

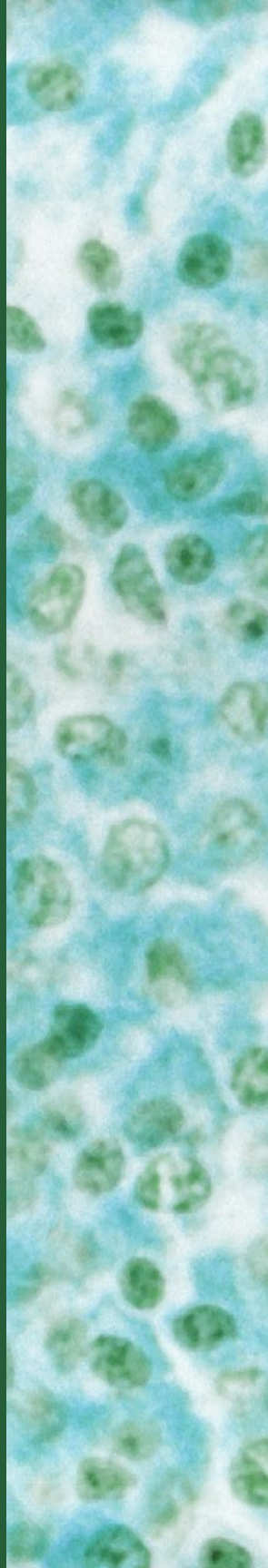


# ANTICIPATE and COMMUNICATE

Ethical Management of  
Incidental and Secondary Findings  
in the Clinical, Research, and  
Direct-to-Consumer Contexts

Presidential Commission  
*for the* Study of Bioethical Issues

December 2013



---

# EXECUTIVE SUMMARY

A healthy young medical student participated in research using functional magnetic resonance imaging to look at brain activity while doing a memory test. During this brain scan, the researcher noticed a concerning mass. The student rushed to the hospital for further examination, which was followed by successful treatment of the incidental finding that she credits with saving her life.<sup>1</sup>

Two years later, a different woman collapsed from over-hydration while running a marathon. During an evaluation, her emergency care team discovered a small brain tumor. She opted, in consultation with her physicians, for a watch-and-wait approach, monitoring the tumor for changes before making any treatment decisions. She has been watching anxiously for almost 10 years, even though the tumor might never affect her health.<sup>2</sup>

Incidental findings—traditionally defined as results that arise that are outside the original purpose for which the test or procedure was conducted<sup>3</sup>—can create a range of practical, legal, and ethical challenges for recipients and practitioners. Discovering an incidental finding can be lifesaving, but it also can lead to uncertainty and distress without any corresponding improvement in health or wellbeing. For incidental findings of unknown significance, conducting additional follow-up tests or procedures can be risky and costly.<sup>4</sup> Moreover, there is tremendous variation among potential recipients about whether, when, and how they would choose to have incidental findings disclosed. Information that one recipient regards as an unnecessary cause of anxiety could lead another recipient to feel empowered in making health-related decisions.

The increasing technological capability of the modalities discussed in this chapter leads to an increased likelihood of discovering incidental and secondary findings. The movement from discrete tests toward large-scale genetic sequencing increases the likelihood that clinicians, researchers, and direct-to-consumer (DTC) providers will confront the issue of incidental and secondary findings. And as payment structures evolve so that bundled tests are presumed to be more cost effective than discrete tests, the number of unintended findings is expected to increase.

In this report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer*

*Contexts*, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) focuses on the distinct ethical issues concerning incidental and secondary findings that arise from various modalities—including large-scale genetic sequencing, testing of biological specimens, and imaging—in contexts that include the clinic, research, and DTC testing. Because the term “incidental findings” as traditionally used can limit consideration of critical ethical issues, the Bioethics Commission considers several types of ethically challenging findings, including incidental, secondary, and discovery findings.

