Nanomedicine regulation in Australia

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Abstract

The relative benefits and risks of nanomedicine have led to global indecisiveness regarding a suitable approach for regulation of this industry, and Australia is no exception. This article proposes a meta-regulation approach for regulating nanomedicine in Australia, demonstrating how this approach enables companies to surpass their compliance requirements and improve stakeholders' capacity to deal with the inherent uncertainty surrounding the emergent science of nanotechnology.

Keywords

Meta-regulation, nanomedicine, regulation, corporate responsibility, risk, health, Australia

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With the recent surge in nanomedicine production, scientists, advocacy groups and citizens alike have raised concerns about nanoparticles in medicines and their potential negative impacts.[1] Some research has shown that nanoparticles used in medicines may lead to undesired interactions in humans at the cellular level due to enzymatic competition and adversely affect the external

[1] Nanomedicine is based on nanotechnology. A particularly important characteristic of nanotechnology is its ability to reduce the size of particles by tapping the composition of molecules at the nano scale. Nano scale denotes an encompassing material between 1 and 100 nanometres in size in at least one dimension. The term nanoparticle refers to any material having one or more dimensions in the nano scale or a material that is itself nano-structured.

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environment.[2] It has also been frequently argued that the impact of such interaction on human health and the environment is expected to be relatively higher than that of comparable conventional medicine and health products.[3] As such, there is a strong need for suitable regulation of the nanomedicine industry to address these health risks and the role of nanomedicine producing companies to minimise these risks. The current lack of a globally accepted approach for regulating the nanomedicine industry, an example of a novel technology-oriented industry, has serious consequences. It places regulators in a dilemma, as they lack tools to govern this technology before it becomes too entrenched. At the same time, however, regulators also generally lack sufficient information to create suitable regulatory tools at the nascent stages of a new technology.[4] This may partially explain why nanomedicine producing countries do not yet have a comprehensive regulatory framework.[5] A variety of different approaches have been previously utilised, including the incremental approach, product specific

[2] Cylindrical nano-forms of carbon used in nanomedicines are characterized by their extraordinary strength and unique electrical properties. For details, see Jeremy A Bartlett et al, 'Summary Report of PQRI Workshop on Nanomaterial in Drug Products: Current Experience and Management of Potential Risks' (2015) 17(1) *The AAPS Journal*, 44–64; ABC News, 'Friends of the Earth Raises Concerns over Nanotechnology in Agricultural Chemicals and Livestock Feed' 26 September 2014 (Sarina Locke) http://www.abc.net.au/news/rural/2014-09-26/nrn-nanotechnology-concerns/5770902.

[3] According to the International Risk Governance Council, nanotechnology raises complex and far-reaching issues compared to many other innovations. The Council finds current regulatory approaches incompetent to deal with the issues nanotechnology poses, therefore hindering the progress of this technology. For details see International Risk Governance Council, *Policy Brief* (2007) 4.

[4] Peter Hoet, Irene Brüske-Hohlfeld and Oleg Salata, 'Nanoparticles: Known and Unknown Health Risks' (2004) 2(1) *Journal of Nanobiotechnology* 12; Volker Wagner et al, 'Nanomedicine: Drivers for Development and Possible Impacts' (European Commission, 2006); Arturo Keller et al, 'Global Life Cycle Releases of Engineered Nanomaterials' (2013) 15(6) *Journal of Nanoparticle Research*, 1692.

[5] J Clarence Davies, *Managing the Effects of Nanotechnology* (Woodrow Wilson International Center for Scholars, 2006) 32; Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (2010); Deryck Beyleveld and Roger Brownsword, 'Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning' (2012) 4(1) *Law, Innovation and Technology*, 35-65; Roger Brownsword, 'Human Dignity and Nanotechnologies: Two Frames, Many Ethics' (2011) 19 *Political Ethics*, 429–39.

approach, pro-active approach, and precautionary approach.[6] However, none of these approaches has emerged as the optimal choice. The inherent uncertainty surrounding the science of nanotechnology along with the various drawbacks of existing regulatory approaches has led to global indecisiveness regarding regulation of the nanomedicine industry.[7]

This article assesses the nanomedicine regulation framework of Australia and explores the possibility of including meta-regulation approaches within a nanomedicine regulation framework. Meta-regulation is a comparatively new regulation

[6] Marjan Peters and Rosa Uylenburg, 'Concluding Observations' in Marjan Peters and Rosa Uylenburg (eds), *EU Environmental Legislation: Legal Perspectives on Regulatory Strategies* (Edward Elgar, 2014).

