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## Symposium

# The Role of Law in the Debate over Return of Research Results and Incidental Findings: The Challenge of Developing Law for Translational Science

Susan M. Wolf\*

### I. THE THREAT OF LAW

The debate over return of individual results and incidental findings to human beings who participate in research or whose specimens and data are used is haunted by law. The recommendations that have emerged so far in this contentious debate typically refer in the United States to the framework set by the federal regulations on human subjects research, federal law and regulations on privacy, and the federal rules on the

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certification of laboratories to offer test results for use in clinical care.<sup>1</sup> Some commentators have ventured into state law on human subjects research, privacy, and ownership and control of specimens and data.<sup>2</sup> But all of this gives little comfort. There is no law directly on point.<sup>3</sup> The federal research regulations say nothing explicitly as yet about incidental findings or return of individual research results. The privacy regulations are equally silent. And the Centers for Medicare & Medicaid Services (CMS), which administers the key federal law on laboratory quality, has issued no official statement or rule.<sup>4</sup> To date, no reported legal case has been discovered that addresses return of results or incidental findings in the domain of research.

Some commentators have taken this as occasion to worry

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1. See, e.g., Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219 (2008); Richard R. Fabsitz et al., *Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants: Updated Guidelines from an NHLBI Working Group*, 3 CIRCULATION: CARDIOVASCULAR GENETICS 574-80 (2010); Susan M. Wolf et al., *Managing Research Results and Incidental Findings in Genomic Research Involving Biobanks & Archived Datasets*, 14 GENETICS MED. 361 (2012).

2. See, e.g., Leili Fatehi & Ralph Hall, *Enforcing the Rights of Human Sources to Informed Consent and Disclosures of Incidental Findings from Biobanks and Researchers: State Mechanisms in Light of Broad Regulatory Failure*, 13 MINN. J. L. SCI. & TECH. 575 (2012).

3. Cf. Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomic Research*, 14 GENETICS MED. 473, 475 (2012) ("There is no legislation requiring disclosure of research results.... [and] no lawsuits have found investigators liable for failing to provide such information...."). For additional legal analyses prior to this symposium that address return of results and incidental findings under U.S. law, see, e.g., Susan M. Wolf, *Incidental Findings in Neuroscience Research: A Fundamental Challenge to the Structure of Bioethics and Health Law*, in THE OXFORD HANDBOOK OF NEUROETHICS 623-34 (Judy Illes & Barbara J. Sahakian eds., 2011); Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343 (2007); Alan C. Milstein, *Research Malpractice and the Issue of Incidental Findings*, 36 J.L. MED. & ETHICS 356 (2008); Anne Marie Tassé, *The Return of Results of Deceased Research Participants*, 39 J.L. MED. & ETHICS 621 (2011); Stacey A. Tovino, *Incidental Findings: A Common Law Approach*, 15 ACCOUNTABILITY RES.: POLICIES & QUALITY ASSURANCE 242 (2008); Susan M. Wolf, Jordan Paradise & Charlissee Caga-anan, *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361 (2008).

4. Some CMS officials have graciously presented at meetings and conferences on this issue, but such presentations do not have the status and force of a rule.

about lurking legal liability. It appears to be little reassurance that no court, to my knowledge, has yet found anyone liable for mishandling return of results or incidental findings in the context of human subjects research. Indeed, no one has apparently even been sued. Yet already, we see views expressed that researchers must navigate between legal threats on both sides – liability for failure to return findings on one side, and liability for wrongly returning on the other. Faced with the specter of this Scylla and Charybdis, it is small wonder that researchers are already showing anxiety.

This symposium can play an important role, offering eight articles on different aspects of law, ethics, and practice. These articles grew out of a two-year project funded by the National Human Genome Research Institute (NHGRI) at the National Institutes of Health (NIH).<sup>5</sup> This project was the second in what has become a trajectory of research efforts on return of results and incidental findings at the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences.<sup>6</sup> Our first grant, the first NIH-funded grant to our knowledge whose focus was on this return of results question, analyzed the approach to incidental findings in imaging and genetics research. Our second grant—which supported development of this symposium in the *Minnesota Journal of Law, Science & Technology (MJLST)*—has analyzed how to handle incidental findings and individual research results in large-scale genomic research involving biobanks and archived data sets. Our third grant, awarded last year, is concentrating on the cutting-edge question of return of findings

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5. NIH, NHGRI grant #2-R01-HG003178 on “Managing Incidental Findings and Research Results in Genomic Biobanks & Archives” (Wolf, Principal Investigator; Kahn, Lawrenz & Van Ness, Co-Investigators) (2009-11).