For purposes of this report, the Bioethics Commission divides the term “incidental finding” into two categories: incidental findings that are “anticipatable” and those that are “unanticipatable.” An *anticipatable incidental finding* is a finding that is known to be associated with a test or procedure. An *unanticipatable incidental finding* includes a finding that could not have been anticipated given the current state of scientific knowledge. A *secondary finding* refers to a finding that is actively sought by a practitioner that is not the primary target. A *discovery finding* refers to the results of a broad or wide-ranging test that was intended to reveal anything of interest. This report focuses primarily on anticipatable and unanticipatable incidental findings as well as secondary findings. For simplicity, the generic term “incidental finding” is used in reference to both anticipatable and unanticipatable incidental findings; distinctions are made as necessary and relevant.

In its previous report, *Privacy and Progress in Whole Genome Sequencing*, the Bioethics Commission addressed incidental findings with regard to large-scale genetic sequencing.<sup>5</sup> A more thorough deliberation about the ethical obligations of clinicians, researchers, and DTC providers, as well as consideration of the incidental findings that arise from various diagnostic modalities, is the goal of this report, which makes 17 recommendations to guide practitioners across modalities and settings.

The current challenge for public policy and professional ethics is to identify through thoughtful deliberation specific criteria that practitioners can use to determine when it is ethically permissible or obligatory for clinicians, researchers, or DTC companies to disclose and not disclose incidental findings to patients, participants, or consumers. The technical aspects of managing the response to incidental findings—including the circumstances under which

practitioners should return particular findings—is best carried out by those with the relevant expertise to make those nuanced determinations. In contrast to developing detailed prescriptions for practice, the Bioethics Commission aims through this report to provide a broad ethical analysis of the principles, virtues, and duties relevant to managing incidental and secondary findings to ground these determinations.

### **ETHICAL BASIS OF THE MANAGEMENT OF INCIDENTAL AND SECONDARY FINDINGS**

Longstanding ethical principles ground the Bioethics Commission’s consideration of incidental and secondary findings. In seeking to create mutually acceptable and justifiable public policy, a process of democratic deliberation can lead citizens, policy makers, and experts to identify common ground and compromise.<sup>6</sup> Because professionals in a variety of contexts can encounter incidental and secondary findings, guidance must appeal to principles that bridge these contexts. The interpretation, application, scope, strength, and stringency of each principle, however, can vary among and within each context.

The Bioethics Commission found four ethical principles to be particularly applicable to the ethical assessment of incidental and secondary findings: respect for persons, beneficence, justice and fairness, and intellectual freedom and responsibility. The principle of respect for persons recognizes the fundamental human capacity for rational self-determination—the autonomous ability to identify personal preferences, act on these desires, and direct the course of one’s life. The principle of beneficence calls on professionals to take actions to ensure the wellbeing of others, while its corollary non-maleficence requires not imposing harms on others. The principle of justice and fairness requires fair and equitable treatment of all. Finally, the principle of intellectual freedom and responsibility protects sustained and dedicated creative intellectual exploration that furthers scientific progress, while requiring that practitioners take responsibility for their actions. A context-specific interpretation of each principle is necessary to translate the principles into actionable guidance,<sup>7</sup> and is undertaken in each of the context-specific chapters that follow.

## RECOMMENDATIONS

In this report, the Bioethics Commission makes two types of recommendations: those applicable to the ethical management of incidental and secondary findings across contexts, and those most relevant in specific settings or situations. The following section provides an overview of these recommendations.

### Overarching Recommendations

Although many ethical considerations concerning the management of incidental and secondary findings are specific to the setting in which they occur—and the type of relationship between the practitioner and the potential recipient—there are several important considerations applicable to these findings in *all* contexts. The Bioethics Commission thus offers five overarching recommendations.

#### Overarching Recommendations

- Informing Persons Tested*
- Evidence-Based Practice Guidelines*
- Additional Empirical Research*
- Educating Stakeholders*
- Justice and Fairness and Health Inequities*

### *Informing Persons Tested*

In all contexts, potential recipients of incidental and secondary findings—patients, research participants, and consumers—should be informed about the likelihood of such findings arising from a particular test or procedure. Providing this information enables a potential recipient to make an autonomous decision about whether and how to proceed. This disclosure also allows practitioners to anticipate and think through the consequences of conducting various tests and procedures. Open communication between practitioners and individuals, accessible and understandable documents and resources, and transparent processes in all three contexts help ensure that individuals understand risks and benefits before they consent.

