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EDITOR'S NOTE

Adrian Thorogood *

The *McGill Journal of Law and Health* (MJLH) strives to attract a diverse cadre of articles befitting this bustling intersection of disciplines. Volume 7 Issue 2 of the MJLH builds on the success of past issues to capture this important diversity, with articles addressing a rich spectrum of debates in public policy, comparative law, and health science.

In the opening article of this issue, Amar Khoday and Anjana Srinivasan explore the public policy landscape relating to breastfeeding in private spaces open to the public. While this activity is implicitly protected, women who choose to breastfeed in these spaces continue to experience discouragement and stigma. The authors call on legislators to affirm that this activity is both natural and acceptable. Added protection could be achieved by explicitly enshrining breastfeeding as a right, or by imposing fines on businesses that discourage it. Notre deuxième article, par la juriste Marie-Ève Arbour, s'attaque à la complémentarité de la prévention et de l'indemnisation du préjudice causé par le fait des produits. Trois états sont considérés dans cette analyse comparative très ambitieuse. Elle nous explique comment l'architecture fédérale d'un état peut influencer non seulement la forme de protection corporelle qu'il offre, mais aussi sa conception même du corps humain.

In our third article, Jacquelyn Shaw explores the tenuous biological premises underpinning our legal definition of death. Beyond biology, various pragmatic considerations inform our legal definition of death. But should the legal definition be more sensitive to biological truths? Few would disagree that biological death occurs on a continuum. Legal death, however, is defined at a single (and possibly shifting) point along this continuum. Professor Shaw builds on her contribution in Volume 6 Issue 2 of the MJLH, which considered whether Canada's decision to recognize brain death earlier in the context of organ donation offended the *Charter* right to life, liberty, and security of the person.

It is with these words that my days as student editor come to an end. My time on the MJLH has been an integral and unforgettable part of my legal formation. I would like to thank the authors, peer reviewers, and editors of Volume 7 for making this publication such a success. Thank you to McGill University, the Law Students' Association at McGill, and Canada's Research-Based Pharmaceutical Companies for their gracious financial support. I would also like to recognize the enormous contributions of the Volume 7 executive over the past year. Daniel Mastine and Kaitlin Soye were inspired promoters of the journal's presence at the faculty and online. Marie-Laure Tapp n'a pas seulement été une rédactrice passionnée, mais

* Editor-in-Chief, McGill Journal of Law and Health, Vol. 7.

aussi une vraie ambassadrice pour le côté francophone de la revue. My thanks as well goes to Jennifer Anderson and François Nolet-Lévesque, the incoming English and French Executive Editors, for keeping the momentum of the journal moving during the change of the editorial guard and bringing the brightest polish to these articles. Finally, my congratulations to the incoming Editor-in-Chief Francesca Taddeo. I have no doubt the journal will thrive in her capable hands.

To our readers, we encourage you to visit our blog and access MJLH articles free of charge on the web (http://mjlh.mcgill.ca/). We also invite you to subscribe to our semi-annual print edition, to send us your tweets (@McGill_JLH), and to join the healthy discussion on our Facebook page. And remember,

Salus populi suprema lex esto!

McGill Journal of Law and Health ~ Revue de droit et santé de McGill

RECLAIMING THE PUBLIC SPACE: BREASTFEEDING RIGHTS, PROTECTION, AND SOCIAL ATTITUDES

*Amar Khoday & Anjana Srinivasan**

Breastfeeding is a normal physiological process. Despite the literature that indicates the importance of breastfeeding in terms of maternal and infant health, there is still opposition to women breastfeeding in public spaces. This manifests itself in private commercial establishments preventing mothers from breastfeeding or ordering them to stop. Mothers are thereby discouraged from feeding in public or in private spaces open to the public (quasi-public spaces). In this article, the authors advocate for stronger legal protections for mothers who seek to breastfeed in public or quasi-public spaces. While breastfeeding in such spaces is implicitly protected under human rights law, this in itself does not send a strong enough message. Accordingly governments should amend human rights legislation to explicitly recognize the right to breastfeed in public and quasi-public spaces. Furthermore, the authors contend that governments should make it an offence to prohibit or prevent women from breastfeeding in public or quasi-public spaces. Punishment for breach of the offence could result in a substantial fine. Importantly, it would place the onus of the litigation on the Crown and relieve mothers who are already burdened from having to litigate the matter. It would

L'allaitement est un acte naturel et biologique. Malgré la présence d'études rappelant l'importance de l'allaitement pour la santé des mères et des enfants, l'allaitement dans les espaces publics demeure parfois stigmatisé. Cette opposition se manifeste avant tout dans certains établissements commerciaux qui empêchent ou exigent des mères qu'elles cessent d'allaiter. Ainsi, des mères découragées se voient interdire de nourrir leurs enfants en public ou dans des espaces privés ouverts au public (espaces quasi-publics). À travers cet article, les auteurs proposent donc de renforcer les protections juridiques offertes aux femmes qui souhaitent allaiter dans des lieux publics ou quasi-publics. Si l'allaitement dans de tels espaces est implicitement protégé par les droits de la personne, cette protection demeure parfois insuffisante. Ainsi, l'article propose une modification des lois relatives aux droits de la personne afin de protéger explicitement le droit d'allaiter dans les lieux publics et quasi-publics. De plus, les auteurs affirment que les gouvernements devrait rendre illégal le fait d'interdire aux femmes d'allaiter dans un espace public ou quasi-public. La violation de ce droit pourrait entrainer une amende substantielle. Ce modèle législatif placerait donc le fardeau de la preuve sur

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also demonstrate the State's interest in assisting those who may be more vulnerable.

la Couronne et déchargerait ainsi les mères déjà accablées par les mesures qu'elles doivent entreprendre pour faire valoir leur droit. Ce nouveau modèle législatif démontrerait également l'intérêt de l'État à aider les citoyens plus vulnérables.

Introduction

A mother who breastfeeds in public can elicit various reactions. Despite the acknowledged public health and other benefits accruing from breastfeeding (as outlined below), mothers who choose to nurse in public are still confronted with recalcitrant attitudes about the appropriateness of doing so. They are given the message expressly or implicitly that doing so constitutes inappropriate conduct because it violates some perceived fundamental socio-cultural norm. This may be manifested through discouraging looks or statements.[1] However, the negative reactions are not limited to this. Increasingly, the public is apprised of incidents where mothers are instructed by a public official or a store employee or manager that they cannot breastfeed on a certain premises or, in the alternative, they are directed to cover themselves or to feed their child in a specified area on the premises – typically a dressing room or the unsanitary confines of a washroom.[2]

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[1] See e.g. Fiachra Gibbons, "In France, breast is definitely not best", *The Guardian* (1 April 2011), online: The Guardian <www.guardian.co.uk/commentisfree/2011/apr/01/france-breast-breastfed-baby-death>.

[2] The incidents that have been publicized serve to raise the question of how many others have taken place that have not received media attention because the mothers in questions have chosen to remain silent about their experience. For incidents involving public officials, see *Québec (Commission des droits de la personne et des droits de la jeunesse) et Giguère c Montréal (Ville de)*, 2003 QCTDP 88, 47 CHRR D/67 [*Giguère* cited to CHRR]; "Woman: I was ejected from courthouse lobby for breastfeeding", *CBS Chicago* (31 May 2012), online: CBS Chicago <http://chicago.cbslocal.com/2012/05/30/skokie-woman-suing-cook-county-over-right-to-breastfeed/>. For incidents involving store employees and managers, see e.g. *Québec (Commission des droits de la personne) c Lee*, [2005] RJQ 2807, JE 2005-1845, 2005 CanLII 35842 (QTDP) [*Lee* cited to RJQ]; "H&M breastfeeding incident sparks human rights protest", *CBC News* (6 August 2008), online: CBC News <www.cbc.ca/news/health/story/2008/08/05/bc-breastfeeding-protest-h-m-vancouver.html>; Ann Hui, "Walmart apologizes for asking BC mom to stop breastfeeding", *The Vancouver Sun* (18 July 2009), online: The Vancouver Sun <www.vancouversun.com/life/Walmart+apologizes+ asking+stop+breastfeeding/1804833/story.html>; "Store apologizes to breastfeeding mother", *CBC News* (10 January 2011), online: CBC News <www. cbc.ca/news/canada/montreal/story/2011/01/10/montreal-breastfeeding-protest.html>; Cheryl Alkon, "Nursing a grudge: breastfeeding in public", *USA Today – Your Life (Healthy Perspective Blog)* (30 December 2011), online: USA Today – Your Life <http://yourlife.usatoday.com/health/healthyperspective/post/ 2011/12/Public-Nursing-Whats-the-Big-Deal-Really/594454/1>; "NB moms defend right to

This leads to questions about what normative protections can shield mothers and their children from those who would hinder or prevent them from breastfeeding in public, and whether such protections are sufficient. While acknowledging that state norms do not hold a monopoly on governing social conduct,[3] they still play a vital role in protecting vulnerable segments of the population from the oppressive dictates of other portions of society. We argue that current protections are not adequately robust and are in need of strengthening. First, we address the noted public health benefits that arise from encouraging breastfeeding. We argue that given the substantial health benefits that come from breastfeeding and its impact on public health, more needs to be done to discourage those who would inhibit its practice. Second, because breastfeeding is intimately bound to issues of gender, we examine some of the feminist literature relating to this practice and the relevance of these perspectives in advancing legal protections against breastfeeding discrimination.

Third, we discuss current legal protections relating to breastfeeding in Canada and raise some ideas for reform. Our suggestions include making breastfeeding discrimination explicitly prohibited under human rights legislation across Canada and employing penal sanctions already available for violations of human rights laws to deter service providers from discriminating against breastfeeding mothers. To date, there has been a rather modest amount of literature addressing the intersection of human rights and breastfeeding. Much of it, however, is focused on international legal norms and

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breastfeed at Moncton Market" CBC (23 June 2012), online: CBC News <www.cbc.ca/news/canada/new-brunswick/story/2012/06/23/nb-breastfeeding-demonstration-401.html> ["NB moms defend right to breastfeed"]; Niamh Scallan, "Breastfeeding mom wants apology from daycare that asked her to leave infant room", The Toronto Star (16 November 2012), online: TheStar.com <www.thestar.com/news/gta/2012/11/16/breastfeeding_mom_wants_apology_from_daycare_that_asked_her_to_leave_infant_room.html>; "Mother angry after being asked to leave Walmart while nursing", *Global News Calgary* (6 December 2012), online: Global News <http://globalnews.ca/news/316697/mother-angry-after-being-asked-to-leave-walmart-while-nursing/>; "'Nurse in' interrupted at NS shopping mall", *CBC News* (31 December 2012), online: CBC News <www.cbc.ca/news/canada/nova-scotia/story/2012/12/31/ns-breastfeeding-protest-dartmouth.html>.

[3] See Daniel Jutras, "The Legal Dimensions of Everyday Life" (2001) 16 CJLS 45; Martha-Marie Kleinhans & Roderick A Macdonald, "What is a Critical Legal Pluralism?" (1997) 12:2 CJLS 25 at 31.

does not discuss legal protections at the domestic level in Canada.[4] This is not to suggest that these international norms are unimportant, but it is useful to remember that as a dualist state, Canada must pass domestic legislation to implement its international legal obligations.[5] As such, it is crucial to scrutinize how Canada and its constituent provinces and territories have (or have not) addressed these issues.

We note that advancing a legal approach to address breastfeeding discrimination should not be seen as a devaluation of the merits of public education related to breastfeeding. Indeed, there is a rather significant role to be played through public education in changing negative attitudes to breastfeeding in public. The consequences of such a campaign may result in a reduction of breastfeeding discrimination and greater acceptance of breastfeeding in public. However, education alone does not provide a complete remedy. State-based law still plays an important role in prohibiting, deterring, and punishing discriminatory conduct.[6] The reforms we propose below are intended to do just that.

We wish to emphasize that by advocating a legal approach to protect mothers who choose to breastfeed in public, we in no way intend to produce or perpetuate feelings of guilt that may be experienced by mothers who do

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[4] See e.g. Naomi Bromberg Bar-Yam, "Breastfeeding and Human Rights: Is There a Right to Breastfeed? Is There a Right to Be Breastfed?" (2003) 19:4 J Hum Lact 357; George Kent, "Child Feeding and Human Rights" (2006) 1 Int Breastfeed J 27 [Kent, "Child Feeding and Human Rights"]; George Kent, "Breastfeeding: A Human Rights Issue?" (2001) 44:2 Development 93; Michael C Latham, "A Mother's Right to Breastfeed: Removing the Obstacles" (1999) 20 Food Nutr Bull 293; Michael C Latham, "Breastfeeding: a Human Rights Issue?" (1997) 5:4 Int'l J Child Rts 397 [Latham, "Breastfeeding: a Human Rights Issue?"].

[5] *Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817, 174 DLR (4th) 193, 14 Admin LR (3d) 173 ("[i]nternational treaties and conventions are not part of Canadian law unless they have been implemented by statute" at para 69).

[6] One American study notes that both breastfeeding initiation rates and rates of breastfeeding at six months were higher in states with legislation that protects and supports breastfeeding in comparison with those that do not. However, the authors cautiously observe that while legislation may raise the profile of breastfeeding as a public health issue, it may also be that legislation in place is merely a proxy for a culture more favourable to breastfeeding already. See Michael D Kogan et al, "Multivariate Analysis of State Variation in Breastfeeding Rates in the United States" (2008) 98:10 Am J Public Health 1872 at 1877.

not breastfeed, either by choice or due to other circumstances.[7] As Tasnim Nathoo and Aleck Ostry observe, because breastfeeding has become associated with being a "good mother", some feel a sense of failure, sorrow, and judgment if they do not breastfeed.[8] Miriam Labbok has written about how the guilt that some non-breastfeeding mothers experience may be due to lack of support by health professionals and the community.[9] Based on the clinical experience of one of the authors (Srinivasan) and that of other health professionals, women who make an informed decision not to breastfeed and are fully supported in their decision rarely feel guilty. Our objective here is not to impose any judgment on mothers, but to highlight that those who can and choose to breastfeed in public ought to be supported and able to do so without discrimination.

I. Breastfeeding, Public Health, and Other Benefits

For years, health professionals and their organizations have stressed the importance of breastfeeding for the child, mother, and society. Among health care professionals, breastfeeding is considered a normal physiological process that occurs after giving birth to an infant. The World Health Organization (WHO) and UNICEF recommend that infants be exclusively breastfed for the first six months of life, with the introduction of complementary foods and breastfeeding continuation for two years and beyond.[10] This recommendation has been endorsed by Health Canada, the Canadian Paediatric Society, the College of Family Physicians of Canada, and the Canadian Nurses Association, among others.[11] The recommended duration of breastfeeding in these

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[7] For a discussion of the experiences of women who did not breastfeed their children, see Kate Williams, Ngaire Donaghue & Tim Kurz, "'Giving Guilt the Flick'? An Investigation of Mothers' Talk About Guilt in Relation to Infant Feeding" (2013) 37:1 Psychol Women Q 97.

[8] Tasnim Nathoo & Aleck Ostry, *The One Best Way?: Breastfeeding History, Politics, and Policy in Canada* (Waterloo, Ont: Wilfred Laurier University Press, 2009) at 211.

[9] Miriam H Labbok, "Exploration of Guilt among Mothers Who Do Not Breastfeed: The Physician's Role" (2008) 24:1 J Hum Lact 80 at 82.

[10] World Health Organization/UNICEF, *Global Strategy for Infant and Young Child Feeding* (Geneva: World Health Organization, 2003) at 7-8. The Global Strategy was endorsed on 18 May 2002 by the Fifty-fifth World Health Assembly, Resolution WHA55.25, and on 17 September 2002 by the UNICEF Executive Board.

[11] College of Family Physicians of Canada, "Infant Feeding Policy Statement 2004", endorsement renewed 2011, online: CFPC <www.cfpc.ca>; Health

guidelines is worth noting, as women are often harassed for breastfeeding older children in public. There is no scientific evidence that breastfeeding a child of two years or above is harmful to his or her health. Indeed, it is quite the opposite.[12] Regardless, this act may still draw stares and unwanted attention, discouraging women from breastfeeding in public.

Current evidence demonstrates that breastfeeding is optimal for infant health and development. A 2010 American study calculated that if 90% of families could breastfeed exclusively for six months, an excess 911 deaths a year in that country could be prevented, of which nearly all would be infants.[13] Infants who are not breastfed have an increased risk of a wide array of infections, sudden infant death syndrome (SIDS), allergies, childhood obesity, diabetes, and certain childhood cancers.[14] Mothers who do not breastfeed may increase their own risk of cardiovascular illness, diabetes, hypertension, breast cancer, and other conditions.[15] Breastfeeding also allows mothers to enjoy a psychological sense of bonding, well-being, and increased self-esteem.[16]

Given these benefits, breastfeeding results in healthier children who will be less likely to be a burden on the public health system. The 2010 study cit-

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Canada, Canadian Paediatric Society, Dietitians of Canada & Breastfeeding Committee for Canada, Joint Statement, "Nutrition for Healthy Term Infants, Birth to Six Months: An Overview" (September 2012), online: HC < www.hc-sc.gc.ca/fn-an/nutrition/infant-nourisson/recom/index-eng.php>; Canadian Paediatric Society, Hospital Paediatrics Section, Nutrition and Gastroenterology Committee (principal authors Catherine M Pound & Sharon L Unger), "The Baby-Friendly Initiative: Protecting, Promoting and Supporting Breastfeeding" (2012) 17:6 Paediatr Child Health 317; Canadian Nurses Association & Canadian Association of Midwives, Joint Position Statement, "Joint Statement on Breastfeeding" (March 2008), online: CAN <www.cna-aiic.ca>.

[12] Kent, "Child Feeding and Human Rights", *supra* note 4 at 6.

[13] Melissa Bartick & Arnold Reinhold, "The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis" (2010) 125:5 Pediatrics 1048 at 1052.

[14] *Ibid*; American Academy of Pediatrics, "Policy Statement: Breastfeeding and the Use of Human Milk" (2012) 129:3 Pediatrics 827 at 828-30.

[15] Eleanor B Schwarz et al, "Duration of Lactation and Risk Factors for Maternal Cardiovascular Disease" (2009) 113: 5 Obstet Gynecol 974.

[16] See e.g. Miriam H Labbok, "Effects of Breastfeeding on the Mother" (2001) 48:1 Pediatr Clin North Am 143 at 144, 154.

ed above calculated not only reduced mortality, but also a savings of $13 billion a year if 90% of families breastfed exclusively for six months.[17] There is thus a substantial economic benefit that accrues from encouraging women to breastfeed.[18]

Despite recommendations and studies, Canadian breastfeeding rates still fall short of goals. According to Statistics Canada, Canadian breastfeeding initiation rates were 87.3% in 2009.[19] However, only 24.4% were breastfeeding exclusively at 6 months.[20] For this reason, various Canadian provincial governments have made breastfeeding support and protection a priority.[21] The adoption of the WHO's Baby-Friendly Hospital Initiative has enabled health care institutions to protect, promote, and support breastfeeding while improving quality of care and decreasing health costs.

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[17] Bartick & Reinhold, *supra* note 13.

[18] *Ibid*. See also Breastfeeding Committee for Canada, "Affordable Health Care Begins with Breastfeeding Support and the Use of Human Milk" (Submission to the Commission on the Future of Healthcare in Canada) (2002), online: BCFC <http://breastfeedingcanada.ca/documents/webdoc47.pdf>; Infant Feeding Action Coalition (INFACT) Canada, News Release, "Health Protection and Health Care in Canada: Protecting the Health of Canadians and the Health Care System in Canada" (13 February 2002), online: INFACT <www.infactcanada.ca/news_releases_Romanow.htm>.

[19] Health Canada, "Breastfeeding Initiation in Canada: Key Statistics and Graphics (2009-2010)", online: HC <www.hc-sc.gc.ca/fn-an/surveill/nutrition/commun/prenatal/initiation-eng.php>.

[20] Statistics Canada, "Breastfeeding 2009", online: SC <www.statcan.gc.ca/pub/82-625-x/2010002/article/11269-eng.htm>.

[21] See e.g. Nova Scotia, Department of Health & Department of Health Promotion and Protection, "Policy Statement: Breastfeeding in Nova Scotia: Responsibilities of the Nova Scotia Department of Health and the Nova Scotia Department of Health Promotion and Protection" (September 2005), online: Government of Nova Scotia <www.gov.ns.ca/hpp/publications/Provincial_Breastfeeding_Policy.pdf>; Ministère de la Santé et des Services sociaux, "L'allaitement maternel au Québec : lignes directrices" (September 2001), online: MSSS <http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2001/01-815-01.pdf>. For an example of a program review, see British Columbia Ministry of Health, "Review of Breastfeeding Practices and Programs: British Columbia and Pan-Canadian Jurisdictional Scan" (March 2012), online: BC MOH <www.health.gov.bc.ca/library/publications/year/2012/breastfeeding-jurisdictional-scan.pdf>.

The act of breastfeeding is extremely valuable for the health of mothers, children, and society in the aggregate. It is little wonder that mothers are encouraged and empowered to breastfeed by their health care workers, who attempt to provide them with much-needed support and guidance if difficulties arise. Yet in addition to being a health issue, it is also a compelling and intimate matter for women. In the following section we discuss feminist discourse on the subject of breastfeeding in public.

II. Feminist Perspectives on Breastfeeding

Given women's unique relationship with breastfeeding and its potential impact on their lives, feminists and feminist scholars have articulated important perspectives on the subject. In this section, we examine some of the key scholarship and highlight tensions that exist amongst feminists concerning breastfeeding. We discuss how these perspectives should inform legislation with respect to the prohibition of breastfeeding discrimination.

One key tension is whether the promotion of breastfeeding impacts on women's freedoms, particularly with respect to employment, mobility, and engagement in everyday society.[22] Feminism was born out of a social movement and long struggle to emancipate women from the normative strictures of patriarchal societies and the social and familial expectations imposed on them.[23] For many feminists, this oppression included social expectations regarding child rearing. Because breastfeeding required time with, and access to the nursing child, it was viewed as hindering women's autonomy, a central mission of "liberal feminism", along with equality of the sexes.[24] Furthermore, WHO recommendations that exclusive breastfeeding should take place for six months, and continue with the addition of complementary foods for

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[22] See Deborah McCarter-Spaulding, "Is Breastfeeding Fair? Tensions in Feminist Perspectives on Breastfeeding and the Family" (2008) 24 J Hum Lact 206 at 207. See also Judith Galtry, "Extending the 'Bright Line': Feminism, Breastfeeding, and the Workplace in the United States" (2000) 14 Gend Soc 295; P Van Esterik, "Breastfeeding and Feminism" (1994) 47 Int J Gynaecol Obstet S41 at S43 (supplement) ("[for] radical feminists who locate women's oppression in their bodies and their reproductive capacities, lactation could hardly be explored as empowerment" at S44); Paige Hall Smith, "'Is It Just So My Right?' Women Repossessing Breastfeeding" (2008) 3 Int Breastfeed J 12 at 13-14.

[23] McCarter-Spaulding, *supra* note 22 at 207.

[24] *Ibid*.

two years and beyond, would seem to require extensive time away from paid work.[25]

Scholars like Penelope Van Esterik have argued that breastfeeding should not be seen as an oppressive burden. Indeed, Van Esterik, as a self-identified feminist, asserts that breastfeeding empowers women and contributes to gender equality in various ways.[26] First, it "confirms a woman's power to control her own body" and her choice as to how it is to be used, that is, to provide sustenance to her child.[27] Second (and connected to the first point), breastfeeding challenges the dominant view of breasts as primarily sexual objects, and by extension the sexualized view of women as well.[28] Third, it forces a redefinition of women's work that "integrates women's productive and reproductive activities."[29] Breastfeeding is a reproductive right because it is a natural biological process that ensues after giving birth, and a maternal right because it allows women to feed their child in an optimal way.

Notwithstanding the empowering aspects of breastfeeding, one of the greatest impediments to its sustained practice is societal hostility to engaging in it in public.[30] One attitude that prompts this phenomenon derives in large part from the social construction of breasts as predominantly sexualized objects.[31] One scholar posits that many people "think breasts are primarily for enhancing sexual activity, which results in widespread discomfort when they are reminded that breasts go into babies' mouths."[32] Consequently, as Glenda Wall observes, numerous studies indicate that new mothers report feeling

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[25] *Ibid*.

[26] Van Esterik, *supra* note 22 at S41-S42.

[27] *Ibid* at S41. See also Smith, *supra* note 22 at 15.

[28] Van Esterik, *supra* note 22 at S45. See also Cindy A Stearns, "Breastfeeding and the Good Maternal Body" (1999) 13 Gend Soc 308 ("the very act of breastfeeding, particularly prolonged breastfeeding, is itself a form of resistance to the sexualized image of the breast and the good maternal body" at 322).

[29] Van Esterik, *supra* note 22 at S42.

[30] Michele Acker, "Breast is Best… But Not Everywhere: Ambivalent Sexism and Attitudes toward Private and Public Breastfeeding" (2009) 61:7/8 Sex Roles 476 at 477.

[31] Glenda Wall, "Moral Constructions of Motherhood in Breastfeeding Discourse" (2001) 15:4 Gend Soc 592 at 598; Stearns, *supra* note 28 at 309-10.

[32] Jacqueline H Wolf, "Got Milk? Not in Public!" (2008) 3 Int Breastfeed J 11.

exposed and vulnerable when breastfeeding in public.[33] As reported in the media, one mother recently commented, "[t]he few women that do breastfeed tend not to do it in public, because it is so stigmatized and it is so over-sexualized, and so we tend to hide."[34] Thus, such attitudes can contribute to mothers' solitary confinement within the home.[35] This sexualisation is accentuated through the sex and beauty industries,[36] as well as in popular media, including film, television, and books.[37] Consequently, women who breastfeed in public may be castigated as bad mothers and derided for their alleged selfishness and shamelessness.[38]

Mothers who breastfeed are characterized as selfish for wanting to go out rather than staying at home and tending to their child's needs.[39] Connected to this, others argue that mothers should schedule their breastfeeding around their outings, so as to avoid having to feed in public. However, the importance of breastfeeding "on demand" is vital, especially during the first few months of life. The breastfed infant may get hungry at irregular times, and it is important to be able to feed "on demand" for optimal growth and development. In fact, breastfeeding often, especially initially, helps the mother maintain an adequate milk supply.[40] Breast milk is also very easily and rapidly digested, often necessitating more frequent feeds compared to formula-fed babies.[41] Critics may say that mothers should bring a bottle of breast milk or formula around with them in case the infant gets hungry. However, giving a bottle may not always be an option, particularly in the case of exclusively breastfed infants, who may not be able to suck from a bottle or may not be able to digest the artificial milk as readily. Furthermore, using a bottle frequently may jeopardize a mother's breast milk supply because of a decrease in breast stimulation, especially if her supply is already

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[33] Wall, *supra* note 31 at 598.

[34] "NB moms defend right to breastfeed", *supra* note 2.

[35] Wall, *supra* note 31 at 598.

[36] Van Esterik, *supra* note 22 at S45.

[37] Latham, "Breastfeeding: A Human Rights Issue?", *supra* note 4 at 403.

[38] Joanna R Davis, "Bad Breast-Feeders/Good Mothers: Constructing the Maternal Body in Public" (2004) 48 Berkeley J Sociol 50 at 56-61.

[39] *Ibid*.

[40] See Ruth A Lawrence & Robert M Lawrence, *Breastfeeding: A Guide for the Medical Profession*, 7th ed (Maryland Heights, Mo: Elsevier Mosby, 2011) at 82.

[41] *Ibid* at 264.

in a vulnerable state due to other reasons.[42] Breastfeeding in a private place, as some may feel is more appropriate, is also not always possible, especially if such a private place is not readily available when the child is hungry. In particular, breastfeeding in the bathroom is inappropriate due to the potentially unsanitary conditions of such an environment.

Mothers who breastfeed in public are also criticized as shameless for doing so without consideration for others, who may view it as obscene or as a threat to common decency.[43] Customers in a store or other commercial enterprise may complain to employees or management, prompting an intervention against the mother. The notion that breastfeeding is not obscene has unfortunately not been sufficiently counteracted by the express exemption from obscenity or indecent exposure laws that have been granted to breastfeeding mothers by courts in Canada and various state legislatures in the United States.[44]

Consequently, we suggest that it is time that the political and legal systems recognize that merely designating public breastfeeding as non-obscene behaviour is insufficient to deter breastfeeding discrimination. As we articulate below, legislatures should set out in clear and unmistakable terms that discrimination against mothers who breastfeed in public or quasi-public spaces is unlawful and a human rights violation. Those found liable should be subject either to damages awarded to the complainant, or to a potential fine if found guilty of committing the act as a penal offence.

III. Breastfeeding Rights and Canadian Legal Protections for Breastfeeding in Public

Does a woman have the right to breastfeed in public or quasi-public spaces? For the purposes of this article, we define a public space as one

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[42] *Ibid* at 82-83, 105.

[43] Davis, *supra* note 38. As Heather Maclean asserts, "[d]espite the widespread flaunting of women's breasts that is so apparent in the media, women who breast feed are encouraged to maintain a virgin-like modesty." Heather Maclean, *Women's Experience of Breast Feeding* (Toronto: University of Toronto Press, 1990) at 94.

[44] See *R v Jacob* (1996), 31 OR (3d) 350, 142 DLR (4th) 411; *Maple Ridge (District of) v Meyer*, 2000 BCSC 902, 77 BCLR (3d) 171; United States Breastfeeding Committee, *State Breastfeeding Legislation* (Raleigh, NC: United States Breastfeeding Committee, 2003), online: USBC <www.us breastfeeding.org>.

owned and maintained by a government entity that is regularly open to the public.[45] Such public spaces include parks, airports, and traditional government buildings like courthouses.[46] Quasi-public spaces, by contrast, are privately owned and operated spaces that are open to the general public.[47] They can include institutions that receive funding from government sources (such as universities)[48] or may be strictly private commercial ventures like shopping centres, shops, restaurants, and other commercial venues.[49] While restrictions on access to government-owned "public" spaces may be subject to *Charter*[50] and "quasi-constitutional" scrutiny (for example, human rights legislation), in addition to other statutory legal regimes such as labour laws,[51] restrictions on access to quasi-public spaces are not subject to the *Charter*. Human rights legislation, given its importance, is considered quasi-

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[45] There are, not surprisingly, a host of government-owned facilities, such as military bases, that are restricted to the general public. Therefore, the fact that a building or space is owned by the government does not render it automatically open to the public.

[46] *Committee for the Commonwealth of Canada v Canada*, [1991] 1 SCR 139, 77 DLR (4th) 385 [*Committee for the Commonwealth of Canada*].

[47] See Eric J Miller, "Role-Based Policing: Restraining Police Conduct 'Outside the Legitimate Investigative Sphere'" (2006) 94:3 Cal L Rev 617 at 672; Katherine Astill, "The right to protest in quasi-public space", *The Guardian* (28 October 2010), online: The Guardian <www.guardian.co.uk>.

[48] See *McKinney v University of Guelph*, [1990] 3 SCR 229, 76 DLR (4th) 545; *Eldridge v British Columbia (AG)*, [1997] 3 SCR 624, 151 DLR (4th) 577.

[49] It is worth noting that statutes do not always differentiate between public and quasi-public spaces. For instance, the *Smoke-Free Ontario Act*, SO 1994, c 10, s 1(1)(a) stipulates that an "enclosed public space" includes "any place, building or structure or vehicle or conveyance or a part of any of them that is covered by a roof, and to which the public is ordinarily invited or permitted access, either expressly or by implication, whether or not a fee is charged for entry." By this description, the legislation incorporates both government-owned and privately owned buildings open to the public.

[50] *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11. For examples of *Charter* restrictions in accessing government-owned property, see *Committee for the Commonwealth of Canada*, *supra* note 46; *R v Behrens*, 2001 CarswellOnt 5785 (WL Can) at paras 102-104, [2001] OJ no 245 (QL) (Ont CT J).

[51] See *Cadillac Fairview Corp v RWDSU* (1989), 71 OR (2d) 206, 64 DLR (4th) 267.

constitutional in nature,[52] and is available to govern the conduct of private actors, including store or shopping centre owners or employees.

Although there is no explicit human right to breastfeed in current Canadian legislation, the Québec Human Rights Tribunal has held in at least two separate cases[53] that forbidding a woman from breastfeeding in public or quasi-public spaces violated the complainants' rights under the Québec *Charter of Human Rights and Freedoms*.[54] The Tribunal found that the complainants' rights were infringed on the basis of their sex in connection with the provision of services. In decisions rendered by the Canadian Human Rights Tribunal and British Columbia Human Rights Council, breastfeeding discrimination was similarly seen as an implied form of sex discrimination (albeit set within the employment milieu).[55] Thus, while there is no express freestanding human right to breastfeed in public established in Canada, such implied norms are nevertheless part of the corpus of human rights law in certain jurisdictions in this country. However, it is unclear whether the cases above have established sufficient precedent to ensure that breastfeeding in public will be considered an implied human right in other Canadian jurisdictions as well. Case law aside, the Ontario and Nova Scotia Human Rights Commissions have published policies that indicate that preventing a mother from breastfeeding in public constitutes discrimination[56] within the context of the Ontario *Human Rights Code*[57] and Nova Scotia *Human Rights Act*.[58] It remains to be seen whether the Human Rights Tribunals of these provinces will agree with the Commissions' policy positions.

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[52] See *B v Ontario (Human Rights Commission)*, 2002 SCC 66, [2002] 3 SCR 403 ("this Court has repeatedly reiterated the view that human rights legislation has a unique quasi-constitutional nature" at para 44).

[53] See *Giguère, supra note* 2; *Lee, supra note* 2.

[54] RSQ, c C-12.

[55] *Cole v Bell Canada*, 2007 CHRT 7 at para 50, 60 CHRR D/216 [*Cole*]; *Poirier v British Columbia (Ministry of Municipal Affairs, Recreation & Housing)* (1997), 29 CHRR D/87 at para 8 (BCHRT) [*Poirier*].

[56] See Ontario Human Rights Commission, *Policy on Discrimination Because of Pregnancy and Breastfeeding* (17 December 2008), at 25-27, online: OHRC <www.ohrc.on.ca/sites/default/files/attachments/Policy_on_discrimination_because_of_pregnancy_and_breastfeeding.pdf>.

[57] RSO 1990, c H.19.

[58] RSNS 1989, c 214.

While implied human rights norms are one tool to protect the rights of mothers and children, we argue that federal and provincial governments throughout Canada should also take further steps to deter businesses from prohibiting or otherwise discouraging women from breastfeeding in public.[59] It has been noted that one of the key obstacles to initiating and maintaining breastfeeding is the lack of community support (this includes businesses).[60] As Deborah McCarter-Spaulding asserts, the decision to breastfeed is not merely about individual choice but also about the structural factors that impact upon that choice.[61] If social and economic conditions are what make breastfeeding possible, then its promotion must be supported socially, economically, and politically.[62] On the political front, this includes legislation protecting against breastfeeding discrimination, as advocated by proponents such as George Kent.[63] We identify two measures in particular. First, governments at the federal, provincial, and territorial levels can enact legislative provisions that explicitly prohibit breastfeeding discrimination. Second, these governments can classify violations of such provisions as offences subject to punishment by fines, should the Crown choose to prosecute. We deal with each in turn.

A. From Implied to Explicit Language

Federal, provincial, and territorial governments in Canada can amend their human rights laws to provide a clear and explicit indication to businesses and other service providers that if they prohibit mothers from breastfeeding on their premises, they will be committing a human rights violation. This legislative approach will also provide clarity to mothers regarding their rights. One way to adopt this approach is to create a stand-alone ground of

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[59] In the United States, efforts have been made to explicitly protect women from being prevented from breastfeeding in public. See e.g. City of Seattle, ordinance No 123863, *An Ordinance Relating to Unfair Public Accommodation Practices; amending sections 14.06.020 and 14.06.030 to add the right of a mother to breastfeed her child in places of public accommodation free from discrimination* (12 April 2012). See also Phuong Le, "Seattle council protects public breastfeeding", *The Associated Press* (10 April 2012), online: Bloomberg Businessweek <www.businessweek.com/ap/2012-04/D9U1LSN03.htm>.

[60] See Latham, "Breastfeeding – A Human Rights Issue?", *supra* note 4 at 413-14.

[61] McCarter-Spaulding, *supra* note 22 at 210.

[62] *Ibid*.

[63] Kent, "Child Feeding and Human Rights", *supra* note 4 at 9-10.

discrimination: the right not to be discriminated against with respect to breastfeeding. Australian federal law, for example, specifically designates breastfeeding as a prohibited ground for discrimination.[64] The language of the relevant section is as follows:

> a person (the ***discriminator***) discriminates against a woman (the ***aggrieved woman***) on the ground of the aggrieved woman's breastfeeding if, by reason of: (a) the aggrieved woman's breastfeeding; or (b) a characteristic that appertains generally to women who are breastfeeding; or (c) a characteristic that is generally imputed to women who are breastfeeding; the discriminator treats the aggrieved woman less favourably than, in circumstances that are the same or are not materially different, the discriminator treats or would treat someone who is not breastfeeding.

Such provisions can then be applied to discrimination in various contexts, including denial of services or access to facilities. The state of Hawaii has similar stand-alone anti-discrimination legislation regarding breastfeeding in places of public accommodation. The relevant statutory language states, "[i]t is a discriminatory practice to deny, or attempt to deny, the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of a place of public accommodations to a woman because she is breastfeeding a child."[65] On the basis of these examples, we propose that an anti-discrimination provision with respect to breastfeeding in public and quasi-public spaces more generally could read, "[i]t is a discriminatory practice to deny, or attempt to deny, the full and equal enjoyment of the goods, services, or facilities situated on public property or private property generally open to the public, to a woman because she is breastfeeding a child."

As an alternative to a stand-alone anti-discrimination provision, another option is to expressly designate breastfeeding discrimination as a form of sex discrimination. This is presently done with pregnancy discrimination. For instance, section 10(2) of the Ontario *Human Rights Code* provides within its interpretation section of the statute that "[t]he right to equal treatment without discrimination because of sex includes the right to equal treatment without discrimination because a woman is or may become pregnant."[66] Just as

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[64] *Sex Discrimination Act* 1984 (Cth), s 7AA.

[65] Hawaii Rev Stat §489.21 (2000).

[66] *Supra* note 57, s 10(2).

discrimination in connection with pregnancy is explicitly made a form of sex discrimination, the Ontario *Code* and other human rights legislation across the country could be similarly amended to include breastfeeding within the definition of sex discrimination. We propose that the following or similar language can be employed in connection with breastfeeding rights within legislation: "The right to equal treatment without discrimination because of sex includes the right of a woman to breastfeed her child at any location on public property or privately owned property that is open to the public."[67] Such language is meant to encompass both refusals to allow women to breastfeed on the premises altogether as well as restrictions or conditions placed on breastfeeding women, such as requiring that they use washrooms, dressing rooms, or other designated spaces. Although our focus is primarily on preventing and prohibiting discrimination with respect to "services, goods, and facilities," such language in the context of the Ontario *Human Rights Code* would also be applicable to discrimination arising in relation to accommodation and employment.[68]

Basing the prevention or prohibition of a mother's ability to breastfeed on the grounds of sex discrimination is logical and appropriate. Like pregnancy, breastfeeding is a condition unique and exclusive to women.[69] To borrow from the logic and language of the Supreme Court of Canada, discrimination on the basis of a mother's choice to breastfeed is a form of sex discrimination because of the basic biological fact that only women have the capacity to lactate and breastfeed.[70] This analogy was upheld by the Canadian Human Rights Tribunal and the British Columbia Human Rights Council in workplace-

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[67] Some authors have argued that discrimination related to pregnancy also incorporates breastfeeding. Put another way, the period following birth and activities affiliated with motherhood, such as breastfeeding, are included as part of pregnancy. However, this approach to the issue of breastfeeding discrimination is counter-intuitive. After all, pregnancy is generally understood as the period encompassing fertilization to birth. Because breastfeeding can only take place after the end of pregnancy (and continues many months after the end), it makes better sense to protect breastfeeding on its own terms.

[68] *Supra* note 57, s 1.

[69] See *Brooks v Canada Safeway Ltd*, [1989] 1 SCR 1219, 59 DLR (4th) 321.

[70] *Ibid*.

related cases[71], and by the Québec Human Rights Tribunal in the service-related cases mentioned above.[72]

Whether a jurisdiction chooses to adopt a stand-alone anti-discrimination provision with respect to breastfeeding as exemplified under Australian or Hawaiian law, or an interpretive provision as in the Ontario *Human Rights Code*, it is important that breastfeeding rights be protected in an obvious and explicit way. Defendants in a potential action, typically service providers in the case of service-related breastfeeding discrimination, will thereby be made aware that denying a breastfeeding mother equal treatment will likely attract liability. Furthermore, given the broad language of the statutory provisions discussed above, one might argue that persons who do not provide service directly (that is, who are not owners or employees) may also incur liability if through their actions, they cause a breastfeeding mother to be denied equal treatment in connection with access to goods, services, or facilities. It would, however, be wise for legislators to establish parameters for the conduct that may lead to personal liability in these contexts. For example, the expression by a customer of mere disapproval of a mother breastfeeding in a space, however unpleasant, should not by itself constitute denial of equal access to goods, services, or facilities resulting in liability. Yet, if such disapproval reaches beyond simple verbal expression and veers toward harassing behaviour or is accompanied by physical or threatening gestures that effectively deny a mother and child the ability to breastfeed in safety, it may be appropriate to extend liability to the aggressor. Liability should also be considered if service-providers witness harassing conduct on their premises and do nothing to halt it.

Inserting more robust and explicit language into federal, provincial, and territorial human rights legislation would also further Canada's international human rights commitments respecting the elimination of sex discrimination. In article 2 of the *Convention on the Elimination of All Forms of Discrimination against Women* (CEDAW), States Parties have vowed to take "all appropriate measures to eliminate discrimination against women by any person, organization *or enterprise*; [and] all appropriate measures, including legisla-

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[71] *Cole*, *supra* note 55 at para 50; *Poirier*, *supra* note 55 at para 8.

[72] *Lee*, *supra* note 2 at paras 44-46; *Giguère*, *supra* note 2 at paras 63-64.

tion, to modify or abolish existing laws, regulations, *customs and practices* which constitute discrimination against women."[73]

If breastfeeding discrimination is considered a form of sex discrimination flowing from Canada's commitments to CEDAW and the provisions cited above, governments should undertake to make breastfeeding discrimination more explicit and clear. In addition, governments can punish those who violate a mother's choice or need to breastfeed. We discuss this below.

B. Convictions and Fines for Breastfeeding Discrimination

The standard way in which human rights legislation is enforced is through the filing of a complaint by the aggrieved individual. If the human rights tribunal determines that the complainant's rights have been violated, damages may be awarded. This is certainly an acceptable way to enforce one's rights but as many mothers already struggle to balance the many demands made on them, the added burden of pursuing human rights litigation and the economic and emotional strain it may produce may discourage many from litigating. Thus, a further way in which governments across Canada can deter breastfeeding discrimination is by passing legislation making it an offence punishable by fine to deny a breastfeeding mother equal treatment in public and quasi-public spaces. Whereas the human rights approach requires an action to be brought by the mother, the mode of enforcement here would be the Crown prosecuting on behalf of the province or territory.

How might such an offence be drafted? Drawing once again from the Ontario *Human Rights Code*, section 46.2 provides that a person who infringes rights protected under Part I of the *Code* is "guilty of an offence and on conviction is liable to a fine of not more than $25,000."[74] Manitoba's *Human Rights Code* also penalizes, more broadly, persons who contravene "a[ny] provision of this Code" or "deprives, abridges or restricts, or attempts to deprive, abridge or restrict, any other person in the enjoyment of a right under this Code."[75] Similar provisions are in place in human rights legislation in New Brunswick,[76] Nova Scotia,[77] Newfoundland and Labrador,[78] and

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[73] *Convention on the Elimination of All Forms of Discrimination against Women*, 18 December 1979, 1249 UNTS 13, art 2, 19 ILM 33 (1980) (entered into force 3 September 1981) [emphasis added].

[74] *Supra* note 57, s 46.2.

[75] *The Human Rights Code*, CCSM c H175, s 51(1)(a)-(b).

[76] *Human Rights Act*, RSNB 2011, c 171, s 25.

the Northwest Territories.[79] These penalties are directed at human rights violations in general. As such, they are a tool available for a provincial or territorial Crown to use with respect to breastfeeding discrimination.

Provincial and territorial governments across Canada can pass legislation making it an offence to commit a human rights violation in connection with breastfeeding and other forms of discrimination. Using their power under section 92(15) of the Constitution, provincial governments may impose punishment such as fines, penalties, or imprisonment for enforcing any law falling under their jurisdiction.[80] Legislative bodies within the territories are similarly empowered by federal legislation to impose such punishments as well as means to enforce territorial legislation.[81] The advantage of this option is that rather than having aggrieved mothers pursue litigation, the Crown would litigate such cases as offences, thus engaging more resources than an individual claimant could access.[82] Given the overall health benefits derived from breastfeeding, provinces and territories have an incentive to prosecute those who violate human rights norms with respect to breastfeeding.

Designating conduct of this type as an offence is unusual but not completely unheard of. In 2004, the Scottish Parliament passed a law imposing fines on businesses if they were found guilty of preventing or stopping a woman from breastfeeding on their premises.[83] In 2009, Indonesia passed a more far-reaching law whereby if a company, co-worker, or family member prevents a mother from breastfeeding, the guilty party may face a year in jail

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[77] *Human Rights Act*, RSNS 1989, c 214, s 38.

[78] *Human Rights Act, 2010*, SNL 2010, c H-13.1, s 45.

[79] *Human Rights Act*, SNWT 2002, c 18, s 72.

[80] *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, ss 92(15), reprinted in RSC 1985, App II, No 5.

[81] See *Northwest Territories Act*, RSC 1985, c N-27, s 16(u); *Yukon Act*, SC 2002, c 7, s 18(1)(y); *Nunavut Act*, SC 1993, c 28, s 23(1)(w).

[82] As indicated in the legislation discussed above that allows for prosecution of human rights violations, in most cases, the authority to prosecute must come from the Attorney General or other designated minister in the government.

[83] *Breastfeeding etc (Scotland) Act*, ASP 2005, c 1; see also Angus MacLeod, "Scotland makes it a crime to prevent public breastfeeding", *The Times* (19 November 2004), online: Times Online <www.thetimes.co.uk/tto/news/uk/article1919203.ece>.

and/or IDR 100,000,000 (approximately CAD $10,000) in fines.[84] While the Indonesian legislation provides for the possibility of imprisonment, such a severe penalty would likely be seen as excessive and unwarranted under Canadian human rights statutes. We would argue that a penalty in the form of a substantial fine would likely be sufficient as punishment. Furthermore, the potential for bad publicity in addition to a fine may prompt more businesses to be vigilant against engaging in such discrimination and to encourage their employees to be aware of their responsibilities under human rights law.

Naturally, such legal initiatives collide with the perceived rights of businesses to exclude people and regulate activity on their property. The right to exclude is often seen as the quintessential right of property owners.[85] However it is not without limits. The right to exclude is already tempered by human rights legislation that restricts a business owner or employee's ability to discriminate against a customer on the basis of, *inter alia*, race, sex, religion, sexual orientation, family status, and disability.[86] Legislation that makes it an offence for store or shopping mall owners to prevent a mother from breastfeeding in quasi-public spaces represents a similar and fair restriction on the right to exclude. Furthermore, it takes the burden of pursuing an action off the complainant-mother and places it on the State, which has an interest in ensuring non-discrimination against mothers and their children. It fosters an ethic of inclusivity in public and quasi-public spaces. It also champions and advances the various reasons for which breastfeeding should be promoted in the name of public health.