6. That trajectory includes NIH, NHGRI grant #2-R01-HG003178 on “Managing Incidental Findings in Human Subjects Research” (Wolf, Principal Investigator; Kahn, Lawrenz, Nelson & Paradise, Co-Investigators) (2005-07); NIH, NHGRI grant #2-R01-HG003178 on “Managing Incidental Findings and Research Results in Genomic Biobanks & Archives” (Wolf, Principal Investigator; Kahn, Lawrenz & Van Ness, Co-Investigators) (2009-11); and NIH, National Cancer Institute (NCI) & NHGRI grant #1-R01-CA154517 on “Disclosing Genomic Incidental Findings in a Cancer Biobank: An ELSI Experiment” (Petersen, Koenig & Wolf, Principal Investigators) (2011-16). A fourth grant recently awarded is a Robert Wood Johnson Foundation Investigator Award in Health Policy Research on “Translating Research into Health Benefits: Returning Research Results & Incidental Findings” (Wolf, Principal Investigator) (2012-14).

to kin.

This symposium is our second published collection of articles funded by the NIH grant on return of incidental findings and research results in large-scale genomic research involving biobanks and archived data sets. That project produced a symposium already published in the April 2012 issue of *Genetics in Medicine (GIM)*. The *GIM* symposium featured a 26-author consensus recommendations article that is discussed by many of the articles in this issue of *MJLST*.<sup>7</sup>

It is fitting that *MJLST* devote an issue to this problem. Concern over law and liability is beginning to loom large in the debate over return of research results and incidental findings. Like many cutting-edge issues in biomedicine, resolution of this one could go seriously astray if anxieties about law and liability become determinative. This is a familiar dynamic – an issue emerges in biomedicine; the law is unclear or in transition; faced with uncertainty, fear of liability and regulatory penalties begins to erupt; mythology about what law requires gains a foothold; and resolutions that would be better guided by ethics, evidence, and established principles of practice, now have to contend with overblown fears of law. There is a classic literature on this dynamic.<sup>8</sup>

Excessive concern with law, especially early in the development of sound practice and ethical consensus on good approaches, can stunt the development of appropriate and effective non-legal norms. Though law and ethics are sometimes confused, they are distinct. Again, a classic literature reminds us that law and ethics are indeed different; in some domains they actually conflict.<sup>9</sup> On emerging

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7. Wolf et al., *Managing Research Results*, *supra* note 1.

8. See, e.g., Emily R. Carrier et al., *Physicians' Fears of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFF. 1585 (2010); Sandra H. Johnson, *The Social, Professional, and Legal Framework for the Problem of Pain Management in Emergency Medicine*, 33 J.L. MED. & ETHICS 741 (2005); S. Van McCrary et al., *Treatment Decisions for Terminally Ill Patients: Physicians' Legal Defensiveness and Knowledge of Medical Law*, 20 L. MED. & HEALTH CARE 364 (1992); Alan Meisel, *The Legal Consensus About Forgoing Life-Sustaining Treatment: Its Status and Prospects*, 2 KENNEDY INST. ETHICS J. 309 (1993); Alan Meisel et al., *Seven Legal Barriers to End-of-Life Care: Myths, Realities, and Grains of Truth*, 284 JAMA 2495 (2000); Mildred Z. Solomon et al., *Decisions Near the End of Life: Professional Views on Life-Sustaining Treatments*, 83 AM. J. PUB. HEALTH 14-23 (1993); David M. Studdert et al., *Medical Malpractice*, 350 N. ENG. J. MED. 283 (2004).

9. See, e.g., GEORGE J. ANNAS, STANDARDS OF CARE: THE LAW OF

biomedical questions, it can be highly adaptive for ethics and biomedical practice (whether clinical practice or research practice) to take the lead, exploring and testing potential approaches. Clarity in the domain of ethics and practice can support the development of good law. Indeed, sound law in the world of biomedicine generally supports ethical and competent practice. In fact, conclusions about what is ethically correct for the research community and individual researchers in dealing with return of results and incidental findings is likely to predate the development of law on these issues.