#### Recommendation 1

---

**Clinicians, researchers, and direct-to-consumer providers should describe to potential recipients incidental and secondary findings that are likely to arise or be sought from the tests and procedures conducted. Practitioners should inform potential recipients about their plan for disclosing and managing incidental and secondary findings, including what findings will and will not be returned.**

Practitioners should facilitate and work to improve the process of informed consent in all contexts. Adequately informing individuals about the potential for discovering incidental findings should include an explanation of the nature of anticipatable incidental findings, as well as the possibility of discovering unanticipatable incidental findings, and a thorough description of any secondary findings that will be sought.

### *Evidence-Based Practice Guidelines*

Practice guidelines can inform practitioners about the anticipatable incidental findings likely to arise during common tests and procedures, and the ways in which practitioners can best manage these findings—including the possibility of actively seeking particular findings as secondary findings. Guidelines tailored to each modality, procedure, or test that address the findings likely to arise in each context can help practitioners develop their own ethically sound policies for managing such findings.

### **Recommendation 2**

---

**Professional representative groups should develop guidelines that categorize the findings likely to arise from each diagnostic modality; develop best practices for managing incidental and secondary findings; and share these guidelines among practitioners in the clinical, research, and direct-to-consumer contexts.**

Professional and institutional guidelines are crucial to ensuring consistent and systematic categorization, disclosure, and management of incidental and secondary findings. In developing guidelines, professional organizations should employ a variety of criteria, including clinical significance and actionability, and should also take into account the economic costs associated with conducting additional diagnostic tests in relation to ascertainable benefits.

As professional organizations increasingly recognize certain anticipatable findings likely to arise from particular tests and procedures, and determine that certain findings are sufficiently significant and actionable to merit disclosure, a number of findings—previously considered anticipatable incidental findings—are likely to become actively sought secondary findings. The transition from unanticipated incidental findings to anticipated or

secondary findings allows for more information to be provided to potential recipients and therefore facilitates more meaningful consent across contexts.

### *Additional Empirical Research*

Additional empirical research and scholarship is needed concerning the discovery, disclosure, and management of incidental and secondary findings. In its report, *Privacy and Progress in Whole Genome Sequencing*, the Bioethics Commission recommended that funders of whole genome sequencing research conduct further studies to evaluate proposed frameworks for offering to return incidental findings and other research results.<sup>8</sup> The Bioethics Commission continues to believe that additional empirical data are critical to informing the ethical management of incidental and secondary findings, and therefore suggests expanding the scope of such recommended empirical research.

### **Recommendation 3**

---

**Federal agencies and other interested parties should continue to fund research regarding incidental and secondary findings. This research should consider the types and frequency of findings that can arise from various modalities; the potential costs, benefits, and harms of identifying, disclosing, and managing these findings; and recipient and practitioner preferences about the discovery, disclosure, and management of incidental and secondary findings.**

Data about incidental and secondary findings can come from a variety of sources. One potential source is practitioners gathering information about incidental and secondary findings through their work, monitoring findings that arise, and developing databases about the disclosure and management of such findings.<sup>9</sup> Professional societies also can address specific questions about findings likely to arise from various modalities and in various contexts, and the professional skills or training necessary to interpret and manage these findings.<sup>10</sup>

### *Educating Stakeholders*

Educating the public about incidental and secondary findings enables those undergoing tests or procedures to make better informed decisions and develop informed preferences about receiving potential findings. Educating practitioners about their ethical obligations enables them to make more



thoughtful decisions about how to anticipate, disclose, and manage incidental and secondary findings.

