision about whether to undergo the treatment or follow the advice.

Liability under the Competition and Consumer Act 2010 (Cth) (formerly the Trade Practices Act 1974) and the Australian Consumer Law. [xx]

Apart from being exposed to liability under tort, doctors and hospitals may have duties to provide correct information under the Competition and Consumer Act and the Australian Consumer Law.

Section 52 of the former Trade Practices Act (s18 of the Australian Consumer Law) (Act) forbids any conduct in trade or commerce that misleads or deceives or is likely to do so. This is a broad provision that covers any representation regarding the characteristics or safety of a product, and extending to conduct "likely to mislead or deceive".

A right of action is created under the Act for those who suffer damage that is said to have been caused by that conduct.

The Act does not seek to impose liability but establishes a norm of conduct that businesses should not mislead consumers.[xxi]

In considering a breach of this duty, courts are not required to consider whether a business intended to mislead or deceive, only that its conduct had the effect of doing so. For this reason, bringing an action under that Act is less onerous for a patient than bringing an action for negligent failure to warn under tort.

It is unclear whether this provision would apply in a case where no information has been given, or where it could be said that the circumstances have been misleading by reason of a failure to provide information. Certainly, it has been held that silence may amount to a breach of section 52 of the former Trade Practices Act, and the essential question is whether, in all of the circumstances constituted by acts, statements or silences, there has been conduct likely to mislead or deceive.

Courts have made it clear, in considering cases brought in the commercial context, that section 52 does not give rise to a duty to inform or provide information. The court in *Fraser v NRMA Holdings Ltd* (1995) 55 FCR 452 stated that: *"[w]here the contravention of section 52 allegedly involves a failure to make a full and fair disclosure of information, the [plaintiff] carries the onus of establishing... how that which was unsaid had the potential to mislead or deceive*."

Section 53 of the former Trade Practices Act (s29 of the Australian Consumer Law) also targets false or misleading representations made in connection with the supply of goods or services. The following are of particular application to cases in which a failure to inform of the reuse of a single use medical device is alleged:

- Falsely representing that goods are of a particular standard, quality,... particular history [xxii]
- Falsely representing that goods are new. [xxiii]

The actions available under these provisions have been largely untested in the context of medical litigation, and for a reason: the Trade Practices Act was amended by the *Trade Practices (Personal Injury and Death) Act* 2006 to exclude the benefit of the consumer protection protections from claims for damages or compensation for death or personal injury, unless resulting from smoking or other use of tobacco products. [xxiv]

It should be noted that the Fair Trading Acts in a number of states had previously restricted the right of patients to bring an action against doctors under that legislation. [xxv]

5. Conclusion: respect of rights: a duty to warn and the right to informed consent

Ethically: Ignoring a duty to warn and thereby failing to inform a patient of a use of a reprocessed single use medical device may conflict with some of the foundations on which the contemporary doctor-patient relationship is premised. These include the respect for the patient's autonomy as an individual, the respect for the patient's right as a consumer and the concern for safety of the patient under care.

Legally the reasoning behind the common law duty to warn further affirms the ethical foundations in a doctor-patient relationship.

> *The decision regarding what to tell, or what not to tell, is not a decision for doctors or healthcare institutions to make based on their own value criteria. The criteria are provided by the law, with reference to what would have been reasonable in the patient's - not the doctor's – position and opinion.*

Current civil liability legislation also recognises this particular focus on the patient's right to know.

While the legislation was originally introduced with a general purpose of curbing the ambit of plaintiff actions, the common law position on the *duty to warn* remains unaffected by the updated legislation and is only likely to be further developed as the demand for information increases.

In some jurisdictions, the statutes have codified doctor's proactive and reactive duty to warn.

It is certainly possible that doctors and healthcare institutions will be exposed to liability. This is especially the case where no disclosure is made to patients regarding the use of a reprocessed single use medical device: particularly if the use is involved with more invasive, complex or costly procedures such as cardiac surgeries or endoscopic procedures.

In respect of negligence, plaintiffs who bring an action under this category would have two hurdles to overcome in order to prove the liability on the part of the doctor or the healthcare institution: firstly, whether the risk associated with the use of a reprocessed device was a material risk, and secondly whether the non-disclosure was causative of the injury.

