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TRANSNATIONAL REGULATORY LAW: DOMESTIC IMPLEMENTATION, TRANSPARENCY AND SCRUTINY

Abstract

Transnational regulatory networks have been subject to a substantial degree of research attention in recent decades. However, less attention has been given to how domestic implementation of their work affects national law-making processes. This article addresses this topic through a case study of the Australian medical devices regulatory scheme. It finds that the Australian medical devices scheme implements decisions made by a transnational network, and that the implementation techniques used avoid — in some important respects — domestic transparency and parliamentary scrutiny processes. This article also offers reform suggestions for aligning the implementation of transnational regulatory networks' actions with domestic democratic law-making imperatives.

I Introduction

The Australian Parliament in the 1990s developed a system for transparency and scrutiny of treaty-making. These developments were prompted by concerns that Parliament's role in relation to treaties was insufficient and the government's treaty-making actions generally lacked transparency.[1] The concerns were addressed in 1996 by establishing a parliamentary committee, the Joint Standing Committee on Treaties ('JSCOT'), and the publication of National Interest Analyses.[2] The implementation of these transparency and scrutiny measures has resulted in the Australian government's treaty actions being more open and accountable.

More recently, however, it has become apparent that the Australian government's international commitments often occur without treaty action and that these commitments circumvent the transparency and scrutiny measures developed in the 1990s. Andrew

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1 Senate Legal and Constitutional References Committee, Parliament of Australia, *Trick or Treaty? Commonwealth Power to Make and Implement Treaties* (Report, November 1995) 191–201, 238–47, 300–4 ('*Trick or Treaty?*').

2 Commonwealth, *Parliamentary Debates*, House of Representatives, 2 May 1996, 233 (Alexander Downer, Minister for Foreign Affairs).

Byrnes has revealed how Australian governments commonly make non-binding agreements that do not have treaty status and are not subject to the parliamentary scrutiny and transparency requirements — yet are significant for Australia at the international level and can affect the rights and interests of Australian citizens and residents.[3] While it is not possible to quantify the extent of these kinds of agreements as there is no register of them, there are views expressed in international law scholarship that they are increasingly important and use of them is proliferating.[4]

This article examines the concerns initially expressed by Byrnes from a different perspective. Rather than examining the bilateral Memoranda of Understanding ('MOU') agreed to by the Australian government and its agencies, this article focuses on government agencies' engagement with transnational regulatory networks. These networks of domestic agencies work together to resolve common regulatory problems in a consistent manner. The members of the network can ensure that domestic laws are consistent across the network by agreeing to particular international standards being adopted in each country. The administrative agencies can then include the standard in their regulations. In this way, the standards agreed to by the network become directly implemented into domestic law.

I examine these aspects of transnational law-making through a case study of Australia's therapeutic goods regulatory scheme for medical devices. These laws regulate a broad range of products used in modern medical practices, such as hip prostheses, breast implants, and transvaginal mesh implants. The case study highlights that Parliament has regularly inquired into and examined medical devices regulation, but there is no systemic check on the transnational law-making processes that are commonly accepted to be the primary influence on Australia's medical devices laws. The case study in Part III of this article reveals that there was no review of the processes or decisions made by the transnational network that influenced Australian legislation and regulations. Parliament has inquired into problems that have been identified with medical devices on numerous occasions, but these inquiries have not included examining the transnational networks, and the processes and decision-making of standard-setting organisations whose standards have been incorporated into Australian law. As the actions at the international level have not involved treaties, the systemic form of review provided by JSCOT was not engaged.

In this article, I argue that the development of Australia's medical devices legislative framework reveals ways in which domestic law-making based on the work of transnational networks can circumvent transparency requirements and parliamentary scrutiny systems. The case study on medical devices exposes important gaps in our law-making institutional arrangements. It reveals how Australian laws regulating an

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3 Andrew Byrnes, 'Time to Put on the 3-D Glasses: Is There a Need to Expand JSCOT's Mandate to Cover "Instruments of Less than Treaty Status"?' (2015) 22(22) *Australian International Law Journal* 1, 2–3.

4 David Mason, Wendy Lacey and Elizabeth Toohey, 'Australian Treaty Practice' in Donald R Rothwell and Emily Crawford (eds), *International Law in Australia* (Lawbook, 3rd ed, 2017) 49, 68. See also ibid 4–5.

important aspect of our health system have been made in a manner that is not transparent and have not been exposed to the general, systemic forms of parliamentary scrutiny. While regulatory systems are highly complex and specific, the problems raised in this article regarding medical devices regulation are also likely to occur in other regulatory systems that rely on the same law-making techniques. I suggest potential reforms to address these gaps through analysing the currently operative transparency and parliamentary scrutiny requirements and offering some proposals for adjustments to be made to them. The problems that I expose have been raised in United States scholarship regarding transnational networks and their effect on US administrative law,[5] but there has been no equivalent study to my knowledge about transnational networks in the Australian context. This article is intended to address this gap in Australian scholarship.

This article is structured as follows. Part II explains transnational networks primarily by reference to the scholarship examining them. It examines their significance for modern forms of government and the potential problems that have been identified in relation to domestic public law. Part III is a case study of medical devices regulation, starting with the development of transnational networks and then moving to the implementation of its decisions in Australian law. Part III includes an analysis of the ways in which the implementation of the medical devices transnational network's decisions into Australian law have been mentioned in parliamentary reports, but have also circumvented the systemic forms of transparency and scrutiny that are established by Australian laws, and carried out by parliamentary committees. Part IV examines considerations relevant to potential reforms.

II Transnational Regulatory Networks

The development of transnational networks and the law-making processes that such networks commonly rely on raises questions about democratic deliberation. The primary deliberation for these laws occurs in the transnational network rather than in domestic institutions. Australian administrative officials may participate in the deliberations of the network, but the decisions are collectively made.

A similar concern was considered in the 1990s reforms that resulted in the transparency and scrutiny scheme for treaties. The prior absence of such measures raised concerns of a democratic deficit.[6] In its report, the Senate Legal and Constitutional References Committee rejected this concern due to decisions to enter into treaties being made by the elected government, and if implementation into Australian law is necessary the implementation is carried out by Parliament.[7] The Committee regarded the pre-reform arrangements for entering into treaties as being democratic but also recognised that the processes could be improved. However, the democratic aspects of treaty-making and implementation referred to by the Senate

5 See below Part II.

6 *Trick or Treaty?* (n 1) 229–34.