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[84] *Undang-Undang Tentang Kesehatan* [*Health Law*], Number 36 of 2009, arts 128, 200. See also Cat Wise, "New Indonesia law: allow breastfeeding, or face punishment" *PBS Newshour* (5 July 2011), online: PBS Newshour <www.pbs.org/newshour/rundown/2011/07/in-indonesia-allow-breast-feeding-or-face-punishment.html>; "Mothers face jail sentence for refusing to breastfeed", *The Jakarta Post* (10 August 2010), online: JP <www.thejakartapost.com/news/2010/08/10/mothers-face-jail-sentence-refusing-breastfeed.html>.

[85] See *Vancouver (City of) v Burchill*, [1932] SCR 620 at 625, [1932] 4 DLR 200 ("[t]he land-owner enjoys the absolute right to exclude anyone and to do as he pleases upon his own property" at 625); *National Trust v Bouckhuyt* (1987), 61 OR (2d) 640, 43 DLR (4th) 543 (Ont CA) ("[t]he notion of 'property' imports the right to exclude others from the enjoyment of, interference with or appropriation of a specific legal right" at para 24); Thomas W Merrill, "Property and the Right to Exclude" (1998) 77 Neb L Rev 730 at 730.

[86] See e.g. Ontario *Human Rights Code*, *supra* note 57, ss 1, 5.

Conclusion

Mothers and their children should not be restricted in their ability to access social spaces by the conceptual limitations of those who do not approve of breastfeeding in public. Prohibiting behaviour that hinders a mother's freedom to nurse her child in public or quasi-public spaces offers some minimal protection to breastfeeding women. It also serves as a disincentive, if not a deterrent, to individuals who would otherwise intervene against breastfeeding in public. Legal measures are admittedly only part of the solution. Public education can also play a significant role in addressing breastfeeding discrimination. Nonetheless, as with other forms of discrimination, public education alone will not suffice. Society must also come to terms with the idea that a woman's breasts can have a dual role, one of which is being an invaluable and normal part of their infants' lives through the act of breastfeeding. Legislation as proposed in this article may help members of society recognize the importance of breastfeeding, or at least deter those who might consider stopping a woman from breastfeeding in public.

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SÉCURITÉ DES PRODUITS, SANTÉ DES CONSOMMATEURS, RESPONSABILITÉS ET CONSTITUTIONS : SYNERGIES COMPARÉES

*Marie-Eve Arbour**

Are prevention and compensation for damages caused by defective products complementary, or do they rather evolve in a reciprocal ignorance? The question has frequently been asked. Beyond theoretical constructions surrounding this theme, it appears necessary to consider constitutional peculiarities that condition interaction modalities between the ex ante and ex post dimensions of risks. Indeed, federal structures and the division of powers that underlie it configure differently the spectrum of liability, narrowing its boundaries or leaving it intact. From a comparative perspective, the European Union, Canada and the United States illustrate different attitudes to the coordination between private law and the constitutional aesthetic of these samples.

La prévention et l'indemnisation de l'atteinte à la santé et la sécurité des consommateurs sont-elles complémentaires ou vivent-elles plutôt dans une ignorance réciproque? La question a souvent été posée. Au-delà des constructions théoriques entourant cette problématique, il importe de prendre acte des particularités constitutionnelles qui conditionnent les modalités d'interaction des versants ex ante et ex post du risque. En outre, les structures fédérales et le partage des compétences qui les accompagnent configurent différemment l'action en responsabilité civile, restreignant son spectre ou le laissant intact. Les exemples de l'Union européenne, du Canada et des États-Unis illustrent, d'un point de vue comparatiste, les différentes attitudes à cet arrimage entre le droit privé et l'esthétique constitutionnelles des échantillons qui se sont ici prêtés à l'observation.

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Introduction

C'est chose connue : selon l'intensité et l'étendue des risques que posent les produits pour les consommateurs, différents législateurs préconisent des stratégies de régulation à géométrie variable[1]. Situées en amont et en aval de la matérialisation des risques – la survenance d'un préjudice –, les formes qu'elles prennent dépendent de la capacité de l'industrie, des consommateurs et des régulateurs à pouvoir les anticiper, les évaluer, les prévoir. Ces choix de régulation les concernant, leurs gouvernements[2] regroupent un amalgame d'instruments qui émanent du droit des obligations (la dynamique contractuelle, la responsabilité civile), de lois et règlements particuliers (au premier chef, celles visant la sécurité des produits[3]), de « droit mou » (*soft law*) (les

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[1] Au Québec et au Canada, voir Nathalie Vézina et Françoise Maniet, « La sécurité du consommateur au Québec … deux solitudes : mesures préventives et sanctions civiles des atteintes à la sécurité » (2008) 49 : 1 C de D 57 ; Jeremy D Fraiberg et Michael J Trebilcock, « Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform » (1998) 43 : 1 RD McGill 835. Pour une perspective comparatiste, voir Guido Alpa, « Rapport général » dans Travaux de l'Association Henri Capitant, *Le consommateur : Journées colombiennes*, t 57, vol 2, Bruxelles, Bruylant, 2007, 273.

[2] Christine Noiville, *Du bon gouvernement des risques : Le droit et la question du « risque acceptable »*, Paris, Presses Universitaires de France, 2003 à la p 11 préconise ce vocable. Nous lui préférons la notion de « régulation », telle qu'appréhendée par Fabrizio Cafaggi, « Le rôle des acteurs privés dans les processus de régulation : participation, autorégulation et régulation privée » (2004) 109 : 1 Revue française d'administration publique 23 ou Jacques Chevallier, « La gouvernance et le droit » dans Gérard Cohen-Jonathan et al, dir, *Mélanges Paul Amselek*, Bruxelles, Bruylant, 2005, 189 à la p 191.

[3] Parmi elles, voir, au Canada, la *Loi canadienne sur la sécurité des produits de consommation*, LC 2010, c 21 [*LCSPC*], notamment commentée par: John F Blakney, Margot Patterson et Andrew Lanouette, « The Canada Consumer Product Safety Act: A Review » (2011) 51 : 2 Rev can dr comm 49 et Marie-Ève Arbour, « Chronique : Petite visite guidée de la Loi canadienne sur la sécurité des produits de consommation » en ligne : *Repères* (Éditions Yvon Blais, *La référence*, EYB2012REP1232 : sept 2012) <http://www.lareference.editions yvonblais.com>. Au sein de l'Union européenne (UE) : CE, *Directive 2001/95/CE du Parlement européen et du Conseil du 3 décembre 2001 relative à la sécurité générale des produits*, [2002] JOL 11/4 [*Directive « sécurité des produits »*] ; aux États-Unis, le *Consumer Product Safety Act of 1972*, Pub L No 92-573 §2, 86 Stat 1207

normes techniques, les règles de l'art), de processus de certification, d'autorisations de mise en marché et de mécanismes de contrôle après-vente (dont les obligations de suivi ou le rappel des produits[4]): l'inventaire n'est pas exhaustif. Ils évoquent pourtant deux univers distincts: ceux, respectifs, du droit public et du droit privé[5], lesquels, en dehors des systèmes juridiques de *common law* (et encore, sauf exception[6]), ont classiquement été appréhendés en vase clos, la plupart du temps de manière sectorielle[7]. Dans ce contexte se pose la question de déterminer les modalités de coordination de ces différents instruments pour mieux circonscrire des territoires d'opposition mutuelle, ou, à l'inverse, dégager des zones de contact à l'intérieur desquelles ces deux univers se juxtaposent ou s'influencent réciproquement.

La prévention et l'indemnisation du préjudice causé par le fait des produits dépassent-elles cette dichotomie? Sont-elles complémentaires? Vivent-elles plutôt dans une ignorance réciproque? Ces questions ont retenu l'attention de certains auteurs[8]. En définitive, l'importance respective accordée à la prévention et l'indemnisation

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(codifié tel que modifié au 15 USC § 2051 (2000)) [*CPSA*] ou le *Competition and Consumer Act 2010* (Cth), (tel qu'amendé en 2011).

[4] Voir Luke Nottage, « Product Safety » dans Geraint Howells, Iain Ramsay et Thomas Wilhelmsson, dir, *Handbook of Research on International Consumer Law*, Cheltenham, Edward Elgar, 2010, 256 à la p 258.

[5] Muriel Fabre-Magnan, *Droit des obligations : Responsabilité civile et quasi-contrats*, t 2, Paris, Presses Universitaires de France, 2007, aux pp 4-5.

[6] Voir les contributions colligées par Fabrizio Cafaggi, dir, *The Institutional Framework of European Private Law*, New York, Oxford University Press, 2006 ; Noiville, *supra* note 2.

[7] Voir notamment Keith Hylton, « When Should We Prefer Tort Law to Environmental Regulation ? » (2002) 41 Washburn LJ 515 ; Kenneth S Abraham, « The Relation Between Civil Liability and Environmental Regulation: An Analytical Overview » (2002) 41 Washburn LJ 379.

[8] Voir Fabrizio Cafaggi, « A Coordinated Approach to Regulation and Civil Liability in European Law: Rethinking Institutional Complementarities » dans Cafaggi, *supra* note 6 à la p 196 (il postule que les dimensions ex ante et ex post du risque « *are functional complements* and not necessarily functional equivalents » – et ajoute – « [i]n fact they often reflect different approaches to individual and collective responsabilities associated with the harmful consequences of unlawful conduct » [nos italiques]).

procéderait de choix essentiellement politiques, dès lors que devant des risques similaires (pensons à l'alimentation ou aux médicaments), différentes stratégies quant à leur gestion et leur prise en charge sont préconisées. En ce sens, Geraint Howells a déjà posé l'hypothèse voulant que devant un risque donné, les réponses institutionnelles opposent, par exemple, l'Union européenne (« UE ») aux États-Unis[9], ces derniers étant plus enclins à concevoir l'indemnisation du préjudice à travers le prisme de la vie économique. Car il suffit d'admettre, avec d'autres[10], que la responsabilité civile est un instrument de régulation comme un autre pour insuffler à la réflexion une perspective nouvelle[11], permettant de concevoir le domaine de la sécurité des produits de consommation et son double, la protection de la santé et de la sécurité des consommateurs, d'une manière holistique, chapeautant le droit public et le droit privé.

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[9] Voir *The Tobacco Challenge: Legal Policy and Consumer Protection*, Farnham (R-U), Ashgate, 2011 aux pp 1, 297 [Howells, *Tobacco*]. D'un point de vue méthodologique, certains doutent de l'opportunité de comparer ces deux modèles, en raison, surtout, du patriotisme américain qui n'a d'équivalent au sein de l'UE et qui teinte, en définitive, tout le débat constitutionnel : voir Paul Magnette et Justine Lacroix, « EU Constitutionalism and the 'American Experience' » dans Gráinne De Búrca et Joanne Scott, dir, *Law and New Governance in the EU and the US*, Portland (Or), Hart Publishing, 2006, 363 aux pp 375-79. La présente étude comparative n'est suspendue, avec Henri Brun, Guy Tremblay et Eugénie Brouillet, *Droit constitutionnel*, 5e éd, Cowansville (Qc), Yvon Blais, 2008 à la p 405 qu'à « existence d'un partage de la compétence législative assurant une décentralisation relativement parfaite ».

[10] Voir par ex Andrew P Morriss, Bruce Yandle et Andrew Dorchak, *Regulation by Litigation*, New Haven, Yale University Press, 2009 ; W Kip Viscusi, dir, *Regulation through Litigation*, Washington, AEI-Brookings Joint Center for Regulatory Studies, 2002 ; Peter Cane, « Tort Law as Regulation » (2002) 31 : 4 C L World Rev 305 à la p 305 (selon qui « The placing of core areas of private law, such as contract and tort, within an instrumentalist regulatory frame can therefore also be seen *as part of a larger project of exploring and mapping the public/private divide in the context of what is often called the 'regulatory state'* » [nos italiques]). Voir aussi Cafaggi, *supra* note 6 à la p 203.

[11] Même dans le contexte de la common law, Morton Horwitz semblait s'étonner du fait qu' « [i]n most general historical studies, fields like torts and contracts, when they are examined at all, are treated as if they stand apart from content or policy » : Morton Horwitz, *The Transformation of American Law 1780-1860*, Cambridge, Harvard University Press, 1977 à la p xii.

En amont de toute réflexion entourant l'interaction entre cet amalgame d'instruments de régulation, deux variables conditionnent leur interaction : l'architecture fédérale – entendue très largement[12] – et la structure des marchés intégrés. Malgré l'existence de plusieurs études s'étant intéressées à la seconde[13], peu d'entre elles ont proposé une analyse comparative des bases juridiques constitutionnelles desquelles s'autorise le domaine de la sécurité des produits. D'où la problématique qui anime la présente contribution, liminaire, en quelque sorte, à tout approfondissement des ramifications de ce thème : comment, au regard de la sécurité des produits et la santé des personnes, le droit constitutionnel conditionne-t-il les rapports entre les sphères du droit public et du droit privé? Cette question en appelle une autre : de quelle manière le droit de matrice fédérale module-t-il la mise en œuvre d'un droit d'action en responsabilité civile? Les réponses à ces interrogations sont tributaires des paramètres juridiques qui conditionnent l'exercice des compétences fédérales autant que des différentes et mentalités, dirait Pierre Legrand[14], que véhicule le fédéralisme. Celles-ci justifient et expliquent à la fois l'étendue des marges discrétionnaires dont disposent les législateurs pour assurer la prévention et l'indemnisation des atteintes à la santé et à la sécurité des consommateurs, de même que l'intensité de ces protections.

Preemption, principe d'attribution, subsidiarité, proportionnalité, partage fédératif des compétences, *paramountcy*, suprématie : cette sémantique constitutionnelle est destinée à dépeindre l'articulation entre des sources du droit plurielles, par moment superfétatoire, sou-

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[12] Peter W Hogg, *Constitutional Law of Canada*, Carswell, Toronto, 2012 aux pp 5-3, 5-4 [Hogg].

[13] David Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy*, Cambridge, Harvard University Press, 1995 ; David Trubek et Thierry Bourgoignie, dir, *Consumer Law, Common Markets and Federalism in Europe and the United States*, New York, Walter de Gruyter, 1987. Ceci est d'autant plus pertinent dans le cadre des négociations entourant la conclusion de l'*Accord économique et commercial global entre le Canada et l'Union européenne* (*AÉCG*). À ce sujet, voir notamment Stanko S Krstic, « Regulatory Cooperation to Remove Non-tariff Barriers to Trade in Products: Key Challenges and Opportunities for the Canada-EU Comprehensive Trade Agreement » (2012) 39 : 1 LIEI 3.

[14] « À propos d'une réflexion sur la comparaison juridique » (1993) 45 : 4 RIDC 879.

vent dénaturée par des traductions approximatives. Cryptique, elle masque fréquemment des réalités distinctes, qui recoupent, d'un point de vue théorique, un double phénomène conjectural et particulier visant, d'un côté, la légitimité de l'occupation, par la sphère fédérale d'un champ du droit particulier[15] et, de l'autre, l'antagonisme entre une norme fédérale et une norme étatique. Variable dans le temps[16], l'étude de leur évolution s'avère pourtant nécessaire parce qu'elle permet de tracer les contours respectifs de la responsabilité civile et de la prévention des atteintes à la santé des personnes. Cet exercice a tôt fait d'ébranler la prémisse beaucoup trop simpliste voulant que la seconde échoie à l'État fédéral alors que la première demeure l'apanage des États fédérés[17]. La superposition est bien imparfaite, sauf, peut-être, au sein de l'UE, qui propose une harmonisation (encore que partielle) des deux les versants de la sécurité des produits (prévention et indemnisation[18]). En cela, cette harmonisation se distingue des droits canadien et américain[19]. Les différentes angulations de cette hypothèse

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[15] Voir Peter H Schuck, « FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot » (2008) 13 Roger Williams UL Rev 73 à la p 80 et s, qui distingue entre *conflict pre-emption* et *field pre-emption*.

[16] Voir la contribution classique de KC Wheare, *Federal Government*, 4e éd, London (R-U), Oxford University Press, 1963 aux pp 10-11. Hogg, *supra* note 12 à la p 5-3, observe une décentralisation croissante des pouvoirs au tournant de la Deuxième guerre mondiale.

[17] Même au risque de pécher par excès de simplification, l'expression réfère ici autant aux « États membres » de l'UE, aux « États » américains et aux provinces canadiennes.

[18] Communauté économique européene (CEE), *Directive 85/374/CEE du conseil du 25 juillet 1985 relative au rapprochement des dispositions législatives, réglementaires et administratives des États membres en matière de responsabilité du fait des produits défectueux*, [1985] JOL 210/29 [*Directive « produits défectueux »*].

[19] Par contraste, les *Restatements* publiés par l'American Law Institute, dont le *Restatement of Torts (Second)* §402A (1965) et le *Restatement of Torts (Third)* (1998) ont un impact fondamental sur la responsabilité du fait des produits (*product liability*). Mais à la différence de la *Directive « produits défectueux »*, *ibid*, les États ne sont pas contraints de les adopter ; ils n'ont qu'une autorité persuasive. Au sujet de la sur-importance qui leur est accordée par la comparaison juridique, voir Matthias Reimann, « American Private Law and European Legal Unification: Can the United States be a Model? » (1996) 3 MJECL 217. Concernant la multiplicité de re-

se vérifient à l'étude du droit comparé, qui se fait particulièrement éclairant quant à l'ancrage juridique du domaine de la sécurité des produits de consommation. Mi-figue, mi-raisin, ce domaine du droit s'érige sur des bases juridiques plurielles, allant de la libre-circulation des marchandises à la protection des consommateurs, en passant par la protection de la santé des personnes, voire le droit criminel.

Par-delà leurs profondes différences historiques, économiques et politiques, l'analyse comparative des expériences américaine (SECTION I), canadienne (SECTION III), et de l'UE (SECTION II) met en relief les contours des points de contact et de répulsion qu'induisent des structures constitutionnelles à géométrie variable, que conditionnent les principes juridiques qui sous-tendent la coordination des compétences. Ces systèmes juridiques qui invitent à l'immersion[20] partagent une conception plutôt similaire de la vie économique (rationalité, compétitivité, déréglementation des marchés[21]) et de la démocratie (parlementarisme, *rule of law*), lesquelles s'observent à travers leur adhésion commune à des traités internationaux[22] ou des accords de principe[23] destinés à assujettir la sécurité des

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cours qui subsistent, voir Jane Stapleton, « Restatement (Third): An Anglo-Australian Perspective » (2000) Wash LJ 362 à la p 374.

[20] Voir Vivian Grosswald Curran, « Cultural Immersion, Difference and Categories in U.S. Comparative Law » (1998) 46 Am J Comp Law 43 aux pp 57-61.

[21] Il faudrait, afin de saisir entièrement toute la matière, dépeindre toutes les nuances qui accompagnent les stratégies de régulation préconisées par les systèmes étudiés (voir parmi beaucoup d'autres Olivier Godard et al, *Traité des nouveaux risques : précaution, crise, assurance*, Paris, Gallimard, 2002; Cass Sunstein, *Risk and Reason: Safety, Law and the Environment*, Cambridge (Mass), Cambridge University Press, 2002). Contrainte à y renoncer, la lecture de Maria Rosaria Ferrarese, *Le istituzioni della globalizzazione, diritto e diritti nella società transnazionale*, Bologne, Il Mulino, 2000; Harm Schepel, *The Constitution of Private Governance : Product Standards in the Regulation of Integrating Markets,* Oxford, Hart, 2005 suffit à tout le moins à poser l'hypothèse d'une convergence des modèles économiques dans le sens suggéré.

[22] Voir par ex *Accord général sur les tarifs douanier et le commerce*, 30 octobre 1947, 58 RTNU 187, RT Can 1947 n° 27 (entrée en vigueur : 1er janvier 1948, révisé en 1994) [GATT] ; *Accord de libre-échange nord-américain entre le gouvernement du Canada, le gouvernement des États-Unis et le gouvernement du Mexique*, 17

produits au respect de normes techniques ou éthiques et à subordonner l'exercice de régulation des marchés aux préceptes de la méthode scientifique. Au prix, certes, de la simplification de certains archétypes constitutionnels (la séparation des pouvoirs, les théories de l'État, etc.[24]), la présente contribution formule l'hypothèse d'un frein que posent des donnes constitutionnelles entrecroisées à la circulation, souvent acquise, d'un triple modèle juridique axé sur l'élimination des obstacles au commerce, la (re)(co)régulation des marchés par des tiers (régulateurs, agences de normalisation) et la responsabilité du fait des produits défectueux (*product liability*).

De fait, la mise en exergue de plusieurs particularités juridiques propres aux États-Unis, au Canada ou à l'UE tend plutôt à dépeindre un panorama juridique éclaté, tributaire de la centralité de l'État nation et du partage des compétences qui accompagne inévitablement les modèles fédéraux. Assez étrangement, la protection de la santé des consommateurs n'est pas le paradigme juridique qui fait contrepoids aux excès du marché, réduite qu'elle est sinon à une peau de chagrin, du moins à une variable secondaire.

Animée surtout du désir de préciser les contours et les limites du droit des systèmes juridiques objet de la présente comparaison, la démarche se veut positiviste[25], inductive et sectorielle, dans la mesure où

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décembre 1992, RT Can 1994 nº 2, 32 ILM 289 (entrée en vigueur : 1er janvier 1994) [ALÉNA].

[23] Voir par ex, dans le domaine pharmaceutique, *l'International Conference of Harmonization*, en ligne : ICH <http://www.ich.org/>.

[24] Concernant les difficultés méthodologiques liées à la comparaison des textes constitutionnels, voir Joseph H Weiler et Joel P Trachtman, « European Constitutionalism and Its Discontents » (1996-1997) 17 Nw J Int'L L & Bus 354 aux pp 355-57 ; Günter Frankenberg, « Comparative Constitutional Law » dans Mauro Bussani et Ugo Mattei, dir, *The Cambridge Companion to Comparative Law*, Cambridge (NY), Cambridge University Press, 2012, 171 aux pp 177-78.

[25] Ce positivisme s'étend toutefois à l'étude des « formants », une notion heuristique qui concoure à expliquer la formation et l'interprétation du droit de chacun de ces systèmes. Leur paternité est attribuable à Rodolfo Sacco, « Legal Formants: A Dynamic Approach to Comparative Law (Installment I of II) » (1991) 39 : 1 Am J Comp L aux pp 24-39.

c'est l'apport de la réflexion constitutionnelle au domaine de la sécurité des produits de consommation qui est ici alimenté, et non l'inverse. En cela, elle pêchera peut-être par son résultat pareil à un archipel, mais elle atteindra plus facilement son but, qui est surtout celui de rendre compte, dans une logique comparatiste descriptive et analytique[26], de l'impact asymétrique des institutions et des structures fédérales sur la régulation des produits de consommation. À ce titre, cette contribution n'emprunte aucun sentier destiné à proposer une piste interprétative plutôt qu'une autre[27]. Elle poursuit, plus modestement, une finalité dialogique[28] (touristique[29] ?) qui consiste à mettre en exergue les points de contact et de répulsion des approches constitutionnelles ici retenues[30], sur la base d'un a priori essentiel – leur esthétique fédérale – mais aussi du tissu socio-économique qu'ils partagent nécessaire à la comparaison[31]. Sous cet angle, l'originalité de la présente contribution est probablement à trouver davantage dans l'objet de son étude – un pan du droit oblique, au corps informe – que dans la méthodologie, classique, qui sous-tend tout le parcours analytique.

I. La *préemption* américaine : du pragmatisme au politique

Aux États-Unis comme au Canada, un débat politico-historique nourrit la question suivante : dans quelle mesure une norme décrétée

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[26] Plusieurs auteurs dénoncent l'absence de cadre méthodologique d'études « comparatives » : voir Cécile Vigour, *La comparaison dans les sciences sociales : pratiques et méthodes*, Paris, La Découverte, 2005; Giovanni Sartori, « Bien comparer, mal comparer » (1994) 1 : 1 Revue Internationale de Politique Comparée 19.

[27] En ce sens, elle ne peut s'autoriser d'aucun des modèles (fonctionnalisme, expressivisme, bricolage) mis de l'avant par Mark Tushnet, « The Possibilities of Comparative Constitutional Law » (1999) 108 : 6 Yale LJ 1225.

[28] Sujit Choudhry, « Globalization in Search of Justification: Toward a Theory of Comparative Constitutional Interpretation » (1998-1999) 74 Ind LJ 819 aux pp 855-66 ; Gunther Frankenberg, « Critical Comparisons: Re-thinking Comparative Law » (1985) 26 : 2 Harv Int'l LJ 411 à la p 414.

[29] La métaphore est empruntée à Frankenberg, *ibid* à la p 412.

[30] Rodolfo Sacco, *La comparaison juridique au service de la connaissance du droit*, Paris, Economica, 1991 à la p 9.

[31] Selon ce critère, d'autres systèmes auraient pu se prêter à la présente étude, dont l'Australie, le Brésil ou la Suisse. L'analyse relève donc de l'échantillonnage plus que de l'exhaustivité.

par le Parlement fédéral fait-elle obstacle à la mise en œuvre du droit étatique? Connue sous le nom de la *preemption* – « préséance », dirons-nous[32] – la problématique est enracinée dans la clause de suprématie (*Supremacy Clause*) prévue à l'article IV §2 de la Constitution telle qu'adoptée en 1789. Elle édicte que « [t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof; […] *shall be the supreme Law of the land* […] » [nos italiques]. En synthèse et pour des raisons qui dépassent largement le cadre de la présente analyse[33], cette préséance chère au juge Marshall veut que le domaine d'action législative fédérale ne soit pas mis à mal par l'immixtion indue des législateurs étatiques. Comme au Canada et à la différence de l'UE, la prépondérance du droit de matrice fédérale est acquise[34], d'où l'importance de circonscrire avec précision les sphères de compétence respectives de l'entité fédérale d'un côté et, de l'autre, celle des États qui composent l'UE. Mais à la différence de la *Loi constitutionnelle de 1867* ou du *Traité sur le fonctionnement de*

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[32] Et non « préemption », qui évoque un droit de premier refus sans lien avec la présente étude. Retenons la définition proposée par Richard A Epstein et Michael S Greve, « Introduction: Preemption in Context » dans Richard A Epstein et Michael S Greve, dir, *Federal Preemption: States' Powers, National Interests*, Washington, AEI Press, 2007 à la p 1, selon laquelle « preemption means the federal government's ability to trump, supersede, or displace state and local law […] ».

[33] Voir l'efficace exposition des raisons sous-jacentes de Robert RM Verchick et Nina Mendelson, « Preemption and Theories of Federalism » dans William W Buzbee, dir, *Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question*, Cambridge (NY), Cambridge University Press, 2009, 13 aux pp 15-19.

[34] Au Canada, *paramountcy* trouve son équivalent, en français, dans la « doctrine de la prépondérance ». Voir *Loi constitutionnelle de 1982*, art 52(1), constituant l'annexe B de la *Loi de 1982 sur le Canada* (R-U), 1982, c 11, qui la consacre ; *Multiple Access Ltd c McCutcheon*, [1982] 2 RCS 161, 138 DLR (3e) 1 [*McCutcheon*] ; *Rothmans, Benson & Hedges Inc c Saskatchewan*, 2005 CSC 13, [2005] 1 RCS 188 (la théorie ne s'applique pas lorsqu'il est possible de se plier, simultanément, aux prescriptions de l'une et de l'autre). Au sein de l'UE, semblable articulation des sources du droit s'observe à travers la jurisprudence de la Cour de Justice des Communautés Européennes (CJCE). Voir *Costa c ENEL*, C-6/64, [1964] ECR I-1149 [*Costa*] ; *Van Gend Loos*, C-26/62, [1963] ECR 1 ; *Brasserie du pêcheur et Factortame III*, aff. jointes C-46/93 et 48/93, [1996] ECR I-1029 [*Brasserie du pêcheur*].

l'Union européenne (« *TFUE* »)[35], la Constitution américaine de 1787 ne décline une liste de compétences qu'à l'endroit de l'appareil fédéral[36], laissant aux États l'exercice des pouvoirs résiduaires. La flexibilité théorique de cette structure explique probablement l'émergence du « quatrième pouvoir » qu'exercent les agences fédérales (la *Food and Drug Administration* (« FDA ») ou la *Consumer Product Safety Commission*[37]) qui concourent, à la différence du Canada, à dessiner graduellement les pourtours de véritables domaines du droit, dont celui de la sécurité des produits.

En parallèle, une tendance s'observe au sein du Canada, des États-Unis et, dans une moindre mesure, au sein de l'UE : les positions polarisées, dualistes, « étanches[38] » au fédéralisme semblent perdre du terrain dans le discours constitutionnel contemporain, qui préfère aux théories de la souveraineté une approche réaliste, pragmatique, qui sied probablement mieux à la régulation des risques que posent les produits de consommation[39]. L'engouement est plutôt à la coopération, la polyphonie[40], voire à la détermination de « planchers » et de « plafonds » normatifs fédéraux : pour William Buzbee, « [i]n statuto-

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[35] 30 mars 2010, C 83/49 [*TFUE*].

[36] US Const art I § 8, incluant la clause 3 portant compétence sur le commerce interétatique (*commerce clause*).

[37] Créée en vertu du *Consumer Safety Act* de 1972, 15 USC §§ 2051−2089. Concernant le contexte présidant à son adoption, voir Nicole L'Heureux, « La sécurité des produits de consommation et le libre-échange », (1988) 29 C de D 323 à la p 326 et s.

[38] La référence est à *Canada (PG) c Ontario (PG)*, [1937] AC 326 à la p 354.

[39] Voir Morton Horwitz, *The Transformation of American Law 1780-1860*, Cambridge (Mass), Harvard University Press, 1977 aux p xii-xiv (il observe que « New Deal historians were much more concerned with finding evidence of governmental intervention than they were in asking in whose interest these regulations were forged »).

[40] L'expression est empruntée à Robert A Shapiro, « From Dualism to Polyphony » dans Buzbee, *supra* note 33 à la p 33, pour qui « [f]rom the polyphonic perspective, federalism consists of independent state and federal voices that interact together » (à la p 42). Il ajoute : « the polyphonic approach produces a system of governance that is more innovative and resilient than the compartmentalized system of dual federalism » (à la p 43).

ry and regulatory regimes, […] Congress and agencies have for many years overwhelmingly manifested a preference for regulatory overlap and interaction, *harnessing the strengths of state and federal institutional actors and forcing the two to interact* »[41].

À ce sujet, une question récurrente nourrit la jurisprudence de la Cour suprême américaine : du fait de sa préséance, l'exercice de compétences fédérales en lien avec la sécurité des produits met-il en échec la mise en œuvre de recours civils intentés en vertu du droit positif étatique (les *torts*, la *product liability*)? Autrement dit, l'occupation, par le législateur fédéral, d'un pan de droit public visant la sécurité des produits (*in primis*, leur étiquetage) subsume-t-il, à moins d'indications contraires, l'action en responsabilité exercée en vertu du droit étatique, dès lors qu'elle aurait déjà été comptabilisée dans le choix de régulation effectué? Un élargissement de la problématique est nécessaire pour comprendre les enjeux politiques qui apparaissent en filigrane car la réponse n'est pas linéaire.

En général et à l'instar du droit de l'environnement, la responsabilité civile échappe la plupart du temps au joug de la préséance par le truchement de clauses de sauvegarde (*saving clauses*) savamment négociées, ayant l'avantage de la clarté[42]. Par exemple, l'article §23(c) de la *Consumer Product Safety Act* aménage des sanctions destinées à se superposer aux actions étatiques en réparation du préjudice : « [t]he remedies provided for in this section *shall be in addition to and not in lieu of any other remedies provided by common law or under Federal or State law* »[43]. Ici, l'ex ante (la prévention des risques) et l'ex post (l'indemnisation du préjudice) vivent dans une ignorance à peu près réciproque, animés qu'ils sont par des raisons politiques hétérogènes. C'est dire que le droit fédéral n'a pas pour effet d'annihiler les recours civils qu'aménage le droit des États.

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[41] « Federal Floors, Ceilings, and the Benefits of Federalism's Institutional Diversity » dans Buzbee, *supra* note 33, 98 à la p 99 [nos italiques].

[42] *Ibid* à la p 101.

[43] *CPSA*, *supra* note 3 [nos italiques].

En dehors de la *Consumer Product Safety Act*, en revanche, des interventions législatives sectorielles, *ad hoc*, dessinent autour de la préséance un paysage juridique irrégulier. Un quatuor de décisions rendues par la Cour suprême américaine alimente une controverse doctrinale (et politique) au regard de certains produits de consommation, dont ceux dérivés du tabac (SOUS-SECTION A) ou les produits de santé (SOUS-SECTION B). À leur endroit, des solutions judiciaires claires-obscures ont été esquissées autour de la question de déterminer dans quelle mesure, par exemple, les normes visant l'étiquetage des produits subsument l'action en indemnisation du préjudice nichée dans le défaut d'information[44].

A. Les produits du tabac : de Cipollone *à* Altria

À moins d'indications claires par le législateur à cet effet (par exemple la *Consumer Product Safety Act*), les tribunaux américains n'ont jamais réellement considéré, avant 1992, que des actions en responsabilité civile puissent entrer en conflit avec les normes fédérales de matrice préventive[45]. Une décision rendue par la Cour suprême dans le contexte du tabagisme – *Cipollone v Liggett*[46] – a abordé les modalités de coexistence des droits fédéral et étatiques. L'affaire est née d'une action en dommages-intérêts intentée par des fumeurs, exercée en vertu des règles étatiques et ancrée dans un défaut d'information concernant l'étendue des risques associés au tabagisme (en clair, une asymétrie informationnelle).

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[44] *Restatement (Third)* §2 (i) (1997) (« [c]ommercial product sellers *must provide reasonable instructions and warnings about risks of injury posed by products.* Instructions inform persons how to use and consume products safely » [nos italiques]).

[45] La préséance a pourtant eu droit de cité dans d'autres domaines du droit : voir *McCulloch v The State of Maryland et al*, 17 US 316 (1819) ; *Rice v Santa Fe Elevator Corp*, 331 US 218 (1947) (où la Cour recentre la préséance autour de l'intention du Congrès de conférer, ou non, préséance à la loi fédérale) ; *Maryland v Louisiana*, 451 US 725 (1981) ; *Malone v White Motor Cor,* 435 US 497 (1978) ; *EPA v State Water Resources Control Board*, 426 US 200 (1976) ; *Hancock v Train*, 426 US 167 (1976) ; *Mayo v United States*, 319 US 441 (1943).

[46] *Cipollone v Liggett Group Inc*, 505 US 504 (1992) [*Cipollone*], commenté notamment par Howells, *Tobacco*, *supra* note 9 à la p 124 et s.

La démarche a été jugée irrecevable à l'issue d'une demande de *certiorari* au terme de laquelle la Cour suprême, préconisant une position mitoyenne, a statué que la *Public Health Cigarette Smoking Act* fédéral adopté en 1969 prohibe un tel recours, dès lorsqu'il prescrit ce qui suit : « [n]o *requirement* or prohibition *based on smoking and health* shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labelled in conformity with the provisions of this chapter »[47]. L'argument mis de l'avant par les défendeurs – qu'avait d'ailleurs avalisé la Cour d'appel fédérale[48] – voulait que l'action en réparation du préjudice, après tout, est un instrument de régulation des produits dérivés du tabac, du fait qu'elle met à charge de l'industrie des obligations d'informations supplémentaires dont l'étendue incertaine est précisée au fil du temps par les tribunaux étatiques. À ce titre et parce que la responsabilité civile est ici assimilable à un *requirement* (lire une « exigence »), elle entre dans le « champ magnétique » d'une loi fédérale qui comptabilise déjà les effets connus de la responsabilité civile (indemnisation, prévention, punition) dans le compromis qu'elle matérialise.

S'exprimant par la plume du juge Stevens, la Cour suprême refuse néanmoins de tracer, autour de cette dernière, les linéaments d'une construction théorique, préconisant plutôt une approche éclatée et pragmatique au fédéralisme qui la porte à analyser chaque conflit à la lumière de l'intention du Congrès pour mieux délimiter le spectre de préséance (qui ne s'étend pas nécessairement à tous les motifs qui

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[47] *Public Health Cigarette Smoking Act of 1969*, Pub L 91-222, 84 Stat 87, tel qu'amendé, 15 USC §§ 1331-1340 [nos italiques] [*Loi de 1969*] (rédigé en lettres majuscules, l'avertissement précise : « Warning: The surgeon general has determined that cigarette smoking is dangerous to your health »).

[48] *Cipollone v Liggett Group Inc*, 789 F2d 181 (CA3 1986). Elle précise (à la p 187) :

> The Act pre-empts those state law damages actions relating to smoking and health that challenge either the adequacy of the warning on cigarette packages or the propriety of a party's actions with respect to the advertising and promotion of cigarettes. Where the success of a state law damages claim necessarily depends on the assertion that a party bore the duty to provide a warning to consumers in addition to the warning Congress has required on cigarette packages, such claims are pre-empted as conflicting with the Act [notes omises].

sous-tendent l'action en réparation du préjudice corporel). En l'espèce, il faut en comprendre que si la portée de la *Loi de 1969* embrasse toute la sphère de l'étiquetage des cigarettes[49] (et pour cela pose un obstacle à l'action en réparation du préjudice ancrée dans le défaut d'information), elle laisse en revanche la porte ouverte à d'autres recours en responsabilité basés sur les fausses représentations, les pratiques de commerce illégales, le défaut de conception, le non-respect des garanties contractuelles, la conspiration, etc.[50]. La préséance ne place pas complètement les fabricants à l'abri de toute poursuite civile, en même temps qu'elle soustrait du domaine étatique la riche problématique de la détermination de l'intensité et de l'étendue du devoir d'information dont sont débiteurs les fabricants devant les consommateurs. Le compromis est éclatant. Mais en distillant le litige à la seule intention du législateur (dans un élan de positivisme qui masque à peine les écueils politiques que la Cour suprême voulait précisément éviter), celle-ci réussit ce double exploit qui consiste à esquiver toute référence au fondement ou aux fonctions de l'indemnisation du préjudice, ainsi qu'à aplanir d'autant les différentes attitudes au fédéralisme.

Pour ou contre la *preemption*? La question est trop simpliste. Le banc *Cipollone* décline bien trois hypothèses de préséance[51], sans pour autant ériger une construction théorique qui s'écroulerait de toute ma-

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[49] La disposition pertinente (§1331) prévoit ce qui suit :

> It is the policy of the Congress, and the purpose of this Act […], *to establish a comprehensive Federal program to deal with cigarette labeling and advertising* with respect to any relationship between smoking and health, whereby: (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) *not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations* with respect to any relationship between smoking and health (*Cipollone*, *supra* note 46 [nos italiques]).

[50] *Cipollone*, *supra* note 46 à la p 531.

[51] Howells, *Tobacco*, *supra* note 9 aux pp 124-25 (pour le juge Scalia, la préséance recoupait, après 1969, toutes les causes d'action ; pour le juge Blackmun, le droit fédéral ne posait aucun obstacle à l'exercice d'actions en responsabilité civile).

nière au gré du *pendulum* politique gauche/droite que l'on connaît. Et la suite des choses était prévisible. Aidée de l'extrême porosité d'un *stare decisis* réductible à la recherche de l'intention du législateur, la jurisprudence successive a réveillé deux positions polarisées[52]: celle voulant que la responsabilité civile soit, par essence, complémentaire et parallèle aux autres modes de régulation des activités économiques (et, qu'à ce titre, elle ne soit jamais éclipsée par le droit fédéral[53]), et celle suggérant plutôt qu'elle chevauche indûment des stratégies de régulation établies, s'avérant, par conséquent, superfétatoire[54].

En particulier, les enseignements de l'arrêt *Cipollone* ont été réitérés dans le contexte de la saga des cigarettes dites « légères »[55], à l'occasion de laquelle le même signataire a dégagé au sein du banc un consensus légèrement plus significatif, malgré son manque, avoue-t-il, « d'élégance théorique »[56]. S'agissant – encore – de déterminer l'étendue du faisceau de préséance de la *Loi de 1969*, la Cour conclut que cette dernière laisse libre cours à une action intentée, cette fois, sur la base de publicités trompeuses interdites au sens d'une loi étatique (la *Maine Unfair Trade Practices Act*[57]). Cette fois, elle estime

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[52] Voir par ex *Geier v Honda Motors Co*, 529 US 861 (2000) [*Geier*] (où la Cour suprême a jugé que l'inclusion d'une clause de sauvegarde (*saving clause*) maintenant l'action en responsabilité à une loi sur la sécurité des véhicules automobile ne faisait pas obstacle à ce que la théorie de la *preemption* puisse s'appliquer). Contra *Sprietsma v Mercury Marine*, 537 US 51 (2002) ; *Bates v Dow Agrosciences LLC*, 544 US 431 (2005) [*Bates*].

[53] Voir *New York State Conference of Blue Cross & Blue Shield Plans v Travelers Ins Co*, 514 US 645 (1995); *Hillsborough County v Automated Medical Labs*, 471 US 707 (1985) ; Bates, *supra* note 52.

[54] Voir *Geier*, *supra* note 52 ; *Buckman Co v Plaintiffs' Legal Comm*, 531 US 341 à la p 348 (2001) (impliquant des dispositifs médicaux) ; *International Paper Co v Ouellette*, 479 US 481 à la p 494 (1987) (dans le contexte d'une *nuisance* causant la pollution de l'eau) ; *Chicago & North Western Transp Co v Kalo Brick & Tile Co*, 450 US 311 à la p 321 (1981) (en matière de transport ferroviaire).

[55] *Altria Group Inc v Good*, US LEXIS 9127, 555 US 70 (2008) [*Altria*] ; *Lorillard Tobacco Co v Reilly*, 533 US 525 (2001).

[56] *Altria*, *ibid* à la p 14, juge Stevens [notre traduction].

[57] *Me Rev Stat Ann,* tit 5, §207 (Supp 2008).

néanmoins que la loi fédérale ne saurait faire obstacle au devoir qui s'impose à tous et qui consiste à éviter de s'adonner à des pratiques interdites de commerce (ce que sanctionne, ultimement, le droit privé[58]). Sous cet angle, le recours intenté se superpose légitimement aux prescriptions fédérales, induisant l'idée d'une stratégie de régulation capillaire, qui naît à Washington et se prolonge ensuite en autant de solutions législatives ex post imaginées par les États.

Le domaine des produits de santé connaît aussi des soubresauts judiciaires similaires.

B. Les produits de santé : de Wyeth *à* Riegel

La question éminemment politique a de nouveau été abordée à l'occasion des affaires remarquées *Wyeth v Levine*[59] et *Riegel v Medtronic Inc*[60] dans le domaine, cette fois, des produits de santé et des dispositifs médicaux. Les faits qui sous-tendent la première affaire sont simples. La demanderesse s'est pourvue devant les tribunaux américains afin d'obtenir l'indemnisation du préjudice causé par un médicament anti-nauséeux fabriqué par le défendeur, utilisé dans le traitement des migraines. À la suite d'une erreur dans la procédure d'injection intraveineuse[61], le médicament a pénétré l'artère de la patiente, provoquant une gangrène à l'origine de l'amputation de son avant-bras. Elle allègue que l'avertissement du fabricant se devait de faire état des contre-indications relatives à cette technique d'injection, considérant les risques élevés qu'elle pose pour la santé des patients.

À la différence de l'arrêt *Cipollone*, la Cour rejette l'argument des défendeurs voulant que l'autorisation de mise en marché délivrée par

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[58] *Cipollone*, *supra* note 46 à la p 529, repris aussi dans *Altria*, *supra* note 55 à la p 16, juge Stevens (« the phrase 'based on smoking and health' fairly but narrowly construed does not encompass the more general duty to not make fraudulent statements »).

[59] 129 S Ct 1187, 555 US 555 (2009) [*Wyeth*].

[60] 552 US 312 (2008) [*Riegel*].

[61] Soulignons que le jury n'a pas considéré que cette erreur professionnelle constituait un *novus actus interveniens* susceptible d'occulter la responsabilité du défendeur dans *Wyeth*, *supra* note 59.

les autorités fédérales (ici, la FDA) fasse obstacle à l'introduction de l'action en responsabilité civile en vertu du droit positif étatique. Ces derniers posaient l'hypothèse de la préséance du droit fédéral sur le droit étatique à la lumière de deux arguments inspirés de l'affaire *Cipollone*. D'abord, et à supposer que le feuillet informatif eût dû, à l'issue d'une condamnation à des dommages-intérêts, être précisé pour satisfaire aux exigences posées par l'État du Vermont, la chose n'aurait pu être effectuée sans enfreindre le droit fédéral[62]; d'où un conflit de lois. Aussi, le maintien d'une action en responsabilité créerait un obstacle indésirable « à l'accomplissement et l'exécution des finalités et des objectifs que poursuit le Congrès »[63], parce qu'elle porterait, au regard de l'évaluation du ratio risque/bénéfice du médicament, à préférer le jugement des membres du jury à celui des experts de la FDA.

La Cour rappelle que la dimension constitutionnelle du litige appelle une analyse de l'intention du Congrès, « *[t]he ultimate touchstone* in every pre-emption case »[64] – et d'ajouter – « we start with the assumption that *the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress* »[65]. En l'absence d'un texte législatif clair – comme celui du *Consumer Protection Act* déjà évoqué –, la recherche de l'intention du Congrès dicte une analyse exégétique des textes de loi qui habilitent la FDA à prendre des mesures pour protéger la santé des personnes et assurer la sécurité des médicaments[66]. Aux yeux de la Cour et à la différence de loi contestée à l'occasion de l'affaire *Cipol-*

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[62] L'argument a été notamment mis de l'avant dans *Fidelity Federal Savings & Loan Association v De la Cuesta*, 458 US 141 (1982).

[63] *Hines v Davidowitz*, 312 US 52 à la p 67 (1941), cité dans *Wyeth*, *supra* note 59 à la p 7 [notre traduction].

[64] *Medtronic Inc v Lohr*, 518 US 470 à la p 485 (1996), cité dans *Wyeth*, *supra* note 59 à la p 8 [nos italiques]. Voir aussi *Retail Clerks v Schermerhorn*, 375 US 96 à la p 103 (1963), et les autre exemples cités par David C Vladeck, « Preemption and Regulatory Failure Risks » dans Buzbee, *supra* note 33 aux pp 61-64.

[65] *Wyeth*, *supra* note 59 à la p 8, référant à *Rice v Santa Fe Elevator Corp*, 331 US 218 à la p 230 (1947) [nos italiques].

[66] *Federal Food, Drug, and Cosmetic Act*, §202 52 Stat 130 (1937-38).

lone, le Congrès n'aurait jamais écarté l'idée qu'une action en responsabilité civile puisse être intentée sur la base d'un défaut d'information[67]. C'est dire que le fabricant répond, devant les victimes, des défauts d'information d'un médicament, même si la commercialisation de son produit est tributaire d'une autorisation de mise en marché qui s'étend à la teneur du feuillet informatif. La majorité du banc réitère ainsi la jurisprudence s'étant opposée auparavant à la dilatation de la préséance au droit pharmaceutique[68].

Dissidents, les juges Alito et Scalia militent en faveur de la préséance du droit fédéral (et de la FDA). Ils s'expriment ainsi : « turning a common-law tort suit into a 'frontal assault' on the FDA's regulatory regime for drug labeling *upsets the well-settled meaning of the Supremacy Clause and our conflict pre-emption jurisprudence* »[69]. Selon eux et dès lors qu'une stratégie de régulation a été esquissée à Washington, elle porte à l'effacement de la responsabilité civile[70]. C'est à cette solution que la Cour avait adhéré en 2008, à peine un an auparavant, dans le domaine des dispositifs médicaux.