The goal of this article is to address emerging legal concerns in the debate over return of results and incidental findings, clarify what is *not* at issue, and then make clear the true nature of the challenge for law. The ultimate purpose of this analysis is not to discourage work on law, which is surely needed, but to optimize its contribution to a sound process of resolution. To shape ethics and practice around premature conclusions of legal threat would be to thwart an extremely important debate in research ethics and practice. Much about law is simply not yet clear in this debate. And this article suggests that there is a reason for this lack of clarity: neither the law of research nor the law of clinical care is fully adequate to govern what is in essence a problem about the translational process of moving research-derived information into the domain of clinical care. We need to develop law that is appropriate for this translational science process. This is a substantial challenge. We need to seize the opportunity afforded by these early days of debate to shape and develop law in a way that will support sound and sustainable answers.

After all, where law works well in biomedicine, it is because law supports practices that make sense medically, scientifically, and ethically. Where law threatens to derail sound research or clinical practice or the translational process between them, it offers answers that are difficult to defend and sustain. Law should ultimately support sound resolution of the issues surrounding return of results and incidental findings.

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AMERICAN BIOETHICS (1993); Alexander M. Capron & Vicki Michel, *Law and Bioethics*, 27 LOY. L.A. L. REV. 25 (1993); Richard Delgado & P. McAllen, *The Moralist as Expert Witness*, 62 B.U. L. REV. 869 (1982); Carl E. Schneider, *Bioethics in the Language of the Law*, 24(4) HASTINGS CENT. REP. 16 (1994); Susan M. Wolf, *Law & Bioethics: From Values to Violence*, 32 J.L. MED. & ETHICS 293 (2004); Susan M. Wolf, *Ethics Committees in the Courts*, 16(3) HASTINGS CENT. REP. 12 (1986).

## II. EMERGING CONCERNS ABOUT LAW

As work on the law of returning results and incidental findings gets under way, a few concerns about law are emerging that warrant careful consideration. More work over time will be needed on law, to make sure law supports sound resolution of the issues raised by return of results and incidental findings. At this early point, one of the biggest dangers is that fear of law will derail good progress in the return of results debate. Below are three concerns that have been voiced as reasons to avoid or minimize return of results and incidental findings. However, careful examination suggests that none of these is a compelling reason. There may be other important reasons to limit return, but these broad legal concerns should not shut down exploration of return of results and incidental findings.

### A. THE CONCERN THAT ETHICS RECOMMENDATIONS WILL BE MISTAKEN FOR LAW

Since at least 1999, over a dozen years ago, we have seen published ethics recommendations on return of results and incidental findings in research. In 1999, the National Bioethics Advisory Commission (NBAC) advised returning results only if “scientifically valid and confirmed,” “the findings have significant implications for the subjects’ health concerns,” and “a course of action to ameliorate or treat these concerns is readily available.”<sup>10</sup> In 2001, a project sponsored by the Centers for Disease Control (CDC) recommended criteria for returning results in population-based genetic research: “When the risks identified in the study are both valid and associated with a proven intervention for risk reduction, disclosure may be appropriate.”<sup>11</sup> In 2004 and 2010, Working Groups sponsored by the National Heart, Lung, and Blood Institute (NHLBI) at NIH issued consensus recommendations; the latter specified when results should be offered and when they may be offered to research participants.<sup>12</sup> In 2005, a Committee of the National

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10. NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC), 1 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 72 (1999).

11. Laura M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 JAMA 2315, 2320 (2001).

12. Ebony B. Bookman et al., *Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group*, 140A

Research Council and Institute of Medicine published consensus recommendations on return of research results in human embryonic stem cell research, stating that the duty to report “depends in large part on the reliability of the findings and the significance of the information to human health.”<sup>13</sup> In 2008, the investigators and Working Group members in our first project on return of incidental findings published a 21-author consensus recommendations article specifying when incidental findings should be returned, may be returned, and should not be returned.<sup>14</sup> Also in 2008, Caulfield and colleagues published recommendations on return of results in whole-genome research.<sup>15</sup> And earlier this year, we published our second consensus recommendations paper on return of results and incidental findings in large-scale genomic research involving biobanks and archived data sets.<sup>16</sup>

All of these papers present ethics recommendations. And to date, not a single one of them appears to have been cited in any legal decision or used to impose liability. There is a very good reason for this: ethics is not the same as law. What is recommended in these papers are general principles, such as differentiate “should return” from “may return,” plan for and be careful about the return process, limit return to findings that are well-understood and actionable, and seek consent from research participants before returning information. It is widely recognized that translating such general principles into action will require a great deal more work. Even devising the roster of results that are indeed established and actionable will be a complex and collaborative process. Research is under way to support specification of the general ethics principles articulated to date. Indeed, in our latest recommendations paper, we separated the process of articulating general criteria for return from the process of analyzing particular findings to decide if they should be returned.<sup>17</sup>

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AM. J. HUM. GENETICS 1033 (2006); Fabsitz et al., *supra* note 1.

