Staking the Public Trust on Newborn Dried Blood Spot Retention: How the **Beleno** *and* **Bearder** *decisions may impact Canadian Newborn Metabolic Screening Processes*

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Introduction

Public trust is fickle. Hard to obtain, even harder to maintain, it can be lost in an instant. From the 1960s onward, the medical community in North America has advocated and implemented a series of tests for newborns to help target, treat and possibly eliminate certain genetic diseases. Newborn metabolic screening (NMS) takes blood drops from a heel poke of an infant, collected on filter paper, which is then sealed when dry. Samples are sent to centralized laboratories where they undergo a battery of tests including mass spectrometry and DNA microarray technology. Such advanced testing is said to help identify dozens of potentially dangerous genetic abnormalities that could affect the future health of a child.[1] What has placed NMS practices in many countries at odds with public perception, however, is what health authorities do with the dried blood spots (DBS) after the screening is completed. Samples are routinely stored for at least one year after testing to ensure there is a specimen available for re-testing if necessary and for on-going quality assurance/quality control of the tests being performed[2]. Members of the public and privacy advocates have expressed concern about the longer term non-consensual retention of DBS for secondary uses such as research.[3] The collection and storage of DBS gives rise to tissue repositories or biobanks. Such collections raise numerous ethical questions, including issues related to access, informed consent and privacy. Canadian jurisdictions have yet to legislate on the practice of DBS retention and secondary use of stored DBS. The first legal challenge to DBS retention in Canada was initiated in British Columbia in May 2010[4] and this case will provide an opportunity to address unsettled issues. This paper provides an overview of the NMS programs and DBS storage practices in Canada. This summary provides a foundation for a discussion of the legal and ethical dilemmas raised by the creation of DBS biobanks. Recent American cases of *Beleno* v. *Texas Department of State Health Services*[5] and *Bearder* v. *Minnesota*[6] groundbreaking precedents concerning the collection of DBS, are incorporated into a larger discussion related to the probable outcome of similar legal arguments in Canadian jurisprudence.

Up until a decade ago, little was known of the retention and storage practices for DBS. With the exponential growth of genetic research worldwide, however, the demand for tissue samples, including DBS, has risen.[7] Biobanks and the millions of infant DNA samples contained within them are said to represent an enormous potential resource for scientific study. In a 2002 workshop, the US Centers for Disease Control and Prevention commented on the importance of access to DBS: "leftover DBS specimens are a unique, valuable population-based source for important public health surveillance and potential epidemiologic research."[8] However, privacy advocates and concerned citizens have seized upon the fact that there is a noted absence of regulatory policy or legal instrument in Canada that controls the retention and dissemination of stored DBS.[9] Such concerns have been distilled into constitutional and legal challenges, discussed in more detail below.[10]

Newborn Screening Programs

In Canada, where NMS is an integral part of the public health program, there is currently no legislation that directly regulates the collection, retention and secondary use of DBS. NMS programs in North America have been implemented by governments as public health initiatives and have progressed over 50 years to become a part of routine, preventive medicine. As such, NMS programs are not required to obtain explicit consent from the parents of newborns for the collection and retention of DBS.[11] The justification for NMS programs is evidenced through the early detection of life threatening genetic conditions in newborns which, in turn, provides a direct benefit to newborns while posing minimal risk of harm. As Bartha Knoppers states, "[I]n newborn screening programs, consent is presumed and justified on the basis that when a disease is treatable, a newborn has a right to be screened and to be treated."[12] Furthermore, as Claude Laberge *et al*. note, "[C]onsent is presumed because it is defined in term of the best interest of the child and of society."[13] Their view aligns closely with that of the World Health Organization (WHO), which believe NMS programs should be mandatory if there is benefit to the newborn.[14] Therefore, it can be adduced that, from a governmental stance, there is an overriding interest in favour of the child to maintain NMS programs. That is not to say that parents are not informed about NMS programs but that countries like Canada "have opted for the presumed consent model where parents are invited to sign admission papers and consent to NBS as part of routine paediatric procedures when they arrive at the hospital at the time of delivery."[15]

