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Pharmacogenomics

AN ETHICAL AND LEGAL OVERVIEW OF PHARMACOGENOMICS: PERSPECTIVES AND ISSUES

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Abstract: Pharmacogenomics, a field of study at the interface of the disciplines of genomics and pharmacology, strives to understand the interaction between genes and the response to therapeutics. Its introduction into clinical research trials and medical practice promises to optimize the effectiveness of medications, reduce the adverse effects experienced by patients, and improve the research and development of new therapeutics. However, while pharmacogenomics promises tremendous health benefits it is still crucial to critically analyze the ethical, social and legal issues surrounding these developments.

First, we present the numerous potential benefits of pharmacogenomics. Then, using a thorough review of relevant jurisprudence, policies and literature, the main ethical, social and legal issues associated with pharmacogenomics will be identified. The likely new responsibilities for health care professionals and pharmaceutical companies as a result of pharmacogenomic development will also be discussed.

Keywords: Pharmacogenomics; research; ethics; professional responsibilities; health professionals; clinical trials

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What is Pharmacogenomics?

Pharmacogenetics and pharmacogenomics are two fields of research intersecting with both genetics and pharmacology. The term "pharmacogenetics" generally refers to the study of the relationship between an individual's genetic constitution and a person's response to medication.[1] The term "pharmacogenomics" emerged more recently and refers to a broader scope of study. Pharmacogenomics studies and compiles all the available information regarding an individual's genetic make-up in order to predict patterns of reaction to medication.[2,3] Pharmacogenomics also facilitates research and development of new targeted therapeutics. Because pharmacogenomics is now considered to include pharmacogenetics, the term "pharmacogenomics" will be used in this article to refer to both pharmacogenetics and pharmacogenomics.

Throughout the centuries, various reactions to medical therapies have been observed.[4] However, observing the correlation between an individual's genotype and one's response to medications is far more recent[5]: in 1902, Archibald Garrod was the first to make a connection between the response to medicine and the laws of familial inheritance, which are now known to be basic genetic principles.[6] The term pharmacogenetics was first used in 1959 but this discipline only began to experience true growth in the 1980's, due in part to joint developments in both bioinformatics and molecular biology.[7] At the end of the 1990's, the study

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1. Adam M. Hedgecoe, *The Politics of Personalized Medicine* (Cambridge: Cambridge University Press, 2004) c.1.

2. J. Steven Leeder, "Translating Pharmacogenetics and Pharmacogenomics into Drug Development for Clinical Pediatrics and Beyond" (2004) 9:13 Drug Discovery Today 567.

3. Urs. A. Meyer, "Introduction to Pharmacogenomics: Promises, Opportunities, and Limitations" in Julio Licinio & Ma-Li Wong, eds, *Pharmacogenomics, the Search for Individualized Therapies*, (Weinheim:Wiley-VCH, 2002) 1.

4. Claus Moldrup, "Ethical, Social and Legal Implications of Pharmacogenomics: A Critical Review" (2001) 4 Community Genetics 204.

5. Urs A. Meyer, "Pharmacogenetics: Five Decades of Therapeutic Lessons from Genetic Diversity" (2004) 5:9 Nature Reviews Genetics 669.

6. Cindy Pham Lorenz, Eric D. Wieben, Ayalew Tefferi, David A. H. Whiteman, Gordon W. Dewald, "Primer on Medical Genomics - Part 1 : History of Genetics and Sequencing of the Human Genome" (2002) 77 Mayo Clinique Proceedings 775.

7. Yann Joly, "Biotechnologies et brevets: le cas de la pharmacogénomique" (2005) 10:2 Lex Electronica, online: LexElectronica http://www.lex-electronica.org/articles/v10-2/joly.pdf [French]

of pharmacogenomics benefited from genome sequencing and the identification of single nucleotide polymorphisms (SNPs*). Together, these innovations resulted in a better understanding of the role of genetics underlying the variable responses to medications. Pharmacogenomics has the potential to accelerate progress in a number of scientific disciplines, and catalyze the development of new medical therapies.