In addition, healthcare institutions may be exposed to further liabilities for non-disclosure under contract, or under the consumer protection provisions of the former *Trade Practices Act* if an action is brought for damages other than personal injury or death, for example, a financial loss, by a consumer group.

Reliance on Therapeutics Goods Administration (TGA) -approved remanufacturing practices will not by themselves be a sufficient preventive measure to avoid liability, from both an ethical and legal perspective.JJ.

Endnotes

[i] Coy, J., A. "Autonomy-based informed consent: ethical implications for patient non-compliance. " Physical Therapy. 69,10 (Oct 1989): 826(8).

[ii] See for example: Eucomed "Stop reprocessing "single-use" medical devices: Patient safety at risk!" *Eucomed Medical Technology Focus* (2006) 50 (March 2006); W Popp, O Rasslan, et al., "What is the use? An international look at reuse of single-use medical devices", *International Journal of Hygiene and Environmental Health* (2010) 213: 302-307.

[iii] See for example: F M Tessarolo et al., "Health technology assessment on reprocessing single-use catheters for cardiac electrophysiology: results of a three-years study", Conference Proceedings: Annual International Conference of the IEEE Proceedings Engineering in Medicine and Biology Society (2007), pp. 1758-1761.

[iv] W Popp, O Rasslan, et al., "What is the use? An international look at reuse of single-use medical devices", *International Journal of Hygiene and Environmental Health* (2010) 213: 302-307, pp.305-306.

[v] Covance Market Access Services, *Reuse of Single-Use Medical Devices: Evidence for Safety and Efficacy* (15 September 2009).

[vi] See for example: M.V. de Silva and F Ribeiro, "Safety evaluation of single-use medical devices after submission to simulated reutilization cycles", *Journal of AOAC International* (2005) 88(3): 823-9; F M Tessarolo et al., "Health technology assessment on reprocessing single-use catheters for cardiac electrophysiology: results of a three-years study", Conference Proceedings: Annual International Conference of the IEEE Proceedings Engineering in Medicine and Biology Society (2007) pp. 1758-1761; K Roth and P Heeg et al, "Specific hygiene issues relating to reprocessing and reuse of single-use devices for laparoscopic surgery" *Surgical Endoscopy* (2002) 16(7): 1091-7.

[vii] K F Browne and R Maldonado et al. "Initial experience with reuse of coronary angioplasty catheters in the United States", *Journal of American College of Cardiology* (1997) 30(7): 1735-40; M Zubaid and C S Thomas et al. "A randomized study of the safety and efficacy of reused angioplasty balloon catheters", *Indian Heart Journal* (2001) 53(2): 167-71.

[viii] Australian Medical Council*, Good Medical Practice: A Code of Conduct for Doctors in Australia* (available at http://www.medicalboard.gov.au/en/Codes-and-Guidelines.aspx), p.5.

[ix] See also National Health and Medical Research Council, *General Guideline for Medical Practitioners for Providing Information to Patients* (2004) (available at http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e57.pdf)

[x] New South Wales Department of Health, *Patient Information and Consent to Medical Treatment* (Circular 2004/84)

[xi] *Rosenberg v Percival* (2001) 205 CLR 434 at 480, per Kirby J.

[xii] R.R. Faden and T.L.Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986); M.G. del Carmen and S Joffe, "Informed Consent for Medical Treatment and Research: a Review", *The Oncologist* (2005) 10(8): 636-641 at p. 636.

[xiii] D Hailey et al. "Reuse of single use medical devices in Canada: Clinical and economic outcomes, legal and ethical issues, and current hospital practice" *International Journal of Technology Assessment in Health Care* (2008) 24(4): 430-436, p. 434.

[xiv] C Delaney, "Making a difference: incorporating theories of autonomy into models of informed consent". *Journal of Medical Ethics* (2008) 34(9), e3.

[xv] J.A. Coy, "Autonomy-based informed consent: ethical implications for patient non-compliance", *Physical Therapy Journal* (1989) 69(10): 826-833, pp. 829-830

[xvi] *Rogers v Whitaker* (1992) 175 CLR 479, per Mason CJ, Brennan, Dawson, Toohey and McHugh JJ.