7 Ibid 246.

Legal and Constitutional References Committee are not the case for transnational networks and the implementation of their decisions. Australia's representatives in these networks are usually unelected administrative officials and, as we will see in the medical devices case study for this article, implementing their decisions relies heavily on incorporating by reference private international standards. Accordingly, questions about democratic deficits are more directly engaged for transnational law-making than for treaties. Questions about transparency and parliamentary scrutiny have greater democratic significance for transnational law-making than for treaties.

The scholarship on transnational networks identifies their development and expansion as occurring in the 1990s[8] — coincidentally the same decade that the scrutiny and transparency measures for treaties were developed in Australia. The most well-known contribution to that scholarship, Anne-Marie Slaughter's *A New World Order*, recognised the development of networks of administrative officials, courts, or parliaments.[9] Other works of that period and since have focused on networks of regulatory agencies.[10] The important feature of these networks is that domestic regulatory agencies join international committees that are established by administrative arrangements rather than treaties.[11] This article focuses on the transnational network for medical devices. The Australian government is represented in this network by the Therapeutic Goods Administration ('TGA'). The network, founded in 1993, initially had the title the Global Harmonization Task Force ('GHTF').[12] In 2011, the network was transformed into a new organisation, the International Medical Device Regulators Forum ('IMDRF').[13]

The scholarship on transnational networks highlights that a common reason for establishing them is for the harmonisation of regulatory laws — establishing consistent approaches in different countries to particular regulatory problems.[14]

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8 Anne-Marie Slaughter, *A New World Order* (Princeton University Press, 2004) 9.

9 Ibid 1–3, 14–15.

10 David Zaring, 'International Law by Other Means: The Twilight Existence of International Financial Regulatory Organizations' (1998) 33(2) *Texas International Law Journal* 281 ('International Law by Other Means'); Kal Raustiala, 'The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law' (2002) 43(1) *Virginia Journal of International Law* 1. For more recent scholarship, see: Tim Legrand, 'Transgovernmental Policy Networks in the Anglosphere' (2015) 93(4) *Public Administration* 973; Peter Drahos, 'Regulatory Globalisation' in Peter Drahos (ed), *Regulatory Theory: Foundations and Applications* (Australian National University Press, 2017) 249.

11 Zaring, 'International Law by Other Means' (n 10) 287; Raustiala (n 10) 4; Slaughter (n 8) 33–4.

12 'GHTF History', *International Medical Device Regulators Forum* (Web Page) <http://www.imdrf.org/ghtf/ghtf-history.asp>.

13 'About IMDRF', *International Medical Device Regulators Forum* (Web Page) <http://www.imdrf.org/about/about.asp>.

14 Zaring, 'International Law by Other Means' (n 10) 326; Raustiala (n 10) 56–8; Slaughter (n 8) 59, 63.

There are different forms of harmonisation. In his analysis of harmonisation of laws among European Union Member States, Stephen Weatherill refers to harmonisation as taking maximum and minimum forms.[15] The difference between them is whether domestic agencies have scope for adjusting or fine-tuning the particular standard for its domestic effect.[16] This article examines a form of maximum harmonisation, where international standards are implemented directly into domestic law.

The simplest, most direct means of implementation is incorporation by reference,[17] where laws or documents are incorporated into legislation and take legal effect as part of that legislation. The legislation, commonly a regulation, simply identifies the other law or document as being part of the regulation. The incorporated law or document is given legal effect as part of the regulation despite the law or document not actually being included within the regulation, a schedule to the regulation, or its accompanying explanatory material. Standards set by international and domestic private standard-setting organisations are commonly incorporated by reference into regulations.[18] The reference to the standard in the regulation is enough to give the otherwise voluntary standard the status of Australian law. A person or organisation seeking to comply with the regulation will have to look up the standard to ascertain and comply with their legal obligations under the regulation. When the standards that are incorporated by reference are made by private standard-setting organisations, members of the public will usually have to purchase the standard in order to understand the legal effect of the regulation.[19] The relevance of incorporation by

15 Stephen Weatherill, 'The Fundamental Question of Minimum or Maximum Harmonisation' in Sacha Garben and Inge Govaere (eds), *The Internal Market 2.0* (Hart Publishing, 2020) 261, 265–8.

16 Ibid.

17 The term 'incorporation' is used here with the meaning it has for domestic regulations rather than its meaning with regard to the relationship between international and domestic law. For its meaning in the latter context, see: Campbell McLachlan, *Foreign Relations Law* (Cambridge University Press, 2014) 85–9; Annemarie Devereux and Sarah McCosker, 'International Law and Australian Law' in Donald R Rothwell and Emily Crawford (eds), *International Law in Australia* (Lawbook, 3rd ed, 2017) 23, 24–6.

18 See, eg: *Consumer Goods (Quad Bikes) Safety Standard 2019* (Cth) reg 9; *National Greenhouse and Energy Reporting (Measurement) Determination 2008* (Cth) regs 1.19E, 2.24, 2.26; *Civil Aviation Safety Regulations 1998* (Cth) reg 21.172 (definition of 'LSA standards'). For general issues regarding incorporation by reference, see Andrew Edgar, 'From Court Rules to Globalised Standards: Incorporation by Reference in Commonwealth Regulations' [2021] (101) *AIAL Forum* 49.

19 Concerns relating to access and purchase of standards made by standard-setting organisations is beyond the scope of this article. The limitations on access to standards has been criticised in reports and legal scholarship dealing with incorporation by reference: see, eg: Nina A Mendelson, 'Private Control over Access to the Law: The Perplexing Federal Regulatory Use of Private Standards' (2014) 112(5) *Michigan Law Review* 737; Senate Standing Committee on Regulations and Ordinances, Parliament of Australia, *Parliamentary Scrutiny of Delegated Legislation* (Report, 3 June 2019) 50–3 [3.64]–[3.75].

reference for the work of transnational networks is that the network can agree to an international standard or standards, and the domestic agencies can simply incorporate them by reference into their regulations.