The Potential of Pharmacogenomics: Future Expectations

Numerous scholars are adamant in their belief that pharmacogenomics will prove to be one of the most significant practical applications resulting from deciphering the human genome. Terms such as renaissance, revival, revolution, hope, new age, and even paradigm shift, have been used in the literature to describe the role pharmacogenomics will play in health care.[8] In response to these optimistic, if not utopic visions, others argue that the impact of pharmacogenomics will be marginal in the short term and that any tangible

* Single Nucleotide Polymorphisms, or SNPs are differences between chromosomes present at a particular site in the DNA sequence. Many SNPs have no effect on cell function, but scientists believe others could predispose people to disease or influence their response to a drug. The International HapMap Consortium, "The International HapMap Project" (2003) 426(6968) Nature 789, online: International HapMap project http://www.hapmap.org/downloads/nature02168.pdf.

8. Allen D. Roses, "Pharmacogenetics and Drug Development : The Path to Safer and More Effective Drugs" (2004) 5:9 Nature Review Genetics 655. Victoria M. Kumorowsky, "Assessing Liability in Pharmacogenetic Cases" (2003) 42 Washburn Law Journal 623. Margit Sutrop, "Pharmacogenetics: Ethical Issues" (2004) 18:4 Bioethics III. Michael P. Murphy, "Pharmacogenomics : A New Paradigm in Drug Development" (2000) Fall. Drug Discovery World 1. Susanne B. Haga, Muin J. Khoury, Wylie Burke, "Genomic Profiling to Promote a Healthy Lifestyle: not Ready for Prime Time" (2003) 34 Nature Review Genetics 347. Bryn Williams-Jones, Oonagh P. Corrigan, "Rhetoric and Hype: Where's the 'Ethics' in Pharmacogenomics" (2003) 3:6 American Journal of Pharmacogenomics 381, cited from : Yann Joly, "La pharmacogénomique: perspectives et enjeux éthico-juridiques" (2004) 9:3 Lex Electronica, online: LexElectronica http://www.lex-electronica.org/articles/v10-2/joly.pdf [French].

benefits of pharmacogenomics will take many years to be realized.[9] Currently, the evidence of pharmacogenomics' scientific validity and clinical utility remains limited.[10] To date pharmacogenomics has only generated a few concrete results that translated into real health care benefits.[11] An enumeration of the potential benefits of pharmacogenomics is presented below.

Understanding the relationship between genetics and response to medicines

By studying the genes involved in the body's response to a particular medicine, pharmacogenomic research will allow to further uncover the significance of different SNPs and the influence of genetic differences on the metabolism of medication.[12] This knowledge could be used to develop new-targeted therapies.[13]

Improving the efficacy of medications and minimizing adverse effects

Research in pharmacogenomics allows scientists to identify the genotypes*

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9. Bryn Williams-Jones, Oonagh P. Corrigan, "Rhetoric and Hype: Where's the 'Ethics' in Pharmacogenomics" (2003) 3:6 American Journal of Pharmacogenomics 381. Daniel W. Nebert, Lucia Jorge-Nebert, Elliot S. Vesell, "Pharmacogenomics and "Individualized Drug Therapy": High Expectations and Disappointing Achievements" (2003) 3: 6 American Journal of Pharmacogenomics 361. Daniel W. Nebert, Elliot S. Vesell, "Advances in Pharmacogenomics and Individualized Drug Therapy: Exciting Challenges That Lie Ahead" (2004) 500 European Journal of Pharmacology 267. Delphine Allorge, Marie-Anne Loriot, "La pharmacogénomique ou la promesse d'une médecine personnalisée : variations du métabolisme et du transport des médicaments" (2004) 62:5 Annales de Biologie Clinique 500 [French], cited from : Yann Joly, "La pharmacogénomique: perspectives et enjeux éthico-juridiques" (2004) 9:3 Lex Electronica, online: LexElectronica http://www.lex-electronica.org/articles/v10-2/joly.pdf [French].

10. Robert L. Davis & Muin J. Khoury, "A Public Health Approach to Pharmacogenomics and Gene-Based Diagnostic Tests" (2006) 7:3 Pharmacogenomics 331.

11. Daniel W. Nebert, Lucia Jorge-Nebert & Elliot S. Vesell, "Pharmacogenomics and 'Individualized Drug Therapy': High Expectations and Disappointing Achievements" (2003) 3:6 American Journal of Pharmacogenomics 361.