[xvii] *Rogers v Whitaker,* at [14] per Mason CJ, Brennan, Dawson, Toohey and McHugh JJ. Also see *Civil Liability Act 2002* (NSW), ss 5O and 5P; *Civil Liability Act 2003* (Qld), s 22; *Civil Liability Act 1936* (SA), s 41; *Civil Liability Act 2002* (Tas), s 22; *Wrongs Act 1958* (Vic), ss 59 and 60.

[xviii] *Civil Liability Act 2002* (NSW), s 5I; *Civil Liability Act 2003* (Qld), s 16; *Civil Liability Act 1936* (SA), s 39; *Wrongs Act 1958* (Vic), s 55; *Civil Liability Act 2002* (WA), s 5P

[xix] *Civil Liability Act 2003* (Qld), s 21; *Civil Liability Act 2002* (Tas), s 21

[xx] The title of the *Trade Practices Act 1974* was changed to the *Competition and Consumer Protection Act 2010* from 1 January 2011. The Australian Consumer Law (ACL) also commenced on this date. The ACL is found in Schedule 2 of the *Competition and Consumer Act* and is a single national law covering consumer protection and fair trading. It replaced the existing national, and State and Territory Fair Trading Acts.

[xxi] The Standing Committee of Officials of Consumer Affairs, *An Australian Consumer Law: Fair markets – Confident consumers* (17 February 2009) (available at http://www.treasury.gov.au/documents/1484/PDF/An_Australian_Consumer_Law.pdf), p.18

[xxii] *Trade Practices Act 1974,* s 53(a) – see Australian Consumer Law s29 (a).

[xxiii] *Trade Practices Act 1974,* s 53(b) – see Australian Consumer Law s29 (c).

[xxiv] *Trade Practices Act 1974,* s 82 (1AAA) and (1AAB) – see ACL s137C

[xxv] See for example: *Fair Trading Act 1987* (NSW), s 68(1A); *Fair Trading Act 1989* (Qld), s 99(2)(b); *Fair Trading Act* (Tas), s 37(2).]

Endnotes

ATTACHMENT B

UK National Joint Registry - Data Collection Form Knee

National Joint Registry
www.njrcentre.org.uk

MDS VERSION 4.0 Knee Operation

Form: MDSv4.0 K1 v1.0

K1 Knee Primary

Patient Addressograph

Important:
Please tick relevant boxes. All component stickers should be affixed to the accompanying 'Minimum Dataset Form Component Labels Sheet'. Please ensure that all sheets are stapled together.

All fields are Mandatory unless otherwise indicated

REMEMBER! MAKE A NOTE OF THE NJR REFERENCE NUMBER WHEN YOU ENTER THIS DATA	NJR REF:

PATIENT DETAILS

Patient Consent Obtained	Yes ☐	No ☐	Not Recorded ☐	
Patient Hospital ID				
Body Mass Index (enter either H&W OR BMI OR tick Not Available box)	Height (IN CM) Weight (IN KG)	BMI		Not Available ☐

PATIENT IDENTIFIERS

Forename				
Surname				
Gender	Male ☐	Female ☐	Not Known ☐	Not Specified ☐
Date of Birth	DD/MM/YYYY			
Patient Postcode			Overseas Address ☐	
NHS Number (if available)				

OPERATION DETAILS

Hospital					
Operation Date	DD/MM/YYYY				
Anaesthetic Types	General ☐ Regional - Epidural ☐		Regional – Nerve Block ☐ Regional – Spinal (Intrathecal) ☐		
Patient ASA Grade	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Operation Funding	NHS ☐	Independent ☐			

SURGEON DETAILS

Consultant in Charge					
Operating Surgeon					
Operating Surgeon Grade	Consultant ☐	SPR/ST3-8 ☐	F1-ST2 ☐	Specialty Doctor/SAS ☐	Other ☐
First Assistant Grade	Consultant ☐		Other ☐		

KNEE PRIMARY PROCEDURE DETAILS

Side	Left ☐ Right ☐
Indications for Implantation (select all that apply)	Osteoarthritis ☐ Rheumatoid Arthritis ☐ Avascular Necrosis ☐ Previous Trauma ☐ Other Inflammatory Arthropathy ☐ Other ☐ Previous Infection ☐
PRE OPERATIVE RANGE OF MOVEMENT	
Fixed Flexion Deformity (degrees)	Less than 10 ☐ 10 to 30 ☐ Greater than 30 ☐ Not Available ☐
Flexion (degrees)	Less than 70 ☐ 70 to 90 ☐ 91 to 110 ☐ Greater than 110 ☐ Not Available ☐