13. NATIONAL RESEARCH COUNCIL AND INSTITUTE OF MEDICINE COMMITTEE ON GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 89-90 (2005).

14. Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219 (2008).

15. Timothy Caulfield et al., *Research Ethics Recommendations for Whole-Genome Research: Consensus Statement*, 6(3) PLOS BIOL. e73 (2008).

16. Wolf et al., *Managing Research Results*, *supra* note 1.

17. *Id.*, at 374-75.



We would all be kidding ourselves to believe that we had already generated such consensus across the research community about return of results and incidental findings and such specificity about what return should look like that courts would find an established standard of care. The reality is that debate, research, and specification are very obviously works in progress. NIH is playing a crucial role in funding the significant quantity of research still needed to form an evidence base for research standards, and linking investigators in a Return of Results Consortium to advance progress.<sup>18</sup> I have written elsewhere that agreeing on well-supported standards for the research community will probably require years of work.<sup>19</sup>

Another reason to look skeptically on claims that our current ethics recommendations will generate legal liability is that the ethics literature to date acknowledges that research studies vary significantly, as do biobanks and other research resources. It is highly doubtful that a single policy or standard will suffice for all. Indeed, our project's recent ethics recommendations for biobank research systems recognized variation in how such systems are structured, whether re-identification of individual participants is possible, and whether return involves retrofitting a preexisting biobank or prospectively designing a new one.<sup>20</sup> Underscoring this, an article published in our project's Special Issue of *GIM* examined the approach to return of results across five biobanks that were all members of the NIH-funded eMERGE Network; the article documented a wide range of approaches to return of results, even though all five sites were considering the recommendations of a joint Return of Results Oversight Committee.<sup>21</sup>

It is true that when consensus recommendations to date consider return of results, they look at a number of informative

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18. See Jeannine Mjoseh, NHGRI Funds Return of Results Studies, Forms Expert Consortium, <http://www.genome.gov/27545526> (last visited May 8, 2012).

19. Susan M. Wolf, *The Past, Present, and Future of the Debate over Return of Research Results & Incidental Findings*, 14 *GENETICS MED.* 355 (2012).

20. See Wolf et al., *Managing Research Results*, *supra* note 1.

21. Stephanie M. Fullerton et al., *Return of Individual Research Results from Genome-Wide Association Studies: Experience of the Electronic Medical Records and Genomics (eMERGE) Network*, 14 *GENETICS MED.* 424 (2012).

sources, including of course the regulations on human subjects research and sometimes statutes such as the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA). Ethics groups examine these sources to try to inform and reconcile their recommendations with already-existing rules. That said, there is no guarantee that ethics groups will find the current law adequate. There are many examples in the history of bioethics and medical ethics of ethics authorities and scholars as well as practicing clinicians finding the law wanting and even in conflict with sound ethics.<sup>22</sup> Because the regulations on human subjects research, CLIA, and HIPAA were devised with no attention to the problem of return of results and incidental findings, we should not be surprised if sustained ethics analysis finds these legal sources wanting and in need of development or amendment to adequately address these issues.

#### B. THE CONCERN THAT RETURN OF RESULTS & INCIDENTAL FINDINGS MISTAKES RESEARCH FOR CLINICAL CARE

The claim that return of research results and incidental findings mistakes research for clinical care restates the question at the heart of the return of results debate, rather than providing an answer. The question of whether to return results and incidental findings from research is a challenging one precisely because the context is research and *not* clinical care. Research is classically defined as the search for generalizable knowledge.<sup>23</sup> Traditionally researchers have recognized no responsibility to communicate clinically important information about individuals, with limited exceptions.<sup>24</sup> Both law and ethics have conceived of the research and clinical spheres as generally quite distinct. The researcher has been seen as owing limited duties to the individual research participants, in contrast to the clinician,

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22. For examples and an exploration of the relationship of law and bioethics, see Susan M. Wolf, *Law & Bioethics: From Values to Violence*, 32 J.L. MED. & ETHICS 293 (2004).