12. Dan M. Roden & Alfred L. George, "The Genetic Basis of Variability in Drug Responses" (2002) 1 Nature Reviews Drug Discovery 37.

13 *Supra* note 3.

* Genotype: An individual's genotype is their entire genetic constitution, as distinguished from their physical characteristics. Nuffield Council on Bioethics, *Pharmacogenetics Ethical Issues* (London: Nuffield Council on Bioethics, 2003), online: Nuffield Council on Bioethics http://www.nuffieldbioethics.org/fileLibrary/pdf/pharmacogenetics_report.pdf.

that influence whether the response to a medication will be more or less favourable. On the one hand, the severity and number of adverse drug reactions (ADRs) could be minimized, and on the other hand, effectiveness of therapeutics could be maximized. Knowledge of an individual's genetic sensitivity to certain medication will allow health care professionals to tailor treatment to the genotype profile by either decreasing the dosage of a medication, or prescribing a different one.[14] Pharmacogenomics could result in the safer use of existing medications and in the development of newer, safer therapeutics, therefore reducing the number of ADR-related hospitalizations and deaths.[15]

Protecting individuals participating in clinical trials

Pharmacogenomic testing during the early stages of clinical trials could help identify those individuals at a higher risk of experiencing ADRs from the study medication. To promote safety, identified at risk participants could either be excluded from the research study or be included under a modified research protocol adapted to their genotypic profile. Pharmacogenomic testing will also help identify participants for whom the drug response is optimal thus resulting in clinical trials that require fewer participants, are shorter in duration, and more cost effective.[16] This stratification of clinical trials raises significant ethical issues that will be discussed further on in this article.

Improve the post-marketing surveillance

A significant percentage of ADRs are only discovered after a drug is already available on the market.[17] Should ADRs occur, pharmacogenomics can serve as an important tool to rapidly identify any underlying genetic causes of adverse effects suffered. Furthermore, it will help pinpoint possible groups within the

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14. *Supra* note 11.

15. Gilbert S. Omenn & Arno G. Motulski, "Integration of Pharmacogenomics into Medical Practice" in Mark A. Rothstein, ed., *Pharmacogenomics: Social, Ethical and Clinical Dimensions* (Hoboken: John Wiley & Sons, 2003) 137.

16. Jeanette J. McCarthy, "Turning SNPs into Useful Markers of Drug Response" in Julio Licinio & Ma-Li Wong, eds, *Pharmacogenomics, the Search for Individualized Therapies*, (Weinheim: Wiley-VCH, 2002) 35.

17. Nuffield Council on Bioethics, *Pharmacogenetics Ethical Issues* (London: Nuffield Council on Bioethics, 2003), online: Nuffield Council on Bioethics http://www.nuffieldbioethics.org/fileLibrary/pdf/pharmacogenetics_report.pdf

general population that are more vulnerable to these adverse effects.[18]

Reinstate previously withdrawn therapeutics

Certain medications are withdrawn from the market despite therapeutic efficacy because of the accompanying high risk or seriousness of adverse effects. If some of these effects were explained by the interaction of a drug with a particular genotype, these medications could be made available for safe use by a population with a lower risk of experiencing ADRs due to their genotypic profile.[19] It is however uncertain that such use of pharmacogenomics will appeal to the economic interests of pharmaceutical companies.

The Ethical Issues of Pharmacogenomics

The developments in pharmacogenomics should be examined in relation to a number of social and ethical issues. Given pharmacogenomics' close connection to genetics, it is likely to raise ethical issues. Several ethical issues that overlap genetics with pharmaceutical development and pharmacogenomics have been discussed at length elsewhere[20,21,22,23,24], and will not be described extensively in this article. These ethical issues include: confidentiality of samples collected for research, the communication of research results to participants, the possibility of discrimination in insurance and employment, and the identification of new categories of orphan patients. The field of pharmacogenomics also raises its

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18. Consortium on Pharmacogenomics, *Ethical and Regulatory Issues in Research and Clinical Practice*, (Consortium on Pharmacogenomics, 2002), online: Consortium on Pharmacogenomics http://www.bioethics.umn.edu/News/pharm_report.pdf

19. *Supra* note 16.

