

Informed Consent and Genetic Information

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In the last 25 years writing in bioethics, particularly in medical ethics, has generally claimed that action is ethically acceptable only if it receives informed consent from those affected. However, informed consent provides only limited justification, and may provide even less as new information technologies are used to store and handle personal data, including personal genetic data. The central philosophical weakness of relying on informed consent procedures for ethical justification is that consent is a propositional attitude, so referentially opaque: consent is given to specific propositions describing limited aspects of a situation, and does not transfer even to closely related propositions. Assembling genetic data in databases creates additional difficulties for ethical justification. This is not because genetic information is intrinsically exceptional, but because the merger of genetic and information technologies make it possible to assemble massive quantities of complex information that defeat individuals' best efforts to grasp what is at stake, or to give or withhold informed consent. The future agenda for bioethics will need to take account of both these limitations of appeals to informed consent. © 2001 Elsevier Science Ltd. All rights reserved.

Keywords: Accountability; Data Protection; Genetic Data; Genetic Databases; Genetic Information; Genetic Tests; Information Technologies; Informed Consent; Propositional Attitudes; Reference Opacity; Trustworthy Institutions.

1. Introduction

In the mid 1970s a group of physicians and philosophers met in New York City under the auspices of the Society for Philosophy and Public Affairs to discuss ethical issues raised by the creation of genetically modified organisms: an exotic theme at the time. The topic and the ethical issues discussed were unfamiliar to everybody present. Towards the end of the evening, an elderly doctor remarked—with mild regret—that when he had been at medical school, medical ethics had been more manageable and had covered only referrals, confidentiality and billing. By contrast, we were talking about informed consent and the imposition of risk, about the rights of research subjects and of patients, about designer organisms and

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the implications of new technologies for human life and the natural environment. The themes that were so new that evening have been formative for medical ethics, and more widely for bioethics, across the subsequent quarter of a century.

I believe that this period of work may now be drawing to a close, and that we can expect rather different themes and philosophical issues to be central in future discussions, and that certain philosophical difficulties that these discussions have constantly shelved rather than resolved over recent years will now command more attention. The basic problem can be stated in simple terms. Bioethics, and more specifically medical ethics, has often viewed action and interventions as ethically acceptable only if they receive the informed consent of those to be affected.¹ Yet this demand will become less and less easy to satisfy if individuals are swamped with information so complex in content and in organisation that few people will be in a position to provide genuinely informed consent, or informed dissent. Yet this is happening in multiple ways.

These problems arise, I shall suggest, not because most members of the public have limited understanding of science, nor because most scientists are poor communicators, but rather because the matters to which consent is sought are more numerous and more complex, and sometimes rendered increasingly opaque by the very structures of accountability that are supposed to protect the public. Even those with a high level of scientific training and culture are challenged by the ways in which information is now organised. The answer to this problem cannot be to provide more information, more regulation and more fine print: there is often all too much information provided, and more fine print around than anyone has time to deal with.

My prime illustration of changes that are now bringing this problem to a head will be the incipient uses of personal genetic data in medical and other practices, and the possibility of presenting, manipulating and using ever larger arrays of genetic data. However, this is only an illustration: many other changes, including the spread of high-tech medicine and the emergence of evidence-based medicine, raise analogous problems for current reliance on informed consent procedures.

2. Informed Consent in Bioethics

Since 1975 work in bioethics has had two principal but distinct foci: medical ethics and environmental ethics. The topics and problems in these two areas have been largely separate, and the underlying ethical and philosophical issues that have seemed most important to those writing on them have often differed.

In medical ethics much time and effort has gone into articulating and advancing a certain conception of respect for persons, and hence for patients, which centres

¹There is of course much more disagreement as to whether informed consent is ever sufficient for ethical justification: some libertarians think that it is, but most others assume or argue only that it is necessary.

on ensuring that nothing is done to persons without their consent. *Informed consent* has been seen as the key ethical requirement for medical treatment and research, to be supported by requirements for *professional confidentiality* and for *personal privacy*. Securing the informed consent of patients and respecting the confidentiality of information they provide have been seen as operationalising the ethical ideals of respecting individuals, their rights and their autonomy.² Medical practice has moved some way from paternalistic traditions that saw professionals as the proper judges of patients' best interests, and some way towards practices which acknowledge patients' capacities to make their own decisions.

The central concerns of environmental ethics have of course been rather different, in that concern for the non-human world cannot be translated into a requirement that animals or plants provide informed consent to the ways in which they are treated. When environmental ethicists claim that the natural world, or some part of it, is owed respect and concern, they do not mean to say that the natural world or its parts are agents, whose autonomy is to be fostered, or whose informed consent to activities by which they are affected should be sought. Their aim is rather to detach notions such as respect and concern from their historic association with conceptions of the person, of autonomy and of informed consent. However, even in environmental ethics discussion of informed consent has played large role. In particular, the ethical acceptability of inflicting unconsented-to risks on others (for example by environmental pollution) has been a constant theme in discussions of risk.

3. Philosophical Sticking Points

I believe that discussions of informed consent have persistently overlooked and so failed to resolve some basic philosophical problems. In making so blunt a statement I may well be shown wrong. I offer some reasons for holding this view.