Riegel v Medtronic Inc relate un cas d'espèce où la victime a tenté d'obtenir la réparation du préjudice causé par un cathéter médical défectueux. La même Cour s'est penchée sur la portée de la section 21

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[67] En outre – c'est là l'opinion de la Cour – le Congrès n'a jamais conditionné la mise à jour, par le fabricant, des avertissements contenus au feuillet informatif à un nouveau processus d'approbation par la FDA ; et même après lui conférer, en 2007, une compétence lui permettant d'exiger une modification dudit avertissement, il n'a pas davantage suggéré que l'industrie soit exemptée de l'obligation de mettre à jour les informations y contenues. La note prévoit : « Instead, it adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels » (*Wyeth*, *supra* note 59 aux pp 10-11).

[68] Voir notamment *Tobin v Astra Pharmaceutical Products*, 993 F2d 528 aux pp 537-38 (6e Cir 1993) ; Catherine Sharkey, « Federalism in Action : FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts » (2007) 15 JL & Pol'y 1013.

[69] *Wyeth*, *supra* note 59 à la p 3 [nos italiques].

[70] Voir par ex *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 US Dist LEXIS 95500 (ND Cal 2006).

USC §360k adoptée en 1976 au lendemain du très médiatisé scandale de Dalkon Shield[71], voulant que

> (a) […] *no State* […] may establish or continue in effect with respect to a device intended for human use *any requirement* –
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter[72].

La disposition emporte-t-elle la préséance? Dans quelle mesure? Avec David Vladeck[73], la seule véritable difficulté est celle de déterminer si le vocable *requirement* s'étend, ou non, à la responsabilité du fait des produits. S'exprimant au nom de la majorité, la Cour convient que la disposition sous examen formule bien une hypothèse de préséance[74]. En ce sens, elle observe : « State tort law that requires a manufacturer's catheters to be safer […] disrupts the federal scheme no less than state regulatory law to the same effect »[75]. La solution proposée par la Cour a pour effet de soustraire le secteur des dispositifs médicaux du domaine de la responsabilité civile.

En marge d'une rhétorique qui affaiblit les motivations, l'effet le plus déplorable de cette jurisprudence éclatée réside dans la variété des manifestations de préséances au regard de la nature du produit, malgré la similitude de textes normatifs héritiers de la volonté du législateur. Ceci concourt à fractionner la discipline des produits défec-

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[71] Voir notamment Joseph A Page, « Asbestos and the Dalkon Shield: Corporate America on Trial » (1987) 85 Mich L Rev 1324 à la p 1326, n 15.

[72] 21 USC §360k (a) (2011) [nos italiques].

[73] *Supra* note 64 aux pp 59-60.

[74] *Riegel*, *supra* note 60 à la p 898.

[75] *Ibid* à la p 903. (Dissidente, la juge Ginsburg conteste la trop vaste portée attribuée à la disposition objet du litige. Selon elle : « Congress […] *did not intend § 360k(a) to effect a radical curtailment of state common-law suits* seeking compensation for injuries caused by defectively designed or labeled medical devices » (aux pp 911-912) [nos italiques]. Dans la foulée de l'arrêt *Wyeth*, la disposition en litige n'aurait jamais voulu restreindre le domaine qui échoit à la responsabilité civile en vertu du droit étatique.)

tueux et embrumer d'autant la compréhension et la mise en œuvre du fédéralisme à l'américaine. Alors que les dispositifs médicaux et les produits dérivés du tabac sont assujettis à la règle de la suprématie du droit fédéral et bénéficient de son effet protecteur (et, pour autant, ils sont soustraits de la sphère de la responsabilité civile), les médicaments défectueux peuvent faire l'objet d'une action en indemnisation du préjudice fondée sur un *tort* issu du droit étatique. Les opinions majoritaires et dissidentes, qui matérialisent des positions en apparence irréconciliables, s'expliquent au regard de différences conceptions des liens qu'entretiennent les versants ex ante et ex post de l'effort de régulation des produits de santé.

D'un côté, l'on soutient que parce qu'elle revêt un caractère scientifique (du fait de l'immixtion de la FDA dans le processus de régulation), l'approche préventive au risque se suffit à elle-même et ne se prolonge pas au-delà de la matérialisation du dommage; de l'autre, on suggère (du moins implicitement) que la responsabilité civile agira par défaut, en présence de failles dans l'exercice de régulation préventif. Sur le plan strictement constitutionnel[76], la réflexion finit par recouper l'opposition entre les conceptions (néo)dualistes et polyphoniques d'un fédéralisme à l'américaine en quête évidente de repères conciliateurs[77]. Et l'on peut probablement supputer que de ces différentes opinions transparaît une propension à croire que les régulateurs sont plus à mêmes de définir les contours de la sécurité des produits que la magistrature (ou vice-versa).

L'UE propose une dynamique bien différente, même si des tensions politiques similaires s'observent en filigrane du cadre strictement juridique qu'il importe pourtant d'exposer.

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[76] Buzbee, *supra* note 33 à la p 100 et s.

[77] Voir par ex la reconstruction proposée par Erin Ryan, *Federalism and the Tug of War Within*, New York, Oxford University Press, 2011 (proposant un nouvel équilibre fédéral après avoir notamment constaté que la résurgence du dualisme alimente, *inter alia*, les litiges, surtout en matière de santé, d'environnement et de sécurité des produits, résumé aux pp 369-72) [Ryan].

II. L'Union européenne et l'idéal d'une construction *sui generis*

L'on conviendra, par-delà les débats entourant le « désert constitutionnel » dans lequel se trouve l'Europe (et que le *Traité de Lisbonne* n'a que partiellement irrigué)[78], que si la nature du projet politique qu'elle poursuit demeure ambiguë, elle nourrit en revanche abondamment la réflexion entourant la régulation suprationale des produits de consommation. Dans un tel contexte, le mot « fédéralisme » n'a longtemps été prononcé qu'au risque de la polémique[79]. Bien qu'il dépeigne une réalité palpable, on préfère encore le maquiller derrière des « bricolages sémantiques » (« eurosceptiques », « pro-européens », etc.)[80], plus susceptibles de dégager un consensus autour de l'opportunité, pour les États membres, d'abdiquer des parcelles de souveraineté au profit d'une entité supranationale politique et juri-

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[78] Joseph HH Weiler, « In Defence of the Status Quo: Europe's Constitutional *Sonderweg* » dans Joseph HH Weiler et Marlene Wind, dir, *European Constitutionalism Beyond the State*, Cambridge (R-U), Cambrige University Press, 2003, 7 à la p 7. Pour une reconstruction doctrinale et une synthèse théorique, voir Paul Craig, « Constitutions, Constitutionalism and the European Union » (2001) 7 Eur LJ 125 (à la p 135 et s), ou, plus récemment, Armin Von Bogdandy, « Founding Principles of EU Law: A Theoretical and Doctrinal Sketch » (2010) 16 Eur LJ 95 (qui discute à l'apport des principes au discours constitutionnel de l'UE aux pp 96-97) ; Neil Walker, « The Shifting Foundations of the European Union Constitution », University of Edinburgh School of Law Research Paper Series No 2012/18. Le refus, par l'Irlande et les Pays-Bas, d'adopter le Projet de constitution pour l'Europe a posé un important frein à cette évolution constitutionnelle, ayant plutôt débouché sur le moins évocateur (*Traité de Lisbonne modifiant le traité sur l'Union européenne et le traité instituant la Communauté européenne*, 13 décembre 2007, JOC 306 [*Traité de Lisbonne*]). Cela dit, la proclamation de la *Charte des droits fondamentaux de l'Union européenne* du 7 décembre 2000, laquelle, au sens de l'art 6 (1) *TFUE*, a « la même valeur que les traités », est à notre avis un adjuvant constitutionnel fort significatif.

[79] Hans-W Micklitz, Thomas Roethe et Stephen Weatherill, dir, *Federalism and Responsability: A Study on Product Safety Law and Practice in the European Community*, Londres, Graham & Trotman, 1994.

[80] Voir François Vergniolle de Chantal, *Fédéralisme et antifédéralisme*, Paris, Presses Universitaires de France, 2005 à la p 4.

dique[81]. Robert Schütze explique: « [i]n the absence of a theory of federalism beyond the State, European thought invented a new word – supranationalism – and proudly announced the European Union to be *sui generis* »[82]. Dans ce contexte, le vocable préséance n'a pas, jusqu'à tout récemment, véritablement intégré le vocabulaire des européanistes pour désigner la coordination des compétences de l'Union et des États membres.

Par contraste, les générations de juristes émergentes[83] semblent beaucoup moins réfractaires à la sémantique que sécrète un peu partout l'esthétique fédérale à l'américaine. Amedeo Arena, par exemple, décrit comme suit l'apport de la préséance au discours constitutionnel européen : « [c]ompetence-based definitions […] identify the notion of preemption as *a phenomenon indistinguishably linked either to the existence of an E.U. competence in the Treaties or to its actual exercise through the adoption of legislation* »[84]. L'on en comprend qu'à la différence du modèle américain, cette forme de préséance beaucoup plus vaste recoupe la détermination de l'étendue d'une compétence d'attribution autant que la légalité de sa mise en œuvre.

Un peu à l'instar de l'expérience canadienne[85], on le verra[86], les compétences de l'UE s'exercent au gré d'une approche mixte, à la fois

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[81] *Costa*, *supra* note 34. Le principe de la primauté du droit communautaire s'observe à travers *Van Gend Loos*, *supra* note 34 et *Brasserie du pêcheur*, *supra* note 34.

[82] Robert Schütze, *From Dual to Cooperative Federalism*, New York, Oxford University Press, 2009 à la p 3.

[83] Voir, *latu sensu*, Amedeo Arena, « The Doctrine of Union Preemption in the EU Internal Market: Between *Sein* and *Sollen* » (2010-11) 17 : 3 Colum J Eur L 477 aux pp 481-85 ; António Goucha Soares, « Pre-emption, Conflicts of Powers and Subsidiarity » (1998) 23 Eur L Rev 132. Voir aussi Anne van Aaken, « Supremacy and Preemption: A View from Europe » dans Epstein et Greve, *supra* note 32. Van Aaken précise que si la notion de « préséance » est surtout utilisée pour désigner le droit dérivé, elle dépend aussi de l'essence du droit primaire. Selon nous, sous cet angle, les sources du droit sont indissociables l'une de l'autre.

[84] Arena, *supra* note 83 à la p 483 [nos italiques].

[85] Voir *Loi constitutionnelle de 1867* (R-U), 30 & 31 Vict, c 3, reproduite dans LRC 1985, ann II, nº 5 (la constitution canadienne qui prévoit plutôt le partage des compétences par domaines en vertu des articles 91 et 92) [*LC 1867*].

fonctionnaliste et sectorielle. Dans la foulée de la conclusion du *Traité de Nice* (2000)[87] et de la *Déclaration de Laeken* (2001)[88], la signature du *Traité de Lisbonne* (2007)[89] marque un effort de résolution au fameux « problème des compétences » entre l'Union et les États membres[90], compétences que l'on veut exclusives (i.e. l'union douanière), partagées (dont la construction du marché intérieur) ou d'appoint, de coordination (dont la protection de la santé). Dépositaire d'un équilibre que cristallise le principe d'attribution et que véhiculent les bases juridiques[91], le respect des principes de subsidiarité (qui cherche à « *régler l'exercice des compétences* de l'Union qui sont des compétences d'attribution »[92]) et de proportionnalité (en vertu de laquelle « le contenu et la forme de l'action de l'Union n'excèdent pas ce qui est nécessaire pour atteindre les objectifs des traités »[93]) sont notamment (et notoirement) surveillées par la Cour de Justice de l'Union européenne (« CJUE », anciennement la Cour de justice des

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[86] Voir la section III, ci-dessus.

[87] *Traité de Nice modifiant le traité sur l'Union européenne, les traités instituant les communautés européennes et certains actes connexes*, 10 mars 2001, JOC 80.

[88] Conseil européen (CE), *Déclaration sur l'avenir de l'Union européenne*, 15 décembre 2001.

[89] *Supra* note 78.

[90] Pour une première introduction, voir Paul Craig et Gráinne de Búrca, *EU Law: Text, Cases, and Materials*, 5e éd, New York, Oxford University Press, 2011, ch 3 (portant sur la compétence).

[91] Voir le *Traité sur l'Union européenne*, art 5(2), 7 février 1992, JOC 83 [*TUE*] (« [e]n vertu du principe d'attribution, l'Union n'agit que dans les limites des compétences que les États membres lui ont attribuées dans les traités pour atteindre les objectifs que ces traités établissent. *Toute compétence non attribuée à l'Union dans les traités appartient aux États membres* » [nos italiques]).

[92] Jean-Louis Clergerie, Annie Gruber et Patrick Rambaud, *L'Union européenne*, 9e éd, Paris, Dalloz, 2012 au para 334 [italiques dans l'original]. Voir aussi Hans-W Micklitz et Stephen Weatherill, « Federalism and Responsibility » dans Micklitz, Roethe et Weatherill, *supra* note 79 (« [s]ubsidiarity is, in fact, itself a shorthand for questions about competence division, which is in turn inextricably linked with the federalist process » à la p 33).

[93] *TUE*, *supra* note 91, art 5, para 4, al 1. Voir aussi Clergerie, Gruber et Rambaud, *supra* note 92 aux paras 341-44.

communautés européennes)[94]. La détermination des marges discrétionnaires que module le partage des compétences s'effectue sous l'éclairage des normes de matrice « constitutionnelle » (soit le *Traité sur l'Union européenne* (« *TUE* »)[95]), et non à partir d'une reconstruction interprétative à l'américaine, qui trouverait son point de départ dans la loi faisant l'objet du litige. Déductive dans le premier cas, inductive dans l'autre, le recours à ces différentes techniques s'explique probablement par le caractère moderne plus fonctionnel du *TUE* que le texte constitutionnel américain, notamment, esquissé à une autre époque.

La sécurité des produits de consommation appartient-elle exclusivement au domaine de la création du marché intérieur? Est-elle dénuée de toute composante socialisante? Ces questions posent la problématique du fondement même de la protection des consommateurs et de la sécurité des produits, en même temps qu'elles soulèvent l'épineuse question de déterminer si la matière ne devrait pas acquérir ses lettres de noblesse. Au sein de l'UE, l'opportunité de doter celle-ci d'une politique sociale communautaire est à l'ordre du jour, bien qu'il ne soit pas certain qu'elle embrasse le domaine de la sécurité des produits (sauf à adopter une définition large qui agrée l'idée que les risques associés à la consommation *sont* une faille du marché). En effet, dans l'état actuel des choses, la politique sociale semble davantage viser le

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[94] Voir *TUE*, *supra* note 91, art 5(3):

> dans les domaines qui ne relèvent pas de sa compétence exclusive, l'Union intervient seulement si, et dans la mesure où, les objectifs de l'action envisagée ne peuvent pas être atteints de manière suffisante par les États membres, tant au niveau central qu'au niveau régional et local, mais peuvent l'être mieux, en raison des dimensions ou des effets de l'action envisagée, au niveau de l'Union.

Voir à ce sujet CE, Commission, *Rapport de la Commission sur la subsidiarité et la proportionnalité : 19e rapport «Mieux légiférer» 2011*, COM(2012) 373 Bruxelles, CE, 2012 à la p 7. Voir aussi Hogg, *supra* note 12 aux pp 5-12, 5-13 ; Erika Arban, « La subsidiarité en droit européen et canadien : une comparaison » (2013) 56 Administration publique du Canada 199 aux pp 225-30 ; *114957 Canada Ltée (Spraytech, Société d'arrosage) c Hudson (Ville)*, 2001 CSC 40, [2001] 2 RCS 241, 200 DLR (4e) 419 au para 3 [*Spraytech*].

[95] *TUE*, *supra* note 91.

droit de l'emploi, du logement, l'égalité des sexes ou la sécurité sociale[96]. La prééminence de la libéralisation des marchés maintes fois dénoncée par plusieurs civilistes européanistes pose un frein à la poursuite d'objectifs qui ne sont pas étroitement liés à la construction du marché intérieur[97]. En matière de sécurité des produits de consommation (incluant la responsabilité du fait des produits défectueux), l'exercice de ces compétences gravite autour de la création du marché intérieur (SOUS-SECTION B) et, dans une mesure moindre, la protection de la santé et la sécurité des consommateurs (SOUS-SECTION A), habituée qu'est cette discipline à osciller entre la protection d'intérêts économiques, consuméristes et relatifs à la santé des personnes. Leur coexistence, néanmoins, n'est pas toujours pacifique : des tensions sont d'ailleurs perceptibles à la lecture de la jurisprudence de la CJUE (SOUS-SECTION C). À bien y voir, le contentieux constitutionnel né de la synchronisation de ces objectifs semble graduellement rapprocher l'UE des parcours canadien et américain, par-delà le caractère beau-

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[96] Voir généralement Stephan Leibfried et Paul Pierson, « Multitiered Institutions and the Making of Social Policy » dans Stephan Leibfried et Paul Pierson, dir, *European Social Policy*, *Between Fragmentation and Integration*, Washington, The Brookings Institution, 1996 à la p 1 ; David M Trubek et Louise G Trubek, « Hard and Soft Law in the Construction of Social Europe: the Role of the Open Method of Co-ordination » (2005) 11 Eur LJ 343.

[97] Voir par ex Geraint Howells et Stephen Weatherhill, *Consumer Law Protection*, 2e éd, Dartmouth, Ashgate, 2005 aux pp 2-8 ; Trubek & Bourgoignie, *supra* note 13 aux pp 1, 6-12 ; Christian Joerges et Ernst-Ulrich Petersmann, dir, *Constitutionalism, Multilevel Trade Governance and Social Regulation*, Oxford, Hart, 2006 ; Stephen Weatherill, « The Constitutional Competence of the EU to Deliver Social Justice » (2006) 2 European Review of Contract Law 136 aux pp 139-41; Tamara K Hervey et Jean V McHale, « Law, Health and the European Union » (2006) 25 LS 228 à la p 242 (qui soulignent que « [a]ny social policy regime within the EU (including health policy) *must now take its place within the 'constitutional' construct of the internal market*, the law of which has been one of the fundamental drivers of the internal market » [nos italiques]). Un débat similaire anime le droit des contrats. Voir par ex Thomas Wilhelmsson, « The Legal, The Cultural and the Political: Conclusions from Different Perspectives on Harmonisation of European Contract Law » (2002) 13 Eur Bus L Rev 541. Comparer Oliver Gertensberg, « Private Law and the New European Constitutional Settlement » (2004) 10 Eur LJ 766.

coup plus centralisateur de ce dernier (du moins lorsqu'il s'agit de la régulation des produits de consommation)[98].

A. La santé et la sécurité des consommateurs

D'un point de vue historique[99], de fragiles racines d'une compétence communautaire en matière de santé et de sécurité des personnes sont ancrées dans le *Traité Euratom* de 1957 visant la prolifération des industries nucléaires[100]. Jusqu'en 1992, cependant, la Communauté économique européenne était dépourvue de toute compétence expresse en matière de santé, même si des traces d'une gestion supranationale des risques étaient perceptibles au travers du droit dérivé[101]. De fait, il aura a fallu attendre l'entrée en vigueur du *TUE* et de son article

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[98] À titre d'exemple, la jurisprudence et la doctrine tissées autour du Xième amendement sont révélatrices de ces parcours constitutionnels distincts; voir US Const Amend X (« [t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people »). Certains auteurs voient toutefois dans cet amendement le fondement juridique permettant une approche dialogique au partage des compétences. Voir Ryan, *supra* note 77 à la p 370. D'autres fondements constitutionnels concourent aussi à configurer le fédéralisme américain (la *commerce clause*, le XI[ième] amendement). Voir George A Bermann, *Regulatory Federalism: European Union and United States* (*Académie de droit international : Recueil des cours*, t 263), La Haye, Martinus Nijoff Publishers, 1997 aux pp 100-114.

[99] Voir Johannes Dommers, « An Introduction to European Union Health Law » (1997) 4 Eur J Health L 19 ; Anne Pieter Van der Mei et Lisa Waddington, « Public Health and the Treaty of Amsterdam » (1998) 5 Eur J Health L 129; et surtout Tamara K Hervey, « Mapping the Contours of European Union Health Law and Policy » (2002) 8 European Public Law 1.

[100] Celui-ci contient des dispositions spécifiques visant la protection des populations contre les radiations ionisantes (art 30-39). Certaines directives s'autorisent de cette base juridique. Voir par ex CE, *Directive 96/29/Euratom du Conseil du 13 mai 1996 fixant les normes de base relatives à la protection sanitaire de la population et des travailleurs contre les dangers résultant des rayonnements ionisants*, [1996] JOL 314/20.

[101] Exacerbée par la libre circulation des marchandises, la crise des vins austro-italiens frelatés – des produits auxquels de l'éthanol avait été ajouté dans le but d'en faciliter la fermentation – a pourtant illustré, en 1985, les dangers liés à une pluralité de registres en matière de gestion des risques. Voir CJCE du 4 juillet 1989, *Francesconi et Commission*, affaires jointes C-326/86 et C-66/88 [1989] ECR II-2087.

129A[102] pour voir poindre à l'horizon une politique sociale de matrice communautaire. Pour la première fois, le droit primaire prenait acte de la spécificité de la protection des consommateurs en lui réservant un *Titre* distinct (« Protection des consommateurs »), chapeautant des dispositions enjoignant à la communauté européenne d'atteindre des niveaux élevés de protection des consommateurs et de la santé humaine « dans la mise en œuvre de toutes ses politiques », incluant le marché intérieur[103]. Cette formule souple cristallisait un compromis visant à concilier la volonté de certains États membres à doter la communauté européenne d'une compétence spécifique en matière de santé avec l'attitude réfractaire de ceux qui préféraient qu'elle demeure l'apanage des États membres.

Malgré sa portée limitée, subordonnée à l'exercice des autres compétences qui échoient aux institutions de l'UE (dont, *in primis*, la création du marché intérieur)[104], cette disposition marquait l'insertion d'un agenda juridique transversal, jusqu'à ce que les crises de la vache folle et du sang contaminé viennent à ébranler ce nouvel équilibre « confédératif » que l'on croyait avoir atteint. Ceci explique qu'à peine cinq ans plus tard, le *Traité d'Amsterdam* (1997) est venu remodeler l'arrimage entre les compétences communautaires et nationales. En marge de certains domaines énumérés de manière exhaustive par le législateur[105] (dont le sang et les produits y dérivés[106] ou la sécurité ali-

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[102] *Supra* note 91. L'article 129A est devenu, après modification, l'art 168 *TFUE*, *supra* note 35).

[103] *TFUE*, *supra* note 35 art 168.

[104] Tamara K Hervey et Jean McHale, *Health Law and the European Union*, Cambridge (Mass), Cambridge University Press, 2004, aux pp 73-74. Voir aussi Howells et Weatherill, *supra* note 97 aux pp 462-63, et plus généralement Vassilis Hatzopoulos, « Health Law and Policy: The Impact of the EU » dans Gràinne de Búrca, dir, *EU Law and the Welfare State: In Search of Solidarity*, Oxford, Oxford University Press, 2005, 111.

[105] *Traité d'Amsterdam modifiant le Traité sur l'Union européenne, les traités instituant les Communautés européennes et certains actes connexes*, 10 novembre 1997, JOC 340, art 152, aux para 4 et 5 [*Traité d'Amsterdam*]. Le choix de ne pas procéder à un « catalogue de compétences » – à l'instar du Canada – découle pourtant d'un choix éclairé du législateur. Quant à contexte, voir Bermann, *supra* note 98 à la p 79.

mentaire[107], justement), la protection des consommateurs, comme d'autres politiques sociales de l'UE, demeure avant tout subordonnée à l'atteinte de l'objectif de libéralisation des marchés, entretenant avec lui un rapport synergétique[108]. Son caractère programmatique a maintes fois été rappelé par la CJUE, qui lui reconnaît néanmoins un rôle interprétatif de premier plan.

À ce jour, donc, la santé et la sécurité des consommateurs demeure avant tout une affaire étatique, même si les institutions communautaires sont dorénavant investies d'un pouvoir de coordination des diverses actions nationales. Le *Traité de Lisbonne*[109] réitère implicitement cet équilibre qu'atteint le droit primaire. L'article 168 *TFUE*[110]

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[106] Voir par ex CE, *Directive 2002/98/CE du Parlement et du Conseil du 27 janvier 2003 établissant des normes de qualité et de sécurité pour la collecte, le contrôle, la transformation, la conservation et la distribution du sang humain, et des composants sanguins, et modifiant la directive 2001/83/CE*, [2003] JOL 33/30.

[107] Voir par ex CE, *Règlement 999/2001/CE du Parlement européen et du Conseil du 22 mai 2001 fixant les règles pour la prévention, le contrôle et l'éradication de certaines encéphalopathies spongiformes transmissibles*, [2001] JOL 147/1 ; CE, *Directive 2003/74/CE du Parlement européen et du Conseil du 22 septembre 2003 modifiant la directive 96/22/CE du Conseil concernant l'interdiction d'utilisation de certaines substances à effet hormonal ou thyréostatique et des substances ß-agonistes dans les spéculations animales*, [2003] JOL 262/17 ; CE, *Règlement 2160/2003/CE du Parlement européen et du Conseil du 17 novembre 2003 sur le contrôle des salmonelles et d'autres agents zoonotiques spécifiques présents dans la chaîne alimentaire*, [2003] JOL 325/1 ; CE, *Règlement 1829/2003/CE du Parlement européen et du Conseil du 22 septembre 2003 concernant les denrées alimentaires et les aliments pour animaux génétiquement modifiés*, [2003] JOL 268/1 qui prennent ancrage dans le *Traité d'Amsterdam*, *supra* note 105 art 152, para 4(b).

[108] En ce sens, pour le CE, « *[l]es consommateurs sont, avec les entreprises, des acteurs clés au sein du marché intérieur.* Le bon fonctionnement du marché intérieur favorisant la confiance des consommateurs dans les transactions transfrontalières aura un effet bénéfique sur la concurrence, ce qui profitera aux consommateurs » [nos italiques] (CE, *Résolution du Conseil du 2 décembre 2002 relative à la stratégie pour la politique des consommateurs de la Communauté 2002-2006*, [2003] JO, C11/1 au para 3).

[109] *Supra* note 78.

[110] *Supra* note 35.

accorde une attention particulière aux effets et aux causes de la dégradation de la santé humaine; il se juxtapose pourtant aux autres politiques communautaires sans jamais s'en affranchir totalement[111]. En ce sens, ses deuxième et troisième paragraphes aménagent les relations entre l'UE et les États membres en termes de coopération.

L'interprétation conjuguée des articles 168 et 169 *TFUE* peut-elle poser les bases à une véritable politique permettant d'accroître la sécurité des produits, à travers, précisément, le prisme de la création du marché[112] ? La réponse est nuancée.

B. La centralité de la création du marché intérieur

Au sein de l'UE, le marché intérieur occupe « un espace sans frontières intérieures dans lequel la libre circulation des marchandises, des personnes, des services et des capitaux est assurée selon les dispositions du présent traité »[113]. À ce titre, il poursuit l'objectif plus général décrit à l'article 3h intégré au *TFUE*, en vertu duquel « [l]'action de la communauté comporte le *rapprochement des législations nationales dans la mesure nécessaire au fonctionnement du marché commun* »[114]. Techniquement, les compétences communautaires poursuivant cette finalité puisent leur source des processus d'unanimité[115] et de codécision (à majorité qualifiée du Conseil et du Parlement)[116]. À la diffé-

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[111] Voir par ex *TUE*, *supra* note 91, art 3, para 1 et art 152, para 1 ; *Commission c Conseil*, C-269/97, [2000] ECR I-02257 ; CE, *Résolution du Conseil du 18 novembre 1999 concernant la garantie de la protection de la santé dans toutes les politiques et actions de la Communauté*, [2000] JOC 86/3.

[112] Le *Règlement 1829/2003*, *supra* note 104 (17e considérant) et CE, *Règlement 1371/2007/CE du Parlement Européen et du Conseil du 23 octobre 2007 sur les obligations des voyageurs ferroviaires*, [2007] JOL 315/14 font figure d'exception. Pourtant, la CE, *Résolution du Conseil du 31 mai 2007 relative à la stratégie communautaire en matière de politique des consommateurs pour la période 2007-2013*, [2007] JOC 166/1 les appréhende ensemble.

[113] *TFUE*, *supra* note 35, art 26, al 2.

[114] *Ibid*.

[115] *Ibid*, art 115.

[116] *Ibid*, art 114 (1) qui réfère à la « procédure ordinaire » née de l'*Acte unique européen* (1986) destiné à catalyser la formation du marché commun. Il dispose que le Conseil peut à l'unanimité « arrête[r] des directives pour le rapprochement des dis-

rence – on l'a dit – des compétences diaphanes portant sur la santé des personnes et la protection des consommateurs[117], ces dispositions habilitent les institutions de l'UE à générer du droit dérivé, incluant des directives et des règlements[118].

Il dispose que le Conseil peut, à l'unanimité « arrêter des directives pour le rapprochement des législations des États membres qui ont une *incidence directe sur l'établissement ou le fonctionnement du marché commun* »[119]. Parce que ledit rapprochement, l'harmonisation, vise souvent les conditions de fabrication, d'emballage, ou d'étiquetage, plusieurs directives « de première génération » adoptées sous son égide (dont celles visant les denrées alimentaires et les automobiles) produisent des effets bien palpables en matière de santé des personnes. Les exemples abondent[120]. Or c'est aussi de cette base juridique que s'autorise la Directive « produits défectueux »[121].

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positions législatives […] des États membres qui ont une *incidence directe sur l'établissement ou le fonctionnement du marché intérieur* » (*ibid*, art 115 [nos italiques]).

[117] *Ibid*, art 168-169.

[118] *Ibid*.

[119] *TUE*, *supra* note 91, art 94 [nos italiques].

[120] Michel Bélanger, *Les communautés européennes et la santé*, Bordeaux, Presses Universitaires de Bordeaux, 1985 à la p 9. Voir par ex CEE, *Directive du Conseil du 26 janvier 1965 concernant le rapprochement des dispositions législatives, réglementaires et administratives, relatives aux spécialités pharmaceutiques*, [1965] JOL 369/65 ; CEE, *Directive du Conseil du 21 mai 1973 modifiant la directive, du 27 juin 1967, concernant le rapprochement des dispositions législatives, réglementaires et administratives relatives à la classification, l'emballage et l'étiquetage des substances dangereuses*, [1973] JOL 167/1 ; CEE, *Directive du Conseil du 6 février 1970 concernant le rapprochement des législations des États membres relatives au niveau sonore admissible et au dispositif d'échappement des véhicules à moteur*, [1970] JOL 42/16 ; CEE, *Directive du Conseil du 13 juillet 1970 relative au rapprochement des législations des États membres concernant les substances ayant des effets antioxygènes et pouvant être employées dans les denrées destinées à l'alimentation humaine*, [1970] JOL 157/31 ; CEE, *Directive du Conseil relative au rapprochement des règlementations des États membres concernant les matières colorantes pouvant être employées dans les denrées destinées à l'alimentation humaine*, [1962] JOL 2645/62 ; CEE, *Directive du Conseil du 26 juin 1964 relative à des problèmes sanitaires en matière d'échanges intracommunautaires de viandes*

D'un point de vue politique, pourtant, la mise en œuvre de cette base juridique a soulevé d'importantes difficultés d'une nature avant tout procédurale[122] : devant l'élargissement imminent de la Communauté économique européenne, son processus d'adoption à l'unanimité était menacé de paralysie. Il devenait alors opportun de lui adjoindre une procédure d'adoption plus flexible, matérialisant un consensus majoritaire. En 1987 naissait l'article 100A CEE (devenu 95 CE, puis 114 *TFUE*) devant contribuer au parachèvement du marché intérieur, permettant en même temps la prise d'actes communautaires touchant accessoirement la santé des personnes et la consommation[123]. En ce sens, l'article 114, paragraphe 3 *TFUE* prévoit que dans l'harmonisation réalisée, un niveau élevé de protection de la santé des personnes est garanti[124]. Mue par des pulsions ordolibérales, cette

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fraîches, [1964] JOL 2013/64 *;* CEE*, Directive du Conseil du 27 juillet 1970 concernant le rapprochement des législations des États membres relatives aux portes des véhicules à moteur et de leurs remorques*, [1970] JOL 176/5 ; CEE*, Directive du Conseil du 22 juillet 1974 concernant le rapprochement des législations des États membres relatives à l'aménagement intérieur des véhicules à moteur (résistance des sièges et de leur ancrage)*, [1974] JOL 221/1.

[121] *Supra* note 18. La prémisse qui la sous-tend veut qu'une responsabilité civile fragmentée se pose en porte-à-faux du principe de la sécurité juridique. En ce sens, son 1er considérant pose que le rapprochement des législations « est nécessaire du fait que *leur disparité est susceptible de fausser la concurrence, d'affecter la libre circulation des marchandises* au sein du marché commun et *d'entraîner des différences dans le niveau de protection du consommateur* contre les dommages causés à sa santé et à ses biens par un produit défectueux » [nos italiques]. Parce que la responsabilité des produits défectueux entretient des liens étroits avec l'idée d'une distribution à grande échelle, l'on suppute que de telles variations législatives freinent la vie économique.

[122] Scott Crosby, « The Single Market and the Rule of Law » (1991) 16 : 6 Eur L Rev 451.

[123] Voir par ex CEE, *Directive du Conseil du 16 juin 1988 modifiant la directive 70/220/CEE concernant le rapprochement des législations des États membres relatives aux mesures à prendre contre la pollution de l'air par les gaz provenant des moteurs équipant les véhicules à moteur (Limitation des émissions de particules polluantes par les moteurs diesel)*, [1988] JOL 214/1.

[124] *Supra* note 35. Il précise que :

> [l]a Commission, dans ses propositions prévues au paragraphe 1 en matière de santé, de sécurité, de protection de l'environnement et de protection des Consommateurs, *prend pour base un niveau de protection élevé en tenant compte*

symbiose entre l'objectif de libéraliser des marchés et celui de protéger la santé des consommateurs a ceci de nouveau que pour la première fois, le droit primaire verbalise l'importance respective de ces deux finalités[125].

Par exemple, la Directive 2001/95/CE sur la sécurité des produits dicte, à l'instar de la *Loi canadienne sur la sécurité des produits de consommation*[126] et la *Consumer Product Safety Act*[127], que tous les produits doivent être sûrs[128]. Elle s'autorise exclusivement de cette base juridique[129], bien que son premier considérant traduise également la nécessité de prendre acte de l'évolution d'un acquis communautaire qui se forme autour de la santé publique, la protection des consommateurs, et le principe de précaution[130]. Cette Directive dépeint une approche préventive à la matérialisation des risques, qu'accompagnent des mécanismes d'autorégulation et de certification visant à assurer un haut niveau de qualité des produits. La dialectique de l'harmonisation

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> *notamment de toute nouvelle évolution base sur des faits scientifiques*. Dans le cadre de leurs compétences respectives, le Parlement européen et le Conseil s'efforcent également d'atteindre cet objectif [nos italiques].

[125] Faut-il toutefois préciser que dans le contexte de la création du marché interne et dès 1957, le couple que formaient les art 30 (posant le principe de la libre circulation des marchandises) et 36 CEE (mesures de sauvegardes possibles dans certaines circonstances) proposait un équilibre inspiré de la même idée.

[126] *Supra* note 3.

[127] *Ibid*.

[128] *Directive « sécurité des produits »*, *supra* note 3, art 3 au para 1.

[129] *Ibid*, 3e considérant :

> [e]n l'absence de dispositions communautaires, la législation horizontale des États membres sur la sécurité *des produits […] pourrait diverger quant au niveau de protection offert aux consommateurs* ». Le texte rappelle encore que « [c]es disparités, ainsi que l'absence de législation horizontale dans certains États membres, *sont susceptibles de créer des obstacles aux échanges et des distorsions de la concurrence dans le marché intérieur* [nos italiques].

[130] *Ibid*, 1er considérant.

des législations n'est pas théorique; une base juridique bancale, purement cosmétique, emporte l'*ultra vires*[131].

C. La dialectique des bases juridiques et la CJUE

La coordination entre le droit primaire (issu des Traités constitutifs) et le droit dérivé (les directives ou les règlements) induit une composante constitutionnelle qui infléchit inévitablement les choix de régulation des produits, dès lors que la validité du second est tributaire de la pertinence de la base juridique de laquelle elle s'autorise. En pratique, les décisions rendues par la CJUE à l'issue d'un contrôle de légalité[132], en manquement[133] ou en réponse à des questions préjudicielles[134] forment un corpus jurisprudentiel qui évoque un véritable contrôle de constitutionnalité des directives ou des règlements communautaires, qu'éclairent les principes de proportionnalité et de subsidiarité. D'un point de vue herméneutique, ce sont souvent les motivations contenues aux « considérants »[135] des textes harmonisés qui permettent d'extraire les éléments permettant de juger de l'adéquation entre le but visé par le législateur et les mesures prises pour y parvenir. Deux exemples jurisprudentiels recoupant les hypothèses avancées par Amadeo Arena[136] permettent d'illustrer ce phénomène : les affaires portant sur la publicité du tabac (1) et l'interprétation de la Directive «produits défectueux»[137] (2). De leur analyse, on comprend que la variable constitutionnelle configure réellement le partage des compétences entre les États membres et le législateur de l'UE.

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[131] Voir Bertrand Peter, « La base juridique des actes communautaires en droit européen » (1994) Rev Marché Com 324 ; Nicholas Emiliou, « Opening Pandora's Box : The Legal Basis of Community Measures Before the Court of Justice » (1994) 19 : 5 Eur L Rev 488.

[132] *TFUE*, *supra* note 35, art 263.

[133] *Ibid*, art 258.

[134] *Ibid*, art 267.

[135] Art 253 CE.

[136] *Supra* note 83.

[137] *Supra* note 18.

1. La prévention des atteintes à la santé des consommateurs

Allemagne c Parlement et Conseil[138] *:* la célèbre affaire portant sur la publicité du tabac est emblématique des obstacles auxquels se heurte la discipline de la santé et la sécurité des consommateurs dans sa tentative d'accéder à l'autodétermination. Elle témoigne de la déconfiture d'un acte communautaire dont la charpente s'est écroulée, à défaut de s'être érigée sur des bases constitutionnelles appropriées. Le contexte factuel est le suivant. Dans la mouvance occidentale, l'UE a subordonné la vente de produits dérivés du tabac au respect de certaines exigences liées à leur fabrication et aux modalités de leur mise en marché[139]. Dans cette optique, la Directive 98/43/CE annonçait son tribut à la création du marché intérieur[140], « considérant qu'il existe des *divergences entre les dispositions législatives réglementaires et administratives des États membres* en matière de publicité et de parrainage en faveur des produits du tabac; que […] ces disparités sont de nature […] *à faire de cette façon obstacle au fonctionnement du marché intérieur* »[141]. Afin d'obtenir l'annulation de l'acte communautaire, la demanderesse – portée par de puissants lobbies – a allégué la prépondérance de l'objectif réel visant à protéger la santé des consommateurs sur celui, artificiel, visant faciliter le fonctionnement du marché, et ce, contrairement à la lettre et à l'esprit de l'*ex* article 95 du

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[138] *Allemagne c Parlement et Conseil de l'Union europeenne*, C-376/98, [2000] ECR 8419 [*Affaire Tabac*], commentée notamment par Tamara Hervey, « Community and National Competence in Health After Tobacco Advertising » (2001) 38 : 6 CML Rev 1421 ; Devika Khanna, « The Defeat of the European Tobacco Advertising Directive: A Blow for Health » (2001) 20 YEL 113. Voir Stephen Weatherill, « European Private Law and the Constitutional Dimension » dans Cafaggi, *supra* note 6 à la p 79.

[139] Voir Tamara Hervey, « Up in Smoke? Community (Anti)-Tobacco Law and Policy » (2001) 26 : 2 Eur L Rev 101.

[140] CE, *Directive du conseil du 30 juillet 1998 en matière de publicité et de parrainage en faveur des produits du tabac*, [1998] JOL 213/9 à la p 11 (celle-ci laissait aux États membres toute la latitude voulue pour « prescrire, dans le respect du traité, *des exigences plus strictes qu'ils estiment nécessaires pour assurer la protection de la santé des personnes en matière de publicité ou de parrainage de produits du tabac* », traduisant une forme d'harmonisation minimale [nos italiques]).

[141] *Ibid*, 1er considérant [nos italiques].

Traité instituant la communauté européenne[142], qui prévoit plutôt, on l'a dit, la subordination du premier au second. De leur opinion, l'acte communautaire s'avérait, tout court, *ultra vires* à défaut par les institutions communautaires d'avoir été investies des compétences d'attribution lui permettant de l'arrêter.

Avalisant cet argument, la CJCE observe que l'« objectif principal » de la directive est celui de la protection de la santé publique, un domaine qui échoit aux états membres. Elle rappelle qu'étant de nature programmatique, l'*ex* article 129 du *Traité instituant la communauté européenne* visant la protection de la santé exclut expressément toute forme d'harmonisation des législations nationales : inchoative, sa dynamique ne lui permet que de jouer un rôle à *l'intérieur des autres politiques* de l'UE[143]. En l'espèce, c'est surtout l'absence de marché intégré autour des publicités du tabac (qui prennent souvent acte des particularités socioculturelles locales pour mieux attendre leur clientèle cible) qui porte la Cour à conclure à l'absence de proportionnalité entre la Directive 98/43/CE[144] et la finalité réelle poursuivie (la protection des consommateurs). Pour cette raison, elle a annulé la directive en son ensemble[145].

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[142] 24 décembre 2002, C 325/35.

[143] *Ibid* aux paras 77 à 79.

[144] *Supra*, note 140.

[145] *Affaire Tabac*, *supra* note 138 aux para 83 et 84. Voir aussi *British American Tobacco (Investments) et Imperial Tobacco*, C-491/01, [2002] ECR 11453 au para 60 ; *The Queen c Secretary of State for Health*, C-491/01, [2002] ECR 11453 (soulignons ici l'étrange position du R-U, qui s'est rallié à la position de la Commission dans la défense de la 1ere directive et qui s'est porté demandeur afin de rechercher l'annulation de la 2e) ; *Arnold André c Landrat des Kreises Herford*, C-434/02, [2004] ECR 11825 au para 30 ; *Swedish Match c Secretary of State for Health*, C210/03, [2004] ECR 11893 au para 29 [*Swedish Match*] ; *Alliance for Natural Health c Secretary of State for Health*, C-154/04 et C-155/04, [2005] ECR 6451 au para 28. D'autres directives issues de domaines différents ont fait l'objet de procédures en annulation pour le même motif : voir, en matière environnementale, Nina Ost, « *European Parliament* v. *Council*, Joined Cases C-164/97 and C-165/97 (Legal Basis for Forest Protection Measures) » (1999) 8 : 3 RECIEL 349 ; en propriété intellectuelle : *Pays-Bas c Parlement et Conseil de l'Union européenne*, C-377/98, [2001] ECR 7079; et en matière de collecte de données person-

Par contraste, la CJCE a statué que la Directive 2001/37/CE en matière de fabrication, de présentation et de vente des produits du tabac esquissée en réponse à l'annulation de sa prédécesseure, s'érige sur une base juridique adéquate[146]. S'agissant, cette fois, de juger de l'opportunité d'asseoir la prohibition de la mise en circulation de « snus » (poudre de tabac humide) au regard de l'*ex* article 95 du *Traité instituant la communauté européenne*, la CJCE prend acte de l'exigence de protection de la santé des personnes et anticipe l'apparition de disparités des législations, parce qu'il est « vraisemblable que des obstacles à la libre circulation de ces produits [surgissent] *en raison de l'adoption par les États membres de nouvelles règles, reflétant cette évolution*, destinées à décourager plus efficacement la consommation de ces produits »[147]. Tempérant fortement la rigidité de la jurisprudence cristallisée dans l'*Affaire Tabac*, la CJCE statue que « le législateur communautaire ne saurait être empêché de se fonder sur [la base juridique relative à la création du marché] du fait que la protection de la santé publique est déterminante dans les choix à faire »[148].

Même à l'issue de cette brève analyse, on peut supposer que dans la foulée des expériences canadienne et américaine, l'UE est de moins en moins réfractaire à la centralisation des compétences en matière de sécurité des produits et son double, la protection des consommateurs. Or, cette préséance graduelle du droit de l'UE sur le droit privé des États membres qu'insuffle la CJCE est aussi visible à l'étude de responsabilité civile. S'agissant de sa composante constitutionnelle, celle-ci s'articule autour de la dialectique de l'harmonisation minimale

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nelles : *Irlande c Parlement et Conseil de l'Union europeenne*, C-301/06, [2009] ECR 0000. En 2003, d'importantes retouches ont permis à une nouvelle directive portant sur la publicité et le parrainage des produits du tabac de satisfaire aux prescriptions dictées par le droit primaire : voir CE, *Directive du conseil du 20 juin 2003 en matière de publicité et de parrainage en faveur des produits du tabac*, [2003] JOL 152/16.

[146] CE, *Directive du conseil du 18 juillet 2001*, [2001] JOL 194/26 (le litige est né d'une question préjudicielle posée dans le contexte du refus, par le R-U, d'accès au marché d'un produit du tabac nommé « snus » en provenance de la Suède).

[147] *Swedish Match*, *supra* note 145.

[148] *Ibid* au para 30.

(*bottom up*, plancher) et de l'harmonisation totale (*top down*, centralisatrice). Ceci n'est pas sans rappeler, dans une certaine mesure, l'interprétation que préconisent ici et là les cours suprêmes canadienne et américaine au regard, d'un côté, de la théorie de la prépondérance, et, de l'autre, de la *preemption*.

2. L'indemnisation du fait des produits défectueux

Subsidiarité oblige, l'harmonisation minimale est souvent privilégiée dans le domaine de la protection des consommateurs parce qu'elle permet le nivellement des législations sans écarter la possibilité que les États membres puissent maintenir des formes de protection plus favorables aux consommateurs[149]. Paradoxalement, elle tend aussi à fragmenter un marché qu'elle tente pourtant d'unifier : ajoutant à une pluralité de règles juridiques nationales une strate normative supranationale optionnelle[150], elle produit en quelque sorte des résultats contraires aux effets recherchés, dès lors qu'elle laisse libre-cours à des solutions juridiques multiples, éclatées. Voilà pourquoi on lui préfère parfois l'harmonisation totale, qui réduit – sinon anéantit – les marges de transposition discrétionnaires des États membres au profit

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[149] Dans un autre domaine, voir par ex CE, *Directive du conseil du 7 avril 2004 relative à l'établissement de normes de qualité et de sécurité pour le don, l'obtention, le contrôle, la transformation, la conservation, le stockage et la distribution des tissus et cellules humains*, [2004] JOL 102/48 (où l'art 4 prévoit un seuil d'harmonisation minimale: « La présente directive n'empêche pas un État membre de maintenir ou d'introduire des mesures de protection plus strictes […] »).

[150] Marie-Eve Arbour, « Armonizzazione del diritto, protezione delle tradizioni giuridiche e l'interpretazione della Corte di giustizia della direttiva 374/85/CEE» [2003] Danno e responsabilità 375. Plus récemment, l'argument est aussi repris dans CE, *Proposition de Directive relative à l'harmonisation des législations des États membres concernant la mise à disposition sur le marché d'articles pyrotechniques*, [2011] COM/2011/0764 final – 2011/0358 à la p 8. Voir aussi, par analogie, un phénomène australien, là où le *Trade Practices Act* a, selon certains, « added another layer of complexity to tort law without creating any real prospect of a uniform Australian product-liability regime » (Kit Barker et al, *The Law of Torts in Australia*, South Melbourne, Oxford University Press, 2012 aux pp 656-57).

d'une solution uniforme[151]. Entre ces deux pôles, plusieurs autres techniques de régulation des marchés existent (autorisations administratives, références à des normes techniques, etc.) : c'est chose déjà dite.