20. *Ibid*.

21. Patricia Kosseim, Martin Letendre & Bartha M. Knoppers, "Protecting Genetic Information: A Comparison of Normative Approaches" (2004) 2:1 GenEdit 1.

22. Bartha M. Knoppers, Yann Joly, Jacques Simard & Francine Durocher, "The Emergence of an Ethical Duty to Disclose Genetic Research Results: International Perspectives" (2006) 14:11 European Journal of Human Genetics 1170.

23. Mark A. Rothstein & Mary R. Anderlik, "What is Genetic Discrimination, and When and How Can it be Prevented?" (2001) 3:5 Genetics in Medicine 354.

24. Health Canada, *Orphan Drug Policy* (Ottawa: Health Canada, 1997), online: Health Canada http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/orph_pol_e.html

own complex and challenging ethical, legal and social, issues.[25] The issues most specific to research in pharmacogenomics will be discussed in this section.

Informed consent and research trials

Ensuring that participants understand the process and the issues involved in pharmacogenomic research is complex. The prospective nature of basic pharmacogenomic research makes the risk/benefit analysis of research trials tenuous, therefore great care must be taken by the research team in explaining the research trial to participants.[26] Ethical safeguards will need to be established to provide adequate limitations, in order to ensure actual *informed* consent, rather than "carte blanche" granted to the research team.

Participation in clinical trials

The aims of clinical research trials include the observation of efficacy and the identification of potential side effects linked to the medication being studied. Thus, pharmacogenomic tests could be used prior to the second and third stage of clinical trials as a means of screening out participants at risk of experiencing genetically related ADRs, as well as participants who do not respond efficiently enough to the medication.[27] Consequently, this may result in clinical trials that are less representative of the population. Therefore, severe side effects that could be experienced by a segment of the population would remain unknown, rendering off-label prescriptions more hazardous for future patients. In addition, since clinical trials could be conducted with reduced sample sizes, the identification of mild side effects may be more difficult.[28] Moreover, if there is less uncertainty about the trials' outcomes due to pharmacogenomic test results, the principle of equipoise, which states that human subjects should participate in clinical trials only if there is uncertainty about the benefits of a treatment, would be challenged.

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25. Mark A. Rothstein & Phyllis Griffin Epps, "Ethical and Legal Implications of Pharmacogenomics" (2001) 2:3 Nature Review Genetics 228.

26. D.C. Anderson *et al.*, "Elements of Informed Consent for Pharmacogenetic Research: Perspective of the Pharmacogenetics Working Group" (2002) 2:5 The Pharmacogenomics Journal 284.

27. *Supra* note 17.

28. *Supra* note 24.

Ethnicity and pharmacogenomics

From the inception of molecular genetics, scientists have attempted to prove that individual differences within the human species are minor and that the concept of "race" is not necessarily well-suited to the context of genetics.[29,30] However, some medications have already been targeted and marketed for individuals belonging to specific ethnic groups.[31] This begs the question: will controversial conclusions[32] resulting from pharmacogenomic research identifying genetic differences along ethnic lines cause prior molecular genetic research to be revisited?

The cost of pharmacogenomic medications

Dividing the population into sub-groups of individuals sharing similar pharmacogenomic profiles and developing new pharmacogenomic tests could increase the cost of developing new medications. An explosion in the number of new drugs produced to meet every emerging genotypic need would result in fragmentation of current pharmaceutical markets.[33] To recoup its cost, the pharmaceutical industry would have to increase correspondingly the sale price of these new specialized products. In countries with a universal health care system, health policy makers will eventually need to decide the extent to which a health care system will be able to absorb the cost of "genotype specific" medications.

Pharmacogenomics and New Professional Responsibilities

The advent of pharmacogenomics may have a significant impact on health professionals. For example, the potential socio-ethical consequences of

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29. Richard S. Cooper, Jay S. Kaufman & Ryk Ward, "Race and Genomics" (2003) 348:12 New England Journal of Medicine 1166.

30. Pamela Sankar & Mildred K. Cho, "Toward a New Vocabulary of Human Genetic Variation" (2002) 298:5597 Science 1337.

31. Jonathan D. Kahn, "How a Drug Becomes "Ethnic": Law, Commerce, and the Production of Racial Categories in Medicine" (2004) 4 Yale Journal of Health Policy, Law, and Ethics 1.