When the work of these transnational networks is directly implemented into domestic law, the domestic law can be understood as a form of transnational law. One common method for this form of transnational law is for the network to agree that particular standards developed by international standard-setting organisations are the accepted laws that should be adopted in the member agencies' domestic regulations. In this way, the decisions of transnational networks working with international standard-setting organisations become domestic law. The transnational networks are not merely working to influence domestic policies — their work is directly implemented in domestic law. This kind of transnational regulatory practice has led scholars to recognise the breaking down of the traditionally sharp distinction between the realms of domestic and international in the law.[20]

Concerns have arisen since the initial scholarship on transnational networks that the results of their work can undermine domestic transparency, public participation, and accountability systems. Slaughter recognised these concerns in her work[21] and the concerns have also been recognised in Richard Stewart's global administrative law scholarship.[22] Stewart highlights that domestic implementation of norms determined at the international level may not be subject to domestic procedures in the manner that is otherwise the case. Stewart stated:

> While such implementation is in many cases subject to domestic administrative law procedures and judicial review, the substantive norm was adopted through supranational processes that are not. Further, the value of these procedures may be undermined by officials' professional and personal pre-commitment to the global norms.[23]

Stewart's concerns relate to domestic implementation in the US and the effectiveness of the regulation-making procedures in the *Administrative Procedure Act*.[24] These administrative law concerns have not been addressed in Australian legal scholarship and will be examined in Parts III and IV of this article. The equivalent processes in Australia for regulation-making are included in the *Legislation Act 2003* (Cth)

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20 See, eg, Terence C Halliday and Gregory Shaffer, 'Transnational Legal Orders' in Terence C Halliday and Gregory Shaffer (eds), *Transnational Legal Orders* (Cambridge University Press, 2015) 3, 3.

21 Slaughter (n 8) 221–4.

22 Richard B Stewart, 'The Global Regulatory Challenge to US Administrative Law' (2005) 37(4) *New York University Journal of International Law and Politics* 695, 705–9.

23 Ibid 707.

24 5 USC § 553 (1946).

('*Legislation Act*') which provides for consultation, explanatory statements, and parliamentary scrutiny of regulations.[25]

Before moving on to the medical devices network and its influence on Australian laws, it should be pointed out that the TGA is not the only Commonwealth regulatory scheme that is linked into a transnational network. There are two that are worth mentioning, financial and aviation networks, due to being well established and because they have been referred to internationally as important examples of transnational law-making.[26] The first is the Commonwealth's financial laws. Australia is a member of the Financial Stability Board, an intergovernmental organisation established in 2009 in response to the Global Financial Crisis. As a member of the Financial Stability Board, the Commonwealth is obliged to implement international financial standards.[27] The most well-known are the prudential standards developed by the Basel Committee on Banking Supervision implemented by regulations made by the Australian Prudential Regulatory Authority.[28] The second is aviation regulatory laws. Australia's airworthiness standards are closely tied to US and European Union regulations. Regulations on the airworthiness of small aircraft from both jurisdictions are adopted in Australian regulations.[29] The US regulator, the Federal Aviation Administration, established a committee made up of aviation agencies from Brazil, Canada, China, Europe and New Zealand when working on their airworthiness regulations for small aircraft[30] and its regulations rely heavily on private international standards.[31]

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25 *Legislation Act 2003* (Cth) ss 15J, 17, 38, 42 ('*Legislation Act*').

26 Regarding financial transnational networks, see: Slaughter (n 8) 42–3; David Zaring, *The Globalized Governance of Finance* (Cambridge University Press, 2019) 14–21, 24–8; Stavros Gadinis, 'The Financial Stability Board: The New Politics of International Financial Regulation' (2013) 48(2) *Texas International Law Journal* 157. Regarding aviation networks, see: George A Bermann, 'Regulatory Cooperation with Counterpart Agencies Abroad: The FAA's Aircraft Certification Experience' (1993) 24(3) *Law and Policy in International Business* 669; Slaughter (n 8) 59–60; Ron Bartsch, *International Aviation Law: A Practical Guide* (Routledge, 2nd ed, 2018) 244–5.

27 Financial Stability Board, *Charter of the Financial Stability Board*, 25 September 2009, art 5(1)(c).

28 *Banking Act 1959* (Cth) s 11AF. See generally Vivienne Bath, 'Australia and International Commercial Law' in Donald R Rothwell and Emily Crawford (eds), *International Law in Australia* (Lawbook, 3rd ed, 2017) 343, 347–9.

29 *Civil Aviation Safety Regulations 1998* (Cth) reg 23.001(1).

30 *Revision of Airworthiness Standards for Normal, Utility, Acrobatic, and Commuter Category Airplanes*, 81 Fed Reg 13452, 13458–9 (14 March 2016).

31 *Accepted Means of Compliance; Airworthiness Standards: Normal Category Airplanes*, 14 CFR § 23 (2018).

III Medical Devices Case Study

A *The Medical Devices Transnational Regulatory Network*

The TGA's membership of the medical devices transnational network reveals issues that can arise in transnational law-making. This case study highlights the primary steps involved in this form of law-making process. Officials from domestic regulators work together in the network to agree on common standards regulating a particular global problem or product that is used globally. A common method chosen by the network is to agree to the use of standards made by a private international standard-setter. The network agrees that each of them will domestically adopt the private international standard-setter's standards. These steps can be seen in the background to the current Australian laws on medical devices.

The founding members of the GHTF were Canada, the European Union, Japan and the US.[32] Australia joined in 1993. The successor organisation, the IMDRF, now also includes members from Brazil, China, Russia, Singapore and South Korea. The TGA represents the Australian government on the IMDRF,[33] as well as participating in other transnational networks.[34]

The harmonisation goal of the medical devices network has been implemented partly through the use of standards made by private international standard-setting organisations, and in particular the International Organization for Standardization ('ISO'). The ISO has participated in the medical devices network since the 1990s, with the relationship being formalised in an MOU.[35] The ISO is the primary international standard-setting organisation. Its members are national standard-setting organisations,[36] which for Australia is Standards Australia.[37] International standard-setting organisations such as the ISO are commonly referred to as private

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32 'GHTF History' (n 12).

33 Therapeutic Goods Administration, 'International Medical Device Regulators Forum (IMDRF)', *Australian Government Department of Health and Aged Care* (Web Page) <https://www.tga.gov.au/international-medical-device-regulators-forum-imdrf>.

34 Therapeutic Goods Administration, 'International Activities', *Australian Government Department of Health and Aged Care* (Web Page) <https://www.tga.gov.au/international-activities>.