Or, l'absence de précisions claires quant au modèle envisagé soulève d'importantes difficultés qu'engendre la juxtaposition de ces méthodes de rapprochement des normes juridiques au sein d'un même texte juridique, et dont témoigne une célébrissime trilogie rendue par la CJCE le 25 avril 2002[152]. Ces décisions naissent toutes trois des difficultés d'interprétation soulevées par l'article 13 de la Directive « produits défectueux » qui précise que « [la Directive] ne porte pas atteinte aux droits dont la victime d'un dommage peut se prévaloir *au titre du droit de la responsabilité contractuelle ou extra-contractuelle* ou *au titre d'un régime spécial de responsabilité* [national] ».[153]

Deux d'entre elles sont nées d'un recours en manquement intenté par la Commission pour défaut de conformité aux prescriptions de la Directive; la troisième, d'une question préjudicielle adressée à la CJCE par un tribunal national espagnol. Elles semblent toutefois soulever une problématique similaire. C'est qu'au passage du processus de transposition, les législateurs nationaux avaient réitéré certaines protections favorables aux consommateurs, dont le principe de la transmissibilité des obligations accessoires au contrat et le renversement du fardeau de la preuve relative à la défense des risques de développements. Était-ce contraire à l'esprit du texte communautaire? La CJCE a écarté l'hypothèse de l'harmonisation minimale en condam-

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[151] Un arrêt rendu dans le contexte de la libre circulation des données à caractère personnel semble étayer cette hypothèse, alors que la CJCE conclut au caractère total de l'harmonisation poursuivie par le législateur communautaire : *Lindqvist*, C-101/01, [2003] ECR I-12992 aux paras 96-98. Voir aussi, en droit des contrats, CE, *Proposition de Règlement relatif à un droit commun européen de la vente*, [2011] COM/2011/0635 final – 2011/0284 à la p 11.

[152] La référence est à la trilogie de la CJCE rendue le 25 avril 2002, composée de : *Commission c France*, C-183/00 [2002] Rec CE 3827 ; *Gonzalez Sanchez c Medicina Asturiana SA*, C-183/00 [2002] Rec CE 3901 [*Sanchez*] ; *Commission c Grèce*, C-154/00, [2002] Rec CE 3879.

[153] *Supra* note 18 [nos italiques].

nant les défenderesses pour défaut de transposition, pour le motif que ces ajouts constituaient un déphasage inopportun entre les sources du droit communautaire et nationales, contraire à l'économie générale de la Directive[154]. Aux yeux de la Cour, la Directive « produits défectueux » propose, dirons-nous, un menu du jour : il n'est pas loisible au client d'en substituer certaines composantes par les choix qu'offre, par ailleurs, la carte, sauf si le restaurateur le lui permet. Elle estime qu'en marge des possibilités expressément prévues à même le communautaire[155], la base juridique « marché intérieur » (art 115 *TFUE*) dont se réclame le 1er considérant « … ne prévoit aucune faculté pour les États membres de maintenir ou d'établir des dispositions s'écartant des mesures d'harmonisation communautaires »[156]. C'est là que le bât blesse : la Directive ne consacrerait pas exclusivement une logique de protection des consommateurs. Elle traduirait plutôt un compromis – est-il mauvais? – entre les intérêts du monde des affaires (la sécurité juridique) et ceux des victimes (l'indemnisation du préjudice subi) au regard des risques que posent les défauts d'un produit. En clair et aux yeux de la CJCE, la Directive est un texte d'harmonisation *partiellement totale*…

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[154] Soit les art 15 (1) b) et 16, et quelques références qui sont faites aux droits nationaux. Voir Simon Whittaker, *Liability for Products: English Law, French Law, and European Harmonization*, Oxford, Oxford University Press, 2005, à la p 440 ; Denis Mazeaud, « Rapports entre le régime mis en place par la directive du 25 juillet 1985 sur la responsabilité des produits défectueux et les autres régimes de responsabilité » (2003) Recueil Dalloz 464. Pour une critique de la multiplicité des actions dans un contexte analogue, voir Stapleton, *supra* note 19. Soulignons que la France, qui n'était pas au bout de ses peines, a été à nouveau condamnée au terme d'une procédure en manquement: *Commission c France*, C-177/04 [2006] Rec CE 246.

[155] *Directive « produits défectueux »*, *supra* note 18, art 15 (1)(b) et 16, et les renvois explicites aux différentes solutions nationales. Voir aussi Simon Taylor, *L'harmonisation communautaire de la responsabilité du fait des produits défectueux : Étude comparative du droit anglais et du droit français*, Paris, LGDJ, 1999 aux pp 28-29 et Miquel Martin Casals et Josep Sole Feliu, « Responsabilidad por productos en España y (des)armonizacion europea » (2001) 4 Revista de responsabilidad civil y seguros 1 à la p 4 (qui avaient déjà anticipé la solution).

[156] *Sanchez*, *supra* note 151 au para 23. Voir aussi Jean-Sébastien Borghetti, *La responsabilité du fait des produits : Étude de droit comparé*, Paris, LGDJ, 2004 aux pp 510-12.

Par conséquent, la CJCE a explicitement condamné, au regard des aspects de la Directive qui ressortent de l'UE[157], le maintien, par les États membres, de mesures visant à augmenter le niveau de protection juridique accordé aux victimes de certains produits défectueux[158]. La doctrine s'était déjà divisée entre les auteurs qui avaient perçu cette matrice « d'harmonisation totale » de la Directive[159], et ceux qui y voyaient là un seuil d'harmonisation minimal[160]. Que le niveau de protection des consommateurs ait pu être réduit au passage de l'acte de transposition de la Directive « produits défectueux » en droit interne est une idée qui a heurté la sensibilité de plusieurs juristes. Pourtant, l'interprétation préconisée par la Cour semble bien refléter l'intention du Conseil en 1985, qui émerge à l'exégèse du texte[161].

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[157] Voir *Moteurs Leroy Somer*, C285/08 [2009] ECR 4733 aux paras 24-25, commentée notamment par Carole Aubert de Vincelles, « Harmonisation totale et directive nº 85/374/CEE relative à la responsabilité du fait des produits défectueux » (2009) Revue des contrats 1448 et par Jean-Sébastien Borghetti, « La responsabilité du fait des produits et la protection des intérêts professionnels » (2009) Recueil Dalloz 1731 (où il a été statué que certains aspects périphériques du droit de la responsabilité sont en dehors du faisceau harmonisant de la Directive). Voir aussi *Aventis Pasteur SA c OB*, C-358/08, [2012] JO C 049/12 et CJUE (Grande chambre) du 21 décembre 2011, *Centre hospitalier universitaire de Besançon c Thomas Dutrueux*, [2012] JOC 049/11.

[158] Cette insertion a notamment été critiquée, surtout en France, par Geneviève Viney, « L'introduction en droit français de la directive européenne du 25 juillet 1985 relative à la responsabilité du fait des produits défectueux » (1998) Recueil Dalloz 291.

[159] Voir quant à ce contexte Borghetti, *supra* note 156 à la p 508, qui note que « [c]ela revenait à considérer que la directive ne visait pas tant à harmoniser les droits européens qu'à instaurer une protection minimale de consommateurs » ; Geneviève Viney et Patrice Jourdain, *Traité de droit civil*, dans J Ghestin, dir, *Les conditions de la responsabilité*, 2e édition, Paris, LGDJ, 1998 à la p 758 et s ; Hans C Taschner, « Harmonization of Product Liability Law in the European Community » (1999) 34 Tex Int'l LJ 21.

[160] Jacques Ghestin, « De la responsabilité du fait des produits défectueux. L'application en France de la *directive sur la responsabilité du fait des produits défectueux après l'adoption de la loi no. 98-389 du 19 mai 1998* » (1998) JCP G I-148 à la p 1201.

[161] Céline Rondey, « Responsabilité du fait des produits défectueux : la France à nouveau condamnée » (2002) Recueil Dalloz 1670.

Un second exemple permet d'illustrer des difficultés de coordinations similaires. Né d'une question préjudicielle, l'arrêt *Skov c Bilka*[162] porte sur la licéité d'une disposition danoise prévoyant, à l'instar du parcours emprunté par la France, l'extension du domaine des responsables à tous les opérateurs économiques impliqués dans la chaîne de commercialisation des produits. Au départ, une intoxication alimentaire induite par la salmonelle après l'ingestion d'œufs explique la demande d'indemnisation du préjudice causé formulée par les victimes qui ont assigné en justice la société distributrice *Bilka*, laquelle a appelé en garantie le producteur (*Æg*). La Cour rappelle les conclusions formulées à l'occasion de la trilogie précitée et réitère qu'au titre du premier article de la Directive « produits défectueux », seul le producteur est responsable du dommage causé par un défaut de son produit[163].

À l'instar de la France et de la Grèce, le Danemark, par évolution prétorienne autant que législative, a étendu les règles de responsabilité objective dérivant des produits défectueux à tous les opérateurs économiques de la chaîne de commercialisation[164]. *A priori*, une telle dynamique apparaît contraire au mécanisme d'application de la Directive « produits défectueux » telle qu'interprétée par la CJCE. Si ce n'est que dans une tentative raffinée de sauvetage de la norme nationale, les représentants danois ont fait valoir que le fondement juridique de cette protection juridique procède d'une double source normative : la pre-

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[162] *Skov Æg c Bilka Lavprisvarehus A/S c Mikkelsen*, C-402/03, [2006] ECR I-223 à la p I-234 [*Bilka*]. Pour une analyse raffinée de cette thématique, voir Marinella M Baschiera, « Dialogo antagonista tra la Corte di Giustizia delle Comunità Europee e corti nazionali : armonizzazione e responsabilità del fornitore-distributore » (2007) 23 : 1 Nuova Giurisprudenza Civile Commentata 80 ; Judith Rochfeld, « Les ambiguïtés des directives d'harmonisation totale. La nouvelle répartition des compétences communautaire et interne » (2009) 30 Recueil Dalloz 2047.

[163] *Supra* note 18 (ce n'est que dans une mesure réduite, subsidiaire, que la responsabilité s'étend à certains intermédiaires de marché, soit, selon l'art 3, s'ils importent un produit à l'intérieur de l'UE ou encore ils fournissent un produit pour lequel il est impossible d'identifier le producteur à l'intérieur d'un délai raisonnable).

[164] *Loi No 371 du 7/06/1989 portant sur les produits défectueux*, modifiée par la *Loi No 1041 du 28/11/2000*, dont l'art 10 prévoit l'extension de l'action a tous les acteurs de la chaîne de commercialisation.

mière, législative, et la seconde, prétorienne, constituant une extension de la responsabilité *pour faute* aux autres opérateurs économiques. Le nœud gordien à trancher devenait celui de déterminer si la Directive pose un obstacle à la survie d'une mesure indemnitaire qui a pour seul effet de *transférer* au fournisseur la responsabilité objective ou ancrée dans la faute imputée au fabricant[165].

Dans la foulée de la tortueuse expérience française, l'argument mis de l'avant par le Danemark préconisait une interprétation *a contrario* de la Directive, centrée sur les articles 1 et 3, laquelle aurait permis de conclure que parce que le texte communautaire n'harmonise pas la responsabilité de ce fournisseur qu'il ne définit même pas, a fortiori peut-on penser que le Conseil a laissé intacte la marge discrétionnaire dont disposent les États membres en la matière[166]. C'est toutefois à la conclusion inverse à laquelle parvient la CJCE, lorsqu'elle observe ce qui suit :

> […] les articles 1er et 3 de la directive *ne se limitent donc pas à réglementer la responsabilité du producteur d'un produit défectueux*, mais déterminent, parmi les professionnels ayant participé aux processus de fabrication et de commercialisation, *celui qui devra assumer la responsabilité* instituée par la directive[167].

Aux prises avec les conclusions dégagées de la trilogie de 2002, la Cour du Luxembourg réitère que la mesure de protection danoise ne constituait, en soi, ni un « régime spécial de responsabilité » (c'est-à-

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[165] *Bilka*, *supra* note 162.

[166] C'est d'ailleurs ce sentier qu'emprunte la Cour dans les affaires CJCE, *Leroy Somer*, C-285/08, [2009] ECR I-04733 (où elle affirme, interprétant l'art 9, que « rien dans le texte de la directive 85/374 ne permet de conclure que le législateur communautaire, *en limitant la réparation des dommages aux biens en vertu de cette directive aux choses d'usage privé ou de consommation privée, a entendu priver les États membres*, […] de la faculté de prévoir, en ce qui concerne la réparation des dommages causés à une chose destinée à l'usage professionnel et utilisée pour cet usage, *un régime de responsabilité qui correspond à celui instauré par ladite directive* » (point 30) [nos italiques]), et *O'Byrne c Sanofi Pasteur MSD Ltd,* C-127/04, [2006] ECR I-313, au regard de la notion de mise en circulation.

[167] *Bilka*, *supra* note 162, au point 30 [nos italiques].

dire limité à un secteur d'activité particulier) ni un régime « basé sur des éléments différents », enraciné dans un autre fondement juridique (c'est-à-dire la garantie des vices cachés ou la faute), qui aurait justifié le maintien du recours de matrice nationale[168]. Au contraire, elle entre dans le « menu du jour » que propose la Directive et ne saurait, pour cette raison, être maintenue[169].

Ayant sans doute anticipé cette prévisible conclusion, le Royaume du Danemark s'était armé d'un argument subsidiaire. Ses représentants ont mis en relief que la mesure de protection nationale réitérée lors du processus de transposition de la Directive « produits défectueux » procède, en réalité, de la responsabilité *pour faute* du fabricant, même si l'exercice du recours s'étend aux intermédiaires de marché afin de faciliter l'indemnisation du préjudice subi par les victimes. L'on en comprend qu'à la différence des affaires grecque ou française, le recours danois se base sur des éléments distincts de ceux qui sous-tendent la Directive : la faute (ici extra-contractuelle). Précisément pour cela, elle échappe au joug de ce faisceau d'harmonisation totale partielle qu'aménage le texte communautaire, puisque l'intermédiaire de marché, dans une telle situation, revêt plutôt la qualité de fidéicommis. Il en résulte que la Directive « produits défectueux » ne pose aucun obstacle à une telle forme de responsabilité, même si un tel recours, en définitive, aboutit lui aussi à une prolifération potentielle d'actions en garantie.

Pour notre propos, on doit retenir que le seuil d'harmonisation effectué par la Directive sous examen dépend de la capacité des juristes

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[168] *Ibid* au para 22 (de cette manière, la CJCE consacre l'impossibilité que l'intermédiaire de marché puisse internaliser les coûts liés à l'indemnisation du préjudice corporel en cas d'insolvabilité du producteur, réduisant d'autant la protection des consommateurs).

[169] Le tout s'inscrit dans la foulée de principes chers à l'analyse économique du droit: voir Anna Lisa Bitetto, « Responsabilità oggettiva solo per il produttore » (2006) 131 : 6 Il Foro italiano 317. Le Danemark a par la suite été condamné pour manquement : voir *Commission c Danemark*, C-327/05, [2007] ECR I-93 ; Duncan Fairgrieve et Geraint Howells, « Rethinking Product Liability: A Missing Element in the European Commission's Third Review of the European Product Liability Directive » (2007) 70 : 6 Mod L Rev 962.

nationaux à détacher leurs recours de la séquence défaut-lien causal-préjudice qui sous-tend la responsabilité du fait des produits défectueux. Et la chose a ceci d'insidieux que seul un repli vers la responsabilité pour faute ou l'ancrage à d'autres fondements juridiques (le risque, la dangerosité d'une activité) permet aux voies d'action nationale de subsister. Ce parcours interprétatif pour le moins alambiqué que préconise la CJCE illustre, à l'instar de l'expérience américaine, un phénomène de rétrécissement de la souveraineté des États membres rattaché à une conception somme toute centralisatrice du partage des compétences. À l'issue de cette analyse, on en comprend que le degré d'harmonisation est surtout tributaire de la nature des bases juridiques utilisées au soutien de l'acte communautaire qui se donne à l'interprétation – ici, la création du marché intérieur – et qui induisent une véritable composante fédérale dans un discours qui semble pourtant appartenir à la sphère des civilistes.

L'instinct (la logique?) voudrait pourtant que si la Directive « produits défectueux » eût effectivement aménagé une protection majorée pour les victimes, l'harmonisation se serait effectuée par le seul effet du temps[170], dans la mesure où le texte communautaire aurait généré un « droit désirable ». Là n'est pourtant pas la clef de lecture adéquate, en raison d'une architecture constitutionnelle beaucoup plus complexe, soucieuse de respecter l'acquis communautaire.

Le Canada a ceci en commun avec l'UE qu'aucune compétence expresse ne vise la sécurité des produits. Il s'en distingue pourtant en ce que les pulsions centralisatrices ont généralement puisé leur légitimité de la compétence portant sur le droit criminel.

III. Le Canada et l'itinéraire d'une discipline en formation

L'on pourrait croire qu'au Canada, la prévention et l'indemnisation des atteintes à la sécurité des consommateurs se superposent, respectivement, au partage des compétences qu'esquissent les articles 91 et 92 de la *Loi constitutionnelle de 1867* (« *LC 1867* »), en vertu desquels, *grosso modo*, les lois de police échoient au législateur fédéral, alors que celles destinées à régir les rapports de droit privé sont de compé-

[170] Voir CE no 241/19, *Responsabilité du fait des produits*, Bull inf 30 à la p 20.

tence provinciale. Cette image simpliste appelle une analyse plus approfondie, capable de rendre compte d'une complexe synergie unissant les sources du droit sécrétées, d'une part, par le Constituant, et, de l'autre, les différents législateurs. À l'instar notamment de la protection de l'environnement[171] ou de la santé publique[172], la protection de la santé des consommateurs et son double, la sécurité des produits, ne s'imbrique dans aucune des compétences issues du partage fédératif de 1867. Comme aux États-Unis ou au sein de l'UE, la matière n'est pourtant pas dépourvue de toute dimension fédérale – tant s'en faut –, dès lors qu'elle fait souvent l'objet d'une récupération par d'autres pouvoirs attributifs d'une compétence exclusive.

Dans le sillon tracé par la métaphore de l'« arbre vivant susceptible de croître et de se développer à l'intérieur de ses limites naturelles[173] », le fédéralisme canadien invite à une approche souple à la coordination des compétences[174]. À la différence du droit de l'UE, il importe moins de préciser la nature des liens qu'entretient la sécurité des produits avec protection des consommateurs ou la création du marché intérieur que de documenter sa filiation avec le droit criminel (SOUS-SECTION A). De fait, l'exercice de cette compétence[175] a enfanté en 2011 la *Loi canadienne sur la sécurité des produits de consommation*, un texte législatif transversal auquel le droit des obligations ne pourra demeurer indifférent[176]. Pour friable, son fondement constitutionnel contraste avec le socle exclusivement provincial sur lequel

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[171] *Friends of the Oldman River Society c Canada (Ministre des Transports)*, [1992] 1 RCS 3 à la p 64, 88 DLR (4e) 1 («[l'environnement est] au sens constitutionnel, une matière obscure qui ne peut être facilement classée dans le partage actuel des compétences, sans un grand chevauchement et une grande incertitude »).

[172] Voir *Schneider c La Reine*, [1982] 2 RCS 112 à la p 142, 139 DLR (3e) 417.

[173] *Edwards c Canada (PG)*, [1930] AC 124 à la p 136, Lord Sankey.

[174] *Renvoi relatif à la Loi sur les valeurs mobilières*, 2011 CSC 66 aux paras 56-57, [2011] 3 RCS 837 (la Cour précise néanmoins au para 62 que « [l]e 'courant dominant' du fédéralisme souple, aussi fort soit-il, ne peut autoriser à jeter des pouvoirs spécifiques par-dessus bord, ni à éroder l'équilibre constitutionnel inhérent à l'État fédéral canadien »).

[175] Nicole L'Heureux et Marc Lacoursière, *Droit de la consommation*, 6e éd, Cowansville (Qc), Yvon Blais, 2011 à la p 10.

[176] Voir à ce sujet Arbour, *supra* note 3.

s'assoit, en vertu de l'article 92(13) *LC 1867*, une action en réparation du préjudice corporel qui ne peut pour autant demeurer indifférence aux influx normatifs venus d'Ottawa (SOUS-SECTION B). Suivant son acception la plus large, la sécurité des produits est donc à cheval entre l'exercice de compétences fédérales et provinciales.

A. Le partage fédératif des compétences et la sécurité des produits

Par analogie, l'analyse du panorama constitutionnel américain ou de l'UE serait de nature à induire l'idée qu'au Canada, la sécurité des produits est étroitement liée au commerce interprovincial. Historiquement, c'est plutôt la compétence portant sur le droit criminel que cristallise l'article 91(27) *LC 1867* qui sous-tend l'adoption de lois destinées à accroître la sécurité des produits (1). Fort de cet héritage interprétatif, on ne s'étonnera guère que le législateur fédéral se soit autorisé de celle-ci pour promulguer sa *Loi canadienne sur la sécurité des produits de consommation* (2). Au fil de l'évolution historique canadienne, le partage des compétences s'est livré à différentes constructions théoriques. Par-delà différentes attitudes devant cette nomenclature imparfaite des pouvoirs[177], cette élasticité, qui propose un calibrage nouveau des rapports fédéral-provinciaux, contourne l'écueil d'une vision dualiste, binaire, étanche[178]. La Cour suprême promeut depuis quelques années une approche beaucoup plus flexible au partage des compétences : celle promouvant un fédéralisme coopératif,

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[177] Voir Brun, Tremblay et Brouillet, *supra* note 9 à la p 445 (qui observent que « dès le départ, on s'est aperçu que la liste des pouvoir fédéraux et la liste des pouvoirs provinciaux entraient en concurrence sur plusieurs points »).

[178] Dans le cadre de l'arrêt *Canada (PG) c PHS Community Services Society*, 2011 CSC 44 au para 58-60, [2011] 3 RCS 134 [*PHS Community Services*], la Cour explique que « [l]a doctrine de l'exclusivité des compétences repose sur la prémisse que les chefs de compétence [respectifs] ont un 'contenu minimum élémentaire et irréductible', qui doit être protégé contre l'ingérence de l'autre ordre de gouvernement ». Elle ajoute : « [s]'il est établi que la doctrine […] trouve application, la mesure législative adoptée par l'autre ordre de gouvernement demeure valide, mais ne s'applique pas à l'égard de ce 'contenu essentiel' ». Voir aussi *Bell Canada c Québec (Commission de la santé et de la sécurité du travail)*, [1988] 1 RCS 749 à la p 839, 51 DLR (4e) 161; *Québec (PG) c Canadian Owners and Pilots Association*, 2010 CSC 39 au para 52, [2010] 2 RCS 536.

qui ne saurait pourtant « autoriser à jeter des pouvoirs spécifiques pardessus bord, ni à éroder l'équilibre constitutionnel inhérent à l'État fédéral canadien »[179]. L'exercice de la compétence fédérale en matière de droit criminel n'échappe pas à cette mouvance.

1. La compétence fédérale en matière de droit criminel

Une loi prise sous l'égide de l'alinéa 92(17) *LC 1867* sera jugée valide « pour peu que la conduite à réprimer mérite le stigmate de criminalité »[180]. Appréhendée très largement, cette exigence peut comporter un aspect préventif[181]. En effet, sous son égide, la Cour suprême a récemment approuvé des interventions ciblées dans les domaines de la santé publique[182], de la bioéthique[183] et, pour notre propos, en matière de sécurité des produits (parmi lesquels les aliments et drogues, les produits dangereux et ceux issus du tabac)[184].

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[179] *Renvoi relatif à la Loi sur les valeurs mobilières*, *supra* note 174 au para 62.

[180] Voir Brun, Tremblay et Brouillet, *supra* note 9 à la p 495. Il embrasse non seulement la paix, l'ordre et la sécurité, mais encore la santé ou l'environnement. Voir à ce sujet *L'Affaire de la margarine*, [1951] AC 179, [1949] RCS 1 ; *R c Hydro-Québec*, [1997] 3 RCS 213, 151 DLR (4e) 32 ; *Scowby c Glendinning*, [1986] 2 RCS 226 à la p 238, 32 DLR (4e)161.

[181] *R c Swain*, [1991] 1 RCS 933 à la p 999, 63 CCC (3e) 481, juge Lamer.

[182] Concernant le couple droit criminel/santé, voir *PHS Community Services, supra* note 178, de même que *R c Morgentaler*, [1988] 1 RCS 30, 44 DLR (4e) 385 ; *R c Morgentaler*, [1976] 1 RCS 616, 55 DLR (3e) 161 ; *R c Morgentaler*, [1993] 3 RCS 463, 107 DLR (4e) 537.

[183] Voir la *Loi sur les activités cliniques et de recherche en matière de procréation assistée*, LRQ c A-5.01 et son *Règlement sur les activités cliniques en matière de procréation assistée*, RRQ c A-5.01, r 1, contestés et partiellement invalidés à la demande du Québec : *Renvoi relatif à la Loi sur la procréation assistée*, 2010 CSC 61, [2010] 3 RCS 457.

[184] Voir *R c Wetmore*, [1983] 2 RCS 284, 2 DLR (4e) 577 où la Cour a statué que les art 8 et 9 de la *Loi des aliments et drogues*, SRC 1970, c F-27, interdisant la vente de drogues préparées dans des conditions non hygiéniques et la publicité trompeuse à leur égard constituaient un exercice valide de la compétence prévue à l'art 92 (27), *LC 1867*, *supra* note 85. Il en va de même avec la *Loi sur les produits dangereux*, LRC (1985), c H-3 (jugée valide par la Cour d'appel du Manitoba dans l'arrêt *R c Cosman's Furniture (1972) Ltd* (1976), 32 CCC (2e) 345, 73 DLR (3e)

On le savait déjà : une loi fédérale n'est pas nécessairement invalide même si elle produit certains effets secondaires sur une autre compétence qui échoit aux provinces[185]. Dès lors, un empiétement accessoire de part et d'autre sera toléré, pour peu qu'il n'entrave pas l'exercice de la compétence convoitée. Des constitutionnalistes expliquent :

> [qu'e]n ce qui concerne le degré d'intrusion requis, la Cour suprême a établi […] qu'il ne suffit plus de 'toucher' ou 'affecter' le cœur d'une matière fédérale pour entraîner l'inapplicabilité de la loi provinciale. Il faut plutôt qu'il y ait 'entrave' ou qu'on porte atteinte à ce noyau de compétence (ou à un élément vital ou essentiel d'une entreprise relevant de cette compétence), qu'il y ait en d'autres termes des 'conséquences fâcheuses', sans nécessairement stériliser ou paralyser[186].

L'analyse jurisprudentielle entourant la conformité constitutionnelle de lois visant la sécurité des produits révèle que le droit criminel sert d'assise constitutionnelle aux initiatives législatives fédérales[187].

La Cour suprême convient le plus souvent de sa pertinence, puisque « [l]e fédéral possède une vaste compétence pour ce qui est de l'adoption de lois en matière criminelle relativement à des questions de santé, *et cette compétence n'est circonscrite que par les exigences voulant qu'elles comportent une interdiction accompagnée d'une sanction pénale, et qu'elles visent un mal légitime pour la santé publique* [nos

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312 et *RJR-MacDonald c Canada (PG)*, [1995] 3 RCS 199, 127 DLR (4e) 1 [*RJR-McDonald*], où une loi restreignant la publicité et l'affichage des produits du tabac a été jugée valide au regard du même article. En revanche, l'exercice de cette même compétence ne s'étend pas à la détermination de la composition d'un produit : voir *Brasserie Labatt du Canada Ltée c Canada (PG)*, [1980] 1 RCS 914, 1979 CanLII 190.

[185] Voir *Banque canadienne de l'Ouest c Alberta*, [2007] 2 RCS 3 au para 28, 281 DLR (4e) 125 ; *Global Securities Corp c Colombie Britannique (Securities Commission)*, [2000] 1 RCS 494 au para 23, 185 DLR (4e) 439.

[186] Brun, Tremblay et Brouillet, *supra* note 9 aux pp 462-63.

[187] *LC 1867*, *supra* note 85, art 91(27).

italiques] »[188]. Et d'ajouter : « [s]i une loi fédérale donnée possède ces caractéristiques et ne constitue pas par ailleurs *un empiétement 'spécieux' sur la compétence provinciale*, c'est alors une loi valide en matière criminelle »[189]. Il semble que la limite de la compétence du droit criminel se trouve dans la dialectique de la prohibition et de la régulation, cette dernière se situant à l'extérieur de la zone législative fédérale que circonscrit, précisément, l'alinéa 92 (17) de la *LC 1867*.

En 1995, la Cour suprême a validé, à l'occasion de l'arrêt *RJR McDonald,* la conformité constitutionnelle de la *Loi réglementant les produits du tabac*[190]**.** Pour sept juges d'un banc plénier, la compétence jouit d'une large portée, pour peu qu'elle n'empiète pas « spécieusement »[191] sur les domaines de compétences qui échoient aux provinces. C'est ce que la recherche du caractère véritable de la loi – son « objet principal », son « idée maîtresse »[192] – permet de déterminer. D'entrée de jeu, la loi annonçait son intention « de s'attaquer, sur le plan législatif, *à un problème qui, dans le domaine de la santé publique, est grave et d'envergure nationale* »[193]. Contrairement à l'*Affaire Tabac* rendue par la CJCE[194], la Cour suprême canadienne fait peu de cas de l'importance que revêt la santé publique au sein de la loi incriminée. Au contraire, elle affirme sans ambages que

> [v]u que la santé comme matière constitutionnelle présente un caractère « informe » et qu'il s'ensuit que *tant le Parlement que les législatures provinciales peuvent validement légiférer dans ce domaine*, il importe de faire ressortir […] la nature plénière de la compétence en matière de droit criminel[195].

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[188] *RJR-MacDonald*, *supra* note 184 au para 32 (juge La Forest, dissident sur d'autres points).

[189] *Ibid* [nos italiques].

[190] LC 1988, c 20.

[191] *RJR-MacDonald*, *supra* note 184 au para 28 (juge La Forest).

[192] *Ibid* au para 29.

[193] *Loi réglementant les produits du tabac*, *supra* note 190 [nos italiques].

[194] *Supra* note 138.

[195] *RJR-MacDonald*, *supra* note 184 au para 32, juge La Forest dissident [nos italiques]. Ce faisant, la Cour réitère les conclusions auxquelles elle était parvenue

En conséquence – de préciser la Cour – la loi dont il est question saurait être qualifiée de « spécieuse », du fait que la criminalisation de la publicité et la promotion des produits dérivés du tabac en soit l'objet[196].

Pourtant, à la suite d'une déclaration d'inconstitutionnalité d'un article visant l'auto-attribution d'avertissements par les compagnies de tabac[197], la loi a été amendée dans le sens indiqué par la Cour suprême[198]. Décrivant son objet sans même, au passage, mentionner sa filiation constitutionnelle avec le droit criminel, elle réitère la nécessité de protéger la santé publique[199]. Reprenant pour l'essentiel les termes de l'article 3 de sa première mouture, l'article 4 – toujours en vigueur – dispose :

> La présente loi a pour objet de s'attaquer, sur le plan législatif, *à un problème qui, dans le domaine de la santé publique, est grave et d'envergure nationale* et, plus particulièrement :

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dans l'affaire *Schneider c La Reine*, *supra* note 172, qui statuait comme suit : « la 'santé' n'est pas l'objet d'une attribution de constitutionnelle spécifique, mais constitue plutôt un sujet indéterminé que les lois fédérales ou provinciales valides peuvent aborder » (juge Estey, à la p 142).

[196] *RJR McDonald*, *supra* note 184 au para 43 (*obiter dictum*, juge La Forest précise même que l'interdiction, tout court, de vente desdits produits serait constitutionnelle, « pour le motif que ces produits constituent un danger pour la santé publique »).

[197] L'analyse des critères dégagés de l'arrêt *R c Oakes*, [1986] 1 RCS 103, 4 OAC 335 porte la Cour à conclure que l'objectif de protection de la santé des personnes justifie bien certaines restrictions à la liberté d'expression. Sous cet angle, il existe bien un lien rationnel entre les mesures destinées à baliser l'étiquetage et la publicité des produits dérivés du tabac adoptées et la finalité de santé publique poursuivie. En revanche, de préciser la Cour, l'atteinte aux droits constitutionnels des compagnies de tabac n'est pas minimale, dès lors que la loi interdisait aux appelantes d'attribuer les messages d'avertissement au gouvernement (i.e. Santé Canada), suggérant ainsi que les fabricants en étaient les auteurs (*RJR-McDonald*, *supra* note 184 au para 73, juge McLachlin). C'est en raison de cette « signature forcée » que les articles ont été jugés inopérants en vertu de l'art 52 de la même *Charte canadienne des droits et libertés*, partie I de la *Loi constitutionnelle de 1982*, constituant l'annexe B de la *Loi de 1982 sur le Canada* (R-U), 1982, c-11.

[198] *Loi sur le tabac*, LC 1997, c 13.

[199] *Ibid*.

> a) *de protéger la santé des Canadiennes et des Canadiens* compte tenu des preuves établissant, de façon indiscutable, un lien entre l'usage du tabac et de nombreuses maladies débilitantes ou mortelles;
>
> b) de préserver notamment les jeunes des incitations à l'usage du tabac et du tabagisme qui peut en résulter;
>
> c) de protéger la santé des jeunes par la limitation de l'accès au tabac;
>
> d) de mieux sensibiliser la population aux dangers que l'usage du tabac présente pour la santé [nos italiques].

Un litige articulé autour de la mise en œuvre des mêmes compétences est né en Saskatchewan lorsque la validité des dispositions contenues à une loi provinciale – le *Tobacco Control Act*[200] – prohibant plusieurs aspects relatifs à la promotion et à la vente des produits du tabac a été contestée par les fabricants de ceux-ci. Il s'agissait, cette fois, de résoudre un conflit potentiel entre la *Loi sur le tabac* fédérale à peine évoquée et celle provinciale, sous l'éclairage de la théorie de la prépondérance législative fédérale (*paramountcy*) qui veut qu' « en cas de conflit entre une loi fédérale et une loi provinciale qui sont validement adoptées, mais qui se chevauchent, la loi provinciale devient inopérante dans la mesure de l'incompatibilité »[201]. Saisie du litige, la Cour du banc de la Reine s'emploie à dégager le caractère véritable

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[200] SS 2001, c T-14.1.

[201] *Gouvernement de la Saskatchewan c Rothmans, Benson & Hedges Inc*, 2005 CSC 13 au para 11, 1 RCS 188. À ce sujet, voir plus largement *Smith c R*, [1960] RCS 776, 25 DLR (2e) 225, *McCutcheon*, *supra* note 34 à la p 191, juge Dickson (où la Cour convient que « there would seem to be no good reasons to speak of paramountcy and preclusion except where there is actual conflict in operation as where one enactment says 'yes' and the other says 'no' [… ;] compliance with one is defiance of the other » ; *Bank of Montreal* c *Hall*, [1990] 1 RCS 121, JE 90-294 (où la Cour spécifie qu'une incompatibilité peut aussi naître si la loi provinciale supplante la loi fédérale ou se pose en porte à faux de la réalisation de son objet), citées dans *Rothmans, Benson & Hedges Inc v Saskatchewan*, 2002 SKQB 382 au para 43, [2002] 10 WWR 733, juge Barclay, de même que *Rio Hotel Ltd c Nouveau Brunswick (Commission des licences et permis d'alcool)*, [1987] 2 RCS 59 et *Spraytech, supra* note 94. Ces sentiers interprétatifs restrictifs de la théorie de la prépondérance sont autant de manifestations du fédéralisme coopératif.

(*pith and substance*) de deux lois par ailleurs intra vires, avant de constater – pour mieux rejeter l'action – l'absence de conflit entre les deux lois. À la différence de la Cour d'appel[202], la Cour suprême avalise les conclusions du tribunal de première instance[203]. Elle conclut que l'absence d'incompatibilité entre les deux lois incriminées suffit à disposer du litige dans le sens voulu par le gouvernement saskois, s'étant porté à la défense d'une loi qui n'entrave pas la réalisation de l'objet de la loi fédérale, non plus qu'elle ne place les justiciables dans l'impossibilité de se conformer aux deux textes[204].

Cette interprétation libérale de la compétence de droit criminel permet au législateur fédéral de valablement promulguer des lois portant sur la sécurité des produits. La suite des choses est connue : sous l'égide de l'alinéa 92 (17) *LC 1867*, le Parlement a adopté un texte législatif parapluie, faisant naître un véritable domaine du droit, n'eut-il été de l'exclusion naturelle des recours civils, toujours nichés dans le droit provincial.

2. La *Loi canadienne sur la sécurité des produits de consommation*

L'objectif que poursuit la *Loi canadienne sur la sécurité des produits de consommation* est clair : il s'agit de « *protéger le public en remédiant au danger pour la santé ou la sécurité humaines* que présentent les produits de consommation qui se trouvent au Canada, notamment ceux qui y circulent et ceux qui y sont importés, et *en prévenant ce danger* »[205]. Ce danger auquel réfère la loi est défini comme suit[206] :

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[202] *Rothmans, Benson & Hedges Inc v Saskatchewan*, 2003 SKCA 93 au para 88, [2003] 232 DLR (4e) 495 (où la Cour conclut ce qui suit: « we are of the opinion that the better view of this admittedly uncertain matter is that there is sufficient inconsistency [between these two tobacco laws] as to engage the doctrine of federal legislative paramountcy »).

[203] *Ibid*.

[204] *Ibid* aux para 22-25.

[205] *LCSPC*, *supra* note 3, art 3 [nos italiques]. Voir aussi le 1er attendu.

[206] *Ibid*, art 2.

> Risque déraisonnable – existant ou éventuel – qu'un produit de consommation présente au cours ou par suite de son utilisation normale ou prévisible et qui est susceptible de causer la mort d'une personne qui y est exposée ou d'avoir des effets négatifs sur sa santé – notamment en lui causant des blessures – même si son effet sur l'intégrité physique ou la santé n'est pas immédiat. Est notamment visée toute exposition à un produit de consommation susceptible d'avoir des effets négatifs à long terme sur la santé humaine.

À l'instar de la Directive 2001/95/CE dite « sécurité des produits »[207] et de ses clones nationaux, le texte législatif fait état de cette nécessité, dans le contexte « du nombre croissant de produits de consommation qui traversent les frontières dans le cadre d'un marché qui se mondialise »[208]. Le lien avec la création du marché apparaît sans équivoque, même si l'analyse du fondement juridique des lois canadiennes visant la sécurité des produits révèle qu'à la différence des modèles que proposent l'UE ou les États-Unis, la compétence fédérale visant le commerce inter-provincial, rappelons-le, a peu souvent servi d'assise à la production législative canadienne[209]. Par contraste et comme la *Loi sur les aliments et drogues*[210], semble-t-il[211], la loi s'autorise plutôt, dans la foulée de l'arrêt *RJR-McDonald*, de la compétence du Parlement fédéral en matière de droit criminel.

La *Loi canadienne sur la sécurité des produits de consommation* redimensionnera néanmoins les rapports de droit privé, dans la mesure

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[207] *Directive « sécurité des produits »*, *supra* note 3.

[208] *Ibid*, 2e attendu.

[209] Voir Brun, Tremblay et Brouillet, *supra* note 9 à la p 508 et s, de même que l'étude longitudinale de François Chevrette, « Prolégomènes à l'étude de la notion de droit criminel en droit constitutionnel canadien » (1969) 4 RJT 17.

[210] LRC (1985), c F-27.

[211] Pour un historique de l'adoption de cette loi et de son fondement constitutionnel, voir Mathieu Gagné, *Droit des médicaments*, 2e éd, Cowansville (Qc), Yvon Blais, 2010 (qui souligne la controverse entourant son fondement (droit criminel? paix ordre et bon gouvernement?), bien que « sa constitutionnalité ne semble plus faire de doute », aux pp 11-12)).

où elle crée une « maxi-obligation » de sécurité[212] qui interdit aux opérateurs économiques de fabriquer, importer ou autrement mettre sur le marché un produit qui ne satisfait pas aux exigences réglementaires[213] ou qui « présente un danger pour la santé ou la sécurité humaines » et si, notamment, il « est visé par un rappel »[214]. Si les sanctions qui y sont prévues sont de nature administrative, il n'en reste pas moins que la violation de la loi fédérale naît, en amont, d'un contenu contractuel imparfait, en deçà du seuil de sécurité que dicte désormais la *Loi canadienne sur la sécurité des produits de consommation*. Cette dimension privatiste n'est-elle pas, au passage, sans également moduler les conditions d'exercice des recours en dommages-intérêts que pourraient intenter, par exemple, les victimes d'un produit défectueux? Au Québec, cette nouvelle donne venue d'Ottawa n'est pas anodine, considérant les difficultés théoriques qu'éprouvent déjà la *Loi sur la protection des consommateurs*[215] et le *Code civil du Québec* (CcQ) à s'arrimer parfaitement. C'est là un tout autre débat.

B. L'infléchissement de la responsabilité civile au contact du droit fédéral

À la lueur, surtout, de l'expérience américaine, une problématique émerge: le droit fédéral canadien portant sur la sécurité des produits se pose-t-il en porte-à-faux de l'action en responsabilité civile de matrice provinciale ? Infléchit-il à tout le moins l'exercice d'actions en responsabilité civile? Au Canada, le domaine de l'indemnisation du préjudice corporel est conditionné par la dialectique de la *common law* et du droit civil qu'a maintenu l'alinéa 92(13) *LC 1867*. C'est dire, de manière générale, que la responsabilité civile (ou les *torts*, dépendamment) échoit avant tout aux législateurs provinciaux. Au Québec, l'on s'en remet à la responsabilité extra-contractuelle (art. 1457, 1468

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[212] L'expression est empruntée à Marie-Ève Arbour et Simon Johnson-Bégin, « L'encadrement juridique des rappels et des retraits de produits de consommation » (2012) 37 Gestion 17 à la p 19.

[213] *LCSPC*, *supra* note 3, art 6.

[214] *Ibid*, art 7.

[215] LRQ 1994, c P-40.1.

et 1469 CcQ), contractuelle (articles 1458, 1726 et suivants CcQ), ou de matrice consumériste (articles 37, 38, 53 de la *Loi sur la protection du consommateur*) pour octroyer compensation aux victimes de produits défectueux. Les provinces de *common law* s'autorisent plutôt de la *negligence* ou des garanties contractuelles, réfractaires qu'elles sont à l'idée d'une responsabilité objective ancrée dans la notion de défaut.

S'autorisant de compétences enchevêtrées, le pouvoir fédéral a toutefois apporté des correctifs ciblés dans les sphères d'activités nucléaires[216], maritimes[217] et, plus généralement, au regard de la responsabilité de la Couronne[218], induisant une composante fédérale à l'action en indemnisation du préjudice. Soulignons que le droit canadien a bien une « loi » uniforme intitulée *Loi sur la responsabilité en matière de produits défectueux*[219] imaginée dans le cadre purement technocratique de la Conférence pour l'harmonisation des lois. Elle n'a, à notre connaissance, aucun impact pratique, ni même, à l'instar des *restatements* américains, persuasif.

À la différence de la jurisprudence dégagée de la Directive « produits défectueux »[220], donc, la zone de contact entre la responsabilité civile – qui est peu harmonisée – et le droit fédéral est différemment délimitée. Et même encore: la synergie entre la sécurité préventive des produits et la responsabilité civile n'a pas soulevé les passions que do-

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[216] Voir la *Loi sur la responsabilité nucléaire*, LRC 1985, c N-28. Cette loi aurait été prise en vertu du pouvoir résiduaire « paix, ordre et bon gouvernement » ou l'art 92A, *LC 1867*, *supra* note 85. Voir aussi *Energy Probe v Canada (AG)*, 1994 CanLII 7247 au para 61 (CS Ont). Aux États-Unis, voir *Price-Anderson Act*, 42 USC § 2210 (1957) ; *Duke Power Co v Carolina Environmental Study Group Inc* (1978), 438 US 59 à la p 83.

[217] Voir la *Loi sur la responsabilité en matière maritime*, LC 2001, c 6.

[218] Voir la *Loi sur la responsabilité civile de l'État et le contentieux administratif*, LRC 1985, c C-50.

[219] Conférence pour l'harmonisation des lois, en ligne : CHLC <www.ulcc.ca/fr/lois-uniformes-fr-fr-1/516-loi-sur-la-responsabilite-en-matiere-de-produits-defectueux/629-responsabilite-en-matiere-de-produits-defectueux>. Elle ne peut en aucun cas être mise en parallèle avec les *restatements* américains ou la *Directive « produits défectueux »*, *supra* note 18.

[220] *Ibid*.

cumente les jurisprudences respectives de la Cour suprême des États-Unis ou celle du Luxembourg[221]. Est-ce pour autant un non-sujet? La réponse est négative. Car l'impact du droit de matrice fédérale sur les législations étatiques est perceptible, bien qu'il se mesure à l'aide de repères différents[222]. Malgré certaines similitudes et pour des raisons qui tiennent probablement au fragile équilibre que la Constitution vise à maintenir, la préséance à l'américaine n'a jamais eu droit de cité dans le cadre d'un litige en responsabilité civile. Ce qui n'empêche pas le droit de la responsabilité d'être mu par deux pulsions contradictoires qu'induisent, d'un côté, la dilatation de son champ par le rejet de la « défense d'autorité législative », et, de l'autre, le confinement de l'action en responsabilité civile par la contraction du *duty of care*.

S'agissant du premier exemple, certaines traces du droit anglais concourent à définir la problématique de la coordination des lois. Elles sont visibles à travers la défense d'autorité législative (*statutory authority*) – à laquelle le droit québécois est plutôt indifférent[223] – dont

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[221] L'esthétique de certaines dispositions de droit fédéral sont pourtant de nature à soulever des débats similaires : voir notamment la *Loi sur la responsabilité nucléaire*, *supra* note 216, art 14(2) qui prévoit ce qui suit : « *Sauf dans la mesure où elles sont incompatibles avec une disposition de la présente loi*, les lois en vigueur dans la province où une action est intentée en vertu de la présente partie […] s'appliquent à l'action » [nos italiques]. Dans le contexte du droit du travail, un tribunal ontarien a d'ailleurs statué que si la loi dessine les contours du devoir de diligence (la faute?), « [a] new 'federal tort' is not created » (*Dionne v Workplace Safety and Insurance Appeals Tribunal*, 93 OR (3d) 61 au para 12, 88 Admin LR (4e) 62).

[222] Abandonnons ici la problématique de la coordination des lois provinciales, qui ne font que rarement obstacle à la mise en œuvre de la responsabilité pour faute, sauf quand il s'agit de créer des régimes d'indemnisation étatiques ; auquel cas la préséance est affirmée par le législateur à même chaque loi particulière : voir par ex la *Loi sur les accidents du travail et les maladies professionnelles*, LRQ 1985, c A3.001, art 438 ; la *Loi sur l'assurance automobile*, LRQ 1989, c A25, art 83.57.