32. Jonathan D. Kahn, "BiDil: False Promises: Faulty Statistics and Reasoning have led to the First 'Racial Medicine'" (2005) 18:6 Genewatch 6.

33. *Supra* note 6.

introducing pharmacogenomics into clinical practice on the legal duties of health care professionals will need to be considered. Civil litigation determining responsibilities of manufacturers and health care professionals in light of pharmacogenomics is new. Consequently, the implications of pharmacogenomics for professionals and pharmaceutical companies are difficult to assess. This section of our paper will briefly outline two recent cases in this emerging field of civil responsibilities.

Cassidy et al. v. SmithKline Beecham[34]

On December 4, 1999, a class action suit was filed against the pharmaceutical company SmithKline Beecham (now GlaxoSmithKline*) by individuals claiming they had developed auto-immune arthritis as a result of using the company's "LYMErix®" vaccine**.[35] The lawsuit alleged the company knew LYMErix® could cause severe adverse effects for those with a specific genetic polymorphism.[36] A novel claim was put before the American courts – «was there a legal duty to warn product users that they may be genetically susceptible to the manufacturer's product».[37,38] In 2002, the plaintiffs received a symbolic out of court financial settlement.[39] In addition to covering costs and fees, the

34. *Cassidy v. SmithKline Beecham Corp.*, No. 99-10423, 2003 WL 22216528 (Pa. Com, Pl. July 1, 2003).

* SmithKline Beecham Corp merged with Glaxo Wellcome in January 2000 to create Glaxo SmithKline.

** LYMErix was the first vaccine approved by the FDA to prevent lyme disease. US Department of Health and Human Services, News Release, "FDA Approves First Lyme Disease Vaccine" (21 December 1998), online: U.S. Food and Drug Administration http://fda.gov/bbs/topics/NEWS/NEW00669.html

35. Holcomb B. Noble, "3 Suits Say Lyme Vaccine Caused Severe Arthritis" *The New York Times* (13 June, 2000), online: The New York Times http://query.nytimes.com/gst/fullpage.html?res=9F01E4DB143EF930A25755COA9669C8B63&secc=health&pagewanted=2On.

36. Gary E. Marchant, "Genetic Data in Toxic Tort Litigation" (2006) 14 Journal of Law and Policy 7 at 15.

37. *Ibid.* at 16.

38. *Supra* note 34.

39. Gary W. Callahan, Berson & Campell P.C., "Genomics and the Evolution of Tort Liability" (Lecture presented at Twenty Fourth Annual Meeting of the American College of Toxicology, November 3, 2003), online: http://www.lawbc.com/other_pdfs/tox3.pdf

settlement ordered the removal of the "LYMErix®" vaccine from the American market. Subsequently, the company did remove the vaccine from the American market, but cited "poor sales".[40] Since the case was settled out of court, it remains unclear whether genetic susceptibility will fall within the scope of a manufacturer's legal duty to provide warnings concerning the inherent dangers of their products. However, this first lawsuit should be taken seriously by pharmaceutical companies as it is likely the harbinger of an extended liability for them in this field.

Adams-Conroy v. Wilkerson

The initial autopsy of young Michael Adams-Conroy revealed abnormally high concentrations of Prozac, a drug prescribed to manage his Attention Deficit Hyperactivity Disorder (ADHD) and Tourette syndrome. His parents were suspected of having deliberately caused this fatal overdose.[41] However subsequent tests revealed the toxic levels of Prozac were accumulated gradually as a result of a defective genetic mutation impeding the ability to metabolize certain drugs, including Prozac.[42] Subsequently, the parents sued Michael's physician, Dr. Wilkerson for negligence. They alleged that the high dosage prescribed and the failure to diagnose an ADR, despite their son's manifestation of severe symptoms (e.g. fever, convulsions) was contrary to the standard of care.[43,44] Following a summary decision in Wilkerson's favour, the parties settled out of court for an undisclosed amount in 2001.[45]

In the current health care system, patients are responsible to inform health care professionals of side effects they experience resulting from the prescribed

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40. "Sole Lyme Vaccine Is Pulled Off Market" *The New York Times* (28 February 2002), online: *The New York Times* http://query.nytimes.com/gst/fullpage.html?sec=health&res=9C00E5D71531F93BA15751C0A9649C8B63

41. David Stipp, "A DNA Tragedy" *Fortune* 140:10 (17 February 2001) 170.

42. *Ibid*.