SURGICAL APPROACH

Patient Procedure	Primary Total Prosthetic Replacement Using Cement ☐ Primary Total Prosthetic Replacement Not Using Cement ☐ Unicondylar Knee Replacement ☐ Patello-Femoral Knee Replacement ☐ Primary Total Prosthetic Replacement Not Classified Elsewhere (eg Hybrid) ☐
Consultant in Charge – Default Technique used?	Yes ☐ No ☐ If Yes, ensure the relevant Surgeon Default Technique is recorded on the Data Entry system. The Surgeon's Default Technique is made up of several data fields.
Approach	Medial Parapatellar ☐ Mid-Vastus ☐ Lateral Parapatellar ☐ Other ☐ Sub-Vastus ☐
Minimally Invasive Technique Used?	Yes ☐ No ☐
Computer Guided Surgery Used?	Yes ☐ No ☐
THROMBOPROPHYLAXIS REGIME (intention to treat)	
Chemical	Aspirin ☐ Warfarin ☐ None ☐ LMWH ☐ Direct Thrombin Inhibitor ☐ Pentasaccharide ☐ Other ☐
Mechanical	Foot Pump ☐ Other ☐ Intermittent Calf Compression ☐ None ☐ TED Stockings ☐
BONEGRAFT USED	
Femur	Yes ☐ No ☐
Tibia	Yes ☐ No ☐

SURGEON'S NOTES

INTRA OPERATIVE EVENT

Untoward Intra Operative Event	None ☐ Ligament Injury ☐ Fracture ☐ Other ☐ Patella Tendon Avulsion ☐

Minimum Dataset Form - COMPONENT LABELS

1. Please affix any component labels to this sheet and ensure any extra component label sheets are attached to the main Minimum Dataset Form.
2. Ensure all component details are provided, including cement.
3. The NJR DOES NOT record the following: wire, mesh, cables, plates, screws, surgical tools, endoprostheses or bipolar heads.

ATTACHMENT B

UK National Joint Registry – Outlier Process

NATIONAL JOINT REGISTRY FOR ENGLAND AND WALES
PROCESS FOR INVESTIGATING HIGHER THAN EXPECTED REVISION RATES (OUTLIERS) FOR SURGEONS

STAGE	REQUIRED ACTION	DETAIL
1	NJR Centre advises that an analysis of revisions suggests a higher than expected rate of failure for a particular surgeon/s-'outlier status'.	• In line with the agreed statistical methodology and reporting timeframes.
2	NJR Centre will notify the NJR Steering Committee Chair, and the Healthcare Quality Improvement Partnership, and provide the supporting statistical analysis.	• Identity of the surgeon/s and unit/s will be anonymous at Stage 2.
3	Healthcare Quality Improvement Partnership/NJR Steering Committee Chair, will notify the NJR Steering Committee surgeon members, and provide a copy of the statistical analysis.	• For appropriate action as outlined in Stage 5 below; • Identity of the surgeon/s and unit/s will be anonymous at Stage 3.
4	Healthcare Quality Improvement Partnership will inform the following, that a potential outlier scenario, which will be investigated under the terms of the approved process: ➢ Department of Health ➢ Welsh Assembly Government ➢ NJR Steering Committee members;	• For information only; • A copy of the statistical analysis will NOT be circulated; • Welsh Assembly Government will be notified via the Deputy Medical Officer; • Identity of the surgeon/s and unit/s will be anonymous at Stage 4.
5	NJR Steering Committee surgeon/s will undertake a review of the data with the NJR Centre, to establish whether the statistical analysis is sound and further 'audit' is required i.e. "Case to Answer"	• Identity of the surgeon/s and unit/s to remain anonymous at Stage 5.
6	NJR Steering Committee surgeon/s to notify, and brief, the NJR Steering Committee Chair, and the Healthcare Quality Improvement Partnership, about the outcome of the data review.	• Results to be documented.
	Outcome of Stage 5: "No Case to Answer"	
7	Healthcare Quality Improvement Partnership to inform the following, that the outcome of the data review had concluded that there was "no case to answer": ➢ Department of Health ➢ Welsh Assembly Government ➢ NJR Steering Committee members	• No further action required; • Identity of surgeon/s and unit/s will remain anonymous at Stage 7.