[223] Voir Jean-Louis Baudouin et Patrice Deslauriers, *La responsabilité civile*, vol 1, 7e éd, Cowansville (Qc), Yvon Blais, 2007 (pour qui « le simple fait qu'à propos d'un incident le défendeur ait respecté les normes législatives ou réglementaires n'exclut pas automatiquement la possibilité que sa responsabilité puisse malgré tout être retenue en vertu du régime de droit commun » à la p 170, au no 1-189). Voir aussi *Ciment du Saint-Laurent inc c Barrette*, 2008 CSC 64 au para 98, [2008] 3 RCS 392. D'ailleurs la responsabilité du fait des produits est basée sur

l'historique illustre la parfaite coordination entre les versants ex ante et ex post de l'exercice de régulation. À l'instar de la préemption à l'américaine, l'activité autorisée par le législateur place son destinataire à l'abri de l'action en responsabilité civile[224]. Les raisons politiques qui la sous-tendent sont similaires à celles qui président à la préséance américaine, sauf à préciser qu'elle a surtout été pertinente dans le contexte de la prestation de services publics (chemins de fer, aqueducs, etc.). Pour Allen M. Linden, « the most important policy reason for the creation of the immunity *was the desire to promote industrial expansion and to refrain from saddling infant industries with legal responsibility for their non-negligent conduct* »[225]. Sa portée a toutefois été fortement tempérée au fil du temps (considérant aussi que le *tort* de *breach of statutory duty* ne s'est jamais enraciné en droit canadien[226]), même dans le secteur pharmaceutique, où le respect des lois visant les médicaments « ne constitue pas une fin de non-recevoir au recours fondé sur le droit civil »[227]. Cette saine ignorance réciproque est ainsi décrite, dans le contexte européen, par Cees Van Dam:

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d'autres prémisses, dont l'usage auquel est destiné le produit, les attentes des consommateurs, la durabilité, etc.

[224] D'un point de vue historique, voir *Geddis v Proprietors of the Bann Reservoir* (1878), 3 App Cas 430 HL (Eng), Blackburn LJ (« it is now thoroughly well established that no action will lie for doing that which the legislature has authorized, if it be done without negligence » aux pp 455-56) ; *City of Manchester v Farnworth*, [1930] AC 171, [1929] All ER Rep 90 HL (Eng). Voir, au Canada, Allen M Linden, « Strict Liability, Nuisance and Legislative Authorization » (1966) 4 : 2 Osgoode Hall LJ 196 ; *Portage La Prairie (City of) v BC Pea Growers Ltd*, [1966] SCR 150, [1966] CanLII 101 (où l'intention de préséance est dégagée de volonté du législateur) et *Tock c St John's Metropolitan Area Board*, [1989] 2 RCS 1181, 64 DLR (4e) 620 à la p 1199 (où, à moins d'une précision expresse du législateur à l'effet contraire, la Cour semble exclure qu'une autorité législative fasse obstacle à un recours ancré dans une *nuisance*, suggérant même que le préjudice découlant du défaut d'entretien du système d'égout par l'organisme gouvernemental pertinent « devrait être à bon droit considéré comme un coût d'exploitation du système » aux pp 1199-1200, juge La Forest).

[225] Linden, *supra* note 224 à la p 199 [nos italiques].

[226] Voir *La Reine c Saskatchewan Wheat Pool*, [1983] 1 RCS 205 (analysé notamment par Allen M Linden et Bruce Feldhusen, *Canadian Tort Law*, 8e éd, Toronto, Butterworths, 2006 aux pp 226-234).

[227] Gagné, *supra* note 211 à la p 409.

« Whereas statutory safety rules are the warning signs and barriers at the top of the cliff, *tort law can be considered to be the ambulance waiting at the bottom of the cliff* »[228] . Le droit canadien, on le verra, illustre la pertinence de cette métaphore.

À l'inverse, le second exemple documente un phénomène de complémentarité de la prévention et de l'indemnisation des atteintes à la sécurité des consommateurs.

L'occupation d'un champ de régulation par l'État fédéral n'est pas sans configurer l'action en responsabilité civile, et, en particulier, les conditions d'appréciation du devoir de diligence – *duty of care* – dont sont débiteurs les opérateurs économiques (au premier chef, les fabricants[229]) et les décideurs publics (pour notre propos, souvent Santé Canada). L'on prendra pour preuve un litige né du contexte des biotechnologies, à l'occasion duquel la Cour du banc de la Reine de la Saskatchewan a refusé à un groupe d'agriculteurs biologiques l'autorisation d'exercer, contre les compagnies *Monsanto Canada Inc* et *Bayer Cropscience Inc*, une action en réparation du préjudice causé par la contamination de semences génétiquement modifiées[230]. En particulier, le tribunal conclut à l'absence d'un devoir de diligence unissant les parties ayant pu faire naître une cause d'action. En ce sens, elle opine:

> [*T*]*here are policy considerations that* […] *bar or limit the imposition of the duty of care alleged on the defendants in the circumstances of this case.* […] [B]oth defendants received approval of the federal government […]. The imposition by the courts of a duty of care not to release these substances into the environment *would therefore appear to be in conflict with express governmental policy*[231].

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[228] *European Tort Law*, New York, Oxford University Press, 2006 à la p 237 [nos italiques].

[229] Voir par ex *Andersen v St Jude Medical Inc*, 2012 ONSC 3660 aux paras 55-57, 14 CPC (7e) 391.

[230] 2005 SKQB 225, [2005] 7 WWR 665.

[231] *Ibid* au para 71 [nos italiques].

L'on en comprend que l'autorisation d'épandage se pose en porte à faux de l'action en réparation, conférant de facto à son titulaire une immunité civile.

Ces motifs découlent probablement d'une extension, dans la sphère privée, de ceux qui alimentent la dialectique du devoir légal et de l'obligation qui se niche dans l'appréciation du rapport de proximité unissant les parties. Autour d'elle gravitent souvent des litiges mettant en cause l'État et ses ramifications, en même temps qu'elles invitent à pondérer des enjeux collectifs (la sécurité des produits) et individuels (l'indemnisation du préjudice éventuellement subi). La sphère politique effleure ici celle juridique, dès lors que le droit n'admet la responsabilité de la Couronne que si une faute a été commise dans la mise en œuvre d'une politique (l'opérationnel), et non le choix de l'une d'elles plutôt qu'une autre (le politique)[232]. Une série de décisions rendues par les tribunaux ontariens illustre la vitalité de cette distinction, qui met, par voie de principe général[233], les décideurs publics à l'abri de toute action en responsabilité.

La première, *Klein v American Medical Systems Inc*[234], impliquait un dispositif médical destiné à réduire l'incontinence chez les femmes dont la distribution au Canada avait été dûment autorisée. Dans le cadre de l'appel d'un moyen déclinatoire présenté par les défendeurs

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[232] *Anns v Merton London Borough Council*, [1997] UKHL 4, [1978] AC 728 HL (Eng) [*Anns*] (dont les conclusions ont été avalisées par la Cour suprême du Canada : voir *Cooper v Hobart*, 2001 CSC 79 au para 30, [2001] 3 RCS 537). Voir Jean-Denis Archambault, « La distinction *politique-opérationnel* fournit-elle une assise judiciaire solide à la responsabilité civile de l'État consécutive à une décision de *politique* administrative ? » (1999) 59 R du B 581 à la p 608.

[233] *Dalehite v United States*, 346 US 15 (1953), 73 S Ct 956 au para 36 en est à l'origine ; mais elle a aussi été avalisée dans les affaires *Laurentide Motels c Beauport*, [1989] 1 RCS 705 à la p 722 et *Just c Colombie-Britannique*, [1989] RCS 1228, 64 DLR (4e) 689 (où la Cour résume la marche à suivre pour distinguer l'opérationnel du politique à la p 1245 et s, juge Cory). Dans le même sens : *Bernèche c Canada (PG)*, 2007 QCCS 2945, [2007] RJQ 1602 ; *Sauer v Canada (Agriculture)*, 246 OAC 256, 2009 CanLII 2924 (C div Ont).

[234] 2006 CanLII 42799 (C div Ont) [*Klein*]. Voir aussi *Attis v Canada (Minister of Health)*, 46 CPC (6th) 129, 157 ACWS (3d) 454, 2007 OJ No 1744 (CS Ont), rendue dans le contexte des implants mammaires [*Attis*].

(une requête en rejet), la Cour supérieure de l'Ontario recentre les doléances des requérants autour de l'arrêt anglais *Anns* afin de statuer sur l'existence (ou non) d'un devoir de diligence envers les victimes. Éclairée de cette démarche analytique en deux temps, la Cour évalue, dans la détermination de l'existence d'un rapport de proximité entre les parties, plusieurs facteurs, dont ceux-ci : « expectations of the parties, physical closeness, representations, reliance, the nature of the property or interest involved, assumed or imposed obligations, and whether there is a close causal connection between the alleged misconduct and the complaint of harm »[235]. À l'issue de son analyse, la Cour statue : « [I]t does not follow from a legislative decision to regulate an activity, product or industry that the legislative scheme created for this purpose *is intended to protect individual users and consumers* »[236].

À ses yeux, et si devoir il y a, c'est envers la collectivité et non envers les individus eux-mêmes qui pourront toujours exprimer leur insatisfaction lors d'élections[237]. Or, la loi (ou les règlements dérivés) n'a jamais investi Santé Canada de la mission de tester ou d'évaluer la sécurité d'un instrument médical. Tout au plus doit-il réviser l'information fournie par le fabricant, s'il nourrit des doutes quant à sa sécurité ou son efficacité : « [t]he duties of care toward the patient or consumer are qualitatively different from any public duty owed by Health Canada as the government regulator. Health Canada has no direct role in the commercial transaction or the medical decision-making that leads to individual use»[238], ce qui fait obstacle à la reconnaissance

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[235] *Klein*, *supra* note 234 au para 23.

[236] *Ibid* au para 24 [nos italiques].

[237] Par analogie et dès lors qu'il s'agit de responsabilité de l'État, la Cour s'autorise des affaires *AO Farms Inc v Canada*, [2000] FCJ No 1771 (QL) ; *Edwards c Barreau du Haut-Canada*, 2001 CSC 80, [2001] 3 RCS 562 au para 14 (impliquant le Barreau de l'Ontario) ; *Eliopoulos v Ontario (Minister of Health and Long Term Care)* (2004), 276 DLR (4e) 411 au para 17, 82 OR (3e) 321 (ONCA) (où le requérant alléguait que l'Ontario se devait de mettre sur pied un programme de prévention du virus du Nil).

[238] *Klein*, *supra* note 234 au para 33.

d'un rapport de proximité unissant les requérants à l'autorité régulatrice[239].

La même solution préside aux conclusions des arrêts *Taylor v Canada (Health)*[240] et *Attis v Canada (Health)*[241], où les demandeurs ont assigné en justice Santé Canada pour avoir omis de réguler adéquatement, conformément à la *Loi sur les aliments et drogues*[242], des implants temporomandilaires[243], dans le premier cas et mammaires dans le second. La Cour observe d'abord que la loi impose des obligations aux opérateurs économiques. Mais outre l'émission d'un certificat de conformité préalable à la mise en marché, elle n'impose pas

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[239] Or la Cour affirme, *obiter dictum*, que même s'il en eût été autrement, l'analyse du second volet du test issu de l'arrêt *Anns*, *supra* note 232 aurait suffi à faire échouer le recours, et ce, pour une raison quintuple : (1) cette situation créerait une responsabilité illimitée pour des groupes illimités ; (2) la chose équivaudrait à mettre sur pied, par voie jurisprudentielle, un circuit assurantiel financé par les contribuables ; (3) cela réduirait la capacité des pouvoirs publics à pondérer tous les intérêts en présence pour prendre des décisions concernant les dispositifs médicaux, en plus de (4) freiner le développement de la science et la technologie et (5) engendrerait un avalanche de poursuites. En conséquence, la Cour a accueilli l'appel (*Klein*, *supra* note 234 au para 34 et s).

[240] *Taylor v Canada (Minister of Health)* (2007), 285 DLR (4e) 296, 160 ACWS (3e) 385 [*Taylor*]. À l'issue d'une motion en vue d'obtenir l'autorisation de faire décider l'exposé de cause en première instance par la Cour d'appel, cette dernière défère au juge du fond la question de déterminer les contours, s'il en est, du devoir de diligence envers les citoyens (voir *Taylor v Canada (AG)*, 2012 ONCA 479, 111 OR (3e) 161 aux paras 121-22).

[241] *Attis v Canada (Minister of Health)*, (2008) 93 OR (3e) 35, 300 DLR (4e) 415 (Ont CA) [*Attis CA*].

[242] LC 1952-1953, c 38 ; LRC 1985, c F-27 (la poursuite fut basée sur la loi datant de 1953, mais la version de 1985 est également citée dans la décision). Selon les demandeurs,

> the Attorney General […] breached a private law duty of care: (a) by not preventing the importation and sale of the implants; (b) by making regulations pursuant to its statutory powers negligently ; (c) by not exercising its statutory and regulatory powers to require Proplast labelling, and compliance with the regulations in other respects; (d) by not warning health care professionals and the potential recipients of the risks attaching to the devices; (e) by not monitoring the consequences of the insertion of the implants ; and (f) by not "remediating" the injuries suffered [*Taylor*, *supra* note 240 au para 16].

[243] Gagné, *supra* note 227.

d'obligations particulières à l'autorité régulatrice, qui n'est pas tenu de procéder à des essais[244]. Il en découle que cette marge d'appréciation évoque l'exercice d'un pouvoir discrétionnaire et non un dysfonctionnement dans la prestation d'un service qui lui seul ouvrirait la porte à une action en indemnisation du préjudice corporel. La situation serait différente – de suggérer, obiter dictum, la Cour d'appel ontarienne – si toutefois le décideur public avait un rapport direct avec le justiciable à l'occasion, notamment, de la mise sur pied de ses politiques publiques: « it is far from 'plain and obvious' that these relationships, constantly evolving through new forms of electronic communication, will not be interpreted as being sufficiently proximate to create a private law duty of care on the part of the regulator. The role of liability for public authorities in Canada continues to be defined »[245]. Ce détour dans la sphère (imaginaire?) de la responsabilité des régulateurs permet de comprendre que le Canada ne s'est pas encore engagé, d'un point de vue constitutionnel, dans une réflexion approfondie autour de la synergie entre la responsabilité civile, la sécurité des produits et le fédéralisme. L'adoption de la *Loi canadienne sur la sécurité des produits de consommation* [246] en sera-t-elle l'occasion?

Conclusion

Dès lors qu'elles interpellent, d'un côté, l'approche ex ante aux risques (laquelle évoque traditionnellement le droit public), et, de l'autre, l'approche ex post à la matérialisation de ces mêmes risques (laquelle renvoie instinctivement à la responsabilité civile), la prévention et l'indemnisation des dommages causés par les produits défectueux apparaissent a priori antinomiques. Des traces d'un nouveau phénomène de porosité entre la prévention des accidents de la consommation et l'indemnisation du préjudice corporel sont perceptibles pour peu que l'on préconise un cadre analytique transversal, articulé autour des fondements, des effets et des finalités qui sous-tendent les

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[244] En conformité avec le *Règlement sur les instruments médicaux*, DORS/98-282.

[245] *Attis CA*, *supra* note 241 au para 66.

[246] *Supra* note 3.

deux corpus de normes[247]. Les catégories traditionnelles du droit privé et de droit public sont appelées à être mises au service d'un exercice commun – la régulation des produits – que cristallisent les trois temps du risque; soit son évaluation, sa gestion et sa communication. Le droit en action matérialise ce souhait ?

L'analyse comparative aura permis de mettre en relief différentes attitudes à la coordination ou l'ignorance mutuelle des versants préventif et indemnitaire des atteintes à la santé et la sécurité des consommateurs, qu'induisent différents modèles de fédéralisme. À son issue, l'on comprend que d'autres variables – le droit criminel, la création du marché intérieur, etc. – déplacent le centre de gravité de la réflexion vers des problématiques parfois plus larges, à l'occasion plus étroites, à première vue périphériques. Parce qu'elle découle, en même temps, d'approches différentes au fédéralisme et de l'expression de choix politiques polyformes, la synergie entre la prévention et l'indemnisation du préjudice corporel connote toujours un caractère éclaté, alors même que l'adoption de textes d'harmonisation, d'unification, semble précisément induire l'idée contraire.

En 1975, le Conseil précisait que la qualité de vie « implique la protection de la santé, de la sécurité et des intérêts économiques du consommateur »[248]. Il préconisait une conception holistique de l'acte de consommation, embrassant toutes ses composantes, dont la sécurité générale des produits[249]. Cette symbiose sous-tend-elle aujourd'hui une politique supranationale cohérente de protection des consomma-

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[247] Cafaggi, *supra* note 6 ; Geraint Howells, « The Relationship Between Product Liability and Product Safety: Understanding a Necessary Element in European Product Liability Through a Comparison With the U.S. Position » (2000) 39 : 3 Washburn LJ 305 à la p 306.

[248] CEE, *Résolution du Conseil du 14 avril 1975 concernant un programme préliminaire des CEE pour une politique de protection de l'information des consommateurs*, [1975] JOC 092. Celui-ci a été précédé de l'adoption de la *Charte de protection du consommateur* (initialement formulée par les Nations-Unies), Résolution 543 (1973) de l'Assemblée consultative du CE.

[249] Cette dialectique est reconduite à l'intérieur du *Traité portant sur la Communauté des Caraïbes* (CARICOM), où les articles 184 et 185 font état de l'impératif de protéger à la fois les intérêts économiques et la protection de la santé.

teurs ? La réponse apparaît négative. Même au sein de l'UE, plus jeune juridiquement, le fondement juridique de la sécurité des produits n'apparaît pas clairement, alors qu'il oscille entre l'exercice de compétences au mieux incidentes, au pire, éloignées. Cette assise plurale, ici et là imprécise, pose un frein à la mise sur pied de stratégies de régulation globales et cohérences, et explique leur nature souvent sectorielle, mue par des crises. Cet éclatement de la matière représente une limite importante à toute tentative de reconstruction théorique autour d'elle; à tout le moins en conditionne-t-elle fortement l'analyse. Le bilan comparatif permet de conclure que par-delà des textes constitutionnels muets quant à la santé et la sécurité des consommateurs, les tribunaux légitiment la plupart du temps l'exercice d'une véritable compétence fédérale. Le défi ultérieur n'est-il pas prévisible? Il consistera, à l'aide d'une approche dialogique mettant en scène les différentes Constitutions (incluant le *Traité de Lisbonne*[250]), à dégager, dans l'optique de la circulation des marchandises et des droits fondamentaux, le fondement juridique de ce champ du droit. Car la sécurité de produits est aussi tributaire de celle des personnes. Une seconde clef de lecture se jouxte alors à l'analyse risque/bénéfice qui sous-tend, à Washington, Ottawa ou à Bruxelles, l'exercice de régulation, et rapproche d'autant la matière du domaine des droits et libertés de la personne.

« Droits à » l'intégrité et à la santé de la personne, voire le spectre de la dignité, ne sous-tendent ils pas, dans une mesure beaucoup plus obscure, ces choix de régulation? Bien au-delà du débat entourant l'étendue et la portée du principe de précaution, la question mériterait d'être posée, à l'heure où le paradigme constitutionnel contemporain est dominé par une protection accrue des droits fondamentaux. Aucun des trois modèles étudiés n'y semble particulièrement sensible.

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[250] *Supra* note 78.

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Of Mitochondria and Men: Why Brain Death is not the Death of the Human "Organism as a Whole"

*Jacquelyn Shaw**

Death is a phenomenon that resists simple explanation. While the cardiopulmonary criterion of death has been used for centuries, in most nations (including the US and Canada) brain death has also been accepted since 1968 as a second legal criterion, held to be biologically equivalent to bodily death. This equivalence has been argued to derive either from the brain's control over body functions or from the brain's work against entropy, with a dead brain thereby producing a dead body. Subsequently, some have found these claims wanting. An alternative body-centred view, based on the functioning of the body's mitochondria, is that in brain death, only the brain is dead, while the body may not necessarily be. Mitochondria are cellular organelles descended from ancient bacteria, symbiotically providing energy for entropy-resistance and sharing control over life processes. All of death's features – its universality, oxygen-dependence, inevitability, link with aging, irreversibility, and association with disintegration and decay – may be explained as logical side-effects of mitochondrial failure. Yet the role of mitochondria in human life and death has been overlooked for over four decades in the legal and bioethical literature, which has focused instead on processes at the whole-organism level. Challenges remain however: if brain death and bodily death are not biologically equivalent, this may prove problematic for organ donation's "dead donor rule," which requires organs to be transplanted only from the bodies of dead consenting donors, not from those who are still dying. Nevertheless, brain death could be retained as a legal fiction satisfying the dead donor rule, which would allow its

La mort est un phénomène qui résiste à une explication simple. Bien que le critère de la mort cardiopulmonaire soit utilisé depuis des siècles, dans la plupart des pays (y compris les États-Unis et le Canada) la mort cérébrale est également acceptée depuis 1968 comme critère juridique alternatif, ce critère étant considéré comme biologiquement équivalent à la mort corporelle. On a avancé que cette équivalence dérive soit du contrôle du cerveau sur les fonctions du corps, soit du travail qu'exerce le cerveau pour contrer l'entropie, un cerveau mort produisant ainsi un corps mort. Par la suite, certains ont trouvé des lacunes au niveau de ces revendications. Un autre point de vue centré sur le corps, axé plutôt sur le fonctionnement des mitochondries du corps, considère que lors de la mort cérébrale, seul le cerveau est mort, ce qui n'est pas nécessairement le cas pour le corps. Les mitochondries sont des organites cellulaires, descendantes de bactéries anciennes, fournissant de façon symbiotique de l'énergie servant à combattre l'entropie et participant au contrôle des processus régissant la vie. Toutes les caractéristiques reliées à la mort – son universalité, sa dépendance à l'oxygène, son caractère inévitable, son lien avec le vieillissement, son irréversibilité et son association avec la désintégration et la décadence – peuvent être expliquées en temps qu'effets secondaires logiques de l'échec mitochondrial. Pourtant, le rôle des mitochondries au niveau de la vie humaine et de la mort a été négligé pendant plus de quatre décennies dans la littérature juridique et bioéthique, celle-ci ayant plutôt mis l'accent sur les processus au niveau de l'organisme entier. Cependant, des questions

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societal benefits to persist. Of fundamental importance is the principle that future patients be adequately informed regarding brain death, in order to ensure legally valid, informed consent for organ donation.

subsistent : si la mort cérébrale et la mort du corps ne sont pas biologiquement équivalentes, cela peut s'avérer comme étant problématique pour la « règle du donneur mort », qui exige que les organes à transplanter proviennent uniquement d'organes de donneurs morts et consentants, et non pas de ceux qui sont encore en train de mourir. Néanmoins, la mort cérébrale pourrait être retenue comme une fiction juridique satisfaisant la règle du donneur mort, permettant ainsi à ses avantages sociaux de persister. Le principe voulant que dans le futur les patients soient informés de manière adéquate concernant la mort cérébrale est d'une importance fondamentale, et ceci afin d'assurer le consentement juridiquement valable et éclairé au don d'organes.

Introduction

Since ancient times, death has been a phenomenon surrounded by mystery. Immediately before and after death, the same physical matter appears present, while after death, something intangible is permanently gone.[1] Like blind men describing an elephant,[2] scholars seeking to define death have unsuccessfully attempted piecemeal explanations of death's strange commonalities in humans and other animals: its universality; its seeming inevitability, irreversibility, and link with aging; and its oxygen-dependence and temporal association with cardiopulmonary cessation, loss of whole-body integration, and decay.

For centuries, human death was diagnosed solely via the cardiopulmonary criterion: the interrelated cessation of breathing and heartbeat. Then, in 1968, Canada and other nations also embraced "brain death" as a second, legally equivalent criterion. Over four decades later, brain death is a familiar

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[1] The search for a definition of death is complicated by the lack of an accepted definition of life. Some resort to religious arguments involving an incorporeal spirit or vital essence. Seeking a more scientific source within the component matter of living things, David Suzuki and Wayne Grady speculate that life is a synergy among inanimate components rather than being due to any one component: "Life itself is … testimony that wholes are greater than the sum of their parts … [I]f there is no vital force or spirit present in the ultimate particles of matter, then life must result from the collective interaction of nonliving parts, a synergy that produces such emergent properties as respiration, digestion, and reproduction": David Suzuki & Wayne Grady, *Tree: A Life Story* (Toronto: Greystone Books, 2004) at 52. This paper explores in detail the idea of synergy within living things.

[2] "A certain raja presented an elephant to a group of blind men … When asked what the elephant was, the man presented with the head answered, 'Sire, an elephant is like a pot.' He who had observed the ear replied, 'An elephant is like a winnowing basket.' Presented with a tusk, another said it was a ploughshare … [Q]uarrelling, each to his view they cling. Such folk see only one side of a thing": Parable of the Blind Men and the Elephant, *Khuddaka Nikaya* 3: Udana 68-69, this version cited in Caitlin O'Connell, *The Elephant's Secret Sense: The Hidden Life of the Wild Herds of Africa* (Chicago: University of Chicago Press, 2007) at 183. Coincidentally, another author has noted the similarity between this parable and the scholarly debate surrounding death, but has adopted a different philosophical position; see D Alan Shewmon, "Constructing the Death Elephant: A Synthetic Paradigm Shift for the Definition, Criteria, and Tests for Death" (2010) 35:3 J Med Philos 256 at 257, 264-65 [Shewmon, "Elephant"].

concept in Canada and other developed nations. Worldwide, most countries apply the "whole-brain" version of the neurological criterion of death, wherein the entire brain (including the brain stem) has permanently ceased functioning; Canada, however, shifted to a brain stem criterion in 2003,[3] and some suggest that the US may one day follow.[4] Overall, many consider the societal acceptability of the concept of brain death settled.[5] Yet others disagree.[6]

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[3] From 1968 to 2003, Canada employed the "whole-brain" criterion, like the US, Australia, and many other nations. However, the issuance of the 2003 Canadian Council for Donation and Transplantation (CCDT) brain death guidelines marked a shift to the brain stem criterion that the United Kingdom adopted in the 1970s. The CCDT authors stated, "In Canada we accept the clinical criteria for brain death (essentially *brain stem* death)" and "All of the clinical criteria for brain death are met with irreversible, total destruction of the *brain stem*. This is confirmed in the recently adopted Canadian [CCDT] guidelines for the neurological determination of death": G Bryan Young et al, "Brief Review: The Role of Ancillary Tests in the Neurological Determination of Death" (2006) 53:6 Can J Anaesth 620 at 620-21 [emphasis added]. However, use of the new criterion has been non-uniform across Canada; see Wayne Kondro, "Fragmented Organ Donation Programs Hinder Progress" (2006) 175:9 Can Med Assoc J 1043 at 1044.

[4] While the 2009 US examination of the defensibility of brain death reaffirmed whole-brain death, some interpret its wording as preparing for a future US move to brain stem death: see D Alan Shewmon, "Brain Death: Can It Be Resuscitated?" (2009) 39:2 Hastings Cent Rep 18 at 20, 22 [Shewmon, "Brain Death Resuscitated"].

[5] "[T]he whole-brain concept of death now has reached a degree of societal acceptance rare for bioethical issues, one that has been sufficient for nearly all jurisdictions in the US and many Western countries … Indeed, some bioethicists no longer regard brain death as a seriously controversial issue and have grown bored with its persisting discussion": James L Bernat, "A Defense of the Whole-Brain Concept of Death" (1998) 28:2 Hastings Cent Rep 14 at 14 [Bernat, "Whole-Brain Defense"].

[6] See e.g. Paul A Byrne & Walt F Weaver, "'Brain Death' Is Not Death" in Calixto Machado & D Alan Shewmon, eds, *Advances in Experimental Medicine and Biology*, vol 550: *Brain Death and Disorders of Consciousness* (New York: Springer Science+Business Media, 2004) 43; Ari Robin Joffe, "The Neurological Determination of Death: What Does It Really Mean?" (2007) 23:2 Issues L & Med 119; D Alan Shewmon, "'Brainstem Death,' 'Brain Death' and Death: A Critical Re-evaluation of the Purported Equivalence" (1998) 14:2 Issues L & Med 125 [Shewmon, "Critical Re-evaluation"].

As one of the few certainties in human life, the declaration of death triggers important legal decisions regarding life support, organ harvesting (with consent), estate settling, care of surviving minor offspring, and culturally appropriate disposal of remains. These decisions are justified by the societal understanding of biological death as irreversible. The biological justification for accepting cardiopulmonary silence as legal death seems straightforward, since the loss of breathing and/or heartbeat has long been observed to generally become irreversible after a period of time. Yet the biological rationale for brain death as a legal criterion of death is less clear. Thus, neurological death may benefit from a new perspective, more consistent with recent scientific evidence.

I. Human Death: Conceptualizing an Ancient Enigma

Among those who theorize about life and death, a diversity of philosophical viewpoints exists. There are, for instance, those who argue (as this paper does) that the major locus of life and death in human beings is the physical organism or body, with the human "mind" (and perhaps also "soul") being mainly an epiphenomenon of one particular body part and its functions, i.e., the brain. In contrast, others maintain that, during life, human beings consist of two components: a body and a mind (where the latter is *not* simply an epiphenomenon of brain functions), possibly in addition to a soul that is linked to either the body or the mind.[7] These various perspectives on human life will obviously entail very different interpretations of what death is. As some authors have noted, these different initial philosophies colour interpretations of empirical observations about life and death in ways that tend to confirm the holder's original philosophical position.[8] Strong opposition and heated debate result.

Two competing conceptualizations of human death have historically dominated scholarly debate. One is the "personhood" camp, which more greatly values the contribution of mental changes in death, and which argues that death represents loss of a human "person" with unique mental attributes (i.e., a mind). The second is the "body-centred" camp, which maintains that death represents the physical end of the human "organism." Despite fierce, protracted debate, there are no signs of agreement or compromise likely be-

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[7] Shewmon, "Elephant", *supra* note 2 at 265.

[8] *Ibid* at 264-65.

tween these two opposing camps;[9] no thought experiments resolve the issue and, as noted, each camp may interpret its empirical observations of death as confirming its original position.

Accordingly, a more detailed elucidation of the personhood perspective on death seems especially useful here. The personhood view argues that a human being possesses mental traits – a unique constellation of mental attributes, skills, memories, relationships, etc. Mental personhood is distinct from "legal personhood" (the legal capacity to hold rights), which all living humans are held to possess after birth. Some scholars, such as Edward Bartlett and Stuart Youngner, have argued that the loss of characteristics typically associated with mental personhood – i.e., consciousness and cognition – should be deemed the key event triggering a declaration of legal death.[10] This would require employing a "neocortical" (or "higher-brain") criterion of brain death, rather than the whole-brain neurological criterion that is currently the most common choice worldwide. However, many view a neocortical death criterion as too radical in relation to societal values;[11] notably, no na-

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[9] *Ibid* at 263-64 ("[t]he question … whether human personhood is actually separable from human organismhood … has been debated intensely by philosophers for a very long time without any signs of rapprochement").

[10] Bartlett and Youngner argue, "Death is not the loss of something … [I]t is the loss of someone. Because a human being is a person, the irreversible destruction of the cortex – i.e., the center of consciousness and cognition – constitutes death"; therefore, they conclude, "We believe that only the higher brain functions, consciousness and cognition, define the life and death of a human being": Edward T Bartlett & Stuart J Youngner, "Human Death and the Destruction of the Neocortex" in Richard M Zaner, ed, *Death: Beyond Whole-Brain Criteria* (Boston: Kluwer Academic Publishers, 1988) 199 at 211, 215.

[11] See e.g. James L Bernat, Charles M Culver & Bernard Gert, "On the Definition and Criterion of Death" (1981) 94 Ann Intern Med 389 ("[t]o bury such patients while they breathe and have a heartbeat, most would view as at least esthetically unacceptable" at 391). This still appears as true today as in 1981, as indicated by the 2008 US President's Council on Bioethics, which stated, "Only when all would agree that the body is ready for burial can that body, with confidence, be described as dead," and, in discussing the potential to harvest organs from patients in a persistent vegetative state, "[If] the Kantian prohibition against treating living human beings merely as means and not also as ends … is worth preserving, … we would do better to restrict donation-eligibility to patients who have died, as determined by clinical tests for … 'whole brain death'": President's Council on Bioethics, *Controversies in the Determination of Death: A White Paper by the President's*

tion has adopted this criterion to date. A neocortical criterion also seems inconsistent with what many ordinary, untrained members of the public may mean by "death," which this paper takes as a valuable perspective. What ordinary members of the public think death involves has relevance to their provision of informed consent (e.g., for processes such as organ donation), so it is important to know if medical perspectives conflict with that view. This "ordinary person" perspective, at least in part, seems to involve the physical death of the body, as explained in Part IV, below.

Neurologist James Bernat, a leading architect of the whole-brain death concept, has argued, "[W]e refer to … the same phenomenon when we describe the death of a dog [and] … the death of a human being."[12] This is the view that the ordinary "man or woman in the street" probably holds regarding death, based on his or her empirical observations. Such "lay" observation suggests that death (a) is irreversible, (b) involves a cessation of all of the observable physical, as well as mental, functions of a human being or other organism, (c) is often associated with aging or (d) with the interruption of oxygen, and (e) closely precedes widespread tissue destruction and the onset of bodily decay. Some argue that death involves a discrete point in time, while others believe it is a process occurring over a period of time.[13]

Empirically too, as Bernat suggests, death is a phenomenon similarly affecting not only humans but all known animal and other life. No scientific evidence suggests that death is a different process having different evolutionary origins in non-human vertebrate animals, such as dogs, than in people. Consistent with the Darwinian view of human beings as animals, death appears to be equivalent and homologous[14] in humans and non-human vertebrates. This being widely accepted, the body seems a key part of explaining death in the commonly understood sense. Thus, if death is, as Bernat argues,

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Council on Bioethics, December 2008, online: PCB Archive <http://bioethics.georgetown.edu/pcbe/reports/death/index.html> at 53, 72 [President's Council].

[12] Bernat, "Whole-Brain Defense", *supra* note 5 at 15.

[13] *Ibid* at 15-16.

[14] "Homologous" characteristics are those that trace from common ancestry, in contrast to superficially similar traits created through convergent evolution from different ancestral origins.

"the same phenomenon" in humans and non-human animals, then it seemingly must involve the body and not just mental personhood; this is because loss of personhood is a criterion that cannot be applied to non-human vertebrates without first ascribing mental personhood to them – an approach which has not found general acceptance. To allow for the observed "trans-species universality," death – whether of humans or of animals – must involve destruction of the body, rather than of the mental person.[15]

However, while this paper accepts the above view – that death is "univocal," i.e., the same process in humans and other (vertebrate[16]) animals – this view is not universally accepted. Some philosophers, adopting a personhood view of human death, suggest that death should be seen as based on mental rather than body-related changes and therefore as a different process in humans (and "higher" animals) compared with "less advanced" animals.[17] As noted, this paper accepts death as a principally biophysical process exhibiting trans-species universality, based on a common explanation in all vertebrates, and it will not further discuss the view that death may differ in humans and non-human organisms.

A second reason to reject the view that death involves simply the loss of mental personhood characteristics is that we would also need to explain by what mechanism mental personhood (and its disappearance) give rise to, or are tightly linked with, an organism's physical life functions (and their permanent loss in death). One illustration of a mental personhood approach to life and death is the view of "transhumanist" author and information technology expert Ray Kurzweil. He argues, based on his observations of a "dynam-

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[15] See Jocelyn Downie, "Brain Death and Brain Life: Rethinking the Connection" (1990) 4:3 Bioethics 216 at 223.

[16] While the present author argues that the same biophysical death mechanism operates in all animals, one cannot argue with complete accuracy that "death is the same process" in invertebrate animals as in humans and vertebrates. This is because invertebrates (but not vertebrates) can reproduce asexually, by subdivision of the body of a "parent" organism into new "offspring." Thus, a significant portion of the original "parent" invertebrate's body may survive and continue functioning in "daughter" organisms, even when the parent is destroyed, potentially adding a dimension to the invertebrate death process that has no counterpart in vertebrates.

[17] See e.g. John P Lizza, *Persons, Humanity and the Definition of Death* (Baltimore: Johns Hopkins University Press, 2006) at 18-19.

ic equilibrium" existing among living and dying cells in a healthy human body, that human beings are "energy patterns," much like computer programs or files, in which some elements (i.e., cells) are continually replaced while the overall life of the program or file (i.e., the human being) persists over time.[18] Kurzweil's argument resembles and may be based upon the earlier claim of cybernetics founder Norbert Wiener:

> Our tissues change as we live: the food we eat and the air we breathe become flesh of our flesh and bone of our bone, and the momentary elements of our flesh and bone pass out of our body every day with our excreta.… We are not stuff that abides but *patterns that perpetuate themselves*.[19]

Kurzweil and other transhumanists anticipate that each human "file" – i.e., the information content of consciousness comprising each individual human "pattern" – will one day be immortalized permanently *in silico*, making death a thing of the past, as we physically and mentally merge with computers.[20] Nevertheless, neither Kurzweil nor Wiener offers a theory regarding how our bodies, housing these mental energy "patterns," persist physically, nor why these physical bodies cease to function at some point and cannot seemingly be repaired by any known means.

As this paper demonstrates, however, there is a plausible scientific mechanism that can explain these human mental patterns' persistence within physical bodies for a finite period, followed by their eventual, irreversible disappearance. For the reasons noted, this paper will accept the view of death as primarily a physical process, involving the body (and the mind as derived from that body). In this view, then, death of the mind is a natural consequence of death of the body. This paper will not further debate the view of

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[18] Ray Kurzweil, *The Singularity Is Near: When Humans Transcend Biology* (New York: Penguin Books, 2005) at 325.

[19] Norbert Wiener, *The Human Use of Human Beings: Cybernetics and Society*, 2d ed (New York: Doubleday, 1954) at 96 [emphasis added].

[20] See DI Dubrovsky, "Cybernetic Immortality. Fantasy or Scientific Problem?", *2045 Initiative* (2 November 2012), online: 2045 Initiative <http://2045.com/articles/30810.html>; see also Lauren O'Neil, "Human immortality could be possible by 2045, say Russian scientists", *CBC News* (31 July 2012), online: CBC <www.cbc.ca/newsblogs/yourcommunity/2012/07/human-immortality-could-be-possible-by-2045-say-russian-scientists.html>.

death as based on loss of mental personhood, beyond acknowledging that a new body-centred explanation for death is unlikely to convince those who take loss of personhood to be the key event in death.

II. Brain Death and Death of the Body: The Search for a Defensible Biological Rationale

If we accept, as this paper does, that death is a physical process, such that the death of a dog and the death of a human being are based on the same physical, biological phenomenon, and if brain death and bodily death are equivalent, then how can we explain the various aspects of the "elephant" – for example, the body's permanent loss of functioning, the irreversibility of this loss, and death's temporal association with disintegration and decay? Several theories have attempted to account for this over the decades in which brain death has been employed as a criterion for legal death.

A. The Brain as "Master Regulator" of the Body's Functions

According to the view articulated by the 1981 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, the first of two US bioethics commissions justifying the use of whole-brain death as a legal death criterion, the functioning brain in a human being (or non-human vertebrate) serves a "master regulatory" role, directing and coordinating all functions of the entire body.[21] In forming its conclusion, the Commission argued that the functioning whole brain makes possible, as well as governs, a kind of synergistic "pseudo-entity" that is more than the sum of its component cells, tissues, and organ systems.[22] The

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[21] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (Washington, DC: President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1981) at 32, 34-35 [President's Commission]. The President's Commission report was, in turn, founded on the analysis of death by Bernat, Culver & Gert, *supra* note 11.

[22] The President's Commission did not actually employ the term "pseudo-entity" in describing the "organism as a whole" that it saw as being formed by the integration and coordination functions of the whole brain. Applying a whole-brain formulation, it stated that "life consists of the coordinated functioning of the various bodily

Commission termed this entity "the organism as a whole."[23] Notably, the component cells, tissues, and organ systems of the organism as a whole display a characteristic degree of "somatic integration" by behaving cooperatively to produce "emergent functions"[24] – functions seen only at the level of the organism (e.g., whole-body movement and consciousness). As Bernat clarifies, the organism as a whole comprises a "set of functions that are greater than the mere sum of the organism's parts,"[25] due to synergistic

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systems, in which process the whole brain plays a crucial role" (President's Commission, *supra* note 21 at 35) and that:

> [t]he functioning of many organs … and their integration are "vital" to individual health in the sense that if any one ceases and that function is not restored or artificially [replaced], the organism as a whole cannot long survive. All elements in the system are mutually interdependent, so that the loss of any part leads to the breakdown of the whole and, eventually, to the cessation of functions in every part [*ibid* at 32].

Thus, "the brain [is given] primacy not merely as the sponsor of consciousness … but also as the complex organizer and regulator of bodily functions.… Only the brain can direct the entire organism": *ibid* at 34. Further, "the centrality accorded the brain reflects both its overarching role as 'regulator' or 'integrator' of other bodily systems and the immediate and devastating consequences of its loss for the organism as a whole": *ibid* at 35. Accordingly, the Commission concluded that the whole-brain concept of death merely "reinforce[s] the concept of death as a single phenomenon – the collapse of psycho-physical integrity.… Although absence of breathing and heartbeat may often have been spoken of as 'defining' death … these [are] merely evidence for the disintegration of the organism as a whole": *ibid* at 58.

[23] The "organism as a whole" concept has been credited to Jacques Loeb: see James L Bernat, "The Whole-Brain Concept of Death Remains Optimum Public Policy" (2006) 34:1 JL Med & Ethics 35 at 38 [Bernat, "Whole-Brain Optimum"].

[24] An "emergent function" has been defined as "a property of a whole that is not possessed by any of its component parts, and that cannot be reduced to one or more of its component parts": *ibid*. Or alternatively: "A property … is defined as 'emergent' if it derives from the mutual interaction of the parts": Shewmon, "Critical Re-evaluation", *supra* note 6 at 137. See also Francis Crick, *The Astonishing Hypothesis: The Scientific Search for the Soul* (New York: Charles Scribner's Sons, 1994) ("[w]hile the whole may not be the simple sum of the separate parts," its properties can be predicted "from the nature and behaviour of the parts *plus* the knowledge of how all these parts interact" at 11 [emphasis in original]).

[25] Bernat, "Whole-Brain Optimum", *supra* note 23 at 38.

interactions among those parts. Somatically integrated living organisms do seem to behave as if the component tissues together pursue the common purpose of one "individual."

Justifying its acceptance of the whole-brain criterion of death, the President's Commission claimed that within the organism as a whole, three organs – the heart, lungs, and brain – form a very close relationship. It held that these three organs form a "triangle of interrelated systems *with the brain at its apex*,"[26] suggesting the brain's greater importance as the supposed regulatory controller of all body functions. This relationship between the three organs was said to be so close that permanent loss of any one "corner" of the triangle would quickly destroy the other two corners.[27] In the Commission's view, emergent life functions of living organisms are produced by synergistic co-operation and integration among specialized body tissues, which in turn originate with the brain's master role:

> One characteristic of living things which is absent in the dead is the *body's capacity to organize and regulate itself*. In animals, *the neural apparatus is the dominant locus of these functions*.[28]

And:

> [In humans and higher animals] the functioning of the whole brain [is understood] as the hallmark of life because the *brain is the regulator of the body's integration*.[29]

Therefore:

> [D]eath is that moment at which the body's physiological system *ceases to constitute an integrated whole*. Even if life continues in individual cells or organs, *life of the organism as a whole requires complex integration*, and without the latter, a person cannot properly be regarded as alive.[30]

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[26] President's Commission, *supra* note 21 at 33 [emphasis added].

[27] *Ibid* at 33.

[28] *Ibid* at 32 [emphasis added].

[29] *Ibid* [emphasis added].

[30] *Ibid* at 33 [emphasis added].

This loss of bodily integration with brain death was argued to be rapid. After brain death, it was claimed, the body quickly ceases operating as a functioning, integrated whole, and its systems become uncontrolled and uncoordinated:

> [T]he brain is necessary for the functioning of the organism as a whole. It integrates, generates, interrelates, and controls complex bodily activities. A patient on a ventilator with a totally destroyed brain is merely a group of artificially maintained subsystems since *the organism as a whole has ceased to function*.[31]

Associated with this view was the argument that, despite ventilator support, cardiopulmonary death will occur reliably and spontaneously soon after brain death. As the President's Commission stated, "[e]ven with extraordinary medical care, these [somatic] functions cannot be sustained indefinitely – typically *no longer than several days*."[32]

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[31] Bernat, Culver & Gert, *supra* note 11 at 391 [emphasis added].

[32] President's Commission, *supra* note 21, cited in Shewmon, "Critical Re-evaluation", *supra* note 6 at 134 [emphasis added]. See also C Pallis, "Whole-Brain Death Reconsidered – Physiological Facts and Philosophy" (1983) 9:1 J Med Ethics 32 ("[t]he reasons why the heart stops *within a short while* when the brain-stem-mediated baroceptor reflexes are disrupted, and when the vasometer centre is destroyed, are complex but the empirical fact is established beyond all doubt" at 36 [emphasis added]). The President's Commission reported that "the heart usually stops beating within two to ten days": *supra* note 21 at 17. It further argued that "the centrality accorded the brain reflects both its overarching role as 'regulator' or 'integrator' of other bodily systems and *the immediate and devastating consequences of its loss* for the organism as a whole": *ibid* at 35 [emphasis added]. A 1977 study claimed 99% of subjects "died *within a week* with evidence of a dead brain," but recommended a larger study: National Institutes of Neurological and Communicative Disorders and Stroke, "An Appraisal of the Criteria of Cerebral Death: A Summary: A Collaborative Study" (1977) 237:10 JAMA 982 at 984-85 [NINCDS]. Shewmon has argued that this conclusion was based on a very limited patient sample (503 patients) with a sizeable (1%) error rate; to lower these error rates to a more acceptable 0.001% (given the high stakes of declaring death), a sample of over one million patients would be needed, a study that has yet to be done: D Alan Shewmon, "The Probability of Inevitability: The Inherent Impossibility of Validating Criteria for Brain Death or 'Irreversibility' Through Clinical Studies" (1987) 6:5 Stat Med 535 at 548. While 503 instances of support for a claimed biological rule may at first blush appear more substantial to some than a

On the positive side, the master regulator view provided a rationale for organs to be harvested without violation of the "dead donor rule" ("DDR"), an ethical rule that requires that organ harvesting not be the proximate cause of a donor's death. Because, under the master regulator view, the body of a brain-dead patient ostensibly is – or shortly will be – dead too, organ harvesting does not violate the DDR. Undoubtedly, many organ recipients have benefited greatly from the donor organs made available by the master regulator perspective. However, while it is a positive result for those organ recipients, this benefit may be outweighed by its costs in terms of the integrity of information provided to patients. In the years after the President's Commission, the master regulatory theory was demonstrated to suffer from a number of defects, especially as regards its account of the integrated "organism as a whole," wherein emergent body functions were argued to originate from brain regulatory function**.**

First, to date, no precise, brain-based mechanism has ever been elucidated for the claimed onset of cardiopulmonary death within days after brain death. Some researchers, such as Paul Byrne and Walt Weaver, argue that no neurological mechanism exists to allow brain-mediated integration of all body systems: "[T]he brain as a whole has no physiologically identifiable … functions that could rightly be called the 'life-giving … functions.'"[33] Neurologist Alan Shewmon has argued that only three anatomical means exist by which the brain *could* coordinate bodily functions: the spinal cord, vagus nerve, and pituitary. Based on these, he concludes that if the master regulator view were correct, the effect of brain death (which often spares pituitary function) on bodily integration would be clinically identical to the combined effects of severance of the cervical spinal cord (cutting off the body from any brain input) and pharmacologically-induced ablation of the vagus nerve function.[34] Yet spinal cord severance is not a condition in which the body is

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175-patient study disproving that rule, in fact, these numbers must be considered in light of the different weight to be given to instances of proof and disproof, the latter being weighted more heavily in scientific research, since they indicate problems with a claimed rule. In addition, the 503-patient study had a high reported error rate. This tends to corroborate (not contradict) the 175-patient study's conclusion of possible unreliability in the claimed rule that brain death leads immediately or rapidly to cardiopulmonary death.