The Alberta Newborn Metabolic Screening Program, based on the NMS program in the Province of Ontario, is not grounded in statute. Run under the auspices of the Chief Medical Officer of Health, the Alberta NMS program currently operates with a primary goal of monitoring quality assurance.[16] This focus directs health care providers to undertake the NMS programs as a means of disease surveillance. Arguably, this surveillance is undertaken at the behest of the Chief Medical Officer under the provisions of Section 15(1) of the *Public Health Act*;[17] however, the regulatory provisions of the Alberta NMS program are currently contained in the *Public Health Act*'s *Standards and Guidelines*, a draft document created in 2000, and have yet to be codified. Such is the trend across Canada as the majority of provinces and territories still do not have legislation specifically mandating newborn screening in Canada.[18] Furthermore, the storage and use of residual DBS are not governed under any Canadian legislation.[19] Arguably, the government's retention of DBS has gone largely unnoticed by the public until recently.[20] As NMS programs "are part of mandated pediatric norms" health care workers throughout Canada have not been required to obtain explicit consent from parents for the collection of DBS.[21] Alberta, like its provincial counterparts, continues to operate within a presumed consent model whereby consent is granted by parents through acknowledgment of NMS "as a part of routine pediatric procedures when they arrive at the hospital at the time of delivery".[22] While the importance of NMS is not in doubt,[23] the storage and secondary use of DBS has become a potential maelstrom of legal, social and political unrest.

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Recent Legal Challenges

On March 12, 2009, five parents in Texas filed a lawsuit against the Texas Department of State Health Services (DHS). In *Beleno v. Texas Dept. of State Health Serv.*[24], the parents claim that the DHS broke both state and federal law when the health authorities failed to obtain the plaintiffs' consent for the collection, retention and secondary use of DBS during the legally mandated newborn screening program process. Although Texas legislation is being amended to deal with the specific issues of parental consent and secondary uses[25], the claim in *Beleno* dealt with the period of time in which there was no legislative instrument. After a failed attempt to have the case dismissed[26], the DHS agreed to a settlement proposal that would see the destruction of five million DBS taken from newborns during the period 2002 to 2009.[27] Despite a number of efficacy and policy arguments to the contrary[28], the destruction order has taken effect and a large repository of genetic information has been lost.

As NMS programs have attracted greater attention due to US litigation, there has been a surge in public concern over the ethical considerations that DBS storage raises.

In a factually similar case, a group of Minnesota parents filed a civil complaint, in June 2009, against the state of Minnesota and the Minnesota Department of Health (MDH) for violating the Minnesota *Genetic Privacy Act* and retaining DBS without parental consent.[29] However, in November 2009, the presiding judge gave an order granting the MDH's Motion to Dismiss.[30] The judge's acceptance of the MDH's position meant that even if the *Genetic Privacy Act* were to be applied in the current case, the statutory interpretation of the *Act* would be such that the MDH would be exempt from the statute in relation to the retention and secondary use of DBS.[31]

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In May of 2010, the British Columbia Civil Liberties Association lodged a complaint with the Privacy Commissioner alleging that the Province, through both past practices and the proposal of Bill-11[32], was violating the privacy rights of its citizens by not having obtained informed consent of parents concerning the NMS process and subsequent retention and secondary use of DBS.[33] From this complaint came the filing of the first legal challenge to the retention and secondary use practices of the province of British Columbia. On 14 May, 2010, Ms. Natalie Docherty, on behalf of her infant children, filed a statement of claim in the Supreme Court of British Columbia.[34] This marks the first such action in Canada but follows a similar path to the legal actions previously commenced in the United States.