	Outcome of Stage 5: Data and Statistical Analysis sound: "Case to Answer"	
8	When requested by the Healthcare Quality Improvement Partnership, the NJR Centre will provide details of the identity of the surgeon/s and unit/s involved, to the following: ➢ The Healthcare Quality Improvement Partnership; who will notify ➢ The NJR Steering Committee Chair; ➢ The Welsh Assembly Government (if surgeon/unit identity is relevant to Wales); ➢ The NJR Steering Committee surgeon members; and ➢ The NJR Steering Committee NHS Chief Executive Officer member (see Stage 11 below)	
9	At the request of the NJR Steering Committee Chair, and/or the Healthcare Quality Improvement Partnership/Welsh Assembly Government, a nominated NJR Steering Committee surgeon member will make initial contact with the 'outlier' surgeon.	• Healthcare Quality Improvement Partnership to provide the NJR Steering Committee surgeon member with the relevant contact details; • An informal approach will be made via a telephone call to the surgeon to notify that; • The NJR database had flagged up results which indicate a higher than expected revision rate, and this now required a process of audit to establish the reason; • The Chief Executive Officer would be notified, so the surgeon should contact the Chief Executive Officer at their earliest convenience; and • A letter would follow from NJR Steering Committee Chair to the Chief Executive Officer, with a copy to the surgeon, who would be invited to verify the NJR data to ensure that it was correct.
10	The nominated NJR Steering Committee surgeon member will notify the NJR Steering Committee Chair, the Healthcare Quality Improvement Partnership/Welsh Assembly Government, and the NJR Steering Committee Chief Executive Officer member, that the 'outlier' surgeon had been contacted, and provide a brief.	
11	At the request of NJR Steering Committee Chair and/or Healthcare Quality Improvement Partnership/Welsh Assembly Government, the NJR Steering Committee Chief Executive Officer member will then make contact with the Unit/Trust Chief Executive Officer.	• Unit/Trust Chief Executive Officer must be notified in line with clinical governance responsibilities; • No contact will be made with the Chief Executive Officer until the 'outlier' surgeon has been contacted, to allow the opportunity for the surgeon to make initial contact with the Chief Executive Officer; • The Healthcare Quality Improvement Partnership will provide the NJR Steering Committee Chief Executive Officer member with the relevant contact details; • An informal approach will be made via a telephone call to the Chief Executive Officer as follows;

		• To notify about the NJR data, and advise that a surgeon has been contacted by an NJR Steering Committee surgeon representative; • To request that an internal audit be undertaken and notified to the NJR; • To offer the assistance of the NJR Centre for providing supporting data; and • To advise that letter from NJR Steering Committee Chair would follow. • If the Chief Executive Officer is not available (i.e. annual leave), then the 'deputy' Chief Executive Officer will be contacted; • **Independent Sector**: Management and clinical governance responsibilities within the independent sector will be taken into account, to ensure contact is made with the appropriate senior manager, who would be requested to notify the Medical Advisory Chair.
12	The NJR Steering Committee Chief Executive Officer member will notify the NJR Steering Committee Chair, and the Healthcare Improvement Partnership/Welsh Assembly Government, that the Unit/Trust Chief Executive Officer has been contacted, and provide a brief.	
13	A letter from the NJR Steering Committee Chair will be sent to the Unit/Trust Chief Executive Officer and copied to the 'outlier' surgeon.	• Letters will be sent only after telephone calls have been made; • Letters will reflect the telephone conversations; • The Chief Executive Officer will be requested to confirm that an internal audit has been undertaken, and the outcome of this audit; and • The 'outlier' surgeon will be requested to confirm if NJR data is correct.
	After Stage 13: No response from Unit/Trust to confirm that requested audit has taken place	
14	The NJR Steering Committee Chair to send a reminder letter to Chief Executive Officer requesting confirmation/feedback that the NJR data has been audited.	• NJR must ensure that it has taken all necessary action.