[7] Richard Handy, Richard Owen and Eugenia Valsami-Jones, 'The Ecotoxicology of Nanoparticles and Nanomaterials' (2008) 17(5) *Ecotoxicology*, 315-325; Jae-Young Choi, Gurumurthy Ramachandran and Milind Kandlikar, 'The Impact of Toxicity Testing Costs on Nanomaterial Regulation' (2009) 40 *Environmental Science & Technology*, 3030-3034; Treye Thomas et al, 'Moving Toward Exposure and Risk Evaluation of Nanomaterials: Challenges and Future Directions' (2009) 1 *Wiley Interdisciplinary Reviews: Nanomedicine and Nano biotechnology*, 426-433; Elena Pariotti, 'Regulating nanotechnologies: Towards the interplay of hard and soft Law' (2009) 25 *Notizie di Politeia*, 29–40; Bärbel Dorbeck-Jung and Clare Shelley-Egan, 'Meta-regulation and Nanotechnologies: The challenge of responsibilisation within the European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research' (2013) 7(1) *Nano Ethics*, 55–68.

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approach that utilises 'multiple fora, interests, tools, and strategies'[8] to reach a public policy goal. This approach may be well positioned to address the uncertainties and risks that characterise the nanomedicine industry.

Lack of regulation addressing nanomedicine

In Australia, nanomedicine is considered a type of medicine and nano health products as a type of therapeutic goods. The legislation and public organisations closely related to nanomedicine and nano health products are the *Therapeutic Goods Act 1989*, Australian Therapeutic Goods Administration (TGA), National Industrial Chemicals Notification and Assessment Schemes (NICNAS), National Nanotechnology Strategy Taskforce (NNST), and Australian Office of Nanotechnology (AON). A detailed study on the need for specific legislation regarding nanotechnology-based products was conducted in 2007.[9] This study stipulates that Australia does not require any specific legislation, concluding that the provisions of the *Therapeutic Goods Act 1989* are sufficient to address the risk and uncertainties inherent in products with nano-particles. Although the National Nanotechnology Strategy and the National Enabling Technologies Strategy raised concerns about the risks attached to nano-products, they do not recommend any changes of the current regulatory framework for the industry. As a result, no specific legislation, codes of conduct, or organisations have been implemented to address the negative impacts and possible threat posed by the nanomedicine industry in Australia.

The *Therapeutic Goods Act 1989* defines medicine as: '(a) therapeutic goods (other than biologicals) that are represented to achieve or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and (b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic device.'[10] This Act acknowledged 'gene technology' in its amendment in 2001, but did not acknowledge nanomedicine as a distinct type of medicine. It elaborated the requirements for 'listing, registering or including medicines, medical devices and biological products' on the

[8] Elen Stokes, 'Demand for Command: Responding to technological risks and scientific uncertainties' (2013) 21(1) *Medical Law Review*, 11–38

[9] This study is commonly known as the Monash Review. This review is a combination of several research papers prepared by researchers at Monash University during 2007.

[10] Section 3 of the *Therapeutic Goods Act 1989*.