While NMS programs accrue a direct benefit to newborns, the benefits of retention and secondary uses of DBS are not as clear. DBS may potentially be used to further scientific discovery but there are fears that dissemination of an individual's genetic information will lead to violations of an individual's privacy and potential abuse.[35] The right to control biomedical samples is a historically divisive issue[36] and one that requires extensive investigation and careful analysis. At the crux of the matter is the issue of consent. The issue of consent, with a particular focus on DBS and secondary research practices, has been a discussion point for many years.[37]

Analysis/Discussion

In relation to the retention and dissemination of DBS, the most common argument made by privacy advocates and concerned parents is that there is not an effective level of communication between members of the public and health care providers conducting the NMS programs. As Beth Tarini noted, "if policy makers fail to engage in a discussion with parents and the public about using the screening results for research, that could create a public backlash and threaten the viability of a potentially valuable public health resource.[38]" To test such a hypothesis, Tarini conducted an Internet-based study of parents which examined their willingness "to permit use of their children's NBS samples for research with/without their permission" and "to allow NBS sample storage".[39] Tarini et al. concluded that "[T]hree-quarters of parents would permit use of their children's [DBS] samples for research if their permission is obtained".[40] The disconnect between state and parent arguably lay in the lack of defined policy statements

concerning the consent rights of parents regarding their children's DBS.[41] Only recently have individual states in the USA begun to legislate the length of time DBS can be stored (ranging from one year to twenty-one years to indefinitely) and how secondary uses of DBS will be regulated.[42] The delay in action, however, has had an associated cost.

The *Beleno* case highlights a loss in public trust in both the scientific community and government. As the Texas Department of State Health Services came to realize, despite their best intentions, years of diligence in the collection of DBS were lost because of a rising fear amongst its citizens. Media centers across the United States and Canada seized upon the concerns voiced by parents and members of privacy advocacy groups. On February 4, 2010, CNN Senior Medical Correspondent Elizabeth Cohen gave the world the story of Isabel Brown, a newborn whose mother, Annie, was concerned about the genetic test results they received. Having been unaware of the NMS testing, Ms. Brown was told that Isabel carried a gene that put her at risk for cystic fibrosis. Ms. Brown was more shocked to learn that the government had mandated NMS and did not require her consent and could store Isabel's DBS indefinitely. "I know the government says my baby's data will be kept private, but I'm not so sure" says Ms. Brown. "I feel like my trust has been taken".[43] Ms. Brown's story and views are not unique. Across North America there has been a rise in public concern. Groups such as the Citizens' Council on Health Care and the Texas Civil Rights Project have spearheaded the movement to publicize DBS retention practices. The unfortunate result, for both the public and science, includes not only the loss of public trust but the potential loss of a valuable reserve of genetic material. As public concern over the practices of tissue storage and genetic research have reached across the border to Canada, the differing outcomes of the *Beleno* and *Bearder* cases leave pause to wonder how Canadian courts might deal with such issues.

As the Supreme Court of British Columbia is now tasked with dissecting the issues connected with DBS collection and retention it is important to consider how the courts might deal with the Docherty claims' assertion that there have been serious deficiencies in the consent process and numerous breaches of privacy. Both the *Beleno* and *Bearder* cases came about as a direct result of the states of Texas and Minnesota proposing new laws to deal with the collection and retention of DBS.[44] As there is no Canadian legislation or case law directly on point, it is likely that an arbiter would turn to existing law on consent. As Caulfield and Knoppers note:

> While the obligation to obtain consent when using health and other personal information is a strong norm in Canada, other social goals, including the pursuit of research, have had an influence on Canadian consent laws. This balancing is most clearly reflected in provincial health information legislation which permits nonconsensual exceptions for research.[45]

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Thus, the issue of consent in the context of DBS collection and retention must be examined by looking at Canadian consent case law and research ethics policy. While Canadian courts have had limited opportunity to define consent in the context of research, the Supreme Court of Canada (SCC) has several decisions emphasizing the importance of informed consent.[46] Such decisions follow a strong tradition in the Canadian legal system of placing a high standard on researchers to disclose all risks to human participants. As the court in *Halushka v. University of Saskatchewan* stated, the duty of disclosure of investigators to their subjects is "at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient."[47] This led authors Kathleen Cranley Glass and Trudo Lemmens to note that the standard for disclosure is higher for research involving human participants than it is for therapy and is the "most exacting duty possible, requiring 'full and frank disclosure'[48] of all risks."[49] The SCC has also stated that health information and tissue "remain in a fundamental sense one's own"[50] and that such information "goes to the personal integrity and autonomy" of the individual.[51] The courts would also have to keep a watchful eye

on the effect a DBS retention and secondary use decision would have on provincial privacy and health information legislation. Each province has legislation that deals specifically with how personal information can be accessed which provide protection to individuals' privacy rights. Any action in this area would need to be sensitive to the federal/ provincial legislative dynamic.