#### **Recommendation 4**

---

**Public and private entities should prepare educational materials to inform all stakeholders—including practitioners, institutional review boards, and potential recipients—about the ethical, practical, and legal considerations raised by incidental and secondary findings.**

In addition to the educational efforts of the Bioethics Commission, a wide variety of groups, governmental bodies, and professional organizations can assist in educating stakeholders about incidental and secondary findings. For example, public and private entities tasked with providing education about and regulation of medical research can bolster existing materials to better address the ethical issues raised by incidental and secondary findings.

#### *Justice and Fairness and Health Inequities*

Justice and fairness in health care requires that all individuals have access to adequate affordable services to meet basic health care needs. Our society should continue to seek cost-effective ways to provide affordable access to health care to as many individuals as possible. The right test at the right time can be lifesaving, while over-testing comes with its own risks that can be detrimental to both mental and physical health. Adequate, affordable care provides the backdrop against which competent health care professionals can offer expert advice, personalized counseling, and follow-up care to harness the benefits of these developing diagnostic technologies. Coupling counseling and guidance with new technologies can help patients and their practitioners make meaningful decisions about turning medical information into actionable clinical knowledge in accordance with personal health care preferences and values.<sup>11</sup> Currently, however, many persons lack access to such services. The principle of justice and fairness suggests finding affordable, cost-effective ways to give all people in need access to informed counseling and related medical care.

## Recommendation 5

---

The principle of justice and fairness requires that all individuals have access to adequate information, guidance, and support in making informed choices about what medical tests to undergo, what kind of information to seek, and what to do with information once received. The principle of justice and fairness also requires affordable access to quality information about incidental and secondary findings, before and after testing, which when coupled with access to care can be potentially lifesaving or life enhancing.

For incidental findings to be managed in an appropriate and ethical way, there must be a health care system available to all that is capable of dealing with medically significant findings, whether discovered incidentally or as primary or secondary findings. This includes support for time afforded to practitioners to discuss with potential recipients how incidental and secondary findings will be handled.

### Context-Specific Recommendations

The overarching recommendations listed above provide guidance for the ethical management of incidental and secondary findings across contexts. However, given the differences among the clinical, research, and DTC settings, the Bioethics Commission also sought to provide specific guidance for practitioners in each context regarding the ethical management of incidental and secondary findings.

#### *Clinical Recommendations*

When clinicians discover incidental findings, or contemplate seeking secondary findings, their professional judgment must include skilled and insightful deliberation guided by ethical principles including respect for persons, beneficence, and justice and fairness. Application of these principles

Context-Specific Recommendations
Clinical Recommendations
<i>Consent in the Clinical Context</i>
<i>Empirical Data in the Clinical Context</i>
<i>Clinical Judgement in Managing Incidental Findings</i>
Research Recommendations
<i>Consent in the Research Context</i>
<i>Planning for Incidental Findings in Research</i>
<i>No Duty to Look for Secondary Findings in Research</i>
Direct-to-Consumer Recommendations
<i>Consent in the Direct-to-Consumer Context</i>
<i>Government Regulation in the Direct-to-Consumer Context</i>
<i>Industry-Wide Best Practices in the Direct-to-Consumer Context</i>

to incidental and secondary findings in the clinical context leads to the following recommendations.

### Consent in the Clinical Context

A primary point of communication between clinicians and patients occurs during the clinical informed consent process, ideally led by the clinician most intimately familiar with the intervention and its possible consequences.<sup>12</sup> As part of the consent process, clinicians should alert patients that a particular test or procedure could or will give rise to anticipatable incidental and secondary findings. Clinicians should also notify patients about the possibility that unanticipatable findings could arise that could lead to additional diagnostic testing or clinical care. The patient should be encouraged to ask questions, state reservations, and express preferences about the return and management of incidental and secondary findings.

### Recommendation 6

**Clinicians should make patients aware that incidental and secondary findings are a possible, or likely, result of the tests or procedures being conducted. Clinicians should engage in shared decision making with patients about the scope of findings that will be communicated and the steps to be taken upon discovery of incidental findings. Clinicians should respect a patient's preference not to know about incidental or secondary findings to the extent consistent with the clinician's fiduciary duty.**

There are multiple points at which a clinician's ability to communicate clearly and effectively about incidental and secondary findings is important. Clinicians should alert patients to the possibility of discovering incidental findings, and any secondary findings that will be actively sought, *before* testing occurs so that patients have the opportunity to express preferences regarding their disclosure and subsequent management.