35 See International Organization for Standardization and International Electrotechnical Commission, *Using and Referencing ISO and IEC Standards for Technical Regulations* (Report, September 2007) 14 ('*Using and Referencing ISO and IEC Standards*').

36 Craig N Murphy and JoAnne Yates, *The International Organization for Standardization (ISO): Global Governance through Voluntary Consensus* (Routledge, 2009) 26–32 ('*International Organization for Standardization*').

37 'What We Do', *Standards Australia* (Web Page, 2022) <https://www.standards.org.au/about/what-we-do>.

organisations.[38] In the ISO's case, that is confirmed by the ISO referring to itself as an 'independent, non-governmental organization' and due to it being funded by its members and the sale of its standards.[39]

One of the primary standards for medical devices that has been adopted in Australia and other countries, ISO 13485 Medical Devices — Quality Management Systems, has been developed by the ISO with contributions from the medical devices network.[40] The ISO's committee responsible for ISO 13485, Technical Committee TC 210, states in its current business plan that the Committee develops this standard in collaboration with the IMDRF.[41] ISO 13485 was developed following a shift in the 1980s in the form of standards made by the ISO. Rather than making standards for the output of a manufacturing process, these standards were made to control manufacturing processes themselves.[42] The initial standards made in this form applied across different industries. However, in the 1990s standards also began to be made for particular industries.[43] ISO 13485 was one of the industry-specific standards made by the ISO in this period. As well as being an industry-specific standard, ISO 13485 also states that it is a process-based standard based on the generally applicable ISO 9001 Quality Management Systems — Requirements.[44] ISO 13485 sets out requirements for management, processes, resources, and documentation for the purposes of ensuring that medical devices are manufactured to a high quality.[45]

38 See, eg: JoAnne Yates and Craig N Murphy, *Engineering Rules: Global Standard Setting Since 1880* (Johns Hopkins University Press, 2019) 1 ('*Engineering Rules*'); Tim Büthe and Walter Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy* (Princeton University Press, 2011) 5.

39 'About Us: Structure and Governance', *ISO* (Web Page) <https://www.iso.org/structure.html>. See also Murphy and Yates, *International Organization for Standardization* (n 36) 25, 42–3.

40 *Using and Referencing ISO and IEC Standards* (n 35) 14–15; 'GHTF History' (n 12).

41 International Organization for Standardization, *ISO/TC 210: Quality Management and Corresponding General Aspects for Medical Devices* (Strategic Business Plan, 12 April 2018) 2–3 [2.1] <https://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/ISO_TC_210__Quality_management_and_corresponding_general_aspects_for_medical_devices_.pdf?nodeid=1161663&vernum=-2>.

42 See Yates and Murphy, *Engineering Rules* (n 38) 298.

43 See generally: Rich Basler and Raymond Pizinger, 'The Arrival of ISO 13485:2003: New Standard Shifts Quality System' (January/February 2004) *Medical Product Outsourcing* 66–7; Yates and Murphy, *Engineering Rules* (n 38) 304.

44 'ISO 13485:2016(en) Medical Devices: Quality Management Systems', *ISO* (Web Page, 2016) [0.3]–[0.4] <https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en>.

45 Ibid [4.1.1]–[4.1.5], [6.1].

ISO 13485 has been adopted in legal form by prominent members of the medical devices network: the European Union;[46] Canada;[47] Singapore;[48] and Australia.[49] While the US has been involved in the medical devices network from its inception, direct legal adoption of ISO 13485 has not occurred there. The current regulation in the US[50] is based on, and implements, ISO 13485 but does not incorporate it by reference.[51]

B *Domestic Implementation*

The medical devices provisions of the *Therapeutic Goods Act 1989* (Cth) ('*Therapeutic Goods Act*') are expressly based on the scheme developed by the medical devices network. In the second reading speech for the inclusion of the medical devices part of the *Therapeutic Goods Act* in 2002,[52] Trish Worth stated that

> [t]he amendments provided for in this bill are necessary to allow the introduction of a world leading, internationally harmonised framework for the regulation of medical devices in Australia. The legislation adopts the global model developed by the Global Harmonisation Task Force, comprising the regulators of Europe, the USA, Canada, Japan and Australia. The amendments will allow better protection of public health, while also facilitating access to new technologies.[53]

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46 *Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices* [1993] OJ L 169/1, arts 3, 5; *Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the Harmonised Standards for Medical Devices Drafted in Support of Council Directive 93/42/EEC* [2020] OJ L 90I/1.

47 *Medical Devices Regulations*, SOR/98-282, s 32(2)(f).

48 *Health Products (Medical Devices) Regulations 2010* (Singapore) regs 33(c)(i), 34(c)(i), 35(c)(i).

49 *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019* (Cth) ord 5, sch 1 ('*2019 Order*').

50 *Quality System Regulation*, 21 CFR § 820 (1996).

51 *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed Reg 52602, 52603, 52605 (7 October 1996).

52 *Therapeutic Goods Amendment (Medical Devices) Act* 2002 (Cth). The 2002 amendments to the *Therapeutic Goods Act 1989* (Cth) were not the first provisions dealing with transnational regulatory measures. The *Therapeutic Goods Amendment Act 1997* (Cth) added provisions to implement a treaty with the European Community regarding conformity assessments of medical devices manufactured in each jurisdiction: see *Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community*, signed 24 June 1998, [1999] ATS 2 (entered into force 1 January 1999) Sectoral Annex on Medical Devices. See also Department of the Parliamentary Library (Cth), *Bills Digest* (Digest No 158 of 1996–97, 27 June 1997) 2–3.

53 Commonwealth, *Parliamentary Debates*, House of Representatives, 14 February 2002, 191 (Trish Worth, Parliamentary Secretary to the Minister for Health and Ageing) ('Medical Devices Second Reading Speech'). See also Senate Community Affairs References Committee, Parliament of Australia, *The Regulatory Standards for the Approval of Medical Devices in Australia* (Report, November 2011) 8 [2.24] ('*Regulatory Standards*').