Without definitive legislation or case law to rely upon, a court could also consider existing research ethics policy. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Canada's de facto research ethics policy, could provide a supplement to existing consent law.[52] Like the law, the TCPS emphasizes the importance of informed consent. However, the TCPS also contains an exception to the requirement to get specific consent, such as when, *inter alia*, a Research Ethics Board (REB) considers that the research is of minimal risk to participants, the consent waiver is unlikely to affect the rights and welfare of participants and the research cannot be practically carried out otherwise (Article 2.1). This point will likely be seized upon by researchers and health care providers as the retention and secondary use of DBS is likely to have minimal risk to the newborns participating. However, the TCPS also focuses on the importance of informed consent while conducting genetic research (Article 8.1) and the collection and storage of genetic material (Article 8.6). [53] Article 10 provides, perhaps, the key principle whereby specific consent is likely required for any research project that involves the collection of genetic material.[54] This may be the most significant factor if the courts incorporate the TCPS in their decision making process as health care providers currently operate under a presumed consent model in their administration of NMS programs in Canada.

Conclusion

Whatever the courts' decision in *Docherty* provides, it is clear that the collection and secondary use of DBS from NMS programs in Canada cannot continue in its current form. The scientific community is desirous of accumulating and disseminating human tissue samples, as such practices have the potential to lead to important medical discoveries; this desire must, however, be weighed against an individual's interest in their tissue and their right to decide its future use.[55] One would hope that the courts do not follow the decision in *Beleno* and require destruction of millions of viable genetic samples but, at the same time, expand upon the decision in *Bearder* and establish a NMS system that offers better communication between parents and health care providers. Only through the creation of a careful balance can the scientific community hope to renew the public's trust.

Graham Barr is a Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta. *This work was supported by AllerGen NCE Inc. (the Allergy, Genes and Environment Network), a member of the Networks of Centres of Excellence Canada program, Genome Canada, and Alberta Innovates Health Solutions, Interdisciplinary Chronic Disease Collaboration (ICDC) Team Grant. I would also like to thank Professor Timothy Caulfield and the Health Law Institute team at the University of Alberta for their knowledge, guidance and support.*

Endnotes

1 See Linda Kharaboyan, Denise Avard, & Bartha Maria Knoppers, "Storing Newborn Blood Spots: Modern Controversies" (2004) 32 J.L. Med. & Ethics 741. For a comprehensive list of screening practices by province, please refer to the Canadian Organization for Rare Disorders' "Newborn Screening in Canada Status Report" Dec. 15, 2009 which can be accessed through <http://raredisorders.ca/documents/CanadaNBSstatusupdatedDec142009.pdf>.

2 Alberta Health and Wellness, *Alberta's Newborn Metabolic Screening Program: Information for Health Care Providers* (April 2007) online: Alberta Health and Wellness <http://www.health.alberta.ca/documents/NMS-Professional-Brochure.pdf >.

3 Dried blood spot storage practices vary both provincially in Canada (from 1-30 years) and internationally (Australia stores DBS until the child reaches the age of 35; France destroys DBS soon after testing is completed; Denmark stores DBS indefinitely; and, in the U.S., retention varies state to state from a period of two weeks to indefinite storage). For an international comparison see Kharaboyan supra note 1 at 743.

4 *L.D. and E.D., Infants by their Guardian Ad Litem, Natalie Docherty v. The British Columbia Women's Hospital and Health Centre and British Columbia Children's Hospital* (14 May 2010), Vancouver S103416 (B.C. Sup. Ct.)

5 Settlement Agreement and Release, *Beleno* v. *Tex. Dept. of State Health Services,* No. SA-09-CA-188-FB (W.D. Tex. 2009).