[33] Byrne & Weaver, *supra* note 6 at 44.

[34] Shewmon, "Critical Re-evaluation", *supra* note 6 at 140-41. Such ablation may be accomplished with atropine: see Young et al, *supra* note 3 at 625.

considered "dead," suggesting that the master regulator view is incorrect. Thus, a mechanism for the rapid cessation of heartbeat in brain death remains lacking.

A second flaw is that the theory that brain function produces emergent functions of the "organism as a whole" cannot account for cases such as hypothermia or barbiturate intoxication, where total brain malfunction occurs even for several days, but is accompanied by only a *reversible* loss of the emergent life properties[35] of the "organism as a whole." In such circumstances, vital signs of neural function or a heartbeat are temporarily so minimal as to be almost imperceptible. Such temporary, reversible mimicry of death is well-known to occur in patients suffering from these conditions, although it is not well-understood. For this reason, physicians have traditionally delayed brain-death testing for hours (in hypothermia) or up to three days (for barbiturate clearance) until these "confounding variables" have resolved,[36] based on an awareness that such patients may recover.

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[35] See Medical Consultants on the Diagnosis of Death to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Guidelines for the Determination of Death" (1981) 246:19 JAMA 2184 ("[c]riteria for reliable recognition of death are not available in the presence of hypothermia … Hypothermia can mimic brain death by ordinary clinical criteria" and "[d]rug intoxication is the most serious problem in the determination of death … Cessation of brain functions caused by the sedative and anesthetic drugs, such as barbiturates, benzodiazepines, [etc.] … may be completely reversible even though they produce clinical cessation of brain functions and electrocerebral silence" both at 2186). The reversible death-like effect of cold and other variables was known as early as 1910-1950: Martin S Pernick, "Brain Death in a Cultural Context: The Reconstruction of Death, 1967-1981" in Stuart J Youngner, Robert M Arnold & Renie Schapiro, eds, *The Definition of Death: Contemporary Controversies* (Baltimore: Johns Hopkins University Press, 1999) 3 at 5.

[36] See Paul A Byrne & Richard G Nilges, "The Brain Stem in Brain Death: A Critical Review" (1993-94) 9:1 Issues L & Med 3 at 6-7. The authors explain that "[i]n cases of suspected intoxication no declaration of death should be made at least until the drug is known to have been metabolized. The waiting period should be at least three days to cover phenobarbital, a drug with a long half-life (fifty or more hours). New drugs, especially illicit drugs, do not have a known half-life": *ibid* at 6. Complicating matters, the authors also argue that "drug blood levels lag behind brain levels" (*ibid*) so that tests showing drug clearance from blood might be an unreliable guide to whether drug residues still affect the brain.

This empirical observation indicates that, in contrast to the President's Commission's claims, a temporary, total loss of neurological functioning, potentially lasting several days and sufficient to cause a disappearance of emergent functions (e.g., neural responsiveness), is still insufficient to produce a permanent loss of integrated functioning of the organism as a whole, i.e., bodily death. As discussed later in this paper, something more appears to be required in order for the temporary loss of integration and emergent properties to become permanent, causing physical death.

A third difficulty with the master regulator theory is that it has long been known that at least some body functions vital to sustaining life are not in fact controlled by the brain. For over 100 years, it has been recognized that the source of the impulse triggering the beating of the human heart (and the heart of other vertebrates) is *not* the brain, as the master regulator view implies, but individual heart cells themselves, which are then synchronized to beat together as a unit by electrical signals that come not from the brain but from the "sinus node," a structure within the heart.[37] Thus, the source of the heartbeat, which circulates vital, oxygenated blood to the body, is the heart itself, not the brain. Because the impulse for the heartbeat originates within the heart, requiring no central nervous system input, vertebrate hearts are termed "myogenic," contrasting with the "neurogenic" hearts of some invertebrates.[38]

The vertebrate heart is therefore said to possess "inherent rhythmicity,"[39] meaning that as long as its component cells remain oxygenated and healthy, the heart will beat independently, coordinated by its internal pacemaker cells, without brain input. There is some minor, brain-based influence by the vagus nerve of the brain stem. However, the vagus is not the source of the heartbeat's stimulus during life, nor does it stop the heart from beating in death. The vagus's influence simply fine-tunes the *rate* of an *existing* heartbeat. The heartbeat's lack of origin within the brain was acknowledged by the second US bioethics commission justifying the continued acceptance of brain death

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[37] Mark E Silverman & Arthur Hollman, "Discovery of the Sinus Node by Keith and Flack: On the Centennial of Their 1907 Publication" (2007) 93:10 Heart 1184 at 1184-87.

[38] Richard W Hill, Gordon A Wyse & Margaret Anderson, *Animal Physiology*, 2d ed (Sunderland, Mass: Sinauer Associates, 2008) at 615, 617.

[39] President's Council, *supra* note 11 at 28.

for determining legal death, the 2008 President's Council on Bioethics: "[T]here is no part of the CNS [central nervous system] that is *absolutely indispensable* for heart contractions in the way that the respiratory center in the brainstem is absolutely indispensable for the muscular contractions involved in breathing."[40]

Oxygenation and heartbeat are interdependent.[41] In contrast to the heartbeat, the stimulus for respiratory rhythm (breathing) does originate in a portion of the brain, specifically thought to be the "pre-Bötzinger complex" within the ventral respiratory group of brain stem neurons.[42] If an injury to this brain stem complex destroys the stimulus for independent breathing, ventilator assistance can oxygenate the lungs and, through them, the blood circulated by the heart. Expert testimony suggests that, while eight to ten minutes of anoxia can produce necrosis of the brain (except the brain stem), an additional 15–18 minutes of anoxia results in brain *stem* necrosis,[43] potentially affecting the pre-Bötzinger complex. Given that the heartbeat is autonomously generated rather than triggered by the brain (as described above), the master regulator theory lacks an account as to how brain death could produce cessation of the heartbeat.

It should be stressed here that a ventilator merely supplies oxygen to the lungs, thereby oxygenating the blood that will be redistributed to the body by an *already-beating* heart, and in turn nourishing all the body tissues, includ-

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[40] *Ibid* [emphasis in original].

[41] For the dependence of heartbeat on breathing, see Bernat, "Whole-Brain Defense", *supra* note 5 at 21 ("in the absence of breathing, heartbeat stops within minutes" at 21). The reverse – i.e., that when a pulse is absent, breathing too will have ceased – appears medically well-accepted as well. For example, advanced cardiac life support manuals suggest that the situation of a pulseless, yet still breathing, patient seems not to exist; see e.g. Joseph J Mistovich, Randall W Benner & Gregg S Margolis, *Prehospital Advanced Cardiac Life Support*, 2d ed (Upper Saddle River, NJ: Pearson Prentice-Hall, 2004) at 305.

[42] See Allan Siegel & Hreday N Sapru, *Essential Neuroscience*, 2d ed (Philadelphia: Lippincott Williams & Wilkins, 2011) at 401. Alternatively, a heart-lung bypass machine can circulate oxygenated blood to the body.

[43] Canada, Law Reform Commission, *Working Paper No 23: Criteria for the Determination of Death* (Ottawa: Minister of Supply and Services, 1979) at 13-14 [Law Reform Commission].

ing the heart tissues that generate the heartbeat. By merely supplying oxygen, a ventilator does not force the heart to beat, nor can it restart the beating of a heart whose pulse has stopped. Thus, it would be inaccurate to state that the ventilator "forces" a patient to remain "artificially alive."

A final difficulty with the master regulator theory involves evidence that cardiopulmonary collapse does not in fact always ensue quickly after brain death, as has been claimed. In a meta-analysis of approximately 175 brain-dead patients, Shewmon found that when organs were not harvested and ventilator support not removed (contrasting with common treatment following brain death), whole-brain death *was* sometimes compatible with bodily "survival" – as indicated by emergent processes such as growth, wound healing, immune response, pubertal development, fetal gestation, etc. – occurring well beyond the "few days" predicted.[44] In one ventilated body, these emergent processes continued for a full 20 years after whole-brain death determination, that diagnosis being confirmed by Shewmon and another research team.[45] The 2008 President's Council on Bioethics conceded the soundness of Shewmon's evidence that brain death *was* in fact compatible with continued, integrated body functions, stating, "The bodies of these patients do not 'come apart' immediately upon succumbing to total brain failure [i.e., brain death]."[46] The Council agreed that the earlier view of the brain as the "*inte-*

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[44] Shewmon, "Critical Re-evaluation", *supra* note 6 at 135-36, 139.

[45] *Ibid* at 136 (describing the patient's body, which, during 15 years on a ventilator, had grown and continued to circulate blood independently, assimilate nutrients by feeding tube, eliminate wastes, and perform many other functions). Regarding the same patient, see also Susan Repertinger et al, "Long Survival Following Bacterial Meningitis-Associated Brain Destruction" (2006) 21:7 J Child Neurol 591 at 592, 594. After 20 years of ventilator support, the patient's heart stopped and he was pronounced dead on a cardiopulmonary criterion. Brain autopsy found a totally calcified ball containing no identifiable brain or cellular structures, which "confirmed that his brain had been destroyed … whereas his body remained alive (brain death with living body) for an additional two decades": *ibid* at 594.

[46] President's Council, *supra* note 11 at 39. The President's Council did not dispute the findings of Shewmon's meta-analysis, which it augmented with updated information regarding his longest-persisting patient: *ibid* at 54. It recognized the work of researchers such as Shewmon as having "soundly criticized" the "exaggerated claims" of the earlier master integrator brain death rationale, and as having "persuasively called into question" the "supposed facts" regarding brain-dead bodies' lack of somatic integration and inability to maintain circulation: *ibid* at 39-40, 90.

grator of the body's many and varied functions" is incorrect.[47] Accordingly, a view of brain death equated with the loss of somatic integration of the "organism as a whole" could not continue to be the biological basis of neurological death. Yet despite abandoning this traditional biological explanation, the President's Council ultimately upheld the whole-brain death criterion, though using a different biological rationale, as discussed in the following section.[48]

B. The Neurological "Self-Preserving Work" of the Organism as a Whole

The 2008 President's Council somewhat confusingly justified its continued support for equating whole-brain death (or "total brain failure") with death of the entire patient. While the Council accepted Shewmon's meta-analysis as sufficient evidence for it to abandon the view of the brain as master integrator,[49] it nevertheless did *not* accept Shewmon's data as sufficient evidence to declare that *life* continued in ventilated, brain-dead bodies displaying such properties as wound healing, fighting infection, or temperature homeostasis.[50] Instead, as explained below, the Council clarified that only

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[47] *Ibid* at 40 [emphasis in original]. The Council went on to state,

> There may be, however, a more compelling account of *wholeness* that would support the intuition that after total brain failure [i.e., whole-brain death] the body is no longer an organismic whole and hence no longer alive. That account … offers a superior defense for "total brain failure" as the standard for declaring death. With that account, death remains a condition of the organism as a whole and does not, therefore, merely signal the irreversible loss of so-called higher mental functions. But reliance on the concept of "integration" is abandoned and with it the false assumption that the brain is the "integrator" of vital functions [*ibid* at 60 [emphasis in original]].

[48] *Ibid* at 90. See also *ibid* at x ("the Council has concluded that the neurological standard [for determination of brain death] remains valid"); *ibid* at 12 ("[i]n the majority view of the Council … today's 'whole-brain standard' [for determination of death] is, in fact, conceptually sound").

[49] See discussion in note 46, *supra*.

[50] President's Council, *supra* note 11 at 60. The Council accepted that if these observations were taken as evidence of life in brain-dead bodies, then total brain failure (whole-brain death) could not be the criterion for organismic death. Ultimately, the Council opted to uphold whole-brain death as the criterion of organismic death, in-

certain persistent properties in a body should be deemed diagnostic of "life." Thus, the Council retained the concept of the organism as a whole, and with it, the view that death represents the irreversible loss of that organism as a whole. However, it defined the concept differently than the earlier President's Commission had done.

The Council now based its conception of the organism as a whole on the idea that a living organism performs certain characteristic, vital, self-preserving "work"; on this view, a dead organism is therefore one that has irreversibly lost the ability to perform that characteristic work.[51] The "work" diagnostic of a living organism, the Council said, involves activities that demonstrate openness to stimuli and signals from the surrounding world, an ability to act selectively upon the world, and a "basic felt need" driving the organism to act.[52] Regarding this vital work, the Council also stated:

> [T]he fundamental vital *work* of a living organism … [is] the work of self-preservation, achieved through the organism's need-driven commerce with the surrounding world.

And:

> To preserve themselves, organisms *must* – and *can* and *do* – engage in commerce with the surrounding world … reaching out into the surrounding environment to secure the required sustenance. This is the definitive work of the organism … and what distinguishes every organism from non-living things.[53]

However, the Council concluded that only *certain* activities reveal the necessary degree of openness to, and engagement with, the world; it is not sufficient for an entity to merely exchange *any* kind of material with the surrounding world. In this regard, the Council stressed that the capacity to

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dicating it did not accept these properties as evidence of life, with the majority agreeing that "the patient with total brain failure is no longer able to carry out the work of a living organism": *ibid* at 90.

[51] *Ibid* at 60-61 (describing this viewpoint as one of two alternatives under study); *ibid* at 90-91 (adopting that viewpoint as the majority's position).

[52] *Ibid* at 61.

[53] *Ibid* at 60-61 [emphasis in original].

breathe spontaneously should be considered diagnostic of living organisms.[54] A second feature that it considered diagnostic of living things was consciousness.[55] In the Council's view, these two features reveal that an organism engages in sufficient commerce with the world to be characterized as living.

The Council further elaborated its reasoning that certain exchanges with the environment – such as the intake of oxygen in breathing – were more indicative of life than other exchanges, explaining, "Self-preserving commerce with the world … involves more than just openness or receptivity. It also requires an ability to *act* on one's own behalf – to take in food and water, and even more basically, to breathe."[56] The Council elsewhere suggested that the drive to breathe was more indicative of life because it was more "appetitive" than other exchanges.[57] It articulated the position that spontaneous breathing reveals not only openness and ability to act upon the world, but also an "inner experience of need" or "drive to breathe."[58]

Yet the Council's reasons for narrowing the range of qualifying "work" diagnostic of living organisms are unpersuasive in several ways. First, the Council did not adequately clarify, in scientific terms, why oxygen intake qualifies, but why other equally vital-seeming processes (such as food and water intake) do not, in the Council's opinion, constitute a necessary element

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[54] *Ibid* at 62-63.

[55] *Ibid* at 61 ("[t]o preserve itself, an organism must be open to the world … In higher animals, including man, [such openness] is evident most obviously in consciousness or felt awareness, even in its very rudimentary forms").

[56] *Ibid* at 62.

[57] See *ibid* at 63 (footnote):

> Shewmon misses the critical element: the *drive* exhibited by the whole organism to bring in air … By ignoring the essentially *appetitive* nature of animal breathing, Shewmon's [meta-analysis conclusion] misses the relevance of breathing as incontrovertible evidence that "the organism as a whole" continues to be *open to* and *at work upon* the world, achieving its own preservation … Bringing air into the body is an integral part of an organism's mode of being as a *needy* thing. More air will be brought in if metabolic need demands it and the body *feels* that need, for example during exercise [emphasis in original].

[58] *Ibid* at 62.

of openness, the ability to act, or an appetitive, inner experience of need. Second, the Council's reasons for requiring *spontaneity* (i.e., independence of technological assistance) specifically in relation to breathing are also not convincing.

A number of scientific errors, inconsistencies, and other puzzling features also appear in the Council's discussion of why brain death is death of the body. For example, the Council's focus on breathing as one of two vital features of the living organism as a whole seems to be lacking in scientific foundation. While suggesting that breathing is more "appetitive" and "even more basic" to life than the intake of other substances such as nutrients, the report does not define the term "appetitive." Elsewhere, breathing is discussed in terms of a felt need or inner drive.[59] "Appetitive" may therefore be intended by the Council to refer to the possession of a basic internal "appetite" or drive to ingest something, in order to meet a hunger or felt need. In view of the Council's discussion of the functional brain stem in relation to breathing and the existence of the living organism as a whole,[60] the idea of breathing as appetitive may have originated in thinking of it as a *brain-mediated* function. Yet if so, the Council's choice of breathing over all other drives seems misguided. Breathing is mediated by part of the brain, but so too are the appetites for food, water, and various other needs. The drive to breathe is triggered in a healthy brain stem by a buildup of carbon dioxide and hydrogen ions in the cerebrospinal fluid ("CSF") and blood.[61] Ordinarily, when brain stem chemoreceptors detect this body signal, they respond by neurologically triggering the diaphragm and intercostal muscles to make

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[59] See *ibid* at 62 ("even when the drive to breathe occurs in the absence of any self-awareness, its presence gives evidence of the organism's continued impulse to live"). Later the Council observes, "The striving of an animal to live, a striving we can discern even in its least voluntary form (i.e., breathing), indicates that we still have among us a living being": *ibid* at 64 (footnote).

[60] See *ibid* at 32-33 ("[o]ne marker of brainstem function … [is] the signal that is sent from the respiratory centers to the muscles of respiration. Thus, the patient's *drive to breathe* [created by that signal] must be tested with an apnea test " [emphasis in original]); *ibid* at 31 ("the functions that depend on the brainstem are central to the basic work of the organism as a whole. This has already been noted with respect to the brainstem's … involvement in breathing").

[61] Gerard J Tortora & Bryan Derrickson, *Introduction to the Human Body: The Essentials of Anatomy and Physiology,* 9th ed (Hoboken, NJ: John Wiley & Sons, 2012) at 500-01.

breathing movements, allowing the lungs to release carbon dioxide and take in oxygen. Response to nutrient needs is similarly brain-mediated. The hormone leptin signals to the brain – specifically the hypothalamus[62] – when the body's fat tissues indicate low triglyceride levels.[63] On receiving this signal, the brain produces hunger pangs and a drive to ingest nutrients[64] – an "appetite" in the traditional sense of the word.

Therefore, if the Council's basis for distinguishing breathing from feeding is that breathing is brain-mediated, then it is inconsistent for it to disregard the similarly brain-mediated drive to ingest nutrients. Both urges are brain-mediated, both are communicated by specific chemical signals received in the brain, and in both, the relevant brain-mediated responses – a neurological impulse triggering the thoracic muscles to breathe and a neurological impulse to ingest food – possess consciously *and* unconsciously controlled aspects. Both seem to reflect a strong inner drive, the source of which is discussed later in this paper. A noteworthy difference between breathing and eating may lie in the timing of the consequences that flow from an unmet appetite. In the case of nutrient ingestion, the body can – for a time – internally recycle its own tissues, such as muscle, to obtain needed nutrients and energy with which to counteract the effects of entropy. However, such recycling has negative health consequences, so the body cannot do this indefinitely or it will eventually starve to death, within weeks or months. Fresh nutrients must be ingested from the environment for the body to remain alive. In the case of breathing, internal recycling of oxygen is not possible in animals, so the consequences of an interrupted oxygen supply from the environment accrue more rapidly, with death resulting in only a matter of minutes. But while timing differs, the drives for both air and nutrients appear very strong. For reasons to be made clear below, self-preservation of the organism as a whole requires that both urges be met within appropriate time

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[62] Mark F Bear, Barry W Connors & Michael A Paradiso, *Neuroscience: Exploring the Brain*, 3d ed (Philadelphia: Lippincott Williams & Wilkins, 2007) at 513.

[63] Tortora & Derrickson, *supra* note 61 at 99.

[64] Bear, Connors & Paradiso, *supra* note 62 at 514.

periods. Therefore, there seems to be no obvious basis on which to distinguish breathing and nutrient ingestion as the Council does.[65]

There also appears to be no obvious reason why breathing must be *spontaneous* to indicate life. In the Council's words:

> The natural work of breathing, even apart from consciousness or self-awareness, is itself a sure sign that the organism as a whole is doing the work that constitutes – and preserves – it as a whole. In contrast, artificial, non-spontaneous breathing produced by a machine is not such a sign … of the organism as a whole. It is not driven by *felt need*, and the exchange of gases that it effects is … [not] a sign of [the organism's] genuine vitality.[66]

Yet if being driven by felt need is what characterizes a process as being diagnostic of life, then it is unclear why the means of oxygen *supply* is relevant. Immediately prior to the mechanical supply of oxygen, an appetitive "felt need" for oxygen will be experienced by the body's cells, tissues, and systems, and this drive will be communicated to the brain stem, regardless of whether the brain stem can translate that signal into action. Technological assistance with oxygen delivery to the body simply replaces the *response* to the felt need, not the body's felt need or drive to obtain oxygen itself. In addition, if the artificially supplied oxygen were not meeting a genuine need felt by the body at the cellular, tissue, and system levels, the heart of a patient on a ventilator would not continue to beat. A heartbeat is something the ventilator does not and cannot produce without the body's continued internal vitality or "life."

By similar reasoning, the Council's conclusion that a patient with total brain failure "has lost – and lost irreversibly – a fundamental openness to the surrounding environment, as well as the *capacity and drive* to act on this environment on his or her own behalf"[67] seemingly fails as well. In a brain-dead individual, the brain stem is irreversibly damaged, meaning that the in-

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[65] A similar argument can be made regarding an organism's drive to ingest water and avoid dehydration, which is also brain-mediated: *ibid* at 527. This drive becomes urgent when unmet for a period of hours to days.

[66] President's Council, *supra* note 11 at 63 [emphasis in original].

[67] *Ibid* at 90 [emphasis added].

dividual has lost *part* of its capacity to act on the world, but *not all* of it, nor has it lost its drive to act. The same appetitive need for oxygen and the same rise in the waste product carbon dioxide that signals that need to the (unreceptive) brain stem are still present. The damaged brain stem is simply unable to translate that signal into the neurological impulse for chest breathing movements. But it does not follow that the body's drive – i.e., its tissues' *felt need* for oxygen – is irreversibly eradicated. By taking in supplied oxygen and maintaining a heartbeat, such bodies indicate a retained openness and inner drive to obtain and use oxygen. Were that not the case, there would be no pulse in a ventilator-supported brain-dead body. Where a pulse exists in such a body, the Council's definition of death of the organism as a whole does not seem to be made out, since neither the drive nor the capacity to act is entirely or irreversibly gone.

Some noteworthy scientific errors also seem to have been made by the Council in reaching its final conclusion. For instance, it writes:

> When a PVS [persistent vegetative state] patient tracks light with his or her eyes, recoils in response to pain, swallows liquids placed in the mouth, or goes to sleep and wakes up, such behaviors – although they may not indicate *self*-consciousness – testify to the organism's essential, vital openness to the surrounding world. An organism that behaves in such a way cannot be dead.[68]

Given that the Council's report had the potential to prompt a shift to a higher-brain criterion of death (which would have resulted in PVS patients being considered brain-dead), the diagnostic picture of PVS in the Council's treatment of brain death should have been a well-researched topic. Yet some elements of the above claim suggest a lack of familiarity with PVS on the part of the Council. According to the 1994 report of American Academy of Neurology's Multi-Society Task Force on PVS,[69] which remains the current authority for PVS diagnostic criteria, most PVS patients *fail* to track light with their eyes[70] and all *fail* to recoil from pain,[71] while some *fail* to retain the

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[68] *Ibid* at 61 [emphasis in original].

[69] Multi-Society Task Force on PVS, Consensus Statement, "Medical Aspects of the Persistent Vegetative State (First of Two Parts)" (1994) 330:21 New Eng J Med 1499.

[70] *Ibid* at 1500.

ability to swallow liquids placed in the mouth.[72] Of the Council's list, only the circadian rhythmicity of sleep-wake behaviours is reliably retained in PVS,[73] reducing the Council's list of life's distinguishing features in these patients to potentially just one in some cases. In such a case – i.e., in the absence of all the other criteria – would the Council still defend the ability of a patient to open or close his or her (possibly sightless) eyes and engage in sleep every 12 hours as sufficient evidence to qualify that patient as living? Instead, one might reasonably ask why the PVS patient's spontaneous *heartbeat* – a feature shared with ventilated, brain-dead bodies – was not mentioned by the Council as being diagnostic of life in such patients, as has often been the case in other discussions of PVS.[74]

To be clear, the argument regarding PVS patients has been made here to illustrate the apparent inadequacy of the Council's chosen distinguishing features of "life," rather than to support reclassifying PVS patients as dead. Recent studies suggest PVS patients may possess more awareness than has been externally evident, or explored, in the past.[75] Nonetheless, it remains noteworthy that many of the reasons the Council supplied to justify PVS patients' retention among the living (in contrast to brain-dead patients) are in fact frequently inapplicable to these patients.

Finally, the report's choice of consciousness as the second, equally vital characteristic of a living organism also contains puzzling elements. For example, the Council stresses that the cortically mediated *awareness* aspect of consciousness can rescue apneic spinal-injury patients from being considered

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[71] *Ibid* at 1500 ("[t]he vegetative state can be diagnosed according to the following criteria: … (2) no evidence of sustained, reproducible, purposeful, or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli").

[72] *Ibid* at 1501 ("[i]n most [i.e. not all] patients, the gag, cough, sucking, and swallowing reflexes are preserved").

[73] *Ibid* at 1500 ("[t]he vegetative state can be diagnosed according to the following criteria: … (4) intermittent wakefulness manifested by the presence of sleep-wake cycles").

[74] See Bernat, Culver & Gert, *supra* note 11 at 391.

[75] For instance, evidence now suggests that some PVS patients can understand and respond to instructions to perform mental tasks: see Adrian M Owen et al, "Detecting Awareness in the Vegetative State" (2006) 313:5792 Science 1402.

dead, despite their being unable to act on the world at the macroscopic level.[76] Yet elsewhere in its report, it appears to prioritize the brain-stem-mediated *wakefulness* aspect of consciousness as more important in indicating the life of an organism as a whole:

> Position Two [which the Council ultimately accepts] … tak[es] the loss of the impulse to breathe and the total loss of engagement with the world as the cessation of the most essential functions of the organism as a whole.… From this philosophical-biological perspective, it becomes clear that *a human being with a destroyed brainstem has lost the functional capacities that define organismic life*.[77]

This is an odd claim, given the Council's ultimate support for a *whole-brain* criterion of death.[78] The Council adds an explanatory claim that:

> if a brain injury has progressed to the point at which the [relatively resilient] brainstem retains no function, it has probably ravaged the more fragile parts of the brain as well. Thus, the bedside tests for brainstem function are tests for the extent of destruction both to the brainstem and to the … [cortical] "higher centers."[79]

Yet this is untrue of isolated brain stem injuries where the cortex remains unimpaired, a fact the report only acknowledges in a footnote.[80] Overall, by focusing on the brain stem and brain-stem-mediated characteristic of wakeful-

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[76] The Council explained that "patients with spinal cord injuries may be permanently apneic or unable to breathe without ventilatory support and yet retain full or partial possession of their conscious faculties. Just as much as striving to breathe, signs of consciousness are incontrovertible evidence that a living organism, a patient, is alive": President's Council, *supra* note 11 at 64. But, it continued, "[i]f there are no signs of consciousness *and* if spontaneous breathing is absent *and* if the best clinical judgment is that these neurophysiological facts cannot be reversed, Position Two [the conclusion the Council majority ultimately accepts] would lead us to conclude that a once-living patient has now died": *ibid* [emphasis in original].

[77] *Ibid* at 66 [emphasis added].

[78] *Ibid* at 60, 89.

[79] *Ibid* at 32.

[80] *Ibid* at 32 (footnote).

ness, rather than giving similar emphasis to the cortex and cortically mediated characteristic of awareness, the Council appears to argue more strenuously for a *brain stem* criterion of death than for the *whole-brain* criterion it ultimately supports. The President's Council's report may therefore anticipate and pave the way for acceptance of a brain stem criterion of death in the United States, as has been adopted in the United Kingdom and, more recently, in Canada.

Interestingly, the Council's emphasis on the *self-preserving* nature of the work of a living organism as a whole was foreshadowed in earlier statements describing brain death from a view based on "thermodynamic and information theory." In Bernat's words, "[a]s … explained using thermodynamic theory, the brain is the critical and irreplaceable system of the organism without which the organism no longer can actively oppose entropy."[81] According to this view, which originated with Julius Korein, a functioning nervous system is necessary for an organism to resist entropy, and without it, the organism can be considered "dead." Later, Korein together with Calixto Machado clarified that the brain's behavioural "output patterns direct the [organism] as a whole towards behavior that will increase survival of the individual … [so that] decision-making processes occurring within the brain result in behavioral output patterns that tend to increase the organism's own organization."[82] That is, they decrease its entropy.

Korein and Machado asserted that "[t]he irreplaceable functioning brain, specifically and especially in an individual adult member of the species Homo sapiens overwhelmingly defines the behavior of the system-as-a-whole [i.e., the organism as a whole] towards decreasing entropy production."[83] It is possible, in making this claim, that Korein and Machado intended the term "behaviour" only to refer to the sorts of mental choices and decisions undertaken at a macroscopic level by an organism, such as those involved in planning how to apprehend prey for food or escape danger. These "behaviours"

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[81] Bernat, "Whole-Brain Defense", *supra* note 5 at 20. Entropy is a thermodynamic concept describing the disorder in a body or system, relative to its surroundings.

[82] Julius Korein & Calixto Machado, "Brain Death: Updating a Valid Concept for 2004" in Calixto Machado & D Alan Shewmon, eds, *Advances in Experimental Medicine and Biology*, vol 550: *Brain Death and Disorders of Consciousness* (New York: Springer Science+Business Media, 2004) 1 at 3.

[83] *Ibid* at 2.

are brain-based and would indeed decrease the organism's level of entropy to some degree.

However, there is another possible interpretation of "behaviour" that does not focus on the mental choices of macroscopic individual organisms, but rather looks at the activities of the more microscopic elements within a system, including within an organism. On this latter interpretation, it would *not* be true to say that the functioning brain "*overwhelmingly defines* the behavior of the system-as-a-whole towards decreasing entropy production." As will become clear from the discussion below, entropy-resistance is the fundamental, signature property of all life – from simple to complex – but it is a process occurring at all levels, including most basically at the molecular level, in the gathering and use of energy to resist the chaotic forces that break down cells. Although a functioning nervous system may permit an organism to engage in additional anti-entropic behaviours beyond the molecular level – e.g. threat-evasion or food-hunting strategies by the whole organism – these are not essential to life in the same defining manner. In fact, the most prevalent anti-entropic functions of living organisms are those taking place below the whole-organism level, at the level of molecules, involving processes that have *no neural component*. As discussed later, in eukaryotes, the locus of molecular anti-entropic functioning is the *mitochondrion*. It is this organelle and not the brain that "overwhelmingly defines the behavior of the [organism]-as a-whole towards decreasing entropy production."

Whether reflecting Korein and Machado's intended or actual meaning, the claim that a functioning human (or other sophisticated) brain has an overwhelmingly significant effect on entropy reduction appears to have subsequently influenced the President's Council in its formation of the concept of the "self-preserving work" of the organism as a whole. The Council majority concluded that retaining brain death as a death criterion was justified on the basis that "the patient with total brain failure is no longer able to carry out the fundamental work of a living organism … [i.e.,] self-sustaining, need-driven activities critical to and constitutive of its commerce with the surrounding world."[84] In using the term "self-sustaining," the Council implied that the work of the organism – specifically, maintaining consciousness and breathing spontaneously – enables that organism to overcome the chaotic forces that attempt to break it down, while the absence of such work makes it inevitable that the organism will irreversibly succumb to those forces:

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[84] President's Council, *supra* note 11 at 90.

"When these signs [of openness, capacity, and drive or felt need to act on the environment] are absent, and these [self-sustaining, need-driven] activities have ceased, then a judgment that the organism as a whole has died can be made with confidence."[85] Yet from a mitochondrial perspective, as discussed later in this paper, this conclusion appears unfounded. Heart-beating, brain-dead bodies on ventilator support do exhibit signs of openness, felt need, and capacity to act, and can engage in self-sustaining, anti-entropic activities other than consciousness and spontaneous breathing.

There is, as supplied by Shewmon, abundant evidence that a brain-dead human body on ventilator support can resist entropy, despite lacking the neural function for consciousness or spontaneous breathing. In Shewmon's meta-analysis, the bodies of some brain-dead patients did not rapidly become uncoordinated, but in certain cases displayed wound healing and immune responses, indicating an ability to resist entropy at the tissue and system levels.[86] Evidence-based medical protocols for the care of brain-dead patients intended for organ donation also clearly *anticipate* and *rely on* these brain-dead bodies having the capacity to take up, metabolize, and utilize oxygen, nutrients, pharmaceuticals, or transfused blood, in the same way as a living human body.[87] Such care is provided specifically to optimize the functionality of harvested organs, by allowing these brain-dead bodies a chance to reverse some physical damage, indicating medical knowledge of a capacity for entropy-resistance in the brain-dead:

> It is important to take the necessary time in the ICU to optimize multi-organ function to improve transplant outcomes. Reversible organ function can be improved … Once organ function is optimized, surgical procurement should be arranged emergently.[88]

Clearly, this preserved capacity for entropy-resistance in the bodies of brain-dead patients cannot flow from brain functions that have been destroyed (unless misdiagnosis of brain death is widespread). Therefore, as clarified later

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[85] *Ibid* at 90-91.

[86] Shewmon, "Critical Re-evaluation", *supra* note 6 at 136, 139.

[87] Sam D Shemie et al, "Organ Donor Management in Canada: Recommendations of the Forum on Medical Management to Optimize Donor Organ Potential" (2006) 174:6 Can Med Assoc J S13 at S16, S18.

[88] *Ibid* at S21.

in this paper, a functioning human brain is *not* necessary for the whole organism to resist entropy and be considered "living."

Ultimately, in accepting whole-brain death, the President's Council's conclusion may have provided the public and health care providers alike with a reassuring sense of consistency with the conclusions of the earlier President's Commission, as well as convenience in continuing to facilitate the worthy objectives of organ transplantation. Yet in terms of its substance, the President's Council's "self-preserving work" rationale appears as inadequate in explaining why brain death should be considered synonymous with human death (death of the organism as a whole) as was the earlier President's Commission's master regulator rationale. As discussed in Part IV below, this inadequacy may have important implications for the informed consent process for procedures such as organ donation, where patient consent is legally required to be free, informed, and competent. The free and informed nature of consent could be jeopardized by scientifically inaccurate information about brain death – that is, that the biological reality of brain death may differ from what patients have been led to understand – and this in turn could invalidate any consent given.

C. Death: A Mitochondrial Account

What follows is an alternative account of processes of life and death from a body-centred perspective, which seems to better account for empirical observations than earlier accounts. The ensuing discussion clarifies how, at the levels of cells, tissues, and whole organisms, this alternative view has more explanatory power regarding death's idiosyncratic features, as well as greater scientific support and internal consistency than earlier scholarship such as the President's Commission and President's Council reports. However, it should be noted that during this next section of the discussion, we are simply discussing *biological* death rather than the *legal* criteria to be used to indicate when death has occurred in order to permit certain actions, such as burial, to take place. The latter are points that will be taken up in Part IV of the paper.

An alternative account of the biological phenomenon of death – in humans, non-human vertebrates, and other eukaryotes[89] – can be made based

[89] Eukaryotes, e.g., plants, animals, and fungi, are organisms whose cells possess nuclei. All extant eukaryotes have, or once had, mitochondria.

on death's bioenergetic aspects. Energy use is an important characteristic of all living things.[90] Energy is required for life processes: growth, development, repair, movement, reproduction, and internal temperature homeostasis in the body.[91] Energy use allows organisms to resist entropic forces that would otherwise irreversibly damage the body's cells and disperse vital cell components (e.g., DNA) throughout the inanimate environment. As physicist Erwin Schrödinger observed, entropy reduction is a fundamental, signature feature of all known life.[92] In contrast to the position of some neurologists cited by the President's Council that destruction of the whole brain dooms the body to "los[e] its integrity as an entropy-resistant system,"[93] the reality

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[90] Energy flow and entropy resistance are key components of "life." All known domains of life share the same mechanism for acquiring energy for life processes from "food": an electron transport chain, coupled with a process for pumping protons across a cell membrane, creating a chemical gradient whose potential energy becomes stored in chemical bonds of adenosine triphosphate ("ATP"), the "universal energy currency." Nick Lane writes, "[P]umping protons across a membrane [to produce chemical energy] is as much a signature of life on Earth as DNA. It is fundamental": Nick Lane, *Power, Sex, Suicide: Mitochondria and the Meaning of Life* (New York: Oxford University Press, 2005) at 91 [Lane, *Power*]. Mitochondrial researcher Douglas Wallace likewise writes, "[l]ife is the interplay between structure and energy": Douglas C Wallace, "A Mitochondrial Paradigm of Metabolic and Degenerative Diseases, Aging, and Cancer: A Dawn for Evolutionary Medicine" (2005) 39 Annu Rev Genet 359 at 359 [Wallace, "Mitochondrial Paradigm"].

[91] Maintaining a certain stable internal temperature allows biochemical reactions to take place at an efficient rate.

[92] "[A] living organism continually increases its [positive] entropy … and thus tends to approach the dangerous state of maximum entropy, which is death. It can only keep aloof from it, i.e. alive, by continually drawing from its environment negative entropy … What an organism feeds upon is negative entropy.… [T]he essential thing in metabolism is that the organism succeeds in freeing itself from all the entropy it cannot help producing while alive": Erwin Schrödinger, *What is life? and Other Scientific Essays* (Garden City, NY: Doubleday & Company, 1956) at 71. James Lovelock adopts a similar view: "[L]ife is a member of the class of phenomena which are … able to decrease their internal entropy at the expense of substances or free energy taken in from the environment and subsequently rejected in a degraded [i.e., higher entropy] form": James Lovelock, *Gaia: A New Look at Life on Earth* (New York: Oxford University Press, 1995) at 4.

[93] President's Council, *supra* note 11 at 41.

appears to be otherwise. Entropy reduction exists at the most basic molecular level, in organisms ranging from the simplest bacteria to more complex, multicellular eukaryotes including humans. In eukaryotes, the cellular organelle known as the mitochondrion is the predominant site of energy production and is responsible for much of the entropy-resistance.

1. The importance of mitochondria in cellular life

In eukaryotes, all of the traditionally noted empirical observations of death may be explained as effects on the mitochondrion.[94] Most human tissues contain 500–2,000 mitochondria per cell, although heart cells, having high energy requirements, may contain 2,000–200,000 mitochondria each.[95] Dubbed the cell's "powerhouse,"[96] this subcellular structure features protein "electron transport chains" embedded in its inner membrane. Mitochondrial energy production, termed "cellular respiration,"[97] occurs via the passage of electrons through these chemical chains. This process pumps protons across

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[94] This article will not focus on non-eukaryotic processes. In non-eukaryotes (all of which are single-celled organisms that do not have a nucleus, for example, bacteria), life and death do not involve mitochondrial processes, because mitochondria do not exist in these organisms. Because bacteria reproduce by simple division, it may, strictly speaking, be slightly more complicated to discuss whether a single bacterial cell is entirely dead, once its contents have been subdivided among generations of surviving "daughter" bacterial cells. Bacterial life is made possible by membranes that both contain vital contents and, among photosynthetic bacteria like the ancestor of the mitochondria, also manufacture energy: see Lane, *Power*, *supra* note 90 at 91. This being the case in life, one may reasonably speculate that bacterial cell death may occur by disruption of the bacterial cell membranes' ability to produce energy and to protect cell contents.

[95] Anna Gvozdjakova, "Mitochondrial Physiology" in Anna Gvozdjakova, ed, *Mitochondrial Medicine: Mitochondrial Metabolism, Diseases, Diagnosis and Therapy* (London: Springer, 2008) 1 at 1 [Gvozdjakova, "Mitochondrial Physiology"].

[96] *Ibid.*

[97] Mitochondrial respiration, i.e., "aerobic" respiration, is a chemical process in which fuel (food) molecules are converted to energy for use by the organism. It is not to be confused with the gas-exchange process of the lungs that is also referred to as "respiration."

the inner mitochondrial membrane, capturing energy in the chemical bonds of adenosine triphosphate ("ATP") molecules.[98]

Ironically, given their vital importance to animal and other eukaryotic cells, mitochondria are only distantly related to their "hosts." Once thought to be of host-cell origin, mitochondria are now widely viewed as descendants of ancient, oxygen-requiring bacteria,[99] which perhaps entered the first eukaryotic cell two billion years ago in a parasitic relationship that became symbiotic.[100] Mitochondria retain recognizably bacterial DNA and other microbial similarities,[101] such as antibiotic sensitivity.[102] Significantly, mito-

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[98] Mitochondria also release some energy as heat, permitting the body's internal temperature homeostasis: see Evangelos D Michelakis, "Mitochondrial Medicine: A New Era in Medicine Opens New Windows and Brings New Challenges" (2008) 117:19 Circulation 2431 at 2431; Douglas C Wallace, "Why Do We Still Have Maternally Inherited Mitochondrial DNA? Insights from Evolutionary Medicine" (2007) 76 Annu Rev Biochem 781 at 782 [Wallace, "Maternally Inherited Mitochondrial DNA"].

[99] This position originated with Lynn Sagan's "endosymbiont theory": see Lynn Sagan, "On the Origin of Mitosing Cells" (1967) 14:3 J Theor Biol 225. The eukaryotic-mitochondrial merger involved a rare combination of events that apparently occurred only once in the four billion years of Earth's history: Lane, *Power*, *supra* note 90 at 17, 25.

[100] *Ibid* at 44, 213-14. Lane also observes that the original relationship may have alternatively arisen not as parasitism but as predation (consumption) of the protomichondrion by the host cell, but in any case the relationship ultimately became symbiotic (*ibid*).

[101] Mitochondria possess bacterium-style ribosomes for protein manufacture, are haploid as bacteria are, and retain recognizably bacterial, circular (rather than linear) DNA, which differs from eukaryotic DNA in having no protective histones, no "junk DNA" stretches, and relatively poor DNA repair. There are thus *two* distinct sets of DNA within any eukaryotic cell (including human cells): the DNA of the mitochondrion and that of the host cell's nucleus: see *ibid* at 15, 279; Inna N Shokolenko, Susan P Ledoux & Glenn L Wilson, "Mitochondrial DNA Damage and Repair" in Stephen W Schaffer & M-Saadeh Suleiman, eds, *Mitochondria: The Dynamic Organelle* (New York: Springer, 2007) 323 at 323, 325.

[102] See Joel N Meyer et al, "Mitochondria as a Target of Environmental Toxicants" (2013) 134:1 Toxicol Sci 1 ("[d]rugs have now been identified that inhibit … mitochondrial protein synthesis (a common mode of toxicity of antibiotics that target bacterial ribosomes, to which mitochondrial ribosomes are similar due to mito-

chondrial DNA is more susceptible to mutation and less easily repaired than host-cell (nuclear) DNA.[103] Mitochondria reproduce under the combined direction of host cell and mitochondrion,[104] and can only form from pre-existing, viable mitochondria.

This relationship is a continuing symbiosis in which the nucleus of the host cell and the mitochondria function interdependently.[105] Due to mitochondrial changes acquired during the two-billion-year relationship, mitochondria cannot live independently – nor be artificially cultured[106] – outside host cells, so strong is their symbiotic dependence. Of originally 1,500 mitochondrial genes, a mere 37 (2.5%) remain physically within the mitochondrion, the rest having been incorporated into host-cell nuclear DNA through

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chondria's evolutionary origins)" at 3). See also Shokolenko, Ledoux & Wilson, *supra* note 101 at 325-26; Lane, *Power*, *supra* note 90 at 15.

[103] See Shokolenko, Ledoux & Wilson, *supra* note 101 at 330. Yet some mitochondrial DNA repair does occur: see Ricardo Gredilla, Vilhelm A Bohr & Tinna Stevnsner, "Mitochondrial DNA Repair and Association with Aging – An Update" (2010) 45:7-8 Exp Gerontol 478.

[104] See Emelie Braschi & Heidi M McBride, "Mitochondria and the Culture of the Borg" (2010) 32:11 BioEssays 958 at 959.

[105] See Wallace, "Maternally Inherited Mitochondrial DNA", *supra* note 98 at 781 ("[t]he human cell is a symbiosis of two life forms: the nucleus-cytosol and the mitochondrion"). There is argued to exist "a complex symbiosis between [two] entities that are [each] partly dictated by a different set of DNA: the cell with all its metabolites and fuels on the one hand and the mitochondrion to generate the necessary energy-rich [ATP] on the other hand": Wim H Saris & Steven B Heymsfield, "All Metabolic Roads Lead to Mitochondrial (Dys)-Function" (2007) 10:6 Curr Opin Clin Nutr Metab Care 661 at 661. Due to gene transfer to the cell nucleus, mitochondria can only produce certain vital proteins by inducing the host cell's nucleus to act. The few genes retained in the mitochondrion may allow especially rapid production of certain proteins, to enable quick adaptation to environmental changes: Wallace, "Maternally Inherited Mitochondrial DNA", *supra* note 98 at 800. Mitochondrial changes relative to their bacterial ancestors seem minor compared with the radical transformation of host cells over the same time period: from bacterium-like (Archaean) single cells into the vast array of multicellular life, including humans, on earth today.

[106] Lane, *Power*, *supra* note 90 at 16.

horizontal transfer over time.[107] In the symbiotic bargain, host cells provide mitochondria with protection from external conditions and raw materials for growth, including vital enzymes that mitochondria can no longer produce for themselves due to previous mitochondrial gene transfer. In exchange, host organisms receive huge quantities of mitochondrial energy for life processes. In addition to directly affecting and regulating bioenergetic functions in the body such as metabolism and thermoregulation, mitochondria are also increasingly implicated as key organelles in a wide array of bodily functions, including the immune system,[108] stem cell functioning,[109] epigenetic alteration of nuclear DNA expression,[110] and possibly circadian rhythms.[111] Cer-

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[107] Wallace, "Mitochondrial Paradigm", *supra* note 90 at 361.

[108] Damien Arnoult et al, "Mitochondria in Innate Immunity" (2011) 12:9 EMBO Rep 901 at 901-02, 906, 909; Laura Vargas-Parada, "Mitochondria and the Immune Response" (2010) 3:9 Nature Education 15; A Phillip West, Gerald S Shadel & Sankar Ghosh, "Mitochondria in Innate Immune Responses" (2011) 11:6 Nat Rev Immunol 389 at 389.

[109] Sudip Mandal et al, "Mitochondrial Function Controls Proliferation and Early Differentiation Potential of Embryonic Stem Cells" (2011) 29:3 Stem Cells 486 at 486, 490; Claudia Nesti et al, "The Role of Mitochondria in Stem Cell Biology" (2007) 27:1-3 Biosci Rep 165 at 165, 167; Thomas Lonergan, Barry Bavister & Carol Brenner, "Mitochondria in Stem Cells" (2007) 7:5 Mitochondrion 289 at 289, 291; Graham C Parker, Gyula Acsadi & Carol A Brenner, "Mitochondria: Determinants of Stem Cell Fate?" (2009) 18:9 Stem Cells Dev 803 at 805; Kati J Ahlqvist et al, "Somatic Progenitor Cell Vulnerability to Mitochondrial DNA Mutagenesis Underlies Progeroid Phenotypes in Polg Mutator Mice" (2012) 15:1 Cell Metab 100 at 105.