With the increasing emphasis on patient autonomy and shared decision making, it is important to employ effective methods of conveying information about risk.<sup>13</sup> Clinicians can facilitate patient understanding by effectively presenting pertinent facts and data. In approaching shared decision making in the clinical setting, clinicians must be aware of factors that shape patients' perceptions of risk in order to communicate effectively. Clinicians should give patients enough information so that they comprehend their options,

and should also protect patients from unnecessary anxiety produced by misunderstood communication of risk.

### **Recommendation 7**

---

**In communicating difficult to understand information about incidental and secondary findings, clinicians should consider providing patients with decision aids and graphical representations, using population-based evidence, and describing a patient’s absolute risk (the chance of any person getting a disease) rather than or in addition to relative risk (whether a person’s chance is higher or lower than another’s).**

Accurate graphical displays of numerical and probabilistic health information can assist patients in accessing, processing, interpreting, and acting on numerical health information.<sup>14</sup> It is also critical that clinicians use relevant and understandable numerical evidence to support shared decision making. When appropriate, numeric assessments of risk should be provided as absolute risk instead of or in addition to relative risk, as relative risk can be easily misinterpreted. Similarly, population-based evidence can help patients understand their overall risk compared with the population as a whole.

### **Empirical Data in the Clinical Context**

Little is known about the cost effectiveness of tests and procedures that generate incidental findings, including using bundled tests or a battery of tests.<sup>15</sup> Seeking cost effectiveness—an outcome that takes into account both the costs and health outcomes of alternative intervention strategies<sup>16</sup>—in laboratory tests or diagnostic procedures is laudable, and in many cases also might help address the issue of ever-rising health care costs. While there have been some cost-effectiveness studies regarding incidental findings, they have generally been limited in scope.

### **Recommendation 8**

---

**Federal agencies and other interested parties should study the comparative benefits to patients and the cost effectiveness of using bundled tests or a battery of tests versus conducting sequential, discrete diagnostic tests.**

To inform individual clinicians, as well as support strong clinical practice guidelines, researchers should conduct reliable comparative- and cost-effectiveness analyses. Evidence regarding comparative benefits to patients of tests that yield

incidental and secondary findings and the cost effectiveness of performing such tests can inform laboratory and payer practices and policies regarding efficient bundling of tests, and can aid clinicians in deciding whether to order a battery of tests rather than sequential, discrete tests.<sup>17</sup>

### Clinical Judgment in Managing Incidental Findings

While empirical analysis is critical to informing cost-effective care choices, it is the art of medical decision making that translates data, education, professional guidance, and personal experience into good clinical care. Prudent judgment, understood through Aristotle’s concept of *phronesis* (or practical wisdom), constitutes a “capstone” virtue, linking intellectual virtues—such as those that make for good scientists—with the moral character traits such as compassion, trustworthiness, and a sense of justice that make one a particularly good caregiver.<sup>18</sup> Exercising professional judgment is a deliberative process combining formal or “book” knowledge of a professional domain with contextual understanding gained through experience.<sup>19</sup> Although professional judgment is required for every decision that involves considering competing values, principles, or virtues, there is no specific formula by which clinicians identify the right action.<sup>20</sup> Many of the attributes that constitute respected clinical judgment can be cultivated and enabled through classroom and clinical education.

### **Recommendation 9**

---

**Medical educators, both in the classroom and clinic, should continue to cultivate “diagnostic elegance” and “therapeutic parsimony” amongst practitioners—ordering and conducting only tests and interventions necessary for addressing health concerns related to their patient.**

Clinicians can minimize the likelihood of incidental findings by engaging in selective diagnostic testing. They can do this by emphasizing thorough communication with patients to better understand symptoms and help narrow the list of potential diagnoses before ordering diagnostic tests. In this way, clinicians can use diagnostic tests to confirm or eliminate specific possible causes of symptoms.