The medical devices regulatory scheme established by the *Therapeutic Goods Act* is complex. The *Therapeutic Goods Act* requires compliance with 'essential principles'[54] which are 15 principles dealing with different aspects of the safety of medical devices included in regulations.[55] The essential principles are stated at a high level of generality. For example, principle 1(a) refers to medical devices being designed in a way that ensures

> 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 …[56]

As recognised by the medical devices network, the essential principles are not intended to operate as standards. They require supplementation by detailed standards.[57] The *Therapeutic Goods Act* enables regulations to be made that identify applicable standards[58] and states that compliance with them is a legally accepted means for compliance with conformity assessment procedures.[59] The *Therapeutic Goods Act* includes criminal offences and civil penalties for manufacturers that fail to comply with conformity assessment procedures[60] and provides an exception to such provisions when the particular medical device complies with standards that have been recognised by the medical devices provisions of the *Therapeutic Goods Act* and relevant regulations.[61]

These standards are currently included in sch 1 of the *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019* (Cth) ('*2019 Order*') and have been included in precursor regulations dating back to 2003. The *2019 Order* incorporates by reference ISO 13485:2016 (with other ISO standards) and previous versions of this standard were included in earlier regulations.[62] The Explanatory Statements for these regulations refer to the medical devices network

54 *Therapeutic Goods Act 1989* (Cth) s 41MA(1)(b) ('*Therapeutic Goods Act*').

55 Ibid s 41CA; *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) sch 1 ('*Medical Devices Regulations*').

56 *Medical Devices Regulations* (n 55) sch 1, cl 1(a).

57 International Medical Device Regulators Forum, *Optimizing Standards for Regulatory Use* (Final Report, 5 November 2018) 9.

58 *Therapeutic Goods Act* (n 54) ss 41DA, 41DC, 41DD.

59 Ibid s 41D.

60 Ibid ss 41ME, 41MEA.

61 Ibid s 41MG.

62 *2019 Order* (n 49) sch 1; *Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008* (Cth) sch 1 ('*2008 Order*'); *Conformity Assessment Standards Order No 1 of 2005* (Cth) sch 1 ('*2005 Order*'); Delegate for the Minister of Health and Ageing (Cth), 'Conformity Assessment Standards Order No 1' in Commonwealth, *Commonwealth Gazette*, No GN 9, 5 March 2003, 757, 758–9 ('*2003 Order*').

encouraging domestic agencies to use ISO 13485 in their regulatory laws,[63] or that adopting it in Australia is necessary to ensure international best practice and to align Australia's laws with other countries in the network.[64] The Explanatory Statement for the *2019 Order* states that ISO 13485:2016 is not available for free, is subject to copyright, and provides the ISO website where it can be purchased.[65] The Explanatory Statement also states that ISO 13485 can be viewed at the TGA's offices in the Australian Capital Territory.

The development of ISO 13485 and its implementation in domestic regulations highlights one form in which transnational networks implement their harmonisation objectives.[66] Regulators from different countries may work together to seek harmonised regulations but implementing their goals at the international level is difficult as such networks operate outside of existing international institutions and have no network-level administrative capacity. International standard-setting organisations such as the ISO can then be seen as a helpful institution for transforming network policy into standards that can be applied by industry. Standard-setting organisations provide the administrative capacity to enable the transnational network's policies to be implemented into a set of standards.

It is then a relatively simple administrative process for domestic agencies to adopt the international standards in their regulations. When domestic regulatory agencies work together to develop common policies on a particular matter, the next step is to consider implementation into binding laws. The crucial last step is incorporation by reference into the domestic regulations of each country. While there may be no particular legal requirement for the participating countries to incorporate the recognised private international standard into their regulations, there is a strong incentive. It would defeat the purpose of transnational cooperation if the participating regulators do not incorporate them by reference into domestic laws.

C *Domestic Transparency and Parliamentary Scrutiny of the Medical Devices Scheme*

The Australian international law literature on the relationship between international and domestic law focuses on governments making decisions to enter into

63 Explanatory Statement, Conformity Assessment Standards Order No 1 of 2005 (Cth) 3 ('Conformity Assessment Standards Explanatory Statement 2005').

64 Replacement Explanatory Statement, Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019 (Cth) 3–4, 9 ('Therapeutic Goods Replacement Explanatory Statement 2019'); Explanatory Statement, Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008 (Cth) 3.

65 Therapeutic Goods Replacement Explanatory Statement 2019 (n 64) 4.

66 See Sidney A Shapiro, 'International Trade Agreements, Regulatory Protection, and Public Accountability' (2002) 54(1) *Administrative Law Review* 435, 436; Slaughter (n 8) 59.

treaties[67] and if implementation is necessary it is commonly referred to as a matter for Parliament[68] or regulations.[69] Transnational law-making highlights a different set of institutions and officials participating in the decisions to enter into the transnational network and a reduced role for Parliament in implementing the decisions, as is often thought to be the case. In this Part, I explain Parliament's role in relation to international treaties and their implementation in domestic primary and delegated legislation in order to contrast it with Parliament's involvement in the transnational aspects of the medical devices laws.

There is now a developed system for parliamentary scrutiny of treaty-making. A National Interest Analysis is tabled in Parliament with the treaty and is published on the Australasian Legal Information Institute ('AustLII'). This informs parliamentarians and the public of the background and characteristics of the treaty, any consultation that has been held, and implementation plans. The parliamentary scrutiny committee, JSCOT, receives submissions, holds public hearings, including questioning government officials, and publishes a report.[70] While there have been some criticisms of whether these developments provide a sufficient check on government action,[71] the adequacy of the government's consultation processes, and the information provided to JSCOT[72] — they provide the basic structure of a transparency and scrutiny system.

However, the actions in the medical devices case study are not to enter into or amend a treaty and accordingly fall outside of the requirements for treaties. The transnational governance highlighted in the case study is to join a transnational network and then implement the decisions made there. This kind of executive action is common in bilateral agreements that are non-binding and for which the

67 The formal decisions to enter into treaties are made by the Governor-General and the Executive Council: see Anne Twomey, 'Procedure and Practice of Entering and Implementing International Treaties' (Background Paper No 27, Parliamentary Research Service, Parliament of Australia, 9 February 1995) 4–5. See also: Mason, Lacey and Toohey (n 4) 50; McLachlan (n 17) 126–9.

68 McLachlan (n 17) 156 [5.20]; James Crawford and Ivan Shearer, 'Reflections on the Occasion of the Third Edition of "International Law in Australia"' in Donald R Rothwell and Emily Crawford (eds), *International Law in Australia* (Lawbook, 3rd ed, 2017) xiii, xvi.