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Australian Register of Therapeutic Goods and thus empowered the government to create an organisation to administer the production and distribution of therapeutic goods in the country. The TGA is the sole public authority for administering therapeutic goods related activities in Australia, approving and regulating therapeutic goods after an assessment of risks against benefits. The TGA relies on its scientific and clinical experts to ensure that the benefits of a product are greater than its risks. Generally, this organisation considers nanomedicine as 'complementary' medicine and it does not outline any specific guidance or instructions for nanomedicine producing companies. Instead, it has recently declared that 'there is currently no evidence to suggest that therapeutic products which incorporate nanotechnologies pose greater safety risks than conventional products'.[11] In fact, like the US Food and Drug Administration, this organisation regulates end-products, not any technology *per se*; it is yet to acknowledge that 'nanoscale' does not just mean that a product is smaller, if often means that the particle is 'fundamentally different'[12].

In Australia, the NICNAS is the primary framework for regulating the industrial use of nanomaterials,[13] placing declared substances under a permit system that requires further information on a case-by-case basis. Simulations of potential uses are utilised to ascertain risks to human health or the environment. When additional information is required, there is no indication of how the health risk assessment is carried out beyond a number of 'exposure-based on use scenarios.' Realistically, this is based on other chemical regulation frameworks; the additional data requirement in this industry is generally subject to variation when novel information on the toxicity of nanomaterials is generated. This has generated concerns regarding the large amount of imported products containing nanomaterials, because manufactured items typically 'slip between the cracks of regulatory bodies... [and] it is possible that later on, if they are broken down or otherwise degraded, these products could present health hazards'.[14]

[11] Therapeutic Goods Administration, *Nanotechnology and Therapeutic Products: Questions and answers* (2018).

[12] Raj Bawa, 'Regulating Nanomedicine: Can the FDA handle it?' (2011) 8(3) *Current Drug Delivery*, 227-234, 230

[13] Karinne Ludlow, Diana Bowman and Graeme Hodge, 'A review of possible impacts of nanotechnology on Australia's regulatory framework' (Monash Centre for Regulatory Studies and the Institute for Environmental and Energy Law, 2007).

[14] ABC Radio National, 'Australian Regulation and Nanotechnology' 25 March 2013 (Gareth Austin) http://www.abc.net.au/radionational/programs/lifematters/australian-regulation-and-nanotechnology/4589238.

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The NNST works under the administrative control of the Department of Industry, Innovation and Science~~Tourism and Resources~~. This task force has created a National Nanotechnology Strategy and the Australian Office of Nanotechnology (AON). The AON is responsible for implementing the National Nanotechnology Strategy.[15] These frameworks aim to develop nanotechnology-based manufacturing and innovation in Australia; they do not have any particular focus on nanomedicine and the responsibility of relevant medicine producing companies to limit the negative impacts of their products. The Health, Safety and Environment Working Group has recently started coordinating public and private agencies to evaluate the health, safety, and environmental impacts of new technologies. This group has acknowledged nanomedicine as an industry that may create a considerable impact on public health and the environment, although it is too early to assess its activities related to nanomedicine companies.[16]

Among the private and civil society groups, Standards Australia (SA) and Friends of the Earth (FoE) Australia have several programs related to nanotechnology. However, they are yet to implement any specific programs for nanomedicine and nanomedicine-producing companies. Although SA has formed a committee termed the Nanotechnology Committee to coordinate with the International Organization for Standardization (ISO), its role in the technology's regulation is limited to its coordination

[15] Michael Lupton, 'Where to draw the line—Regulation of therapeutic applications of nanotechnology' (2014) 9(1) *Asian Journal of WTO & International Health Law and Policy*, 197–216.

[16] Ibid.

between ISO and Australia.[17] FoE Australia is a federation of grassroots groups. In its 2014 report on nanotechnology in Australia, it urged for mandatory registration of nanotechnology-related operations, so that it is possible to track the product risks of registered nanotechnology-based operations. However, FoE is yet to consider nanomedicine production as a distinct nanotechnology-based operation.[18]

Australia currently has a working definition of nanomaterials, but there is no definition for nanomedicine; as such, the country does not consider the production of nanomedicine to constitute an industry. The governmental organisations closely related to chemical and medicine production do not have any specific focus on nanomedicine and nanomedicine-producing companies. For instance, the TGA requires all products attempting to access Australian markets to contain this statement:

> Procedures for proper handling and disposal of anticancer drugs should be considered. Several guidelines on this subject have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate.[19]

There is no explicit provision or guidelines for this organisation to evaluate the downstream risks of imported nanomedicine.