Another important tool that clinicians have to enhance their exercise of professional judgment is the ability to rely on evidence-based standards,

including recommendations from professional organizations. One critical area in which professional organizations make recommendations is preventive screening programs—programs in otherwise healthy populations that aim to identify undiagnosed diseases and conditions before symptoms develop.<sup>21</sup> This type of evidence-based deliberation is critical to ensuring that patients have access to preventive screening programs that offer health care benefits appropriately calibrated to any foreseeable risks—including those that can arise from incidental findings.

### **Recommendation 10**

---

**Professional and public health organizations should produce evidence-based standards for proposed screening programs that take into account the likelihood that incidental findings will arise. Professional organizations should provide guidance to clinicians on how to manage these incidental findings.**

The implementation of evidence-based standards in screening programs would assist physicians in exercising clinical judgment about any findings that might arise. Proposed screening programs that take into account the possibility of incidental findings enable clinicians to exercise their professional judgment in deciding whether to conduct a screening test or procedure for a particular patient.

### *Research Recommendations*

Existing scholarship regarding incidental and secondary findings in research reflects both the research community's deep concern for research participants' wellbeing, and an emerging consensus regarding what is ethically required, permissible, and impermissible. The Bioethics Commission therefore makes the following recommendations to guide the ethical management of incidental and secondary findings in the research context.

#### Consent in the Research Context

In response to the trust imparted to them, researchers owe society and research participants obligations to design and implement research in a responsible manner.<sup>22</sup> During the informed consent process, researchers should describe the types of incidental and secondary findings that might arise to ensure that participants are as informed as possible. This includes, but is not limited to, disclosing anticipatable incidental findings, any

deliberately sought secondary findings, and the possibility of unanticipated incidental findings.

Researchers should also clearly communicate to participants the plan for disclosing and managing anticipatable incidental findings as well as any possible secondary findings, and the distinction between research and clinical care. This communication is essential to ensure that participants understand what to expect as a result of their decision to participate in research. Clarity with respect to whether and how researchers will disclose anticipatable and unanticipated incidental findings, and any secondary findings that are deliberately sought, can help sustain public and participant trust in the research enterprise.

### **Recommendation 11**

---

**During the informed consent process, researchers should convey to participants the scope of potential incidental or secondary findings, whether such findings will be disclosed, the process for disclosing these findings, and whether and how participants might opt out of receiving certain types of findings.**

If researchers plan to inform participants of certain types of incidental findings, they should decide in advance how to respect the wishes of those who choose to opt out of receiving incidental findings. If researchers have ethical objections to allowing participants to opt out of receiving clinically significant, actionable, and lifesaving findings, they need not enroll such individuals in their research study. Delineating such exclusion criteria for study enrollment will minimize this type of ethically challenging situation once the research protocol is underway.

Alternatively, given that participants have the right to opt out of research at any time,<sup>23</sup> if researchers do not object to allowing participants to opt out of receiving incidental findings—and participants are well informed regarding what opting out could mean for their health and wellbeing—researchers may enroll such participants in the research. In the event a researcher discovers a potentially lifesaving unanticipated incidental finding for a participant who has opted out of receiving incidental findings, the investigator should seek advice from an institutional review board (IRB) about whether and how to disclose it.

## Planning for Incidental Findings in Research

Given that certain findings are predictably associated with a particular modality or type of research, researchers have a duty to anticipate such incidental findings—whether common or rare—to the extent possible. Researchers should develop a plan to manage *anticipatable* incidental findings based on a careful balancing of the risks and benefits of disclosure, along with evidence about the analytic and clinical validity of the findings and their clinical or reproductive significance, in addition to considering actively seeking them as secondary findings. Researchers should submit their proposed plan for the ethical management of incidental findings to an IRB for review and approval. IRBs then would be responsible for assessing the ethical adequacy of the plan.