69 Anne Twomey, 'Federal Parliament's Changing Role in Treaty Making and External Affairs' (Research Paper No 15, Parliamentary Library Information and Research Services, Parliament of Australia, 7 March 2000) 24 ('Federal Parliament's Changing Role').

70 See, eg: Joint Standing Committee on Treaties, Parliament of Australia, *Film Co-Production: Malaysia; Radio Regulations: WRC-19; Tax Information Exchange: Timor-Leste* (Report No 195, May 2021) 2 [1.9]–[1.11]; Hilary Charlesworth et al, 'Deep Anxieties: Australia and the International Legal Order' (2003) 25(4) *Sydney Law Review* 423, 441.

71 See, eg: Charlesworth et al (n 70) 443–4; Madelaine Chiam, 'Evaluating Australia's Treaty-Making Process' (2004) 15(4) *Public Law Review* 265, 265–9.

72 Twomey, 'Federal Parliament's Changing Role' (n 69) 33.

parliamentary scrutiny and transparency mechanisms do not apply.[73] There are many examples of the Commonwealth entering into treaties when joining international organisations,[74] however, they are different to the transnational networks in which Australian government agencies' participation does not require a treaty. Yet, international organisations and transnational networks have similar general characteristics. For both there is Australian government action at the international level and decisions made at that level may require domestic legal implementation.

As we have seen, the medical devices transnational networks were not established by treaty and the TGA's participation in them was not authorised by a treaty. The GHTF was established in January 1993 prior to the transparency and scrutiny requirements becoming operative but even if these requirements had commenced by then, the treaty processes would not have applied to the TGA's participation in the GHTF. The GHTF was replaced by the IMDRF by way of an announcement by the newly established organisation,[75] which meant that the transparency and scrutiny requirements for treaties were not applicable.

This indicates that transnational networks do not engage Parliament's transparency and scrutiny requirements for treaties in the way that would occur for Australia's participation in international organisations established by binding international law. However, that does not mean that Parliament has had no role in relation to medical devices laws. The process for making the Australian legislation for medical devices indicates the ways in which this occurs.

The parliamentary process for amendments to the *Therapeutic Goods Act* relating to medical devices included information about the provisions being influenced by the medical devices transnational network, at that time the GHTF. The information was included in the Explanatory Memorandum for a Bill that was introduced in 2001 but lapsed[76] and was included again in the Explanatory Memorandum for the 2002 Bill that was passed by Parliament.[77] Reference to the GHTF was also

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73 Byrnes (n 3) 4–5; Mason, Lacey and Toohey (n 4) 67.

74 See, eg: *Articles of Agreement of the International Monetary Fund*, opened for signature 27 December 1945, [1947] ATS 11 (entered into force 27 December 1945); *Convention on the Organisation for Economic Co-Operation and Development [OECD], and Supplementary Protocols 1 and 2*, opened for signature 14 December 1960, [1971] ATS 11 (entered into force 30 September 1961); *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, [1995] ATS 8 (entered into force 1 January 1995).

75 'Ottawa, Canada Meeting Outcome Statement', *International Medical Device Regulators Forum* (Web Page, 7 October 2011) <https://www.imdrf.org/documents/ottawa-canada-meeting-outcome-statement>.

76 Explanatory Memorandum, Therapeutic Goods Amendment (Medical Devices) Bill 2001 (Cth) 1–2.

77 Explanatory Memorandum, Therapeutic Goods Amendment (Medical Devices) Bill 2002 (Cth) 1–2 ('Therapeutic Goods Amendment Explanatory Memorandum 2002').

included in the Bills Digest prepared by parliamentary staff for the 2001 Bill[78] and in the second reading speech in the House of Representatives.[79] This information was provided for parliamentarians, however it was very brief and was provided as part of background information. The information provided did not include the network's reasons for its recommendations and who participated in developing them. The primary explanation of the network's significance was that its work should be understood to be 'internationally accepted best practice'.[80]

As the administrative steps for joining the transnational network and contributing to its decisions did not involve binding treaty actions, JSCOT did not review any of these actions. However, the medical devices networks have been recognised in treaties that have included provisions for medical devices. This recognition was referred to in some of the documentation for the particular treaties but, again, did not involve scrutiny of the actual network and its decisions.

This can be seen in the 2016 amendment to the *Singapore–Australia Free Trade Agreement* which includes an annex dealing with medical devices.[81] This part of the agreement incorporates the GHTF definition of 'medical device' and obliges the parties to contribute to international fora:

> The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support of those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for medical devices.[82]

A National Interest Analysis was prepared for the amendment which included a brief mention of medical devices without referring to the harmonisation provisions or the medical devices network.[83] JSCOT reported on the amendment but that report did not extend to the medical devices aspect of the treaty.[84] This example indicates

78 Department of the Parliamentary Library Information and Research Services (Cth), *Bills Digest* (Digest No 149 of 2000–01, 7 June 2001) 3.

79 Medical Devices Second Reading Speech (n 53) 191. Note that the medical devices networks were also referred to in the background documents for amendments to the *Therapeutic Goods Act* enacted in 2021: Explanatory Memorandum, Therapeutic Goods Amendment (2020 Measures No 2) Bill 2020 (Cth) 113–15; Department of Parliamentary Services (Cth), *Bills Digest* (Digest No 45 of 2020–21, 2 February 2021) 5.

80 Therapeutic Goods Amendment Explanatory Memorandum 2002 (n 77) 1.

81 *Agreement to Amend the Singapore–Australia Free Trade Agreement*, signed 13 October 2016, [2017] ATS 26 (entered into force 1 December 2017) ch 5, Sectoral Annex on Medical Devices.

82 Ibid art 8.

83 National Interest Analysis, *Agreement to Amend the Singapore–Australia Free Trade Agreement*, [2017] ATNIA 9 [20].

84 Joint Standing Committee on Treaties, Parliament of Australia, *Singapore Free Trade Agreement*: *Amendment; Defence Supplies and Services: Japan* (Report No 172, August 2017).

that while the transnational network's actions may surface in Australia's treaties, that does not mean that its decisions are transparent or scrutinised in Australia's treaty processes.