The chemical industry in Australia only nominally examines the explosive potential of nanotechnology-based products. It has introduced worksafe management for unknown exposure products, but there appears to be little consideration of environmental exposure of nanomedicines and therapeutic goods containing nano-particles. The medical industry largely focuses on patient outcomes of nanomedicine, disregarding adequate consideration of the management of nanomedicine-generated waste beyond standard practice. There is also a lack of suitable reporting schemes for nanomedicine producing companies in this country. Some companies produce reports on their production, though such reporting is often vague and does not assist stakeholders to adequately examine the claims of a nano-product.[20]

The need to involve nanomedicine companies in a novel regulation framework

There is currently no nano-specific legislation in Australia. Existing provisions designed to manage risks associated with conventional

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medicines are also applied to nanomedicine. Conventional medicine regulation generally fails to address the fact that nanoparticles within medicines do not emulate 'conventional scale materials in their behavior and effects'.[21] However, as the use of nanomaterials is relatively new in this country, most of these materials fall outside the prescribed definition of a 'regulated' substance. Consequently, nanomedicine producing companies in this country do not have any particular regulatory obligations after sale management and disposal of these products. Stokes notes that this is the result of two key regulatory shortfalls. First, inappropriate threshold, in which mandatory specification standards are suitable for bulk-scale materials, but not nanoparticles;[22] and secondly, inappropriate read-across, 'in which information on bulk-scale materials is incorrectly extrapolated and applied to nanomaterials'.[23] As such, the producer and supplier 'inappropriately choose not to assign a classification to nano-scale substances, or assign a classification which fails to convey their potential hazardousness'.[24]

Under these circumstances, regulation of potential risks of nanomedicines is not straightforward, and examination of alternative regulatory approaches is necessary. This paper describes how the incorporation of a meta-regulation mode within a nanotechnology industry regulation framework may assist regulators to hold nanomedicine producing companies accountable.

~~17 For details, visit http://www.industry.gov.au/industry/IndustrySectors/nanotechnology/SafetyStandardsAnd Regulations/Pages/Standards.aspx [LINK DOES NOT WORK]~~

~~18 For details, visit http://emergingtech.foe.org.au/wp-content/uploads/2014/10/Nanotechnology-Regulation-Fact-heet.pdf. [LINK DOES NOT WORK]~~

19 This is the standard statement printed on the packages of cytotoxic drugs in the US. For details, see Cell Therapeutics, *Trisenox Package Insert* (Cell Therapeutics, 2003); Martha Polovich, 'Safe Handling of Hazardous Drugs' (2004) 9(3) *Online Journal of Issues in Nursing* 6.

20 For an overview, see 'Information from industry on applied nanomaterials and their safety: Background paper on experiences with reporting mechanisms' (Milieu Ltd and RPA, 2009); Agnes Omen et al, 'Nanomaterials in Consumer Products: Detection, characterisation and interpretation' (National Institute for Public Health and the Environment, Report 320029001/2011, 2011).

21 Elen Stokes, 'Regulating nanotechnologies: Sizing up the option' (2009) 29(2) *Legal Studies* 281–304

22 Ibid 285.

23 Ibid 286.

24 Ibid 288; see also *Review of the adequacy of current regulatory regimes to secure effective regulation of nanoparticles created by nanotechnology* (Health and Safety Executives, 2006).