43. *Ibid*.

44. The standard of care for physicians has been defined as the conduct of a prudent and diligent doctor in the same circumstances. Allen M. Linden, Lewis N. Klar & Bruce Feldthusen, *Canadian Tort Law*, 12th ed. (Markham : LexisNexis Butterworths, 2004) at 218.

45. *Supra* note 41.

treatment.[46] If the use of pharmacogenomics becomes common medical practice, it would then be possible to better predict and therefore prevent the adverse effects of medications. As a consequence of pharmacogenomics' predictive and preventive capabilities and its clinical use, this may mean that various stakeholders involved in the development, manufacturing, and prescription of pharmacogenomic medication may subsequently face increased responsibility towards patients and consumers.

Pharmaceutical companies:

Manufacturers have a common law duty to take reasonable care to manufacture products that are free of dangerous defects.[47] In addition, they must warn consumers of their products' inherent risks.[48] Depending on how these established legal obligations are interpreted, pharmaceutical companies may become obligated to develop pharmacogenomic tests for clinical research participants[49] or to provide pharmacogenomic information on medication labels, warning consumers of the risk of ADRs due to genetic susceptibilities to products. Requiring mandatory pharmacogenomic labelling for new medications could in turn translate into a duty to develop pharmacogenomic tests to accompany the use of their medications already on the market. As the law adjusts to new scientific realities, pharmaceutical companies are encouraged to provide an increasing amount of pharmacogenomic information from the

46. Moira A. Stewart, "Effective Physician-Patient Communication and Health Outcomes: A Review" (1995) 152:9 Canadian Medical Association Journal 1423.

47. Philip H. Osborne, *The Law of Torts*, 2nd ed. (Toronto: Irwin Law, 2003) at 127.

48. *Ibid*.

49. *Supra* note 17.

research trials or market use to officials responsible of regulating the health care system[50,51,52,53].

Researchers in Pharmacogenomics:

A researcher's duty of care towards a research participant has long been recognized in common law.[54] Some recent jurisprudence suggests that this duty of care may also extend in certain circumstances to the research institution (e.g. hospital) and the affiliated research ethics review board.[55] Whether a clinical trial offers a personal therapeutic benefit for participants or not, investigators must disclose all known risks including those rare and remote.[56] Researchers may eventually be required to administer pharmacogenomic tests to exclude certain genetically at-risk participants from the research trial to guard against negligence claims.[57] In addition, researchers may face an obligation to inform participants and their blood relatives of clinically relevant pharmacogenomic research results.[58] These ethical or legal obligations would

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50. Health Canada, *Draft Guidance Document: Submission of Pharmacogenomic Information* (draft) (Ottawa: Health Canada, 2006), online: Health Canada http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/draft_pharmaco_ebauche_e.pdf

51. United States, Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), *Guidance for Industry - Pharmacogenomic Data Submissions* (Rockville: Food and Drug Administration, 2005), online: Food and Drug Administration http://www.fda.gov/cber/gdlns/pharmdtasub.pdf

52. Elizabeth Wager, "Good Practice for Publishing the Results of Clinical Trials" (2005) 11:3 *The Journal of the British Menopause Society* 109.

53. Iain Chalmers, "In the Dark: Drug Companies Should be Forced to Publish all the Results of Clinical Trials." (2004) 181:2437 New Scientist 19.

54. Barney Sneiderman, John C. Irvine, Philip H. Osborne, *Canadian Medical Law : An Introduction for Physicians, Nurses and Other Health Care Professionals*, 3rd ed. (Toronto: Thompson Carswell, 2003) at 90.

55. Randi Zlotnik Shaul, Shelly Birenbaum & Megan Evans, "Legal Liabilities in Research: Early Lessons from North America" (2005) 6 BMC Medical Ethics, online: BioMed Central http://www.biomedcentral.com/1472-6939/6/4

56. *Ibid*.

57. *Supra* note 17.