6 Order Granting Motion to Dismiss, *Bearder* v. *Minnesota*, No. 27-CV-09-5615 (D. Minn. 2009).

7 As Sharon Terry of the Genetic Alliance says of the importance of DBS: "We consider [DBS] a national treasure… they offer us the beginnings of a national blood bank to understand disease at an early age and follow people longitudinally over time." Quoted in Rob Stein, "Blood Samples Raise Questions of Privacy" *The Washington Post* (30 June 2009), online: The Washington Post </www.washingtonpost.com/wp-dyn/content/article/2009/06/29/AR2009062903118.html>.

8 Cited in Citizens' Council on Health Care, *After Newborn Genetic Testing of Baby is Done: State by State Government Newborn Blood and Baby DNA Retention Practices* (St. Paul, Minn.: Citizens' Council on Health Care, 2009) online: Citizens' Council on Health Care <http://www.cchconline.org/pdf/50_States-Newborn_Blood_Retention_Policies_FINAL.pdf>,

9 The work of Twila Brase of the Citizens' Council on Health Care (CCHC) and the Texas Civil Rights Project (TCRP) has been instrumental in bringing both media and judicial attention to the issues surrounding NMS programs in the United States and the associated legal/ethical positions related to the storage and secondary use of DBS.

10 See *Beleno* supra note 5 and *Bearder* supra note 6.

11 Claude Laberge, Linda Kharaboyan & Denise Avard, "Newborn, Screening and Consent" (2004) 2:3 GenEdit 1 at 2, online: <http://www.humgen.org/int/GE/en/2004-3.pdf>.

12 Bartha M. Knoppers, "Newborn Screening and Informed Consent" in Jean-Pierre Farriaux, Jean-Louis Dhondt, eds., *New Horizons in Neonatal Screening* (Amsterdam: Excerpta Medica, 1994) 15.

13 *Supra* note 11 at 2.

14 World Health Organization (WHO), *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* (Geneva: World Health Organization, 1998) online: World Health Organization <http://whqlibdoc.who.int/hq/1998/WHO_HGN_GL_ETH_98.1.pdf>.

15 *Supra* note 11 at 3.

16 Alberta Health and Wellness, *Review of Newborn Screening for Inborn Errors of Metabolism and Cystic Fibrosis: Synthesis Report Review # 5 AHTDP# 05-03 and 05-04* by Charis Management Consulting Inc. Synthesis Report 06-03S-2 (2006) at 10, online: Alberta Health and Wellness <http://www.health.alberta.ca/documents/AHTDP-IEM-CF-consult.pdf>.

17 Public Health Act, R.S.A. 2000, c. P-37 at section 15(1) Where:
(a) a disease is not prescribed as a notifiable disease under the regulations, and
(b) the Chief Medical Officer considers that it is advisable to keep the disease under surveillance in order to assess the impact of the disease and the need for further intervention under this Act, the Chief Medical Officer may by notice in writing require a medical officer of health, a physician or a director of a laboratory to provide to the Chief Medical Officer at the time and in the manner set out in the notice any information in respect of the disease that is set out in the notice.

18 *Supra* note 11 at 5.

19 For a comprehensive analysis of international NMS Programs and the processes of infant metabolic screening, see Claude Laberge, Linda Kharaboyan & Denise Avard, " Newborn, Screening and Consent" (2004) 2:3 GenEdit at 5, online: <http://www.humgen.org/int/GE/en/2004-3.pdf>.