23. This is based on the Common Rule definition of “research” as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 C.F.R. § 46.102 (d) (2011).

24. Exceptions would include duties to report “significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation” (45 C.F.R. § 46.116 (b) (5) (2011)).

who undertakes a broad duty of care toward the individual patient.

The discovery that research routinely and predictably generates information of clinical significance to individual participants, whether in the form of individual research results or incidental findings, has challenged this traditional dichotomy between research and clinical care.<sup>25</sup> When some findings have urgent clinical significance (such as pharmacogenetic findings revealing that the individual may have a catastrophic reaction to a commonly used drug), the tradition of researcher silence becomes more difficult to defend. Indeed, it has become hard to find participants in the return of results debate who maintain that no individual results or findings should ever be returned, no matter how clinically urgent the information. Imaging researchers long ago accepted responsibility for reporting findings of serious clinical significance.<sup>26</sup> Genetic and genomic researchers have come more slowly to this acceptance of responsibility, but now are hard at work fleshing out what it should mean in research practice.

The literature increasingly offers ethical theories and argument about the grounding and scope of the responsibility. But for our purposes here, the key insight is that the research context is precisely what necessitates this philosophical work. Were we instead talking about the clinical context, no complex argument would be needed to support the notion that a clinician treating malady X who stumbles upon additional malady Y has a duty to convey that information to the patient, so that the patient can decide whether and how to address the newly discovered problem.

The challenge of the return of results debate is that it forces us to rethink the traditional wall between research and clinical care, by raising the question of whether researchers have some informational duties to convey findings of high clinical significance to the individual participant. This is a deep challenge to the traditional architecture of both health law and bioethics, which have largely accepted and built upon a dichotomy between the two spheres. To restate the difference

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25. See Susan M. Wolf, *Incidental Findings in Neuroscience Research*, *supra* note 3.

26. See Wolf et al., *Managing Incidental Findings*, *supra* note 1.

between research and clinical care is no answer to what to do in the face of this challenge; it merely recapitulates the question.

Just as it is increasingly difficult to find commentators who argue for no return, no matter how urgent the information, it is also increasingly difficult to find commentators who argue for conveying all information derived in the research sphere, at least at this juncture. Too much of that information still remains uncertain and even mistaken, to dump it all on research participants. Thus, the scope of the responsibility to return is at this point limited. This accounts for the effort in publication after publication to articulate the criteria that should be met before return is undertaken.

There is no denying that allowing the traditional wall between research and clinical care to give way is unsettling. The wall is starting to resemble something more like a membrane allowing some kinds of information through. We remain in the early days of the research required to figure out what to return and how—the appropriate functioning of this permeable membrane. But it is no accident that this conceptual shift is happening now. The rise of a translational concept of genetics and genomics has brought into focus the precise process by which research moves into clinical practice. Increasingly, the goal of research is to move information and interventions into clinical use. And not just for populations—individualized or personalized medicine embraces the reality of individual genetic and genomic difference. When translational science is combined with personalized medicine, it is inevitable that researchers have to confront the question of how and when research information should be offered to individuals because of that information's potential clinical significance. Instead of two domains separated by a wall, research and clinical care have become part of a spectrum that moves research insights into clinical use.

In the face of this, to say that the return of results mistakes research for clinical care is a throwback to a time before we embraced that continuum, with all of its challenges. There is no going back to the two-world vision. What has emerged is more complex and continuous.

C. THE CONCERN THAT RESEARCH RESULTS &  
INCIDENTAL FINDINGS CANNOT MEET STANDARDS  
FOR RESPONSIBLE RETURN

There is wide agreement that returning findings to research participants calls for confidence that the test performed and information derived have acceptable accuracy, the clinical implications are understood, and the sample and data in question indeed belong to this participant. Thus we see a near-universal demand for analytic validity as a precondition for informational return.<sup>27</sup> A further recommendation has been that an individual research result or incidental finding has “established” risk or meaning.<sup>28</sup> There is debate about how established the risk or meaning should be to allow return, and whether to offer research participants not only findings, but also information on how well understood and established the associated risk or meaning is. Yet another recommendation on the protective standards that should condition return is the frequently stated—but still somewhat controversial—requirement that any findings to be returned are generated and/or confirmed in a CLIA-certified laboratory.<sup>29</sup>