[110] Patrick F Chinnery et al, "Epigenetics, Epidemiology and Mitochondrial DNA Diseases" (2012) 41:1 Int J Epidemiol 177 at 177, 180; Sheroy Minocherhomji, Trygve O Tollefsbol & Keshav K Singh, "Mitochondrial Regulation of Epigenetics and Its Role in Human Diseases" (2012) 7:4 Epigenetics 326 at 326; Douglas C Wallace & Weiwei Fan, "Energetics, Epigenetics, Mitochondrial Genetics" (2010) 10:1 Mitochondrion 12 at 12, 21-23; DC Wallace, "Mitochondria, Bioenergetics, and the Epigenome in Eukaryotic and Human Evolution" (2009) 74 Cold Spring Harb Symp Quant Biol 383 at 390.

[111] Sonja Langmesser & Urs Albrecht, "Life Time – Circadian Clocks, Mitochondria and Metabolism" (2006) 23:1-2 Chronobiol Int 151; Stuart Brody, "Circadian Rhythms in *Neurospora crassa:* The Role of Mitochondria" (1992) 9:3 Chronobiol Int 222.

tain serious, life-threatening illnesses typically appear in individuals with congenital or acquired mitochondrial defects.[112] Given the observed associations, a general causal relationship is strongly suspected between (congenital or acquired) mitochondrial mutations and disease; however, further research is needed to confidently establish causality more broadly than in the current subset of diseases where it has been shown.[113]

2. Mitochondria in the life of somatically integrated organisms

In several ways, mitochondria appear vital to "life," at whole-organism as well as cellular levels, in human beings and other eukaryotes. First, mitochondria vastly increase the energy available to eukaryotic organisms, making possible the activities and characteristics of multicellular life. Most eukaryotes can produce only very small quantities of energy – just one-sixteenth of the amount – without mitochondria,[114] an amount insufficient to power the activities of complex organisms, especially neural activity. With-

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[112] The first identified mitochondrial disease, Luft's disease, was identified in 1959–62. By 1984, over 120 mitochondrial diseases were known: see Anna Gvozdjakova, "Mitochondrial Medicine" in Anna Gvozdjakova, ed, *Mitochondrial Medicine: Mitochondrial Metabolism, Diseases, Diagnosis and Therapy* (London, England: Springer, 2008) 103 at 103-04; Michelakis, *supra* note 98 at 2432-33; Arnold Y Seo et al, "New Insights into the Role of Mitochondria in Aging: Mitochondrial Dynamics and More" (2010) 123:15 J Cell Sci 2533 at 2533; Wallace, "Mitochondrial Paradigm", *supra* note 90 at 361; Tobias A Weber & Andreas S Reichert, "Impaired Quality Control of Mitochondria: Aging from a New Perspective" (2010) 45:7-8 Exp Gerontol 503 at 504, 506.

[113] Meyer et al, *supra* note 102 at 2-3.

[114] In humans and other mammals, glycolysis allows production of very small amounts of energy anaerobically, if oxygen supplies are low. The amount of energy generated from glucose by glycolysis plus mitochondrial *aerobic* respiration is far greater, at 32 ATP molecules per molecule of glucose, compared with just two ATP molecules per molecule of glucose released by glycolysis alone (i.e., without the aid of mitochondria): see Denise R Ferrier, *Lippincott's Illustrated Reviews: Biochemistry*, 6th ed (Philadelphia: Lippincott Williams & Wilkins, 2014) at 104, 114; EW Nester et al, *Microbiology: A Human Perspective,* 7th ed (Toronto: McGraw-Hill, 2012) at 134; Scott K Powers & Edward T Howley, *Exercise Physiology: Theory and Application to Fitness and Performance*, 7th ed (New York: McGraw-Hill, 2001) at 43-44. Based on this figure, mitochondrial aerobic respiration provides an energy gain of 1600% over glycolysis alone.

out the energetic gain from mitochondria, it seems likely that multicellularity would never have evolved. Certainly it has not done so in prokaryotes (bacteria), which as noted above do not have mitochondria, in the 2.5 billion years since the "endosymbiont" event, to use Lynn Sagan's terminology.[115]

This vast mitochondrial supply of energy fuels both cellular and whole-organism activities. Most basically, vital homeostatic processes of cell growth, repair, and reproduction require constant energy to counteract the damaging, chaotic effects of entropy. Mitochondrial energy also makes possible other whole-organism "emergent properties" such as whole-body movement, observed in the whole body but not at the cellular level, enabling threat evasion, food-seeking, or other self-sustaining activities. Another emergent process using large amounts of mitochondrial energy is neural activity,[116] which permits sensory processing, reflexes, learning, communication, and consciousness. These whole-body, emergent properties require considerable energy and would be impossible without mitochondria.

A second way that mitochondria are important to whole organisms is through their vital role in shaping specialized tissues. This occurs through the mitochondrially directed process of "apoptosis" (programmed cell death), during both embryogenesis and maintenance in later life. In multicellular organisms, tissue specialization distinguishes simple, undifferentiated cell colonies that are able to reproduce asexually by division when a colony portion separates (e.g., sponges) from true multicellular "individuals" (such as animals) whose interdependent tissues are devoted to specific functions. Such

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[115] See discussion in note 99, *supra*. Lane argues, "The efficiency of [mitochondrial] energy metabolism may have been the driving force behind the rampant ascent of eukaryotes to diversity and complexity": Lane, *Power*, *supra* note 90 at 153. Furthermore, "[m]itochondria made larger size probable … [and w]ith larger size came greater complexity": *ibid* at 187.

[116] "The neural processing of information is metabolically expensive. Although the human brain is 2% of the body's weight, it accounts for 20% of its resting metabolism": David Attwell & Simon B Laughlin, "An Energy Budget for Signaling in the Grey Matter of the Brain" (2001) 21:10 J Cereb Blood Flow Metab 1133 at 1133. Energy in the form of ATP is used in the brain to create concentration gradients between neurons and their surroundings; it is vital to their electrical activity, may be used as a neurotransmitter, and causes depolarization of neural pain-receptors: Bear, Connors & Paradiso, *supra* note 62 at 35, 147-48, 408.

functions include sexual reproduction, in which the organism as a unit is reproduced using dedicated reproductive tissues.

These specialized, interdependent tissues, shaped as well as fuelled by mitochondria, together produce a kind of "somatic integration" in a living organism, synergistically creating whole-organism, emergent characteristics not seen among component cells – e.g., the coordination of muscles and nerves to allow whole-body movement. The term "integrative unity"[117] is also sometimes used to describe such "somatic integration," and both terms are strongly evocative of the concept of the "organism as a whole," which the 1981 President's Commission thought definitive of biological life. Through control over tissue specialization, mitochondria permit the development, from a single-celled zygote, of multicellular "individuals" with a characteristic form, functioning as self-perpetuating, somatically integrated units.[118] Long after embryogenesis, mitochondria maintain an organism's distinctive, integrated form through removal (by apoptosis) of damaged or tumorous cells that threaten the organism's structural integrity and energetic sustainability.[119]

In contrast to the brain-based argument of the President's Commission, the mitochondrial function of apoptosis appears to more effectively explain the appearance of an integrated, synergistic "organism as a whole," that is, the co-operative somatic integration of cells in a living body. In this explanation, the mitochondria, and not the brain, are more likely to play a master regulator role in the body, as mitochondrial apoptosis maintains proper tissue functioning and integration. In addition, mitochondria provide the fuel for all

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[117] See Shewmon, "Critical Re-evaluation", *supra* note 6 at 137 (defining integrative unity of an organism as the possession of at least one emergent holistic-level property).

[118] Some researchers think that population-level metabolic synchrony among cells of a yeast colony may derive from synchronized mitochondrial processes: see D Lloyd, EL Rossi & MR Roussel, "Introduction: The Temporal Organization of Living Systems from Molecule to Mind" in David Lloyd & Ernest L Rossi, eds, *Ultradian Rhythms from Molecules to Mind: A New Vision of Life* (Dordrecht: Springer, 2008) 1 at 4-5.

[119] See Lane, *Power*, *supra* note 90 at 189. For information on the process of apoptosis, see Vinay Kumar, Ramzi S Cotran & Stanley L Robbins, *Basic Pathology*, 6th ed (Toronto: WB Saunders, 1997) at 13.

bodily processes, including the energy-intensive activity of the brain, which is responsible for 20% of the body's energy expenditures despite accounting for only 2% of the body's weight.[120] It seems that, even were the brain to act as a master regulator over the entire body, it is the mitochondria that fuel and enable the functions that the brain performs. Accordingly, functional mitochondria appear to exhibit a higher level of regulatory behavior and control over both body and brain.

From a mitochondrial perspective, the President's Council's emphasis on breathing as a truly important exchange between an organism and its environment, and thus as being diagnostic of life, is not without some basis. Breathing allows the body to take in oxygen for use as the final electron acceptor in the electron transport chain, enabling mitochondrial energy (ATP) production from the complete oxidation of fuel. Just as importantly, breathing expels waste carbon dioxide, avoiding an obstacle to further aerobic respiration, since high carbon dioxide levels increase dissociation of the oxygen delivery molecule, oxyhemoglobin,[121] preventing sufficient oxygen delivery to cellular respiration sites. Yet from the same mitochondrial viewpoint, it is incorrect to characterize breathing as a more important exchange than nutrient ingestion. Nutrients supply the fuel molecules that are the only other vital ingredient in producing ATP via the mitochondrial electron transport chain. Thus, food ingestion is no less important – no less appetitive – than is breathing for the life of the organism as a whole. The ATP produced from both nutrients and oxygen allows a ventilated brain-dead body to do what Shewmon observed: to maintain circulation and resist disintegration, that is, to resist the forces of entropy.

3. Mitochondria and the mystery of life's oxygen-dependence

The significance of oxygen to mitochondrial energy production, and thus to the life of eukaryotic cells and whole organisms, cannot be overstated. Oxygen is vital for aerobic cellular respiration, serving as an electron acceptor in the mitochondrial respiratory chain that transforms food into energy,[122]

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[120] See Attwell & Laughlin, *supra* note 116 at 1133.

[121] See Tortora & Derrickson, *supra* note 61 at 497.

[122] See Powers & Howley, *supra* note 114 at 37, 43. In some non-eukaryotes living in oxygen-deficient environments, a bacterial ATP-production process that is analogous to mitochondrial aerobic respiration has the flexibility to use molecules such

although lesser amounts of energy can be produced by eukaryotes without oxygen.[123] The original mitochondrial symbiosis paired an anaerobic (i.e., non-oxygen-using) host cell with an aerobic mitochondrion, allowing early eukaryotes to exploit what would otherwise have been toxic, oxygen-rich environments, but at a cost: it appears that as a result of this symbiosis, at some point in their evolution, eukaryotes became dependent on oxygen, a feature still characteristic of modern eukaryotic organisms, including humans.[124] Thus, for eukaryotes, a brief period without oxygen may be lethal. As the physician Paracelsus noted in 1535, "man dies like a fire when deprived of air."[125]

Without oxygen – or especially, for some reason, if oxygen flow is interrupted and then restored[126] – mitochondria may become damaged and unable

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as thiosulphate, sulphide, or nitrogen oxide as the final electron receptor, as well as oxygen. Since no such substitution has been reported in mitochondrial cellular respiration, oxygen seems to be essential to eukaryotes for this energy production process: see Nick Lane, *Oxygen: The Molecule that Made the World* (New York: Oxford University Press, 2002) at 31-32 [Lane, *Oxygen*].

[123] See note 114, *supra*; see also Powers & Howley, *supra* note 114 at 34, 36.

[124] See Lane, *Power*, *supra* note 90 at 45-46:

> Even if energy was not the basis of the [mitochondrion-host cell] relationship, the rise in [atmospheric] oxygen levels might still explain the initial benefits. Oxygen is toxic to anaerobic … organisms.… If the guest [proto-mitochondrion] was an aerobic bacterium, using oxygen to generate its energy, while the host was an anaerobic cell (generating energy by fermentation [i.e., glycolysis]), then the aerobic bacterium may have protected its host against toxic oxygen … [As] atmospheric oxygen levels r[o]se , the relationship beg[an] to pay dividends to both.

See also Lane, *Oxygen*, *supra* note 122 at 51.

[125] Cited in Bernard Jaffe, *Crucibles: The Story of Chemistry from Ancient Alchemy to Nuclear Fission,* 4th ed (New York: Dover Publications, 1976) at 78.

[126] Interruption and re-establishment of oxygen flow is referred to as "reperfusion." The mechanism for the paradoxical phenomenon of "reperfusion injury" is emerging, including the role played by mitochondria: see e.g. Hamid Moradi & Ping H Wang, "Renoprotective Mechanisms of Ischemic Postconditioning in Ischemia-Reperfusion Injury: Improved Mitochondrial Function and Integrity" (2013) 28:11 Nephrol Dial Transplant 2667; Xiaohua Tan et al, "Postconditioning Ameliorates

to produce energy, potentially triggering cell death. Oxygen deprivation may be termed "hypoxia" (i.e., low oxygen), "anoxia" (i.e., no oxygen), or, in cases of deprivation of oxygenated blood flow, "ischemia," but the oxygen concentration denoted by these terms varies.[127] Oxygen-deprivation effects seem especially severe in tissues with high energy demands, such as neural tissues.[128] In mammals, a five-minute interruption of oxygenated blood may lower brain function by 90%,[129] and is associated with long-term risks of brain-cell death. In contrast, non-neural tissues such as human heart muscle may tolerate 20–30 minutes without oxygen, while certain leg muscle tissues may tolerate two to three *hours*' anoxia before cell death occurs.[130] Even among energy-intensive neural tissues, however, some cell types are more hypoxia-sensitive than others. The more energy-intensive neurons[131] (with larger mitochondrial populations) are more severely affected by ischemia

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Mitochondrial DNA Damage and Deletion after Renal Ischemic Injury" (2013) 28:11 Nephrol Dial Transplant 2754.

[127] See Lane, *Oxygen*, *supra* note 122 at 165.

[128] Grey matter uses an especially large proportion of brain energy. The work done by the brain's cells is energetically equal to "human leg muscle running the marathon": Attwell & Laughlin, *supra* note 116 at 1143. The brain's high energy demand may make it vulnerable to hypoxic damage.

[129] See Jeremy E Niven & Simon B Laughlin, "Energy Limitation as a Selective Pressure on the Evolution of Sensory Systems" (2008) 211:11 J Exp Biol 1792 at 1794 (note that brain function was measured via the proxy of brain ATP use).

[130] Kumar, Cotran & Robbins, *supra* note 119 at 6.

[131] The metabolism of energy by the brain is "tightly coupled to neuronal activity": Renaud Jolivet, Pierre J Magistretti & Bruno Weber, "Deciphering Neuron-Glia Compartmentalization in Cortical Energy Metabolism" (2009) 1:4 Front Neuroenergetics 1 at 1. The authors of that study found that, during high levels of brain activity in both human and rodent data, "about 80% of energy is produced to support neuronal signaling while glia only use up a small fraction of energy to recycle neurotransmitters (5–6%)": *ibid* at 2. They also observed that "a significant [proportion] of glucose is taken up by astrocytes [a form of glia] while oxygen is mostly consumed within the neuronal population," a "bias" that increases such that "the higher the activation state [of the brain], the higher the proportion of oxygen being used by neurons and the higher the proportion of glucose entering glia": *ibid*.

than lower-energy glia (possessing fewer mitochondria).[132] Thus, tissues differ in their needs for oxygen and mitochondrial energy, and those with greater energy requirements – and thus more mitochondria – seem to fare worse during oxygen deprivation. Emerging evidence regarding mechanisms of ischemic brain damage strongly implicates mitochondrial involvement.[133]

Despite the general requirement for continuous oxygen in multicellular animals, some exceptions exist. As noted above, eukaryotic cells can manufacture tiny amounts of energy without oxygen and mitochondria. For the normal activities of most vertebrates, these amounts are insufficient. Nonetheless, some vertebrates and invertebrates can, in harsh conditions, lower their metabolic needs to survive for days, months, or years with seemingly negligible oxygen and energy use, in states of daily torpor or seasonal hiber-

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[132] Kumar, Cotran & Robbins, *supra* note 119 at 717; see also O Kempski, "Mechanisms of Ischemic Cerebral Damage: The Role of Glial Cells" (1989) 1:3 J Neurosurg Anesthesiol 267 at 268-69 (glial brain cells may play a protective, homeostatic role in the brain, by swelling in ischemia, clearing away harmful substances, and buffering neurons against hypoxic damage). Rodent neurons and glia differ greatly in energy use; even at resting potential, neurons may use over three times the energy of glia, while signalling neurons use 15 times more. This energy apportionment roughly parallels the observed mitochondrial distributions among these brain cell types. Consistent with the greater glial hypoxia-tolerance, human glia need only 5% of the brain's energy and contain only 2% of its mitochondria: see Attwell & Laughlin, *supra* note 116 at 1139.

[133] See e.g. Dennis W Choi, "Cerebral Hypoxia: Some New Approaches and Unanswered Questions" (1990) 10:8 J Neurosci 2493 at 2493 (ischemic brain damage is not due solely to an energy deficit, i.e., mitochondrial inability to produce energy without oxygen; actual cell damage is also involved); Kyungsun Choi et al, "Oxidative Stress-Induced Necrotic Cell Death via Mitochondira [*sic*]-Dependent Burst of Reactive Oxygen Species" (2009) 6:4 Curr Neurovas Res 213 (mitochondria may play a central role in necrotic cell death after brain ischemia or reperfusion); PG Sullivan et al, "Mitochondrial Permeability Transition in CNS Trauma: Cause or Effect of Neuronal Cell Death?" (2005) 79:1-2 J Neurosci Res 231 at 231; Seema Yousuf et al, "Resveratrol Exerts a Neuroprotective Effect by Modulating Mitochondrial Dysfunctions and Associated Cell Death in Cerebral Ischemia" (2009) 1250:1 Brain Res 242 at 242.

nation,[134] resuming normal metabolism and energy use when conditions improve.

Clearly, for an animal to be able to detect improved external conditions, arouse, and resume normal, energy-consumptive functions, some viable mitochondria must persist. In such animals, special mitochondrial adaptations have been found, including processes that prevent or reduce hypoxic mitochondrial damage.[135] In addition, in contrast to the usual hypoxia-sensitivity of neural tissues, the nervous systems themselves of hypoxia-tolerant animals also seem to possess adaptations that ultimately protect mitochondria. For instance, energy-intensive neural functions such as consciousness may be greatly reduced, allowing these organisms to hibernate during hypoxic periods.[136] While humans cannot survive hypoxia by hibernating, similarly unresponsive neurological states do occur in humans affected by hypother-

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[134] It seems that animals adapted to survive anoxia or cold in this way (e.g., turtles) may greatly limit their mitochondrial consumption of ATP and increase their dependence on non-mitochondrial energy production through glycolysis, thereby matching the low ATP supply (available mainly from the latter process): see PW Hochachka & PL Lutz, "Mechanism, Origin, and Evolution of Anoxia Tolerance in Animals" (2001) 130:4 Comp Biochem Physiol B Biochem Mol Biol 435 at 439, 442, 451. A possibly related phenomenon in humans subjected to cold or other abnormal conditions is noted later.

[135] For example, in animals that tolerate lengthy hypoxia (such as turtles under winter ice), permanently reduced mitochondrial membrane permeability and reversible blocking of mitochondrial membrane pores may occur, and tissue mitochondrial populations may be reduced during dormancy: *ibid* at 437, 439, 447. See also Matthew T Andrews, "Advances in Molecular Biology of Hibernation in Mammals" (2007) 29:5 BioEssays 431 at 432 (mitochondria are implicated in hibernation strategies to survive non-anoxic energy-depletion as mitochondrial enzyme PDK4 blocks glycolysis, preventing mitochondrial ATP production and decreasing metabolism); Stephen C Land, "Hochachka's 'Hypoxia Defense Strategies' and the Development of the Pathway for Oxygen" (2004) 139:3 Comp Biochem Physiol B Biochem Mol Biol 415 (in the human fetus, too, hypoxia-resistance involves reduced mitochondrial biogenesis and energy production).

[136] Niven & Laughlin, *supra* note 129 at 1794. Drastic (i.e., ten-fold) reductions may occur in hibernating vertebrates' neural firing, reducing energy use in anoxic conditions: see Hochachka & Lutz, *supra* note 134 at 437.

mia,[137] certain drugs,[138] exsanguination, or other conditions, with brain, heart, and lung functions becoming imperceptible. Due to the ethical difficulties of experimentation, these states are not well understood in humans.

In organisms lacking such adaptations, hypoxia initiates a predictable sequence of cellular damage, centrally affecting the mitochondria. This begins with significant decreases in mitochondrial respiration, reducing intracellular ATP production.[139] After short hypoxic episodes, reversible changes occur,[140] including phospholipid deposition in the mitochondria (suggesting mitochondrial membrane degradation) and mitochondrial swelling (suggesting loss of osmotic regulation by mitochondrial membranes). Longer hypoxia produces worsening energy production and increased membrane permeability, which can lead to additional morphological deterioration.[141] Empirically, after extended hypoxia, a "point of no return" is reached, such that "mitochondrial dysfunction cannot be reversed and irreversible damage and cell death occur" even when oxygen is restored.[142]

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[137] Cold is a well-known confounding variable in brain death determination. In hypothermia, human beings with core temperatures below 32° Celsius may enter a reversible state mimicking brain death, becoming temporarily unconscious, neurologically unresponsive, and exhibiting no apparent breathing, brain stem reflexes, or other life signs: see Eelco FM Wijdicks, "Determining Brain Death in Adults" (1995) 45:5 Neurology 1003 at 1004; Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, "A Definition of Irreversible Coma" (1968) 205:6 JAMA 337 at 338, 340.

[138] As noted earlier, barbiturates may reversibly produce symptoms resembling brain death, including central nervous system depression, respiratory depression, lowered cardiac output, and poor temperature regulation: see RM Schears, "Barbiturates" in Judith Tintinalli et al, eds, *Tintinalli's Emergency Medicine: A Comprehensive Study Guide*,(New York: McGraw-Hill, 2011) at Clinical Features, Treatment sections.

[139] Kumar, Cotran & Robbins, *supra* note 119 ("[t]he first effect of hypoxia is on the cell's aerobic respiration … by mitochondria; as a consequence of reduced oxygen tension, the intracellular generation of ATP is markedly reduced … [with] widespread effects on many systems within the cell" at 6).

[140] *Ibid* at 7.

[141] *Ibid* at 8.

[142] Ibid.

While the characteristics of this "point of no return" are still emerging, they appear to be triggered by cellular pH and ATP changes, producing irreversible mitochondrial swelling and cellular calcium influx.[143] Oxygen reperfusion (i.e., reintroduction of oxygen) is particularly damaging in this context because it opens a mitochondrial membrane pore, making the inner mitochondrial membrane permeable and triggering the membrane protein ATP synthase to operate in reverse, consuming energy instead of creating it.[144] Calcium coalesces in the mitochondrial matrix, especially if oxygen is restored,[145] which may physically obstruct further cellular respiration. However, simply interrupting mitochondrial energy production does not always appear to be sufficient by itself to trigger cell death.[146] Instead – whether or not oxygen is restored – when cell death ensues, it is preceded by a burst of oxygen free radicals that is damaging to mitochondrial membranes and DNA. This free radical burst appears to be a mitochondrial signal triggering the host cell to begin enzymatic self-destruction, a process that was perhaps once a mechanism permitting an ancestral mitochondrion to escape to a new host cell.[147]

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[143] See Gvozdjakova, "Mitochondrial Physiology", *supra* note 95 (at this point, "excessive accumulation of Ca^{2+} leads to formation of [oxygen free radicals] and opening of the mitochondrial transition permeability pore (MPTP), which depolarizes the mitochondria[l] [membrane] and leads to mitochondrial swelling" at 16).

[144] Roberta A Gottlieb & Raquel S Carreira, "Autophagy in Health and Disease. 5. Mitophagy as a Way of Life" (2010) 299:2 Am J Physiol Cell Physiol C203 at C205.

[145] It is unclear why oxygen *restoration* has such severe negative effects. More free radicals may be released in tissues with partial (reperfused) oxygen than with no oxygen: see Choi, *supra* note 133 at 2497. Oxygen restoration may increase intracellular pH following acidic conditions (produced by the lack of aerobic respiration), opening the mitochondrial membrane pore, triggering mitochondrial swelling and other damage: see JJ Lemasters et al, "The Mitochondrial Permeability Transition in Cell Death: A Common Mechanism in Necrosis, Apoptosis and Autophagy" (1998) 1366:1-2 Biochim Biophys Acta 177 at 178 [Lemasters et al, "Mitochondrial Permeability Transition"].

[146] See Kumar, Cotran & Robbins, *supra* note 119 ("it has been possible experimentally to dissociate … ATP depletion, from the inevitability of cell death" at 8).

[147] The free radical burst occurs when respiration in mitochondrial electron transport chains is interrupted, as stalled electrons release free radicals, possibly because oxygen is suddenly unavailable as an acceptor for respiratory chain electrons: see

4. Mitochondria in the pathways of cell death

In general, cell death is triggered in two ways, both of which centrally involve mitochondria: (1) events external to the cell (e.g., hypoxia) may trigger the process of "necrosis," and (2) internal cellular events may trigger "apoptosis" (i.e., internally programmed cell death).[148] Apoptosis may allow cells with mitochondria too damaged to produce energy to be removed and replaced by cells with viable mitochondria.[149] In apoptosis, the damaged cell

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Lane, *Power*, *supra* note 90 at 222, 260. The enzymes used in the ensuing cell destruction appear to have bacterial genetic origins and are similar to those used by modern bacterial parasites escaping dying host cells: see *ibid* at 212-13; Braschi & McBride, *supra* note 104 at 961. Although mitochondria of fully differentiated host cells also break down, rather than escape and transfer to new hosts, mitochondria have been observed to transfer into damaged *stem cells*, restoring their functionality: see Nesti et al, *supra* note 109 at 168.

[148] In necrosis and apoptosis, mitochondria and the ATP they produce play key roles. A key step in both involves the opening of a pore in the inner mitochondrial membrane (the "mitochondrial permeability transition pore" or MPTP). In both necrosis and apoptosis, when oxygen is disrupted, then re-established, the return to normal (higher) pH triggers pore opening, allowing in water and calcium, causing mitochondrial swelling and cytochrome c release. This interrupts respiration and triggers cell death, either immediately (via necrosis) or later (via apoptosis). MPTP opening makes the inner mitochondrial membrane permeable and forces the membrane protein ATP synthase to operate in reverse, *consuming* ATP. See Gottlieb & Carreira, *supra* note 144 at C205. Cellular ATP levels seem to determine which cell death process occurs: if cellular ATP levels are low, rapid cell necrosis occurs, while if ATP levels are higher, apoptosis occurs later: see Lemasters et al, "Mitochondrial Permeability Transition", *supra* note 145 at 177; JJ Lemasters et al, "Mitochondrial Dysfunction in the Pathogenesis of Necrotic and Apoptotic Cell Death" (1999) 31:4 J Bioenerg Biomembr 305. Opening of the MPTP pore can be partially blocked by some drugs, such as the transplant anti-rejection drug cyclosporine A, or by pH below 7.4, thereby protecting the mitochondrion from damage: see Jae-Sun Kim et al, "Nitric Oxide: A Signaling Molecule Against Mitochondrial Permeability Transition- and pH-Dependent Cell Death after Reperfusion" (2004) 37:12 Free Radic Biol Med 1943 at 1944; J-S Kim et al, "Role of the Mitochondrial Permeability Transition in Apoptotic and Necrotic Death after Ischemia/Reperfusion Injury to Hepatocytes" (2003) 3:6 Cur Mol Med 527 at 527.

[149] Lane speculates "that any cells that acquir[e] an unworkable load of [mtDNA] mutations [a]re simply eliminated by apoptosis, giving an impression that mitochondrial mutations d[o] not accumulate with age," due to the remaining cells with less severely damaged mitochondria continuing to divide: Lane, *Power*, *supra* note 90

is destroyed from within by the enzyme caspase 3, which digests the cell, mitochondria, and other cell contents.[150] In contrast, cell death by necrosis occurs more rapidly than by apoptosis, and is triggered by more severe cell damage.[151] While it was once thought that the mitochondrial damage seen in necrosis occurred secondarily to cell damage, evidence now indicates the reverse: that in necrosis, mitochondrial damage is primary, itself triggering cellular destruction.[152] In summary, apoptosis and necrosis share common pathways, both triggered by mitochondrial damage.[153] Thus, in addition to facilitating and controlling eukaryotic cellular life, mitochondria appear to direct eukaryotic processes of cellular death.

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at 300. The same may be true of necrosis in more severely damaged cells, over the short-term.

[150] *Ibid* at 207, 209.

[151] For example, in pancreatic cells, a shorter or less intense chemical insult was observed to produce apoptosis, while a lengthier or more intense insult led more rapidly to necrosis: see Jeanette M Dypbukt et al, "Different Prooxidant Levels Stimulate Growth, Trigger Apoptosis, or Produce Necrosis of Insulin-Secreting RINm5F Cells: The Role of Intracellular Polyamines" (1994) 269:48 J Biol Chem 30553 at 30557, 30559-60.

[152] See BK Siesjö et al, "Role and Mechanisms of Secondary Mitochondrial Failure" (1999) 73:1 Acta Neurochir Suppl 7.

[153] Necrosis may result when cellular ATP stays high in a hypoxia-damaged cell; apoptosis may result when cellular ATP in a hypoxia-damaged cell is low: see Gvozdjakova, "Mitochrondrial Physiology", *supra* note 95 at 16. Thus mitochondria may be energy sensors as well as energy producers, monitoring cellular ATP supplies and triggering changes via apoptosis or mitochondrial biogenesis when cells fail to meet some bioenergetic threshold: see Lane, *Power*, *supra* note 90 at 293. The mitochondrial protein cytochrome c that stops chemical respiration and activates caspase 3, triggering cell apoptosis or necrosis, is noteworthy for its symmetric role in cellular life and death. "[A]n integral component of the respiratory chain (which generates the energy needed for the life of the cell) turns out to be an integral component … responsible for the death of the cell. The link between life and death hinges on the subcellular location of a single molecule": *ibid* at 209.

5. Mitochondria in the aging and death of the organism as a whole

Mitochondrial involvement in death does not appear to stop at the cellular level. In healthy human beings, 10 billion cells die daily[154] without producing functional deficits at the organism level. Cells of the human body are regularly replaced.[155] There exists a "dynamic equilibrium" in multicellular organisms whereby dying or dead cells[156] are continuously replenished by new cells. In good health, most cells of each tissue remain alive, thereby permitting vital emergent processes of the living organism. However, at some point, if the cell death rate exceeds the dynamic equilibrium replacement rate, this may precipitate the death of the entire organism through means such as widespread systemic infection or vital organ failure. Arguing that brain death triggers the death of the organism as a whole, Bernat stated that "[t]he irretrievable loss of the organism's *emergent functions* … is the death of the organism."[157] Given this causal chain, our preceding discussion prompts us to consider whether mitochondria appear centrally implicated in the death not merely of cells, but of the "organism as a whole."

As noted, some organisms (including humans under certain conditions) can survive reversible, death-mimicking states, wherein emergent functions –

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[154] *Ibid* at 215.

[155] Cells of the human body are replaced at different rates, with skin cells lasting just five days, while other cells may be replaced much less frequently: see Nicholas Wade, "Your body is younger than you think", *New York Times* (2 August 2005) online: NYT <www.nytimes.com/2005/08/02/science/02cell.html?pagewanted =all>.

[156] Certain body parts of living multicellular organisms may be "dead" or "inanimate," e.g., hair, nails, the mineral portions of bones or teeth, a shell, furry coat, or feathers. Conversely, organisms resident on or in a living organism's body may contribute to its overall life and health through protective, structural, or homeostatic functions. For instance, in addition to the mitochondria in each human cell, beneficial and parasitic bacterial and fungal "flora" inhabit the human skin, oral cavity, intestinal tract, and other body parts in a ratio of ten non-human cells to one human cell: see Science News, "Humans have ten times more bacteria than human cells: how do microbial communities affect human health?" *Science Daily* (5 June 2008), online: SD <www.sciencedaily.com/releases/2008/06/080603085 914.htm>. Such features may make the human body more like a miniature ecosystem than a single entity.

[157] Bernat, "Whole-Brain Optimum", *supra* note 23 at 38 [emphasis added].

e.g., detectible neural activity – disappear temporarily. Thus, while the disappearance of emergent functions is *necessary* for an organism's death, it is not *sufficient* to establish death. Something more is needed to render the disappearance of emergent functions permanent, thereby explaining death's permanence and irreversibility. Death appears to require some irreparable[158] destruction of vital structures or processes, making *resumption* of emergent functions impossible. As demonstrated above, mitochondria appear vital to generating emergent life functions of whole organisms, and therefore, one might suspect that mitochondria may also be the key structures involved in the "irretrievable loss" of these same emergent functions, i.e., death. Based on the discussion of mitochondria so far, the physical death of an organism might be predicted to occur when mitochondria become damaged beyond their self-repair or replacement capacities.

Research into aging supports this view. Mitochondria appear to play an important role in age-related decline,[159] ultimately leading to the death of whole organisms. It is now widely believed that increasing mitochondrial mutation levels, rising free radical production, and declining ATP production

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[158] "Irreparable" in this context means unable to be repaired naturally by the body or by existing (or imminently available) medical technology.

[159] For the origin of this theory, see Denham Harman, "The Biologic Clock: The Mitochondria?" (1972) 20:4 J Am Geriatr Soc 145 (Harman's "mitochondrial theory of aging" argued that aging is due to accumulated mitochondrial mutations caused by oxygen free radicals). Modern speculation is that a more dynamic "quality control" relationship may exist between host cell and mitochondrion. In this view, mitochondria monitor dysfunction in cellular energy production and correct it (via cell death and replacement), until dysfunctional cells become so numerous that correction is no longer possible, due to the proportion of mutant mitochondria: see Lane, *Power*, *supra* note 90 at 274, 288, 300; Gilad Twig, Brigham Hyde & Orian S Shirihai, "Mitochondrial Fusion, Fission and Autophagy as a Quality Control Axis: The Bioenergetic View" (2008) 1777:9 Biochim Biophys Acta 1092 at 1092; Seo et al, *supra* note 112 at 2533; Weber & Reichert, *supra* note 112 at 503. Mitochondrial mutations can cause traits of aging, such as osteoporosis, hair loss, lower fertility, and heart enlargement: see Mügen Terzioglu & Nils-Göran Larsson, "Mitochondrial Dysfunction in Mammalian Ageing" in Derek J Chadwick & Jamie Goode, eds, *Mitochondrial Biology: New Perspectives* (London, UK: John Wiley & Sons, 2007) 197 at 203. Chronic degenerative diseases of aging linked to mitochondrial abnormalities include diabetes, congestive heart disease, cancer, and Alzheimer's: see Shokolenko, Ledoux & Wilson, *supra* note 101 at 330-31.

in an organism may cause or contribute to aging.[160] Mitochondria may function as a "biological clock,"[161] dictating organisms' life expectancy.[162] The mechanism for this mitochondrial biological clock may involve the greater – possibly as much as twenty-fold greater – mutation-susceptibility of mito-

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[160] See Yau-Huei Wei et al, "Respiratory Function Decline and DNA Mutation in Mitochondria, Oxidative Stress and Altered Gene Expression during Aging" (2009) 32:2 Chang Gung Med J 113; Gredilla, Bohr & Stevnsner, *supra* note 103 at 478, 484-85. Significantly, mutated mitochondria may be preferentially reproduced over normal mitochondria within host cells, possibly in compensation for the low energy production of mutated mitochondria: see Wallace, "Mitochondrial Paradigm", *supra* note 90 at 366-67.

[161] There is much speculation over the inevitability of eukaryotic aging and death, and why natural selection has not removed these phenomena from the gene pool. Controversially, some suggest that aging and death offer advantages (to species) by making room for new individuals and improving species overall: see Randolph M Nesse & George C Williams, *Why We Get Sick: The New Science of Darwinian Medicine* (New York: Vintage Books, 1996) at 109. As Lane explains, in essence "ageing [and death] doesn't seem to benefit the individual … but *does* look like a useful service to the species, for it leads to population turnover, preventing overcrowding and over-consumption of lean resources": Lane, *Power*, *supra* note 90 at 191 [emphasis added]. Yet natural selection is theorized to act upon individuals, not *groups* (except possibly kin): *ibid* at 191-92. Thus, an alternative view, possibly more consistent with mitochondrial science, is that aging is a "dust-bin of late-acting mutations" which natural selection cannot eliminate due to the mutations' post-reproductive onset: see Nesse & Williams, *supra* note 161 at 113-14, citing JBS Haldane, *New Paths in Genetics* (New York: Harper, 1942) and PB Medawar, "Old Age and Natural Death" in PB Medawar, ed, *The Uniqueness of the Individual* (London, UK: Methuen, 1957) 17 at 38.

[162] Nesse & Williams, *supra* note 161 at 108 ("life expectancy" is the *maximum* age an individual of a species may attain, while "life span" is the *average* age an individual of that species attains). More efficient mitochondria are associated with a longer life in some animals. Lower free radical damage (by more efficient mitochondria) is linked to longer life expectancy in laboratory mammals: see Gredilla, Bohr & Stevnsner, *supra* note 103 at 484. Conversely, birds tend to have more efficient mitochondria and correspondingly long lifespans: see Lane, *Power*, *supra* note 90 at 269, 308. Experimental animal research has also demonstrated that *congenital* mtDNA mutations can exacerbate phenotypic signs of aging: see Jaime M Ross et al, "Germline Mitochondrial DNA Mutations Aggravate Ageing and Can Impair Brain Development" (2013) 501:7467 Nature 412 at 412.

chondrial DNA than nuclear DNA.[163] This vulnerability may be due to the physical proximity of mitochondrial DNA to the electron transport chain, which continuously leaks low levels of damaging free radicals, an arrangement that might be likened to a mitochondrion's keeping its genetic blueprint too near its own internal "incinerator."[164] Other features of mitochondrial DNA leave it unprotected and less easily repaired than nuclear DNA.[165]

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[163] See Lane, *Power*, *supra* note 90 at 245; see also Shokolenko, Ledoux & Wilson, *supra* note 101 at 330 (giving a figure of a ten-fold greater rate of mutation). The precise mitochondrial mutation rate is difficult to assess, since the observed rate represents the result *after* natural selection: Lane, *Power*, *supra* note 90 at 245, 260, 285-86. The high mitochondrial mutation rate raises the question why all mitochondrial genes were not transferred to the nuclear genome, which is better protected from damage. The reason may be that mitochondrial retention of some genes may enable a more rapid response to changing oxygen levels: see Lane, *Oxygen*, *supra* note 122 at 265-66, n 7.

[164] Douglas C Wallace, founding Director of the Center for Molecular and Mitochondrial Medicine and Genetics, University of California at Irvine, likens mtDNA to the genetic blueprint for a house's electrical wiring. He explains in lay terms, "The mitochondria are unique because they have their own DNA (labeled mtDNA) and that DNA is the blueprint to determine how energy is generated and used. So, as we age in the process of making energy, the mitochondria also make … oxygen radicals. The oxygen radicals are just like smoke; they will damage their environment.… The mitochondria [are] constantly struggling between the process that is making energy, which makes the smoke, and the smoke, which intoxicates the cell. The consequence is that the cell then has to use the information in its [mt]DNA to repair this damage": Interview of Douglas C Wallace, "Mitochondria and Aging" (March 2008) on Action Bioscience – American Institute of Biological Sciences, online: ABS: <www.actionbioscience.org/genomics/wallace.html> [Wallace Interview]. See also Lane, *Power*, *supra* note 90 at 279-80. An alternative view suggests that, rather than being a passive "incinerator," the mitochondrion's role may be more as an active energy-monitoring system: see Braschi & McBride, *supra* note 104 at 959.

[165] Meyer et al explain, "mtDNA is more vulnerable than nDNA [nuclear DNA] to some environmental genotoxins although the opposite is also true in some cases … A number of explanations for this observation have been presented, including mtDNA's physical location [near the electron transport system], its reduced protein packaging compared with nDNA, and its reduced repair capacity": *supra* note 102 at 5. Meyer et al acknowledge some (partial) protective effect of the high mtDNA copy number and of certain proteins that associate with mtDNA, reducing its vulnerability to reactive chemicals, but emphasize that:

Therefore, over time, it appears mutations may accumulate faster in mitochondrial DNA than in host DNA.[166] As old mitochondria divide to produce new mitochondria, these mutations are duplicated in subsequent daughter mitochondria, reducing their energy production and eventually triggering apoptosis of affected cells. Normally, this allows surviving, healthy cells to repopulate the tissue in a self-correcting manner. However, as a self-correcting system, apoptosis does not appear to keep pace with the mitochondrial mutation rate, so mutations accumulate and a "vicious cycle"[167] of reduced energy production and increased apoptosis intensifies over time:

> In ageing cells, mitochondrial genes accumulate new mutations.… [Mitochondrial r]espiratory function declines, free-radical leakage rises, … the mitochondria begin to promote apoptosis[,] … energy diminishes, we become far more vulnerable to all kinds of diseases, and our organs shrink and wither.… [Thus] mitochondria are central not only to the beginning of our lives, but also to their end.[168]

> [a] very large difference between nDNA and mtDNA is the relative lack of repair pathways present in the mitochondria, at least in humans … [with] many types of damage [being] irreparable or only very slowly repaired. Base excision repair is present in mitochondria, but nucleotide repair … is not, and recombinational and mismatch repairs are either absent or quite limited … The sole replicative mtDNA polymerase, DNA polymerase γ, appears to have very little translesion synthesis capacity …, so that this damage tolerance mechanism is also lacking or very limited [*ibid* at 6].

[166] This would appear to follow from the combined effects of a faster mtDNA mutation rate as compared to nDNA and a lesser mtDNA repair capacity than in nDNA.

[167] Age-related diseases leading to death demonstrate a positive feedback loop ("vicious cycle" or "self-reinforcing spiral"): see Seo et al, *supra* note 112 at 2533; Mary-Ellen Harper et al, "Ageing, Oxidative Stress and Mitochondrial Uncoupling" (2004) 182:4 Acta Physiol Scand 321 at 321. Conversely, in life, mitochondrial "quality control" mechanisms (autophagy removing damaged mitochondria) permit the opposite pattern, i.e., a negative feedback loop, whereby mitochondria maintain high energy production, despite mutations, as long as possible: see Braschi & McBride, *supra* note 104 at 959; Gottlieb & Carreira, *supra* note 144 at 203; Twig, Hyde & Shirihai, *supra* note 159 at 1092.

[168] Lane, *Power*, *supra* note 90 at 265.

Since new mitochondria can only form from pre-existing mitochondria,[169] in old age, when many mitochondria in tissues contain mutations, fewer healthy templates exist for future mitochondrial generations. Possibly as a result, according to an empirically observed phenomenon termed the "Hayflick Limit," normal cells can only undergo a fixed, species-specific number of divisions during an organism's lifespan.[170]

Irreversibility has long been considered an essential aspect of death by philosophers, physicians, and laymen alike. Yet such "irreversibility" may have many possible definitions. Stuart Youngner and colleagues cite three possible interpretations of the term (from strongest to weakest), which they attribute to David Cole:

> 1. "[The] lost function cannot be restored by anyone under any circumstances at any time now or future."
>
> 2. "[The] loss of function cannot be reversed by those [means or individuals] present at this time."
>
> 3. "[The] function is irreversibly lost if a morally defensible decision has been made *not* to try to reverse the loss."[171]

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[169] *Ibid* at 195.

[170] Lane, *Oxygen*, *supra* note 122 at 267-68. As Lane indicates (*ibid*), different cell types possess different Hayflick limits, with the cells of short-lived species usually possessing lower limits; for instance, human fibroblast cells are capable of 50 to 70 divisions, whereas mouse fibroblast cells can divide only 15 times. Cancer cells are an exception: they appear to have no Hayflick limit and divide indefinitely. Notably, Lane observes, cancer cells tend to operate on anaerobic respiration and have low levels of (functional) mitochondria, rendering the problem of mitochondrial mutation moot: *ibid* at 273.

[171] Stuart J Youngner, Robert M Arnold & Michael A DeVita, "When is 'Dead'?" (1999) 29:6 Hastings Cent Rep 14 at 16, citing David Cole, "Statutory Definitions of Death and the Management of Terminally Ill Patients Who May Become Organ Donors after Death" (1993) 3:2 Kennedy Inst Ethics J 145 [emphasis added]. Note that while interpretations 1 and 2 are taken by Youngner, Arnold & DeVita verbatim from Cole, the third does not in fact appear as such in Cole's paper, but rather emerges indirectly from his criticism of the University of Pittsburgh Medical Center's policy on organ removal ("the UPMC protocol countenances pronouncing as dead persons who may well have sufficient CNS function to permit resuscitation, and the protocol sees this interpretation of statutory definitions of death as satisfy-

Jeff McMahan argues that only in the first case is an organism actually dead in the commonly accepted sense. In the second case, he argues, "[i]f an organism stops functioning but its function could be recovered by means of a device that we do not in fact possess, it is not *dead*."[172] This view has been taken up by others, as discussed below. Regarding the third case above, McMahan argues that a human *decision* not to revive an organism – for example, not to replace its lost function technologically – does not equate to the irreversibility of death in the usual, accepted sense. If a lost human function *can be* repaired or replaced with existing technology, but *will not be* for moral, social, or legal reasons (a "do not resuscitate" order, for example), such a decision should not be conflated with a conclusion that a biologically irreversible change in its life status has occurred.

In the spirit of the second definition of irreversibility, "transhumanists" such as Ray Kurzweil, Richard Feynman, and James Hughes argue that conquering aging and death is purely a matter of time, technological capacity, and human willpower, a feat they believe will someday be accomplished.[173]

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ing the requirement that the cessation of cardiopulmonary function is *irreversible*": Cole, *ibid*, at 148 [emphasis in original]).

[172] Jeff McMahan, "An Alternative to Brain Death" (2006) 34:1 JL Med & Ethics 44 at 45.

[173] Kurzweil argues that the ideas of life as finite and death as inevitable are so deeply ingrained that we continue to rationalize death's necessity instead of focusing on its reversal: *supra* note 18 at 326. Similarly, nanotechnology founder Richard Feynman views death as a disease, rather than as an inevitable biological endpoint: "[T]here is nothing in biology yet found that indicates the inevitability of death. This suggests to me that it is not inevitable at all and that it is only a matter of time before biologists discover what is causing us the trouble and this terrible universal disease … will be cured": Richard P Feynman, "What Is and What Should Be the Role of Scientific Culture in Modern Society" in Jeffrey Robbins, ed, *The Pleasure of Finding Things Out: The Best Short Works of Richard P Feynman* (Cambridge, Mass: Perseus Books, 1999) 97 at 100. James Hughes thinks that cryonic suspension and nanotechnology will increase the longevity of human bodies, but looks toward a time when, like computer files that can be backed up and preserved and/or merged with others, human physical boundaries will vanish and "perhaps we will also then be beyond death": James J Hughes, "The Death of Death" in Calixto Machado & D Alan Shewmon, eds, *Advances in Experimental Medicine and Biology,* vol 550: *Brain Death and Disorders of Consciousness* (New York: Springer Science+Business Media, 2004) 79 at 81-82, 85.