### **Recommendation 12**

---

**Researchers should develop a plan to manage anticipatable incidental findings, including but not limited to those findings known to be significant and clinically actionable (and, when relevant, analytically valid and clinically valid). The plan should be reviewed and approved by an institutional review board.**

Even with an IRB-approved plan for managing anticipatable incidental findings, researchers nevertheless might discover *unanticipatable* incidental findings. The unexpected nature of these findings makes it difficult to ascertain at the outset what responses might be required. Despite, and indeed because of, this uncertainty, researchers should have a process in place ahead of time to manage these unanticipatable incidental findings as well.

When researchers are uncertain whether an unanticipatable incidental finding might have clinical or reproductive significance, researchers should seek out qualified clinical or diagnostic experts for consultation. Consultation with subject matter experts can help researchers resolve uncertainty, determine the significance of the finding, and develop and implement an informed and appropriate response.

### **Recommendation 13**

---

**Researchers should develop a process for evaluating and managing unanticipatable findings. The plan should be reviewed and approved**



**by an institutional review board. During the informed consent process, researchers should notify participants about the possibility of unanticipated incidental findings, including lifesaving incidental findings, and the plan for their management. Researchers who discover an unanticipated incidental finding of concern should assess its significance, consulting with experts as appropriate.**

An incidental findings management plan should include specific information regarding the method of disclosure. Nonclinical researchers also might involve clinicians in discussions with participants about incidental findings.

The plan for managing incidental findings should also include a description of the research team's responsibilities following disclosure of such a finding. In some cases, researchers might provide basic educational information about the nature of the finding, advice regarding how to seek care from a clinician or specialist, or guidance about obtaining health insurance to secure treatment. If a clinical specialist is required, researchers should provide the participant with a referral when possible. Disclosure of an incidental finding, however, does not transform a research relationship into a clinical one.

#### No Duty to Look for Secondary Findings in Research

Researchers' obligations of beneficence raise questions about whether and to what extent they might have a duty to look for secondary findings. While some researchers have research funding to look for secondary findings, this will not be true for many of those conducting valuable research endeavors. Prioritizing a duty to look for secondary findings over the creation of generalizable knowledge has the potential to undermine the research enterprise.

#### Recommendation 14

---

**Researchers should consider carefully the decision to actively look for secondary findings. In certain circumstances, with approval from an institutional review board, researchers can justifiably adopt a plan that includes looking for selected clinically significant and actionable secondary findings. Approved plans should be disclosed to prospective participants during the informed consent process.**

Even without an ethical duty to actively look for secondary findings, researchers could, in some circumstances, justifiably adopt a plan to look for secondary findings. For example, a research team investigating the genetics of a particular community could decide—but would not be obligated—to implement the advice of a community advisory board that recommends looking for a particular variant if requested by a participant, even if the variant is outside the aims of the research. By acknowledging the community’s interest and simultaneously completing their research, researchers could advance both the public and individual components of beneficence. Also, while researchers do not have an affirmative duty to look for secondary findings, this does not dilute the importance of developing a plan for managing those that they find and of educating participants about the details of this plan.

### *Direct-to-Consumer Recommendations*

Members of the general public have increasingly gained access to medical tests and procedures outside of traditional clinical or research settings. Situated at the intersection of medicine and business, DTC companies offer the public additional mechanisms for obtaining health-related information. Thus far, the full breadth of DTC activities and their associated ethical considerations have been relatively underexplored in the literature.

#### Consent in the Direct-to-Consumer Context

DTC testing can offer individuals a means through which they can exercise self determination, including by providing increased access, reduced cost, or greater confidentiality of health information. But the benefits of DTC services are contingent upon the quality of the testing and analyses, and the informed and voluntary nature of the transaction. To enable consumers to make responsible and informed choices regarding DTC testing, consumers must be told what these procedures entail, including the possibility of incidental and secondary findings. Information provided before selecting a DTC procedure can assist consumers in deciding what services are worth pursuing.