20 Canadian media outlets have only recently seized upon the DBS retention and secondary use debate. See e.g.: Laura Baziuk, "Baby's birth-blood complaint sparks privacy probe" *The Province* (13 May 2010), online: The Province <http://www.theprovince.com/story_print.html?id=3021322&sponsor=>; Andrea Woo, "Authority denies secret storing, testing of baby blood: Hospital used kid's data without consent: couple" *Vancouver Sun* (13 May 2010), online: Vancouver Sun <http://www.vancouversun.com/health/Authority+denies+secret+storing+testing+baby+blood/3021942/story.html#ixzz0r3Oo0mw1>; Jane Armstrong, "Storage of newborns' blood samples raises privacy concerns" *The Globe and Mail* (11 May 2010), online: The Globe and Mail <http://www.theglobeandmail.com/news/national/british-columbia/storage-of-newborns-blood-samples-raise-privacy-concerns/article1565582/>; and "Storing B.C. babies' blood violates privacy: group" *CBC News* (12 May 2010), online: Canadian Broadcasting Corporation <http://www.cbc.ca/health/story/2010/05/12/bc-infant-blood-samples-privacy-violations.html>.

21 *Supra* note 11 at 2. Because NMS programs operate as public health initiatives that provide routine or preventative medicine there is no requirement for health care providers to obtain separate written consent for the collection and retention of DBS.

22 *Ibid.* For a Canadian perspective on consent models for biobanking see also: Timothy Caulfield and Jane Kaye, "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas" (2009) 10 Medical Law International 85 and Timothy Caulfield, "Biobanks and Blanket Consent: The Proper Place of the Public Perception and Public Good Rationales" (2007) 18 King's Law Journal 209.

23 The Advisory Committee on Heritable Disorders in Newborns and Children states that: newborn spot samples "have the potential to generate population-based knowledge that can improve the health of children, support families, and provide information critical to understanding the antecedents of adult diseases." Quoted in Matt Jones, "HHS to Weigh Blood Spot Screening Storage Issues" *GenomeWeb Daily News* (26 August 2010), online: GenomeWeb Daily <http://www.genomeweb.com/hhs-weigh-blood-spot-screening-storage-issues>.

24 *Supra* note 6.

25 For changes to the legislation see Texas Health and Safety Code, Chapter 33: Phenylketonuria, Other Heritable Diseases, Hypothyroidism, and Certain Other Disorders, online: Statutes of Texas <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.33.htm#33.011>. For changes in the manner in which health care professionals in Texas conduct NMS programs, please see Texas Occupations Code, Chapter 58: Use of Genetic Information, online: Statutes of Texas : <http://www.statutes.legis.state.tx.us/Docs/OC/htm/OC.58.htm#58.103>. The proposed legislation takes from H.B. 1672, 81st Leg. (Tex. 2009): An act relating to the confidentiality of newborn screening information. Available from: <http://www.legis.state.tx.us/BillLookup/Text.aspx?LegSess=81R&Bill=HB1672>.

26 Order Regarding Defendants' Motion to Dismiss and Defendants' Motion to Dismiss or for Summary Judgment Based on Mootness, Beleno v. Tex. Dept. of State Health Servs., No. SA-09-CA-188-FB (W.D. Tex. 2009), online: <http://www.genomicslawreport.com/wp-content/uploads/2010/01/Beleno-order.pdf>.

27 Settlement Agreement and Release, Beleno v. Tex. Dept. of State Health Servs., No. SA-09-CA-188-FB (W.D. Tex. 2009).

28 See e.g., American College of Medical Genetics, *Position Statement on Importance of Residual Newborn Screening Dried Blood Spots* (29 April 2009), online: American College of Medical Genetics <http://www.acmg.net/StaticContent/NewsReleases/Blood_Spot_Position_Statement2009.pdf>.

29 Plaintiffs' Complaint, *Bearder v. Minnesota*, No. 27-CV-09-5615 (D. Minn. 2009), online: <http://www.cchconline.org/pr/FINAL_Plaintif_s_v_MDH_complaint.doc>.

30 Order Granting Motion to Dismiss, *Bearder v. Minnesota*, No. 27-CV-09-5615 (D. Minn. 2009), online: <http://www.cchconline.org/pdf/JudgeRosenbaumOrder113009.pdf>.

31 For discussion, see e.g. Katherine Drabiak-Syed, "Newborn Blood Spot Banking: Approaches to Consent," *PredictER Law and Policy Update* (12 March 2010), online: Indiana University Center for Bioethics <http://www.bioethics.iu.edu/body.cfm?id=133>. She writes: "… the court's conclusion the GPA did not apply to MDH's treatment of the [DBS] following screening meant that its research activities were within its discretion and did not violate plaintiffs' rights. As a result, Judge Rosenbaum stated that plaintiffs had no viable claims and dismissed plaintiffs' complaint entirely."