All of these issues are aspects of a single question: What standards should apply to govern the quality of information that is offered to research participants? In addressing this question, it is important to recognize that notifying research participants of an incidental finding or individual research result of concern is typically not suggested as a substitute for clinical diagnosis and care. In imaging research, for example, research scans may not be of clinical grade and optimized for clinical diagnosis. Thus, what research will often generate is findings and results of *potential* clinical concern. So the question is what level of confidence about the finding and its clinical implications is necessary before sharing this

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27. See, e.g., Fabsitz et al., *supra* note 1, at 575, 578; Wolf et al., *Managing Return of Results*, *supra* note 1, at 378. In genomic testing, “analytic validity” refers to “[h]ow accurately and reliably the test measures the genotype of interest.” “Clinical validity” refers to “[h]ow consistently and accurately the test detects or predicts the...outcomes of interest.” Centers for Disease Control and Prevention, *Genomic Testing: ACCE Model Process for Evaluating Genetic Tests*, available at <http://www.cdc.gov/genomics/gtesting/ACCE/index.htm> (last visited May 3, 2012).

28. See, e.g., Fabsitz et al., *supra* note 1, at 575.

29. On the CLIA controversy, see, e.g., Fabsitz et al., *supra* note 1, at 576-77; Wolf et al., *Managing Return of Results*, *supra* note 1, at 371.

information in order to trigger the research participant's pursuit of definitive clinical diagnosis and care.

To simply say that the standards of clinical testing and diagnosis should apply wholesale is to avoid what is at the heart of the return of results and incidental findings debate – a translational question<sup>30</sup> of what research information is appropriate for return. This is a complex question, whose answer may vary depending on a range of variables, including the nature of the research participant population in question, whether the research participants are healthy volunteers or individuals affected by a condition they are trying to cope with and understand, and whether clinical work-up is readily available once the research-generated information is offered to trigger that clinical consideration. Returning results and incidental findings meeting all of the quality standards for communication in a clinical setting (including findings that are already routinely communicated in clinical settings) may turn out to be the easy case. More challenging will be consideration of other cases, such as cases in which a novel genetic or genomic abnormality is found with too little literature to say its meaning is “established,” but raising such concern among genetics professionals that they consider sharing the information to contribute to diagnostic efforts that have thus far been unavailing. This is a scenario that would require careful and detailed consideration, but is already of concern to researchers.

## II. THE REAL CHALLENGE: DEVISING TRANSLATIONAL ETHICS, PRACTICE, & LAW

Making progress in the debate over return of research results and incidental findings requires recognizing that the debate is fundamentally about the translational process. Return of information generated in the process of conducting research, because of the potential clinical importance of that information, is a practice that occupies the space between research and clinical care. It does not fit neatly into the preexisting ethics or law of either research or clinical care. It

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30. On translational genomics and translational science more generally, see, e.g., Muin J. Khoury et al., *The Continuum of Translation Research in Genomic Medicine: How Can We Accelerate the Appropriate Integration of Human Genome Discoveries into Health Care and Disease Prevention?*, 9 GENETICS MED. 665 (2007); Elias A. Zerhouni, *Translational and Clinical Science—Time for a New Vision*, 353 N. ENG. J. MED. 1621 (2005).

lies in the domain between them. There is no escaping that this translational practice is calling for the development of new ethical approaches and insights. It similarly calls for the development of legal standards that fully consider the translational character and complexities of this practice.

The traditional ethics and law of research (on the one hand) and clinical care (on the other) are surely relevant to developing this translational ethics and law. But they were not developed with careful attention to this problem and are not adequate to its resolution. The emergence of translational genomics requires an ethics that is evolving. And it requires the development of law that addresses the complexities of translational practices soundly and sustainably. We do not yet have such law in place. Developing translational law lies largely ahead of us.<sup>31</sup> This symposium aims to contribute to that effort.

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31. For beginning efforts, see, e.g., Gary E. Marchant, *Personalized Medicine and the Law*, ARIZONA ATTORNEY, Oct. 2007, at 12, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1469686](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1469686) (last visited May 8, 2012); Michael Tomasson, *Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests*, 18 ANN. HEALTH L. 231 (2009).