Theoretical support exists for this view. Technological replacements for lost functions, e.g., heart-lung bypass machines, now prolong human life where death would once have seemed inevitable. It may one day be possible to isolate or engineer mitochondrial-protectant drugs, based on observations of hypoxia-tolerant species. Genetic engineering may also offer some potential to repair mitochondrial mutations.[174] For instance, placing mitochondrial genes into the host nucleus might better protect mitochondria against age-related free radical damage and mutation, by removing the mitochondrion's genetic blueprint from the "incinerator" where oxygen free radicals are generated.[175]

Yet these are currently distant possibilities.[176] Mitochondria have resisted efforts to culture and replace them.[177] Their "alien" nature – as organisms of a distant biological relationship to our animal cells – and their highly complex and poorly understood symbiotic relationship with host cells seem likely to challenge technological manipulation for some time to come. Given the complexity of the mitochondrial symbiosis and our rudimentary understanding of it, new treatments may have unforeseen negative consequences, such as the significant fatigue and reduced exercise tolerance suffered by users of cyclosporine A, a mitochondrial-protectant drug whose side effects appear to result from the suppression of mitochondrial energy production.[178] The po-

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[174] See Eric A Schon et al, "Therapeutic Prospects for Mitochondrial Disease" (2010) 16:6 Trends Mol Med 268; DS Kyriakouli et al, "Progress and Prospects: Gene Therapy for Mitochondrial DNA Disease" (2008) 15:14 Gene Ther 1017; K Irwin, News Release, "UCLA scientists find a way to repair mutations in human mitochondria" (12 March 2012), online: UCLA <www.newsroom.ucla.edu/portal/ucla/ucla-scientist-find-way-to-repair-230241.aspx>.

[175] Mauro Scarpelli et al, "Current Options in the Treatment of Mitochondrial Diseases" (2010) 5:3 Recent Pat CNS Drug Discov 203 at 203.

[176] As Wallace explains, "Right now, we cannot manipulate mtDNA in the same ways that people can manipulate the nuclear DNA; it is in a very different part of the cell, in a very different environment. So the same tools can't be used": Wallace Interview, *supra* note 164.

[177] Lane, *Power*, *supra* note 90 at 16.

[178] Cyclosporine A protects mitochondria somewhat against hypoxic damage by preventing opening of the mitochondrial permeability transition pore: see Eloisa Arbustini & Jagat Narula, "Cyclosporin A in Reperfusion Injury: Not Opening to Cell Death Knocking at the Door?" (2010) 89:5 Ann Thorac Surg 1349. Yet cyclospor-

tential for effects on a vital symbiosis suggests that any treatments affecting or directly targeting mitochondria must be explored with caution.

At present, no known way exists by which to "turn back the clock" on mitochondrial aging and death.[179] When a threshold mitochondrial mutation rate is reached, causing energy production to be significantly reduced, it presumably follows that breathing or circulation will cease due to infection, injury, organ failure, or other causes. As described above, once a sustained cessation of oxygenated blood occurs, mitochondria are irreversibly damaged, with calcium deposits preventing future energy production and releasing the free radical signal for enzymatic cell destruction. This destruction will occur first in hypoxia-sensitive tissues (e.g., the cortex of the brain, and later the brain stem and the heart) and subsequently in more hypoxia-resistant tissues. Without viable mitochondria, the cessation of energy production becomes permanent, and without energy, the body can neither sustain emergent functions nor resist entropy. The cells of the body begin to self-destruct *en masse*, and their component molecules are dispersed into the inanimate environment or taken up by other life forms as nutrients.[180] Thus, the death of the "organism as a whole" occurs and cannot be reversed.

A body-centred, mitochondrial mechanism for biological death can explain all of death's common features,[181] with death being an unfortunate side

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ine A's side effects may reduce mitochondrial energy production in skeletal muscle, causing significant fatigue and reduced exercise tolerance: see James F Hokanson, Jacques G Mercier & George A Brooks, "Cyclosporine A Decreases Rat Skeletal Muscle Mitochondrial Respiration *in vitro*" (1995) 151:6 Am J Respir Crit Care Med 1848 at 1848.

[179] However, caloric restriction and/or regular aerobic exercise may *slow* the "ticking" of the mitochondrial clock, by lowering free radical production: see Michelakis, *supra* note 98 at 2432; Wallace, "Mitochondrial Paradigm", *supra* note 90 at 365; Saris & Heymsfield, *supra* note 105 at 663.

[180] After death, body parts may be ingested by predators, scavengers, or decomposing organisms, such that the normal microbial body "flora" present during life are replaced by other microbes associated with decay.

[181] Some question whether "death" is the same process for organisms that reproduce asexually, by division: see e.g. McMahan, *supra* note 172 at 44. Bernat has argued that there *may* be differences in the biological death process between the deaths of vertebrate and invertebrate animals, e.g., planaria (flatworms): see James Bernat, "Are Brain-Dead Patients Really Dead?" (Lecture delivered at the Brain Matters:

effect of the eukaryotic dependence on mitochondrial energy. This dependence may be stricter in complex, specialized organisms (e.g., humans) performing high-energy activities than in simpler eukaryotic organisms (e.g., yeast) whose less sophisticated activities can be fuelled even with a 94% drop in energy supply. Death's universality and similarity among multicellular eukaryotes are both explained by the fact that mitochondria are a universal feature of all free-living (non-parasitic) eukaryotes,[182] performing the same functions in all of them that permit emergent properties. In animals, a mitochondrial role explains life's oxygen-dependence and the temporal link between death and the lost circulation of oxygenated blood.[183]

Death's inevitability and link with aging are also explained by the mitochondrial "biological clock" function, which accumulates mutations faster than apoptosis can eliminate them. The irreversibility of death reflects the body's inability to create new functional mitochondria when template mitochondria are damaged, coupled with our present technical inability to repair, culture, and replace mitochondria. Finally, death's temporal association with disintegration and decay results from the loss of mitochondrial energy, without which the body cannot resist entropy and disintegration. This may also explain why the same physical matter is present immediately before and after death, yet afterwards the body seems to lack some "animating spark" – the energy produced by mitochondria.

New Directions in Neuroethics Conference, Halifax, NS, 26 September 2009) [unpublished]. Based on a mitochondrial mechanism, death should occur via the same mechanism for all eukaryotes – i.e., irreversible mitochondrial damage leading to cell, tissue, and whole-organism death – but in animals that reproduce (in part) by division, the question of when death occurs is complicated by the fact that a portion of the original individual may persist, still functioning, in subsequent "daughter" organisms; in this particular respect they are similar to prokaryotic organisms.

[182] The exception to this otherwise universal rule is certain eukaryotic parasites, all of which descend from ancestors with mitochondria: see Lane, *Power*, *supra* note 90 at 17, 51; see also *ibid* at 46-48. These exceptional eukaryotes appear to have lost their mitochondria over time, perhaps finding it more efficient to rely on host ATP supplies.

[183] However, blood circulation need not be maintained by natural cardiopulmonary means. For instance, isolated heads have been maintained "alive" (i.e., exhibiting tissue viability and emergent properties) using artificial re-oxygenation and circulation of blood by heart-lung machine: see Pernick, *supra* note 35 at 5.

III. Mitochondrial Viability in the Brain-Dead Body

Empirical observations do suggest that the bodies of heart-beating, brain-dead donors continue to exhibit mitochondrially integrated, emergent properties of the "organism as a whole." For instance, Shewmon notes that the best cardiac donors are those "with intrinsic somatic integration not deriving from the brain."[184] Shewmon illustrates this concept with two examples, breathing and nutrition, both of which integrate the body through biochemical processes.[185] In the first example, Shewmon specifically mentions the mitochondrial use of oxygen in chemical respiration as an illustration of a somatically integrating function not deriving from the brain. This process integrates by providing the entire body with vital fuel, i.e., ATP. Yet overall, "somatic integration not deriving from the brain" appears a fitting description of the bodily integration that functioning mitochondria impose even more broadly by maintaining energetically functional, co-operating body tissues.

As this paper has explored in some depth, mitochondrial functioning appears to be responsible for many fundamental integrating functions of whole organisms. This seems to support Shewmon's claim that "[i]ntegrative unity is *not* a top-down imposition from a 'central integrator' on an otherwise unintegrated collection of organs."[186] In contrast, Korein and Machado, citing previous works by Machado, claim that "consciousness … is the most integrative function of the [human] body."[187] Even if that were so, there is evidence connecting mitochondrial malfunction to disorders of consciousness and physical dysfunction, specifically Alzheimer's and Parkinson's disease.[188] Further contradicting Korein and Machado, when consciousness fails permanently, mitochondria in the bodies of brain-dead donors can still remain viable, allowing body systems to function (with breathing support) and permitting successful transplants. This suggests that consciousness is a less integrating force in the body than is mitochondrial function.

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[184] Shewmon, "Critical Re-evaluation", *supra* note 6 at 139.

[185] *Ibid* at 138.

[186] *Ibid* at 140 [emphasis in original].

[187] *Supra* note 82 at 9.

[188] Dong-Hyung Cho, Tomohiro Nakamura & Stuart A Lipton, "Mitochondrial Dynamics in Cell Death and Neurodegeneration" (2010) 67:20 Cell Mol Life Sci 3435 at 3435, 3441-42.

Shewmon's claim regarding superior cardiac donors is also consistent with the observations of Lane that successful transplantation appears to require viable mitochondria in donor organs.[189] Taken together, these observations suggest that viable mitochondria exist in the bodies of ventilated, brain-dead donors who donate successful transplants. Yet the existence of viable mitochondria – mitochondria still capable of using oxygen, producing energy, and maintaining co-operating tissues[190] – in a ventilated, brain-dead body contradicts the 2008 President's Council's analysis that such bodies lack a "needful openness" and cannot engage in "commerce with the world." This contradiction suggests a need for further research on bodily death and brain death, informed by a mitochondrial perspective.

Among brain-death scholars, Shewmon comes closest to arguing for a mitochondrial explanation of life's somatic integration[191] and its loss in death, although he does so without discussing mitochondrial viability in much depth.[192] He observes, "[A] *sine qua non* of the opposition to entropy is energy, generated by [mitochondrial] chemical respiration, and a *sine qua non* of somatic integration is the circulation of [oxygenated] blood."[193] Nota-

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[189] Empirically, following kidney transplant, "[m]itochondrial function in those first few minutes [after transplantation] foretold the outcome, perhaps weeks later – if the mitochondria failed in the first few minutes, the [transplant] inexorably failed": Lane, *Power*, *supra* note 90 at 314. To prevent organ rejection, a mitochondrial pore-protecting drug (cyclosporine A) is taken by transplant recipients: Hokanson, Mercier & Brooks, *supra* note 178 at 1848. These observations indicate a correlation between mitochondrial viability and transplant success.

[190] President's Council, *supra* note 11 at 64.

[191] Shewmon summarizes that "some [claimed] key 'integrative functions,' if understood as *brain-mediated*, are not *somatically integrating*, and if understood as *somatically integrating*, are not *brain-mediated*": Shewmon, "Critical Re-evaluation", *supra* note 6 at 138 [emphasis in original]. He cites cellular respiration as a chemical function of mitochondria as an illustration of this point: *ibid*.

[192] Shewmon's meta-analysis also noted a possible positive relationship between a very young age at the time of the declaration of brain death and a longer period before the occurrence of spontaneous cardiac cessation on ventilator support: *ibid* at 135. Since younger patients will generally have fewer acquired mtDNA mutations, tissue functionality unimpeded by the effects of aging may be a possible explanation for his observation.

[193] *Ibid* at 142 [emphasis in original].

bly, he too describes human death as a *somatic* (i.e., body-centred) process, involving:

> a critical degree of molecular-level damage … throughout the body, beyond a thermodynamical "point of no return." The body's intrinsic tendency to active, anti-entropic … self-maintenance … is irretrievably lost, so that physico-chemical processes now follow the path of increasing entropy characteristic of inanimate things (i.e., decay). [Death] does *not* require supracritical damage of every single cell in the body, but rather supracritical damage of enough cells of enough different types that the body as a whole loses its intrinsic ability to counteract entropy.[194]

He continues, "A clinical test for the 'point of no return' is therefore sustained cessation of circulation of oxygenated blood … [U]nder ordinary circumstances … an educated guess is that twenty to thirty minutes [of cessation] probably suffice to surpass 'the point of no return.'"[195]

While Shewmon did not explain his choice of duration, it is consistent with the 20-to-30-minute period of ischemia noted earlier, after which heart muscle may be permanently damaged,[196] causing irreversible injury to the heart's mitochondria-rich cells and leaving an insufficient number of functional heart cells able to synchronously pump blood. In a later paper, he nuanced this time estimate, noting that in actuality it will be highly dependent on ambient temperature.[197] Human death, based on a mitochondrial mechanism, does appear to involve a thermodynamic no-return point at which many mitochondria, irreversibly damaged by lengthy hypoxia, trigger enzymatic cell destruction. This would produce the widespread "supracritical" damage Shewmon described as occurring as a body loses its battle with entropy. Consistent with a mitochondrial mechanism for death, Shewmon argues that "[n]either spontaneous heartbeat nor breathing through the lungs is

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[194] *Ibid* at 141-42 [emphasis in original].

[195] *Ibid* at 142.

[196] Kumar, Cotran & Robbins, *supra* note 119 at 6.

[197] Shewmon, "Elephant", *supra* note 2 at 284-85.

essential for life (as cardiopulmonary bypass machines effectively prove), but circulation and [mitochondrial] chemical respiration *are*."[198]

Despite the apparent similarity between Shewmon's reasoning and the views of this paper, his more recent publications reveal his perspective as grounded somewhat differently. Shewmon argues that a human being is a hybrid of a physical organism with a psychospiritual human mind, the latter being irreducible to the functions of the human brain. Quoting Pope John Paul II, he suggests that biophysical death (which he terms "deanimation") is:

> a single event … result[ing] from the separation of the life-principle (or soul) from the corporeal reality of the person … an event which *no scientific technique or empirical method can identify directly* [but after which] … *certain biological signs inevitably follow*.[199]

Nevertheless, his sufficient and necessary criterion for the occurrence of biophysical death – "the irreversible cessation of the anti-entropic exchange of substances with the environment"[200] – again sounds evocative of a mitochondrial basis for biophysical death.

In contrast, as noted earlier, this paper adopts the perspective that the life and death of a human being are biological phenomena affecting the body, one aspect of whose functioning is the human mind. According to this view, then, death of the organism or body will automatically bring about death of the mind. Specifically, this paper has argued that, based on a mitochondrial mechanism, death of the organism occurs when the whole body undergoes hypoxia for a period sufficient to destroy most of the body's mitochondrial populations, resulting in a loss of energy supply and the associated emergent properties of the whole body (including the brain). In turn, loss of the brain's functional mitochondria causes the collapse of the epiphenomenon (or emer-

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[198] Shewmon, "Critical Re-evaluation", *supra* note 6 at 142 [emphasis in original].

[199] Shewmon, "Elephant", *supra* note 2 at 283, citing Pope John Paul II, "Address of the Holy Father John Paul II to the 18th International Congress of the Transplantation Society" (Speech delivered 29 August 2000), online: The Holy See <www.vatican.va/holy_father/john_paul_ii/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants_en.html> [emphasis in original].

[200] Shewmon, "Elephant", *supra* note 2 at 281.

gent property) of the human mind. However, if hypoxia persists only long enough to cause destruction of the brain alone (which depends more heavily on mitochondrial energy supplies), mental emergent properties such as consciousness will vanish, while other tissues in the rest of the body that are less heavily energy-dependent (e.g., the heart) may continue to function, continuing to produce physical emergent properties of a complex body system, as Shewmon's meta-analysis observed.

How does life-support technology affect the picture? To a mitochondrion, it seems immaterial whether blood circulation is natural or artificial.[201] As long as oxygenation and blood circulation continue by *some* means, mitochondrial energy production and entropy resistance can continue, avoiding widespread enzymatic cell destruction. With mechanized support, the mitochondria in a brain-dead body can remain viable, at least until factors such as systemic infection intervene. If populations of viable mitochondria – permitting whole-organism emergent functions and systemic integration – are what distinguish living from dead organisms, then we should consider as "living" a brain-dead patient whose breathing is supported, permitting a cardiac pulse to be generated by its heart cells and thereby allowing circulating, oxygenated blood to sustain the body's mitochondria sufficiently that the body can resist entropy. This is what Shewmon's study of ventilated, brain-dead patients appeared to observe.

IV. Addressing the Lack of Equivalence between Brain Death and Death of the Human "Organism as a Whole"

While some argue that "death is best understood as an event and not a process,"[202] this appears inconsistent with the fact that hypoxia leads to tissue destruction at different rates in various tissues. The mitochondrial view correctly predicts that the first tissues affected by a loss of oxygenated blood are high-energy tissues such as neural tissues, resulting in the disappearance of energy-consumptive processes such as consciousness and the rapid onset of brain damage. More resistant tissues, such as leg muscle or glia, may remain viable longer than neurons or heart tissues, but eventually all will succumb to oxygen deprivation and necrosis. Thus it appears more likely that, as Bryan

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[201] "Natural" circulation uses heart and lung tissue, human or non-human, as in xenotransplantation. "Artificial" circulation of blood can be accomplished by an artificial heart or heart-lung bypass machine.

[202] Bernat, "Whole-Brain Defense", *supra* note 5 at 15.

Jennett argues, "[d]eath is a process rather than an event"[203] – that is, a biological continuum of lost functions.[204]

Nevertheless, to facilitate social and legal necessities, it seems essential that death continue to be treated as a discrete event or "moment" rather than as a process, in order to enable important social processes such as the settling of estates and harvesting of donor tissues to continue without undue delay. Bearing societal needs in mind, how should we proceed? That is, if – as argued in this paper – mitochondrial viability provides a better explanation for the biological process of death than past scholarship has provided (which, admittedly, some may hotly dispute), are changes needed to the status quo regarding our treatment of death, in light of this new understanding?

One point requiring clarification is that accepting a mitochondrial mechanism for *biological* death does not inevitably mean that we would have to maintain brain-dead patients on ventilators, possibly for decades, while awaiting the expiry of all of the body's mitochondrial populations. First, few people seem likely to desire decades of life support for themselves or their loved ones, especially those patients who identify more strongly with their mental personhood characteristics than with their bodies. Advance directives allow life support to be withdrawn at a chosen point prior to death, and currently many PVS patients (who, by definition, are not "brain dead") have life support withdrawn well before death would occur "naturally." These observations provide precedent for the early removal of life support in cases where a patient's bodily mitochondrial populations still persist.

More importantly for both patients and families wishing to rely on life support and those who do not, it has always been customary, for purposes of social practicality, to set particular criteria for when human *legal* death is deemed to have occurred. This is done by physicians drawing a line – i.e., selecting *legal* criteria of death – at a point along the biological "dying continuum" of functional losses. The line-drawing process is intimately connected with the setting of specific tests, which are usually based on macroscopic,

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[203] Bryan Jennett, "Brain Death" (1981) 53:11 Br J Anaesth 1111 at 1111.

[204] Death may be a continuum of body cooling, rigor mortis, dependent lividity, putrefaction, and, after centuries, mineralization of bony remains: Charles M Culver & Bernard Gert, "The Definition and Criterion of Death" in Thomas A Mappes and David DeGrazia, eds, *Biomedical Ethics*, 6th ed (Toronto: McGraw Hill, 2006) 312 at 313.

externally ascertainable signs (e.g., a heartbeat, breathing reflexes) that can be assessed non-invasively, without harming the patient. As mitochondrial populations appear to expire at different rates in different tissues, if we use mitochondrial expiry as a legal criterion of death, this would require that we specify which tissue(s) are to be tested. Even then, mitochondrial viability cannot provide a useful test that is non-invasive and externally ascertainable: the very act of sampling will destroy mitochondria by exposing the sample tissues to ischemia. Thus, even with a mitochondrial mechanism for biological death, we will require, for practicality's sake, *macroscopic* legal criteria of death that can be easily tested.

Therefore, the real issue to be decided is the choice of the legal criterion (or criteria) we ought to use for death, in light of our knowledge regarding mitochondrial contributions to life. More particularly, if we agree that, based on a mitochondrial mechanism, brain death and death of the "organism as a whole" are not actually biologically equivalent – contradicting many scholarly claims made since 1968 – should we continue to use brain death or abandon it as a legal criterion of death?

To some, one option might be a "business as usual" approach, ignoring what mitochondrial science tells us and continuing to state that brain death is identical to bodily death. Yet this seems less than ideal, since this approach – maintaining increasingly convoluted and contradictory explanations of brain death[205] – may be creating cognitive dissonance and moral distress among health care workers as to whether they should treat brain-dead patients as

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[205] As noted earlier, the President's Council report sets three minimal criteria for living organisms: openness to environmental stimuli, a felt drive to act on the environment to meet some need, and a capacity to act on its own behalf to meet that need: *supra* note 11 at 61. Yet its application of these criteria is error-prone and contradictory. For instance, to distinguish PVS patients from the dead (*ibid*), the Council cites several characteristics not actually possessed by PVS patients: see text at notes 68-75, *supra*. The Council also seems to imply initially that the intake of *both* "food and water" and "even more basically" air may both be sufficient evidence of a living organism's capacity for action: *ibid at* 62. But by the end of the paragraph and subsequently (e.g., at 63-65, and implicitly at 90-91), only spontaneous breathing (which brain-dead bodies do not display) is cited as potential evidence of capacity and appetitive drive to act. The reasons for not considering water and nutrient intake (which brain-dead bodies do exhibit) as evidence of life are not clarified.

"really dead."[206] Surveys indicate that 71% of Canadians surveyed also do not understand the term "brain death" to be equivalent to death in the commonly understood sense.[207] Conceivably, low organ donor rates[208] may be connected with this public skepticism about brain death.[209] Furthermore, it seems that continuing to provide outdated, scientifically unsupported information and to omit salient details about brain death is inconsistent with legal requirements for informed consent, a basic tenet of modern health care. This may render any consent given invalid, which would make organ harvesting a battery on the patient (as discussed in greater detail later in this section), regardless of the patient's desire during life to donate his or her organs.

A new approach to death therefore seems highly advisable, an approach whose guiding principle is that we not mislead patients by omission or otherwise, and thus avoid abusing their trust and invalidating their consent. It is no answer to argue that the accuracy of the information provided to patients about death matters little, on the grounds that existing patient choices – e.g., a patient's advance directive requesting that life support be withdrawn long before death, upon the loss of personhood features – may in practice truncate some patients' lifespans. Exercise of such choices is a separate legal matter, one that does not render accuracy in discussing biological death any less a requirement *generally*, simply because *some* patients may choose life-support withdrawal early in the dying process. Death is a highly emotional issue for most people and declaration of death, according to whatever crite-

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[206] Robert D Truog, "Brain Death – Too Flawed to Endure, Too Ingrained to Abandon" (2007) 35:2 JL Med & Ethics 273 at 274-75, 277.

[207] Canadian Council for Donation and Transplantation, *Public Awareness and Attitudes to Organ and Tissue Transplantation Including Donation after Cardiac Death: Final Report*, December 2005, online: CCDT <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Public_Survey_Final_Report.pdf> at 8.

[208] While 96% of the public and 99% of medical professionals "approve of" organ donation after death, only 55% of the public and 68% of medical professionals, respectively, have decided to donate their own organs: see *ibid* at 7; Canadian Council for Donation and Transplantation, *Health Professional Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation after Cardiocirculatory Death*, August 2006, online: CCDT <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Survey-Health-Prof.pdf> at 14-15.

[209] See Shewmon, "Critical Re-evaluation", *supra* note 6 at 129-30.

ria, signifies a major withdrawal of legal rights. Given the important social and legal implications that flow from death declaration, a "casual" approach to providing patients with information about the nature of *biological* death – and how it may diverge from those criteria – cannot be regarded as acceptable.

Also, while organ donors and those using advance directives can exercise some choice by requesting that their deaths occur relatively early, for everyone else there is currently no option available as to when death will be declared. There has been no societal decision in Canada (e.g., through Parliament) regarding the point in the dying continuum at which death should be declared. Adoption of brain death as a second legal death criterion was not a choice made by society as a whole, but was imposed by members of the medical profession in 1968. Although the 1981 Law Reform Commission of Canada urged that a legislative (and therefore democratic and societal) definition of death be adopted, this recommendation was never acted upon. Thus, for most Canadians, the current arrangements and information regarding brain death cannot be said to reflect socially agreed-upon choices.

Approaching the issue afresh suggests that, ideally, death should be declared only when a significant proportion of the body's mitochondrial populations has been destroyed. Given the current lack of satisfactory means to assess this point in a patient using external signals,[210] as an alternative we might concede the inequality of brain death and bodily death, and abandon brain death as a legal criterion, retaining only the time-honoured cardiopulmonary criterion of death. Using a cardiopulmonary criterion provides a more certain indication that the body's mitochondrial populations will have succumbed to the effects of hypoxia. It bears noting, however, that the cardiopulmonary criterion is also an imperfect estimate of when death occurs, as it also reflects a line drawn at an easily testable point within the "dying continuum." Mitochondria in the body do not die immediately upon cardiopulmonary arrest (nor for some time if artificial oxygenation and recirculation of blood continue). Therefore – like brain death – the cardiopulmonary death criterion indicates only approximately when the death of the entire organism, in the absolute or commonly understood sense, occurs.

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[210] To assess mitochondrial viability in a donor organ, Lane used near infrared and another unspecified form of spectroscopy: Lane, *Power*, *supra* note 90 at 312-13. This technique cannot be used non-invasively, however.

Using only a cardiopulmonary criterion also poses disadvantages. Due to the fact that individuals declared dead using a cardiopulmonary criterion undergo a damaging period of warm ischemia, transplants from heart-beating, brain-dead donors are preferred.[211] Transplants from donors with a heartbeat can be harvested earlier and are more successful than those obtained via a cardiopulmonary criterion. Abandoning brain death would therefore substantially decrease current organ availability and successful transplantation rates, which are already inadequate to meet present needs.[212] More patients would die awaiting transplants, and the health care costs of providing other therapies in place of transplants (where such therapies are possible) might in-

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[211] Transplant success increases with earlier organ harvesting and better hypoxia protection. Organs from brain-dead bodies experience less hypoxic exposure of mitochondria than those in bodies that have undergone cardiopulmonary death, as noted by the President's Council:

> If surgeons wait for the more traditional signs of death [e.g., a cessation of cardiopulmonary activity], the organs endure a period of "warm ischemia" during which they are deprived of nourishing blood and oxygen. While it is possible to procure some organs under these circumstances, concerns about ischemic damage make the heart-beating, "brain-dead" donor the preferred source of organs [*supra* note 11 at 8].

A 1977 study also observed that "if the pronouncement of death were delayed until the heart stopped beating, the organs underwent so much deterioration that a successful transplant was jeopardized": see NINCDS, *supra* note 32 at 982. The later time of cardiopulmonary declaration may mean that organs will be harvested later from patients, exposing organs to a longer period of deterioration due to infection, drug side effects, etc., in addition to warm ischemia. Before 2006, Canadian organs from deceased donors were *only* obtained from brain-dead patients. However, by 2009, four Canadian provinces (British Columbia, Ontario, Quebec, and Nova Scotia) had begun to harvest some organs after "cardiocirculatory" death (i.e., death declared based on cardiac rather than neurological criteria), although these represented fewer than 10% of donations: see Canadian Institute for Health Information, "Organ Donor Activity in Canada, 1999 to 2008" (22 December 2009), online: CIHI <https://secure.cihi.ca/free_products/CORR_AiB_EN_20091222_rev20100106.pdf> at 1.

[212] See Canadian Blood Services, *Call to Action: A Strategic Plan to Improve Organ and Tissue Donation and Transplantation Performance for Canadians,* online: CBS <www.organsandtissues.ca/s/wp-content/uploads/2012/06/OTDT-INDX-final-C2A.pdf> ("[t]he acute shortage of organs means provinces and programs must share organs to minimize the number of deaths of critically ill patients on waitlists" at 77).

crease.[213] Therefore, from a utilitarian perspective, reverting to a solely cardiopulmonary criterion is not ideal, although it could be considered.

Alternatively, to protect organ transplantation, we could acknowledge that brain death is not equivalent to bodily death, but abandon the DDR,[214] under which organs must only be obtained from patients considered "dead." If brain death does not necessarily indicate bodily death based on mitochondrial function, then, biologically speaking, a brain-dead, heart-beating patient can only be said to be "dying," rather than fully dead, despite having been declared *legally* dead. Abandoning the DDR would permit organ harvesting from brain-dead donors during the period that their bodies are legally, but not biologically, dead.

While this could preserve organ donation, some may argue that, according to Kant's categorical imperative, such brain-dead individuals will thereby be treated unethically, as means rather than as ends in and of themselves. Yet it may be countered that if we agree to accept brain death as a legal criterion but abandon the DDR, then for a human being who autonomously consented during life to organ harvesting, brain death could be held to mark the point where that patient as a legal person disappears. Under this account, Kant's categorical imperative might not be violated by the use of the mitochondrially still-living body of a brain-dead patient as a "means" (in ways to which the patient has consented). Yet admittedly, others may strongly disagree, seeing the removal of organs from a consenting donor's "still-living" body as inherently unethical and a crime.[215] Even if it is acceptable, it will only be so if an important legal consideration – valid donor consent – is satisfied, mean-

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[213] The cost effects are unclear, but those associated with end-stage kidney disease, at least, might rise due to the potential that costly dialysis would have to be provided longer and to more patients to address a decline in the availability of kidneys for transplant.

[214] Truog, *supra* note 206 at 279-80.

[215] See Christian Munthe, "Why I'm Sceptical to the Idea of Harvesting Donor Organs from Living People" (23 March 2013), *Philosophical Comment* (blog), online: PC <www.philosophicalcomment.blogspot.ca/2013/03/why-im-sceptical-to-idea-of-harvesting.html> ("[t]he problem is, … if we are to take away the DDR – we would have to say that intentionally cutting up a living person so that he or she dies is sometimes not a crime").

ing that the consent is voluntary and informed. Thus, the information provided to patients on brain death and organ donation must be accurate.

A final option might be to acknowledge that brain death is not death of the body or organism, and to explicitly declare brain death as a "legal fiction" – either a common law or statutory rule that claims as legally "true" a state of affairs that may not be literally accurate. One example is "legal blindness," in which a person may not be completely blind, but is treated from a legal standpoint as if he or she were totally blind; the same social benefits thereby flow to the partially sighted as to the totally blind.[216] This uses the term "blind" "in a biologically incorrect way for its socially beneficial purpose."[217] Unlike in legal blindness, the benefit of a legal fiction regarding brain death would flow mainly to third parties (e.g., organ recipients), rather than to the individual who is the subject of the legal fiction.

Legal fictions have been used to *deny* some human beings legal recognition.[218] For instance, via a legal fiction applied to cases of missing persons, legal recognition can be removed from an individual not known to be biologically dead, but *presumed* dead after a number of years' absence. That is, it is understood that a missing person might still be biologically alive, but that he or she may be unable or unwilling to be found. The legal fiction of the person's death permits heirs and creditors to dispose of the missing person's estate without fear of legal repercussions, should the "deceased" reappear.

Some might argue that in a missing persons case, we do not know if the missing individual is dead or alive, whereas after applying a medical test for death, we would know that the individual is dead, making a legal fiction unnecessary. But this ignores the fact that our "knowledge" about someone's death – an inherently subjective experience of another individual – is necessarily limited to what we can ascertain *externally* about that individual's state, based on information obtained from the tests for death. These tests assess whether the individual's functional losses meet the legal line (criterion)

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[216] The analogy between a legal fiction for death and the legal fiction for visual impairment was proposed in Robert M Taylor, "Reexamining the Definition and Criteria of Death" (1997) 17:3 Semin Neurol 265 at 269.

[217] Bernat, "Whole-Brain Optimum", *supra* note 23 at 41 (referring to the argument in Taylor, *supra* note 216).

[218] See Hughes, *supra* note 173 at 82-83.

drawn in the biological "dying continuum" from birth to final decay as an approximation of death that facilitates social decisions. Our knowledge of a patient's real experience is only as good as our tests for death, tests which are always somewhat deficient, insofar as they are both external observations of the patient's subjective reality and approximations. Thus, we do not know, based on test results, that an individual who tests as brain-dead is in fact "dead" according to the patient's own subjective experience.

This uncertainty is compounded by the use of improper or inadequate tests for death, as discussed in an earlier paper published by the present author.[219] It appears likely, according to the best scientific information, that use of these tests has sometimes led to false declarations of brain death in cases of reversible conditions created by confounding variables, e.g., barbiturate intoxication. However, once ventilator support is withdrawn after a positive brain-death test determination, we do know from a mitochondrial perspective that the patient will shortly become dead, since hypoxia will rapidly destroy the body's mitochondria within some tens of minutes at room temperature, as noted earlier.

It seems, based on existing examples, that the public is willing to accept various legal fictions that permit extension of benefits to society's more vulnerable members or that prevent indefinite disruption of important social processes. Similarly, brain death could be acknowledged as a legal fiction permitting a patient to donate needed organs when permanent loss of brain function has occurred. This fiction would recognize that, although the body of the affected individual is not biologically dead, the patient's cortex and brain stem are so severely damaged that they are extremely unlikely ever to recover functionality, even while the heart and body tissues may still be mitochondrially functional. This fiction would benefit not only organ recipients, but also those wishing to leave a "living legacy" through organ donation. Publicly acknowledging the lack of equivalence of brain death and bodily death might also increase public trust in, and better understanding of, the diagnosis of brain death. Dropping the claim of equivalence might also foster greater trust in organ donation, with gains in donor numbers being a possible result.

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[219] Jacquelyn Shaw, "A Death-Defying Leap: Section 7 *Charter* Implications of the Canadian Council for Donation and Transplantation's Guidelines for the Neurological Determination of Death" (2012) 6:1 McGill JL & Health 41.

However, others may disagree. Some may fear that abandoning the claim of brain death and bodily death equivalence may cause more patients to refuse organ donation. Several considerations have relevance here. First, as noted above, some patients value and strongly identify with their mental personhood characteristics and so would not wish to continue existence once personhood has vanished in a seemingly irreversible manner. Indeed, some already draw up advance directives reflecting this position. While not all hold this view, those who do appear highly unlikely to alter their views after being told that in brain death, the mitochondria of much *of the body* may persist, a consideration having no bearing on mental personhood characteristics. Thus, for patients who primarily value personhood, this change in information should have little effect on a choice to donate.

But not all patients share a view prioritizing mental personhood over all else and, therefore, some might refuse to donate organs if more accurate information is provided. Yet it must be remembered that this is a patient's legal right in a health care system that prioritizes patient autonomy over physician paternalism. In Canada, the "therapeutic privilege exception" to fully informing patients is now very narrow where it exists at all, and it is not available to prevent patients from refusing to consent to a physician's preferred choice of procedure.[220] Outside the therapeutic privilege exception, it is a legal *requirement* in health care to supply accurate information; what patients may do with that information is never an acceptable basis for denying, downplaying, or distorting it.

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[220] In Canada, based on the *Reibl v Hughes* standard, a patient (or his/her proxy) must be informed of all of the material risks of which an objective, reasonable patient would want to know, in addition to more specialized risks that the particular patient may subjectively value: *Reibl v Hughes*, [1980] 2 SCR 880 at 899-900, 114 DLR (3d) 1. An exception proposed by Laskin CJC in that case is "therapeutic privilege" (*ibid*), which in theory could permit a physician to withhold or downplay negative information that, in his/her opinion, may have a negative or counter-therapeutic effect on a vulnerable (e.g., young or suicidal) patient's outcome. However, jurisprudence and doctrinal writing suggest that "[i]f available at all, [therapeutic privilege] has a very limited scope" and would stand at best "on narrow and shaky grounds": Jocelyn Downie, Timothy Caulfield & Colleen M Flood, *Canadian Health Law and Policy*, 6th ed (Markham, Ont: LexisNexis, 2011) at 173-74. Thus, therapeutic privilege could not be used to justify providing inadequate information about brain death to patients, simply out of a concern that better-informed patients will refuse to consent to organ donation.

The reason for this is that, like any medical procedure performed on a patient, organ harvesting will constitute battery if it turns out that valid (i.e., voluntary, informed, competent) consent for the procedure was not obtained. Specifically, in the case of surgery, a battery occurs "where there is no consent to the surgery at all, where the terms of the consent have been clearly exceeded, or *where the nature and character of the surgery have been misrepresented*."[221] The last possibility exists where a patient – or family member – has been led to consent only to surgical organ harvesting from a body which is no longer living, biologically speaking, and not one which still possesses an independent pulse and living tissues. As Shewmon observes,

> [w]hen they read the phrase "after my death" [on an organ donor card or other authorization document], many imagine a pulseless corpse and might be horrified to learn that it really means "after I become comatose and apneic but all my other organs are working fine," and that "I will be eviscerated while still pink and warm, with my heart still spontaneously beating and blood circulating."[222]

More recently, an editorial in the journal *Nature* suggested that "[i]deally, the [US] law should be changed to describe more accurately and honestly the way that death is determined in clinical practice.… The time has come for a serious discussion on redrafting laws that push doctors towards a form of deceit."[223] Other than the fact that organ harvesting is performed on an individual who has been declared dead rather than on a still-living patient, the circumstances of organ harvesting do not appear to differ in any way from other medical procedures for which informed consent is required. The legal need for informed consent to medical care stems from respect for the patient's physical body and for his or her competent wishes as to what may be done to it; as in other areas of the law, such as wills and estates, the requirement to respect the wishes of the deceased should not end with declaration of the patient's death, but should survive it.

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[221] Philip H Osborne, *The Law of Torts,* 4th ed (Toronto: Irwin Law, 2011) at 283 [emphasis added].

[222] Shewmon, "Critical Re-evaluation", *supra* note 6 at 144.

[223] "Delimiting Death: Procuring Organs for Transplant Demands a Realistic Definition of Life's End", Editorial (2009) 461:7264 Nature 570 at 570.

For those patients and families willing to give informed consent, if we choose to retain brain death as a legal fiction, then it is suggested that a *whole-brain* criterion be selected for neurological death declaration. Clearly, some might disagree with this choice, including transhumanist author James Hughes, who believes that "[t]his century will begin to see a shift toward consciousness and [mental] personhood-centered ethics as a means of dealing … with brain death."[224] In a patient affected by hypoxia, it seems likely that the high-energy neural tissues of the cortex will likely be among the first to die, due to their significant mitochondrial energy needs, supporting the view that the patient's mental personhood characteristics may be lost. Yet societal values suggest that we *not* adopt the "neocortical" criterion of death that Hughes mentions, since neocortical destruction is the diagnostic picture presented by the case of PVS patients, who may often breathe independently, requiring no ventilator assistance. The presence of these features is likely to trigger a strongly negative societal reaction to treating these still-breathing, heart-beating patients as a source of organs or as ready for burial. Attesting to this, no country to date has adopted a neocortical criterion. Moreover, some patients diagnosed as being in a PVS have later reawakened, even decades after their initial diagnosis,[225] and recent studies have shown high levels of PVS misdiagnosis (i.e., the patients in fact suffered a less serious impairment than PVS).[226] These factors suggest that there is too much we do not yet understand about these disorders to risk disposing of PVS patients as "dead" through the adoption of a personhood-centred, neocortical criterion of death.

A brain *stem* criterion of death also appears unwise. As noted above, the brain stem is more anoxia-resistant than the cortex,[227] probably due to relative differences in neural composition and mitochondrial energy needs. Thus, in injuries caused by systemic oxygen-deprivation, it might be expected that death of the hardier brain stem will predict a mitochondrially dead cortex.

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[224] Hughes, *supra* note 173 at 85.

[225] See Peter McCullagh, *Conscious in a Vegetative State? A Critique of the PVS Concept* (New York: Kluwer Academic Publishers, 2004) at 163-70.

[226] In one study, 43% of PVS patients were misdiagnosed: see Keith Andrews et al, "Misdiagnosis of the Vegetative State: Retrospective Study in a Rehabilitation Unit" (1996) 313:7048 Brit Med J 13, cited in McCullagh, *supra* note 225 at 150.

[227] See Law Reform Commission, *supra* note 43 at 13-14.

However, as alluded to earlier, this is not necessarily so. Brain stem damage can occur via means other than systemic anoxia or hypoxia, e.g., through isolated brain stem injury. As acknowledged by Bernat in rejecting a brain stem criterion, an isolated brain stem injury could leave the cortex unimpaired, permitting retention of a patient's capacity for residual awareness, possibly including pain awareness.[228] Consequently, neither the higher cortical criterion nor the brain stem criterion seems socially acceptable for approximating the time of death. It is concerning, therefore, to note Canada's recent adoption of the brain stem criterion and the possibility (suggested by some authors) that the US may follow suit in the future.[229]

Thus, if we employ brain death as a legal fiction and legal death criterion, the least objectionable version of the neurological criterion of death seemingly remains a whole-brain criterion, which, if assessed carefully using appropriately set tests, will provide a reasonably high degree of assurance as to whether both the potential for conscious awareness (the cortex) and the capacity for wakefulness (the brain stem) have been destroyed. Although the mitochondria of the brain stem and cortex may no longer be viable once whole-brain death has occurred, the mitochondria within the body's tissues may still function with ventilator support, due to the different energy needs of these various tissues; thus, effective transplantation of organs and tissues would still be possible.

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[228] Bernat, "Whole-Brain Optimum", *supra* note 23 at 39. See also PJ Young & BF Matta, "Anaesthesia for Organ Donation in the Brainstem Dead – Why Bother?" (2000) 55:2 Anaesthesia 105 at 105-06. While these anaesthetist authors note (at 106) that it is "probable" that brain-stem-dead donors have no consciousness during organ harvesting, they observe that this is not certain and that there exist signs, e.g., significant blood pressure and heart rate increases, that "demand caution before assuming that anaesthesia is not required" in the operation: *ibid* at 105. They conclude that "[f]aced with the knowledge of the persistence of higher brain and spinal function in some donors, … sedation and *analgesia* [i.e. pain reliever] should be given with muscle relaxation for organ donation": *ibid* at 106 [emphasis added].

[229] This possibility arises from the US choice of "apneic coma" as the conceptual essence of neurological death criterion, since this may be produced by either brain stem or whole-brain death: see Shewmon, "Brain Death Resuscitated", *supra* note 4 at 22.

Conclusion

Humankind has long pondered death's enigmatic commonalities: its trans-species universality; its apparent inevitability and link with aging; its irreversibility; and its association with the loss of somatic integration, the loss of whole-organism emergent properties, and the onset of entropic decay. Earlier scholarship has not successfully explained all of these features. The lost viability of the body's mitochondrial populations appears to offer a coherent explanation of death. That is, death involves irreversible damage – e.g., by prolonged hypoxia – to the body's mitochondria in vital tissues or in a sufficiently wide range of tissues, leading the mitochondria to trigger cell death *en masse*. On this view, once a critical number of mitochondria is destroyed by hypoxic damage or mutation, there is no longer sufficient energy to fuel anti-entropic life processes, and bodily disintegration becomes inevitable.

Unfortunately, no current means allow non-invasive testing of mitochondrial viability, suggesting that at present we should continue to use more approximate, externally testable death criteria, such as the cardiopulmonary and neurological criteria. However, to satisfy the legal requirements of informed consent for organ donation, any continued use of brain death *must* occur in the context of providing patients with fuller and more scientifically supported information about brain death. In future cases, consent will not be valid if the biological reality of brain death (the point when organ harvesting becomes legal) does not match patients' understanding of it, based on what they have been told; where the patients are misinformed, organ harvesting will potentially constitute a battery.

From a body-centred perspective on death, our complex relationship with mitochondria may account for some of death's more mysterious aspects: its intangible losses, its seeming inevitability, and our current inability to reverse it technologically. Ironically, this explanation means that human life, at all levels of sophistication, is utterly dependent on the viability of simple bacterial symbionts only very distantly related to human beings. The role of mitochondria in human life and death has been overlooked for over four decades in the legal and bioethical literature, which has focused instead on processes observable at the whole-organism level. These omissions are understandable given the complex relationship between mitochondria and host cells and the fact that the relationship has only quite recently – in the past 20 years – begun to be understood as the unique symbiosis that it is.

Occam's razor suggests that the most "parsimonious" explanation of phenomena be adopted.[230] The adoption of brain death predates the mainstream scientific acceptance of mitochondria as ancient bacteria,[231] before which it was more "parsimonious" to view humans as monolithic, single organisms. This view requires modification. It is now widely accepted that mitochondria are descended from ancient bacteria; that they supply the vast proportion of the energy that eukaryotic organisms consume; that they are intricately and symbiotically engaged with host cells in directing cell death, bodily development, and aging; and that their dysfunction is increasingly linked to serious diseases. Thus, it may now be more parsimonious to view the human organism as a symbiotic, co-operative venture, rather than as a monolithic entity.[232] A new paradigm appears to be emerging in medicine in which the central role of mitochondria in life, aging, and disease is explored,

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[230] Also known as *Ockham*'s razor or the "Law of Parsimoniousness," credited to medieval Friar William of Ockham, who stated in his writings, "Plurality must never be posited without necessity" ("*Numquam ponenda est pluralitas sine necessitate*"): William of Ockham, *Sentences of Peter Lombard* (1495). This rule urges choosing the hypothesis that makes the fewest assumptions, while still adequately explaining observed phenomena.

[231] Although the endosymbiont theory of mitochondria as former bacteria was proposed in 1967, it was rejected by mainstream science until 1981: Lane, *Power*, *supra* note 90 at 14-16. Harman's mitochondrial theory of aging, *supra* note 159, emerged in 1972. Therefore the idea of a human-mitochondrial symbiosis would not have been part of mainstream science in 1968, when brain death was first adopted.

[232] Human cells may be likened to miniature ecosystems. As Lewis Thomas wrote,

> [a] good case can be made for [human] nonexistence as entities. We are not made up, as we had always supposed, of successively enriched packets of our own parts. We are shared, rented, occupied. At the interior of our cells, driving them, … are the mitochondria, and in a strict sense they are not ours. They turn out to be little separate creatures.… Without them, we would not move a muscle, … [nor] think a thought [Lewis Thomas, *The Lives of a Cell: Notes of a Biology Watcher* (New York: Viking Press, 1974) at 3-4].

Yet "reductionist" human thinking may "prefer a top-down perspective," focused on the whole human organism and its emergent processes (e.g., consciousness), while ignoring less visible cellular or molecular activity: Lloyd, Rossi & Roussel, *supra* note 118 at 5.

understood, and finally acknowledged. Accordingly, a new biological perspective on the criteria of legal death seems appropriate.[233]

Since 1968, mainstream medicine has maintained – despite evidence to the contrary – that in brain death, the body is dead (or will be within days), permitting organ harvesting under the DDR. Yet a mitochondrial mechanism for death implies that brain death is *not* equivalent to death, in the commonly understood bodily sense of that word. Other authors, such as Shewmon, have previously suggested this same conclusion, but without fully exploring the relevance of mitochondrial function. Based on a mitochondrial perspective, the lack of equivalence between brain death and bodily death may appear to threaten the DDR. Ultimately, however, recognizing the non-equivalence of brain death and bodily death need not necessitate abandoning brain death and, with it, organ donation. A simpler option may be to retain whole-brain death as a criterion of death, while acknowledging it as a biologically incorrect "legal fiction," much like legal blindness. This more frank approach may better assist patients needing transplants, as well as those wishing to donate organs, thereby creating opportunities to share the life-giving energy – and co-operative spirit – of an ancient symbiosis.

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[233] See e.g. Michelakis, *supra* note 98 at 2431-34; Wallace, "Mitochondrial Paradigm", *supra* note 90 at 393; Ryan L Parr & Luis H Martin, "Mitochondrial and Nuclear Genomics and the Emergence of Personalized Medicine" (2012) 6:3 Hum Genomics 1 at 2. Conversely, in his analysis of death, Shewmon argues that a new integrating paradigm seems warranted, given the incompatibility of many individual observations regarding death: "Attempts to construct the entire 'death elephant' from all the disparate perspectives [of previous scholars] have been stymied by the apparent incompatibility between certain features, … a sure sign that a fundamental paradigm shift is required": Shewmon, "Elephant", *supra* note 2 at 290.

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