32 Bill 11, *Miscellaneous Statutes Amendment Act (No. 2)*, 2nd Session, 39th Parliament, British Columbia, 2010. Bill 11 contains a number of amendments including specific legislative provisions that give the Minister of Health power to collect, gather, use and share personal information without any notice to or consent from affected individuals (see sections 165-167).

33 BC Civil Liberties Association, Media Release, "New law may create largest DNA database in Canada" (12 May 2010), online: BC Civil Liberties Association <http://www.bccla.org/pressreleases/10DNA.html>.

34 *Supra* note 4. Docherty's claim for damages is centred on the allegation that the BC Women's and Children's Hospitals violated the B.C. *Privacy Act*, the B.C. *Freedom of Information and Protection of Privacy Act*, and breached Section 8 of the *Canadian Charter of Rights and Freedoms* by retaining and disseminating stored DBS collected from newborns.

Ms. Docherty also requests an order to destroy all current samples in the possession of the hospital. Her claims (also filed as a class action) mirror those made in the *Beleno* and *Bearder* cases.

35 *Supra* note 11 at 2-4. Laberge *et al*. note that access to genetic information by law enforcement officials, insurers and employers could lead to abuse.

36 For an international perspective, see the case of *Gudmundsdóttir v. the State of Iceland,* (2003) Icelandic Supreme Court No. 151/2003, online: <http://epic.org/privacy/genetic/iceland_decision.pdf>, where the Supreme Court of Iceland considered privacy implications of a national health sector database that compiled "extensive information … on people's health, their medical treatment, lifestyles, social circumstances, employment and family." home, and family life'51 – apply to information of this kind and …guarantee protection of privacy in this respect." Also, look to the United Kingdom and the fallout of the Alder Hey incident. For discussion, see e.g. V. English & A. Sommerville, "Presumed Consent for Transplantation: A Dead Issue after Alder Hey?" (2003) 29 Journal of Medical Ethics147;. Kenyon Mason & Graeme Laurie, "Consent or Property - Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey" (2001) 64 Mod. L. Rev. 710; and C. Seale, *et al*., "Effect of Media Portrayals of Removal of Children's Tissue on UK Tumour Bank" (2005) 331 British Medical Journal 401

37 As Therrell *et al*. state, "[S]olutions to the legal and ethical concerns about the retention of residual DBSs are unclear. As more and more screening programs consider retaining DBSs and as the use of DNA technology in detecting genetic disorders rapidly expands, a more formal approach to legal and ethical concerns should be taken." In Bradford L. Therrell *et al*., "Guidelines for the Retention, Storage, and Use of Residual Dried Blood Spot Samples after Newborn Screening Analysis: Statement of the Council of Regional Networks for Genetic Services" (1996) 57 Biochemical and Molecular Medicine 116 at 116.

38 "Ask Permission To Use Newborn Data, Parents Say" *ScienceDaily* (16 July 2009), online: ScienceDaily <http://www.sciencedaily.com/releases/2009/07/090715112037.htm>

39 B.A. Tarini *et al*., "Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research" (2010) 13 Public Health Genomics 125 at 125.

40 *Ibid.*

41 See also Laberge *et al., supra* note 11 at 6, who believe that:

"The prospect of storing newborn bloodspots raises questions of when and how to inform parents. Some guidelines have stated that information about additional uses of newborn samples should be conveyed to parents and that an up-front mechanism of informed consent, at the time of heel prick collection, would be a logical way of initiating the process. Indeed, this process seems acceptable if a research project is foreseen before sample collection. But what about when consent to storage and future research use is required before the actual research protocol has been elaborated? The WHO as well as the Danish Neonatal Screening Programme have recommended blanket consent for all residual bloodspot use. Whilst constituting an efficient and economical method, this approach can be criticized based on the fact that it does not allow parents to fully understand the exact future purposes of stored samples and prevents them from providing a truly informed consent. It has been suggested that specific consent, through re-contact, should be obtained for each research study that requires coded or identified samples."