### **Recommendation 15**

---

**Direct-to-consumer companies should provide consumers with sufficient information about their services to enable consumers to make informed decisions regarding purchasing their product. Companies should clearly**

**communicate the scope of procedures and the types of findings that the companies could or will discover and disclose, as well as any findings that they know in advance will not be disclosed.**

DTC companies must inform consumers considering their services about the procedures and results included in the commercial arrangement. Among the information needed by consumers is an understanding of the anticipatable incidental findings commonly associated with particular modalities and any secondary findings that will be deliberately sought. If certain results are not returned according to company policy or contractual agreement, this must be disclosed to consumers as well.

### Government Regulation in the Direct-to-Consumer Context

From air bags and seatbelts to the proper construction of cribs, the government has responsibility for ensuring the safety of certain products and services offered to consumers.<sup>24</sup> As a matter of policy, society has chosen to impose oversight to place legitimate limits on the principle of *caveat emptor* or “buyer beware.”<sup>25</sup> The primary goal of this oversight is to establish consumer protections—to ensure that companies make good on both explicit and implicit guarantees that the goods and services proffered are suitable for the purposes for which companies sell them.<sup>26</sup> Federal and state governments can also provide citizens with assurance that DTC companies are conducting business in a transparent and responsible manner.

### **Recommendation 16**

---

**Federal agencies should continue to evaluate regulatory oversight of direct-to-consumer health services to ensure safety and reliability. State governments should also adopt regulations that ensure a consistent floor of protections for consumers who purchase direct-to-consumer testing.**

Policy makers at the state and federal level should examine existing regulations governing DTC services to identify gaps in and barriers to ensuring the safety and reliability of DTC testing. Policy makers should consider adopting regulations governing disclosure of incidental and secondary findings. Policy makers at the state and federal level should remain mindful of the principle of regulatory parsimony, limiting restrictions on the ability to freely engage in commercial transactions only to the extent necessary to prevent serious harm.

### Industry-Wide Best Practices in the Direct-to-Consumer Context

The DTC market is relatively new and growing, and the technologies used are often still evolving. Given the diversity in the DTC industry, and the evolving practices employed by DTC companies, DTC companies are uniquely positioned to understand the nature of their own industry. This knowledge could enable DTC companies to develop best practices that are consistent with relevant ethical principles.<sup>27</sup> For example, DTC providers who discover clinically actionable incidental or secondary findings that have health implications could provide consumers with educational information about the nature of the finding, advice about how best to seek care from a clinician or specialist, or even a referral to a clinician who could assist in the management of the finding. If companies adopt voluntary best practices, such best practices could become standard expectations for consumers who choose to undergo DTC testing, giving other companies incentive to adopt and implement these practices, thereby leveling the playing field.

#### **Recommendation 17**

---

**Direct-to-consumer companies should aid in the creation of industry-wide best practices concerning the management of incidental and secondary findings. These best practices should include when and how such findings will be disclosed and standards for referral to necessary clinical services. Direct-to-consumer companies should make these “best practices” publicly available to encourage broader adoption.**

Voluntary industry-wide best practices can be developed by collaboration among companies and through professional organizations whose members work in the DTC industry. DTC companies should develop best practices regarding disclosure of incidental findings and when secondary findings should be deliberately sought, including the types of findings that ought to be disclosed and the methods for communicating these findings.

## CONCLUSION

Although the issue of incidental and secondary findings has been considered by several groups focused on concerns that are context- and modality-specific, the ethical obligations associated with the discovery, disclosure, and management of such findings have not been comprehensively considered across contexts and modalities. This report seeks to fill this void. In *Anticipate and Communicate*, the Bioethics Commission concludes that in any setting, potential recipients should be properly informed about the possibility of incidental or secondary findings before the start of a test or procedure. Practitioners should also recognize the potentially life-changing nature of certain incidental or secondary findings, and should take care to minimize harm when disclosing these findings. Practitioners and potential recipients benefit from empirical evidence about the likelihood of incidental and secondary findings arising from a particular test or procedure. And everyone—practitioners and recipients alike—can benefit from broader, more inclusive discussions about the ethical concerns, and associated practical and legal considerations, raised by incidental and secondary findings.