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Hutter defines the meta-regulation approach in a regulatory framework as 'the state's oversight of self-regulatory arrangements'.[25] To Parker, this approach is a tool for 'regulation of the regulators, whether they be public agencies, private corporate self-regulators or third-party gatekeepers'.[26] Akin to these definitions, Rahim positions this approach in the intersection of state promulgated regulation strategies and self-regulation strategies.[27] Within meta-regulation, both the regulator and regulatees can regulate each other in many forms with horizontal and vertical influence.[28] Hence the formation and impact of meta-regulation differs from traditional command-and-control and self-regulation modes in a regulatory framework. Although the purpose of meta-regulation varies with the objectives of regulators in different circumstances, a predominant objective in creating this mode is to ensure that companies adhere to market rationales and established social norms. As meta-regulation encourages efficiency and flexibility in internal corporate management, it is widely used to improve compliance with environmental standards,[29] to implement occupational health and safety guidelines,[30] to involve stakeholders in regulation, and to increase fair competition in business and society.[31]

One prevailing assumption in embedding this mode in nanomedicine regulation is that most companies want to act rationally and therefore are expected to increase their roles in reducing the risks and uncertainties attached to their products when they are assisted with suitable expertise, incentives, and balance through persuasive pressure and deterrence. However, these

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[25] Bridget Hutter, 'Risk, Regulation and Management' in Peter Taylor-Gooby and Jens Zinn (eds), *Risk in Social Science* (Oxford University Press, 2006) 215.

[26] Christine Parker, *The Open Corporation: Effective self-regulation and democracy* (Cambridge University Press, 2002) 15.

[27] Mia Mahmudur Rahim, *Legal Regulation of Corporate Social Responsibility: A meta-regulation approach of law for raising CSR in a weak economy* (Springer, 2013).

[28] Christine Parker, 'Restorative Justice in Business Regulation? The Australian Competition and Consumer Commission's use of enforceable undertakings' (2004) 67(2) *Modern Law Review* 209, 6.

[29] Hutter, above n 25. Keith Hawkins, *Environment and Enforcement: Regulation and the social definition of pollution* (Clarendon Press, 1984).

[30] Neil Gunningham and Richard Johnstone, *Regulating Workplace Safety: Systems and sanctions* (Oxford University Press, 1999); Sidney Shapiro and Randy Rabinowitz, 'Voluntary Regulatory Compliance in Theory and Practice: The case of OSHA' (2000) 67(2) *Administrative Law Review* 97; Andrew Hopkins, *Making Safety Work: Getting management commitment to occupational health and safety* (Allen & Unwin, 1995).

[31] Christine Parker, 'Public Rights in Private Government: Corporate compliance with sexual harassment legislation' (1999) 6(5) *Australian Journal of Human Rights* 6.

companies are 'motivationally complex' and directing 'corporate repute, dignity, self-image and the desire to be responsible citizens'[32] is difficult, as these are integral to a company's perception. This particular issue connotes that, due to the inherent mixture of responsive and reflexive elements, a meta-regulation mode in nanomedicine regulation may ensure that companies respond to the ethos of a public policy goal and interact with other subsystems to efficiently reflect on the goal by incorporating the ethos into their self-regulation strategies. For these companies, especially given the current lack of scientific capacity to thoroughly assess nanotechnology, such interactions could increase their expertise and thereby reinforce the sustainable development of this industry. Public agencies play vital roles in such interactions; through laws, 'they can set the limits of technological innovation … coordinate the assessment and management of risk … design procedures for public participation, and … set the terms of compensatory responsibility'.[33] Long-term, such action will reduce the negative impacts of nanomedicines and increase the level of effective management of the inherent uncertainties of nanomedicines.

There are myriad ways to create a meta-regulation mode in the regulation of this industry. For instance, laws that ensure the rights of individual professionals and detail their responsibilities can insist that these professionals have an organised institution that systematically interacts with nanomedicine companies. This can benefit a variety of stakeholders, including certified chemists, qualified social workers, human rights activists, researchers, and environmentalists. This registry of interested professionals could be administered by another institution, such as the TGA in Australia. As an example of such a meta-regulation approach, in the US, thea legislation on the ~~law created the~~ Securities and Exchange Commission allows this public agency to oversee the Financial Industry Regulatory Authority. This regulatory authority has its own enforceable industry rules (the US Occupational Health and Safety Administration Standards) and a program to help companies that deal with highly hazardous substances (the 'hazardous analysis and critical control point' program). The incentives for a professional person or institution to be included in such a registry are numerous, including economic incentives, enhanced reputation, social

[32] Brent Fisse and John Braithwaite, *The Impact of Publicity on Corporate Offenders* (SUNY Press, 1984) 190.