58. *Supra* note 21.

be subject to and complicated by the duty of a researcher to respect the right of participants not to know these results.

Physicians:

Physicians' traditional duties include: to diagnose, to treat with due care, to inform patients of their illness and the risks and benefits of the proposed treatment, as well as to ensure patient confidentiality.[59] In addition to a general duty of care, physicians have fiduciary obligation towards their patients.[60] Fiduciaries must act in the best interest of the beneficiary and must meet more stringent standard of obligations.[61] Therefore, in light of these heightened obligations, physicians may face a legal duty to stay up to date on the latest developments in pharmacogenomic research.[62] Also, courts may eventually recognize that certain therapeutic circumstances give rise to a physician's duty to prescribe available pharmacogenomic tests. Furthermore, the discretion of physicians to choose from various therapeutic options may become curtailed. Eventually, doctors could be legally required to ensure that their prescribed course of treatment incorporates pharmacogenomic test results.

Pharmacists:

Pharmacists' duty of care to patients requires them to warn of any potential drug-related adverse effects and provide the most effective and safe treatment according to the patient's prescription and in light of individual circumstances.[63] As key actors in preventing ADRs within the population, it could be argued that pharmacists should be required to remain up to date on developments in pharmacogenomic research. Also, novel negligence claims could eventually

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59. World Medical Association International, *Code of Medical Ethics* (London: World Medical Association, 1949) online: World Medical Association http://www.wma.net/e/policy/c8.htm.

60. Mark A. Hall, Ira Mark Ellman & Daniel S. Strouse, *Health Care Law and Ethics*, 2nd ed. (St.Paul: West Group, 1999) at 116.

61. *Black's Law Dictionary*, 7th ed., s.v. "fiduciary".

62. John A. Robertson *et al*. "Pharmacogenetic Challenges for the Health Care System" (2002) 21:4 Health Affairs 155.

63. David B. Brushwood & Bernadette S. Belgado, "Judicial Policy and Expanded Duties for Pharmacists" (2002) 59:5 *American Journal of Health-System Pharmacy* 455.

result in the additional responsibility of identifying patients or drugs where a pharmacogenomic test would be indicated, even if not prescribed by the doctor.[64]

Nurses and Genetic Counsellors:

The role of nurses and genetic counsellors is to educate and support patients and their families through the course of their medical journey.[65,66] For genetic counsellors, and sometimes nurses, this includes educating patients about genetic diseases and traits, so that the patients can better understand the implications of their genetic test results. Where genetic test results may prompt important life decisions, these health care professionals may be obliged to determine the necessity and consequences of a pharmacogenomic test, as well as analyse and discuss the results and possible therapeutic options associated with such a test.[67]

CONCLUSION

In this paper, we have discussed ethical, legal and social issues associated with pharmacogenomics both in research and clinical contexts. In addition, we have analysed the important obligations that could arise for health professionals as well as drug manufacturers, should the use of pharmacogenomics become widespread. Pharmacogenomics could provide the field of medicine with a panoply of new drugs and tests to improve patient care. Gradually, the precise role it will play as well as the ethical challenges it raises will emerge. This transition period should be used to provide training and education to health care professionals. Suggested educational strategies could include updating current

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64. Julie A. Johnson *et al*., "Pharmacogenomics: A Scientific Revolution in Pharmaceutical Sciences and Pharmacy Practice. Report of the 2001-2002 Academic Affairs Committee" (2002) 66:4 Supplement American Journal of Pharmaceutical Education 12.

65. Dale Halsey Lea, "A New World View of Genetics Service Models" (2000) 5:3 Online Journal of Issues in Nursing, online: Nursing World http://www.nursingworld.org/ojin/topic13/tpc13_6.htm

66. National Society of Genetic Counselors. *Code of Ethics* (Wallingford: National Society of Genetic Counselors, 1992), online: National Society of Genetic Counselor http://www.nsgc.org/about/codeEthics.cfm

67. *Ibid*.

medical curricula and continuing education programs, to reflect these new advances. The introduction of pharmacogenomics into research and clinical practice raises a number of complex ethical issues. Considering the potential new legal and ethical duties that may result from pharmacogenomic developments, educational programs could prevent unethical behaviours and costly lawsuits.

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