Other Commonwealth parliamentary committees have referred to the medical devices transnational network in their inquiries. The Senate Community Affairs References Committee has held inquiries into Australia's medical devices regulatory system in relation to devices that have harmed patients, such as hip prostheses, breast implants, and transvaginal mesh implants. In some of these inquiries, the Committee's reports have explained the transnational nature of the Australian medical devices regulatory system.[85] But that is not the case for all of these inquiries.[86] This indicates that medical devices networks have been recognised and referred to in committee inquiries into the medical devices regulatory scheme generally. However, this has been as part of the background of the regulatory scheme and peripheral to the primary issues examined in the inquiry, such as the particular medical devices that have been problematic and the administrative aspects of the scheme. As such, while the influence of the medical devices transnational network has been referred to and recognised in parliamentary committee inquiries, there has been no specific analysis of its decisions or decision-making processes.

The medical devices legislation is a complex but important part of Australia's health system. That makes the legislation very likely to be subject to some degree of transparency and parliamentary scrutiny. We have seen different ways in which this has occurred. While the transnational aspects of the legislative scheme may not directly be subject to the treaty scrutiny system, the transnational features have been referred to in more general forms of parliamentary scrutiny. This raises a question as to whether more systemic scrutiny of Australian agencies' actions on the international stage is necessary. Transnational networks' actions may be thought to not require such scrutiny as their decisions do not have any legal status. However, there are reasons for systemic scrutiny that I will consider in Part IV.

D *Transparency and Parliamentary Scrutiny of Regulations*

The medical devices transnational network's goal of harmonising the domestic regulatory schemes of its members was intended to be implemented through their reliance on common standards, in particular ISO 13485 and other ISO standards. Reliance on internationally developed standards is a common feature of transnational networks' actions. The adoption of such standards into Australian medical

85 *Regulatory Standards* (n 53) 7–9 [2.18]–[2.28], 97–8 [5.8]; Senate Community Affairs References Committee, Parliament of Australia, *The Role of the Therapeutic Goods Administration regarding Medical Devices, Particularly Poly Implant Prothese (PIP) Breast Implants* (Report, 31 May 2012) 9 [2.14].

86 See, eg: Senate Community Affairs Legislation Committee, Parliament of Australia, *Therapeutic Goods Amendment (2016 Measures No 1) Bill 2016 [Provisions]* (Report, 27 March 2017); Senate Community Affairs References Committee, Parliament of Australia, *Number of Women in Australia Who Have Had Transvaginal Mesh Implants and Related Matters* (Report, 28 March 2018).

devices regulations raises a question as to whether this aspect of the transnational law-making system is transparent and scrutinised by the relevant parliamentary committee, the Senate Scrutiny of Delegated Legislation Committee. The answer is that there is minimal scrutiny of standards adopted in regulations.

Just as questions were raised in the 1990s regarding transparency and parliamentary scrutiny for the government's actions regarding treaties, there is a history of questions being raised about the transparency and parliamentary scrutiny of regulations. However, the concerns stretch back much further to the 1930s and the initial parliamentary scrutiny requirements that were established then.[87] Transparency requirements are now included in the *Legislation Act*, which has provisions for consultation and for explanatory statements to be provided for each regulation.[88] Regulations are tabled in Parliament and subject potentially to disallowance.[89] Parliamentary scrutiny is provided by the Senate Scrutiny of Delegated Legislation Committee.[90]

The implementation of the transnational network's scheme for medical devices highlights that the Australian agency relied on regulations to implement the detailed standards. The ISO standards were included in Australian regulations through being incorporated by reference. Regulations that include standards that are incorporated by reference are subject to the transparency and parliamentary scrutiny system. The text of the regulation is subject to the consultation requirements and parliamentary scrutiny set out in the *Legislation Act*, but the incorporated standard included within the regulation is not required to be included in those processes. That means that the incorporated standard is not required by the *Legislation Act* to be provided to those who seek to make submissions in consultation processes or to Parliament for scrutiny, notwithstanding that the standard becomes Australian law due to being incorporated by reference into the regulation.

The Commonwealth legislation that controls regulation-making includes requirements relating to the form of incorporation by reference[91] and information on how to access the law or document.[92] However, these requirements for incorporation by reference are not directed to ensuring transparency and parliamentary scrutiny. They are directed to providing for legal certainty by enabling persons and organisations who are required to comply with the incorporated standard to know the details of the standard and how to access it.

87 See Dennis Pearce and Stephen Argument, *Delegated Legislation in Australia* (LexisNexis Butterworths, 5th ed, 2017) 60.

88 *Legislation Act* (n 25) ss 3(b), 15J, 17.

89 Ibid ss 38, 42.

90 Senate, Parliament of Australia, *Standing Orders and Other Orders of the Senate* (at July 2021) ord 23.

91 That is, whether the regulation incorporates a particular version of the standard or the standard with subsequent changes that are made to it: *Legislation Act* (n 25) s 14(2).

92 *Legislation Act* (n 25) s 15J(2)(c).

The Commonwealth regulations that contain the standards which medical device manufacturers must comply with have incorporated by reference ISO 13485 since the medical devices scheme was established in 2002.[93] Some aspects of the standard are briefly described in the explanatory statements for these regulations, including changes that have been made to the standard since the previous regulation incorporating it.[94] However, the text of the standard was not included with the regulations, their explanatory statements, or tabled separately in Parliament.[95]

That means that while ISO 13485 has been incorporated by reference into Australian law for two decades, the actual standard has not been exposed to public or parliamentary scrutiny as is required for other aspects of Commonwealth regulations. Parliament has power to require documents such as standards that are incorporated by reference in regulations to be made available to the Parliament.[96] However there is no evidence of that occurring for ISO 13485 or, to my knowledge, any other private standard incorporated by reference in Commonwealth regulations. The implementation of the medical devices transnational network's program in Australian primary legislation and regulations has therefore occurred without explanation of the substantive features of that program or the important details of the particular standards by which medical device manufacturers ensure they comply with Australian legal requirements. The medical devices network is referred to in numerous parliamentary documents relating to medical devices policies and laws, but its actions and influence on Australian law have circumvented the primary schemes for transparency and parliamentary scrutiny. The treaty requirements were avoided as the medical devices network's actions are non-binding and not treaties. The implementation of the details of the program through incorporation by reference of private standards into regulations avoids the primary features of the transparency and scrutiny requirements for regulations.