[33] Roger Brownsword and Han Somsen, 'Law, Innovation and Technology: Before we fast forward' (2009) 1(1) *Law, Innovation and Technology* 1–73, 71.

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exposure, etc. Nanomedicine companies are likely to be interested in interacting with the members of this registry either to avail themselves of the incentives detailed in relevant laws or to be more resourceful than their competitors in the market. These interactions could occur in many forms, where the core of the formation of each of the meta-regulation strategy is holding the following modalities in a regulatory framework: rule-making power of the government, social norms, market rationale, and context architecture.[34]

Australia can incorporate provisions into laws regarding nanomedicine so that professionals, professional bodies, and industries can be empowered to systematically support nanomedicine companies' social responsibility performance. With such empowerment, public agencies can relate, for instance, corporate tax calculation and registration processing time to negative impacts incurred by nanomedicine. Further, legal provisions may facilitate self-audits and self-inspections for nanomedicine companies, thus allowing these companies to raise their budget for social performance (to a certain extent). Moreover, this may encourage judges in the courts of law to consider corporate social responsibility performance when deciding any penalties against such companies. Denoting the label 'nano' (and instructions for disposing of unsecured nanomedicines) as a legal condition for market entry is another strategy to ensure the safety of nanomedicines and the company compliance.[35] These strategies are not entirely based on coercion and prescriptions provided by legislation; rather, they are based on economic factors that can encourage companies to exceed the legal requirements. These strategies in regulation acknowledge the right of the society to engage (through a defined way and under legal guidance) in the development of a new biotechnology-based industry.[36] Such strategies can be designed in such a way that they are economically able to offset the cost of exceeding compliance standards.[37] Raising corporate accountability practice is another viable strategy to create a meta-regulation mode in a nanomedicine regulation framework.

[34] Ibid.

[35] Stokes, above n 8.

[36] Therese Murphy, 'Reception, Revolution and Resonance: An introduction to new technology and human rights' in Therese Murphy (ed), *New technology and human rights* (Oxford University Press, 2009).

[37] Neil Gunningham, *Beyond Compliance: Next generation environmental regulation* (Paper presented at the Current Issues in Regulation Conference, Melbourne, 2–3 September 2002); John Conley and Cynthia Williams, 'Engage, Embed, and Embellish: Theory versus practice in the corporate social responsibility movement' (2005) 31 *Journal of Corporate Law* 1–36.

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This strategy can generate a considerable gain or loss to companies if they are not eager to respond to a public policy goal and do not effectively incorporate such policy goal. Most importantly, with such strategies, regulators can insist that the stakeholders of new technologies are capable of being deployed as regulatory instruments.[38]

Conclusion

Australia is eager to encourage the growth of nanomedicine production and the nanomedicine industry as a whole. Yet in order to achieve this goal, Australia requires a regulatory framework that enables companies to produce high-quality nanomedicines while also holding these companies accountable for mitigating the potential negative impacts of their products. This article proposes that such a regulatory framework should draw on a meta-regulation approach. A meta-regulation mode in a regulatory framework encourages different actors and factors to work collectively to achieve a public policy goal. Public agencies are integral components in this regulation mode; they indirectly use rule-making power to coordinate stakeholders and create peer-competition, but do not impose prescriptions that may hinder efficiencies in companies' self-regulation strategies. In this mode, both public and private agencies complement each other. The inclusion of such a mode into the regulatory framework for nanotechnology would hold Australian nanomedicine companies responsible for minimising related health risks and improving stakeholders' capacity to deal with the inherent uncertainty surrounding the emergent science of nanotechnology.

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[38] Brownsword and Somsen~~Roger~~, above n 3~~4~~1, 71. ~~[DO YOU MEAN n 33? IF SO, SHOULD "Brownsword and Somsen" not "Roger".]~~

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