42 See e.g., Texas *Health & Safety Code,* Sec. 33.017(b)-(c). The Citizens' Council on Health Care has produced a list of State DBS retention practices and corresponding legislation which can be accessed through: <http://www.cchconline.org/pdf/50_States-Newborn_Blood_Retention_Policies_FINAL.pdf>. The range on DBS storage in the United States varies from a period of 2 weeks to an indefinite period.

43 Quoted in Elizabeth Cohen, "The government has your baby's DNA" *CNN* (04 February 2010), online: CNN <http//www.cnn.com/2010/HEALTH/02/04/baby.dna.government/index.html>.

44 See H.B. 1672, 81st Leg. (Tex. 2009): An act relating to the confidentiality of newborn screening information. Available from: <http://www.legis.state.tx.us/BillLookup/Text.aspx?LegSess=81R&Bill=HB1672> and MINN. STAT. § 13.386 (2010): Treatment of genetic information held by government entities and other persons. Available from: <https://www.revisor.mn.gov/statutes/?id=13.386>. While the results of each case were different, the plaintiffs both based their arguments on the fact that there was a

period of time in which the health care providers of each state collected and retained DBS after the new statutes had taken effect. Before that time the collection and retention of DBS had been governed by normal pediatric practices. However, after the new laws were in place, the plaintiffs believed that they had certain rights over their newborn's DBS which the State's actors had subsequently violated.

45 Timothy Caulfield & Bartha Maria Knoppers, "Consent, Privacy & Research Biobanks," Policy Brief No. 1, Genome Canada (26 January 2010), online: Genome Canada <http://www.genomecanada.ca/medias/pdf/en/GPS-Policy-Directions-Brief.pdf >.

46 See *Reibl v. Hughes* (1980), 114 D.L.R. (3rd) 1 and *Ciarlariello v. Schacter,* [1993] 2 S.C.R. 119.

47 *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) at 443-44.

48 *Ibid*.

49 Kathleen Cranley Glass & Trudo Lemmens, "Research Inolving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham: Butterworths, 2002) 459 at 485.

50 *R. v. Dyment*, [1988] 2.S.C.R. 417.

51 *McInerney v. MacDonald*, [1992] 2 S.C.R. 138 at para 18.

52 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Supply and Services Canada, 1998). Though it is unclear how a court would use the TCPS in the absence of legislation and/or precedent.

53 Under the *Revised Draft 2nd Edition of the TCPS* (December 2009), the collection, retention and secondary use of DBS from NMS programs would also seem to conform to the ethical framework. As long as researchers followed the privacy and confidentiality components of Articles 5.5 and 5.6 it would seem as though the DBS would be categorized as "identifiable human biological materials for research purposes" and undergo secondary use. Secondary use of "identifiable human biological materials for research purposes" is governed by Chapter 12 of the *Revised Draft 2nd Edition of the TCPS* (December 2009). Articles 5.5 and 5.6 govern privacy and confidentiality in Chapter 5 of the *Revised Draft 2nd Edition of the TCPS* (December 2009).

54 From Caulfield & Knoppers, *supra* note 47 at 4: "Article 10 states that research participants should be told, at a minimum, about the purpose of the research; the potential uses for the tissue including any commercial uses; the safeguards to protect the individual's privacy and confidentiality; identifying information attached to specific tissue, and its potential traceability; and how the use of the tissue could affect privacy."

55 As Kerruish *et al*. note: "Within public health in general an underlying ethical tension between individualism and autonomy on the one hand and solidarity on the other is recognised. In relation to genetic screening this can be articulated as the potential conflict between autonomy-based arguments for a right to know in order to promote one's own (or one's child's) interests and the willingness to share information for the benefit of others." N.J. Kerruish, D. Webster & N. Dickson, "Information and Consent for Newborn Screening: Practices and Attitudes of Service Providers" (2008) 34 Journal of Medical Ethics 648 at 648.