IV Reform Options and Considerations

As we have seen, the medical devices case study highlights that while the transnational network has been referred to in many different parliamentary materials, its decision-making processes and reasons for decisions are not captured by the current systemic transparency and scrutiny mechanisms. The question then is how Commonwealth transparency and parliamentary scrutiny requirements can be adapted to include them. Australian agencies that participate in such networks are

93 *2019 Order* (n 49) sch 1; *2008 Order* (n 62) sch 1; *2005 Order* (n 62) sch 1; *2003 Order* (n 62) sch 1.

94 See, eg: Therapeutic Goods Replacement Explanatory Statement 2019 (n 64) 9; Conformity Assessment Standards Explanatory Statement 2005 (n 63) 2–3.

95 Parliament has specific power to require documents such as standards that are incorporated by reference in regulations to be made available to the public: *Legislation Act* (n 25) s 41. However, that has not occurred for ISO 13485 or, to my knowledge, any other private standard incorporated by reference in Commonwealth regulations.

96 *Legislation Act* (n 25) s 41.

not necessarily secretive about their membership and contributions to transnational networks. The TGA, for example, has a webpage acknowledging its role in the IMDRF.[97] However, that is not the same as the transparency and scrutiny provided by Parliament, the primary democratic institution. The question is: how can Commonwealth transparency and parliamentary scrutiny measures be adapted to include transnational law-making?

It is helpful to distinguish the establishment of transnational networks and their decision-making from domestic implementation of their decisions. In his article focusing on MOUs, Byrnes recommended publishing the text of MOUs in a public register, reporting to Parliament of instruments that are less than treaty status, and broadening JSCOT's remit to include MOUs.[98] His focus on MOUs does not quite fit the activities of transnational networks as they are less formal than agreements made in the form of MOUs. However, Byrnes' reform proposals suggest that some reforms could be developed and adjusted to fit the nature of transnational networks.

It would be possible to treat participation of a Commonwealth agency in a transnational network as requiring express authorisation in legislation establishing the agency. For example, the Australian Accounting Standards Board is subject to a statutory provision authorising it 'to participate in and contribute to the development of a single set of accounting standards for world-wide use' and is authorised to 'make or formulate an accounting standard by issuing the text of an international accounting standard'.[99] This requirement for statutory authority could be used more broadly. It would be the appropriate place to include safeguards such as requiring agencies to provide an explanatory statement of their transnational activities on a regular basis, for example in annual reports, and provide that statement to Parliament. Parliamentary scrutiny, either by committees with subject matter responsibilities or JSCOT, could then be extended to review the explanatory statements and the activities. Such measures would support transparency and parliamentary scrutiny of an agency's membership of a transnational network by requiring them to report on the policy development activities of the network.

Transnational networks are also designed to have their decisions and activities implemented in domestic legislation in order to enable harmonisation of the domestic laws of different countries. The medical devices case study highlights that this may require primary legislation, such as the amendments to the *Therapeutic Goods Act* made in 2002,[100] and more commonly implementation in regulations, including through incorporation by reference of private international standards. It would be possible for transparency to be provided by requiring an explanation of the decisions made by the transnational network that are being implemented. For implementation

97 Therapeutic Goods Administration, 'International Medical Device Regulators Forum (IMDRF)', *Australian Government Department of Health and Aged Care* (Web Page) <https://www.tga.gov.au/international-medical-device-regulators-forum-imdrf>.

98 Byrnes (n 3) 14.

99 *Australian Securities and Investments Commission Act 2001* (Cth) ss 227(1)(d), (4).

100 *Therapeutic Goods Amendment (Medical Devices) Act 2002* (Cth).

in primary legislation, this would be subject to scrutiny by the Senate Standing Committee for the Scrutiny of Bills.

More substantive changes would be required for transparency and parliamentary scrutiny for regulations incorporating by reference international standards. As explained in Part III(D), the current provisions for incorporation by reference provide for legal certainty and access to incorporated standards rather than transparency and parliamentary scrutiny of the processes and substantive decisions underpinning the standards. This indicates that the existing transparency and scrutiny measures could be adjusted to include the decisions of the transnational network and the incorporated standard.

There are three changes that could accommodate transnational law-making practices within the Commonwealth's transparency and parliamentary scrutiny of regulations requirements. One would be to require agencies to include in explanatory statements for regulations an explanation of the transnational network's decisions that underpin the regulation and the manner in which they are implemented within the regulation. This would require amending s 15J(2) of the *Legislation Act*, which provides for the content of explanatory statements for regulations. A second change would be to include standards that are incorporated by reference into regulations to be included in the parliamentary scrutiny of regulations for their compatibility with human rights. This could be done by an express requirement for scrutiny of such regulations by the Parliamentary Joint Committee on Human Rights and for statements of compatibility with human rights that are included in explanatory statements for regulations to extend to any standard that is incorporated by reference with the regulation. The third would be to require the incorporated international standard to be provided with the text of the regulation for public consultation[101] and for its automatic tabling in Parliament with the regulation rather than on request of members of Parliament.[102] This would expose the incorporated standard to public consultation, general scrutiny by Parliament, and more focused scrutiny by the Senate Standing Committee for the Scrutiny of Delegated Legislation.

The purpose of these suggested reforms is to address the concerns that transnational law-making affects the current procedures and institutions that make parliamentary and administrative law-making democratically legitimate. While it is possible that different reforms than those proposed could better achieve this purpose, the important point is to recognise that changes are required to reconcile recent developments regarding transnational networks and transnational law-making to Australia's democratic institutions.

101 See *Legislation Act* (n 25) s 17.

102 Ibid ss 38, 41.

V Conclusion

The medical devices case study in this article described an elaborate transnational scheme for harmonising domestic laws. The implementation of the network's plans and goals in Australia's and other countries laws has facilitated the trade of medical devices. However, little attention has been given to how this transnational scheme and others like it, affect domestic law-making processes designed for democratic deliberation and scrutiny.

In this article I have attempted to explain the primary features of transnational networks through the case study of medical devices laws. I have highlighted how this form of law-making circumvents transparency and scrutiny processes and institutions that provide the democratic basis for Australian laws. This suggests that some reforms would help to reconcile the Commonwealth domestic law-making processes to transnational law-making. There seems to have been no attempt to improve the transparency and scrutiny system for MOUs following Byrnes' analysis of them. The same fate is likely to be the case for the reforms suggested in this article. However, if Commonwealth agencies continue to rely on MOUs and transnational networks in the long term, the issues raised in Byrnes' article and this article are likely to be raised by those concerned about the relationship between governments' international and domestic law-making activities.