Those ethical debates that argue for respect for agency (persons, autonomy, individuals) distinguish between treatment that is appropriate for agents and treatment that is appropriate for (various sorts of) beings that are not agents. In trying to spell out (some version of) the idea that agents are owed a distinctive sort of respect, and are not to be (mis)treated as mere things, many writers have deployed versions of the well known idea that respect for agents and persons requires that nothing be done to them without their consent. The traditional rationale for this thought is that where consent is forthcoming, nobody's status as agent is overridden: in consenting to the ways in which others treat us, we authorise such action, so are not injured by it.

²Among the most influential works insisting on the importance of autonomy for bioethics is Beauchamp and Childress (1989, 1994). For a more sociological view see Wolpe (1998). Although interpretations of autonomy have varied, most writers have identified it with independent choosing, and almost none has been interested in the Kantian conception of autonomy that grounds it not merely in free but specifically in reasoned choice.

This thought is promising only if it can be linked to a convincing distinction between genuine consent that legitimates the action or intervention to which consent is given, and spurious formulae or fragments of consent that do not legitimate. There is formulaic agreement that legitimating consent must be based on the *right sort of cognition* and the *right sort of choice*: legitimating consent is ‘fully’ informed and free. Consent that is uninformed (for example, based on ignorance or deception) does not legitimate; consent that is not free (for example, based on duress or manipulation) does not legitimate. Without informed consent, the treatment of a particular patient or research subject will amount to assault, or at least to unwarranted violation of privacy. Without informed consent by patients, hospitalisation might amount to forced detention. Without informed consent by individuals, doctors who disclosed information about them to insurers or employers or other third parties would breach confidentiality and show lack of respect. It is little wonder that so much work in medical ethics has been concerned with clarifying the notion of informed consent, and with the difficult but numerous issues that arise when some individuals are temporarily or permanently unable to give consent.

However, the difficulty of establishing a satisfactory account of informed consent is, I believe, much deeper than most writing on the subject suggests. Much of the literature concentrates on the ‘hard cases’ that arise when ordinary cognitive and decision-making capacities are undeveloped or impaired, and informed consent is therefore hard or impossible. This focus misleadingly suggests that in standard cases, when persons are ‘in the maturity of their faculties’, appeals to consent will provide a clear demarcation between legitimate medical or other interventions and action that would be wrong and unacceptable. Unfortunately I do not believe that we have an account of informed consent that is robust enough to work well in the standard case where individuals ‘in the maturity of their faculties’ give consent.

Consent is a *propositional attitude*: it is always directed to some description of a proposal, situation or action. Its object is always some specific *propositional content*. Where a proposition consented to misdescribes a proposed action, or is economical with the truth, consent may be misdirected and so will not legitimate. This is all too common. Even when consent is well directed to propositional content that is true of a situation (as far as can be judged), and is not economical with the truth, that consent will not automatically transfer to other closely related propositions. In particular, consent will not transfer, and may not be given, to the logical implications, the causal consequences or the more specific aspects of a proposal, situation or action towards which consent has been accurately directed. The ethical implications of the *referential opacity of propositional attitudes* are massive. We generally consent in the required, informed and freely chosen way to rather little: so rather little can be legitimated by appeal to consent.³

A well known—and still quite popular—rejoinder is that where informed consent

³For the classic discussion see Quine (1953).

fails, there may still be some form of tacit or implied consent, which can legitimate. The danger of this line of argument is that it is too capacious: if taken seriously it may suggest that there is consent to everything to which an agent does not explicitly and actively dissent. Yet there are lots of reasons for suspecting that countless aspects of failure to protest or to dissent actively are not evidence of any sort of consent. Inaction may be evidence of failure to notice or understand what is going on; acquiescence may reflect mere idleness or adaptive preferences, mere cynicism or frightened awareness that dissent has costs. Bernard Williams was surely right when he suggested that in ethics we should not place too much weight on the fragile structure of the voluntary;⁴ *a fortiori* we should not place too much weight on the yet more fragile structure of informed consent inferred from silence and inactivity.

Countless examples reveal the limits of consent. I may consent to a diagnostic genetic test, but if I have not been told or not understood the implications of receiving a 'positive' result, I will not have consented to receiving the bad news.⁵ I may consent to an operation, yet for whatever reason not see its consequences—even its likely consequences—as something to which I have consented. I may go along with proposals for treatment and care that strike me as far from desirable because I am too weary or despairing or unconfident to do otherwise, or because I falsely believe that there are no other options or that I have to do what my doctor appears to want.⁶

Consent is particularly problematical in medical practice, because it is commonplace even for patients who are in the maturity of their faculties to find themselves at a time of weakness and distress surrounded by others who seem (and may be) more knowledgeable, whose influence and power are considerable, whom they very much do not want to offend. If consent is to be a governing principle in medical ethics, we seemingly need to be ideal rational patients; but when we are patients we are often furthest from being ideally rational (this can be true even of patients who intimidate their doctors with medical information acquired from the internet).

Considerations such as these—they could be exemplified in many ways—might be thought to suggest that environmental ethics is on firmer philosophical ground than medical ethics, precisely because it does *not* centre on notions of agency, personhood or autonomy, because it does *not* assume away ignorance or vulnerability, because it does *not* presuppose demanding cognitive or decision-making

⁴See Williams (1985).

⁵The problem can be addressed only in part by providing, even requiring, extensive prior genetic counseling for those offered DNA tests whose results may be particularly difficult. Such requirements would prove hard to maintain in a world in which DNA testing becomes more commonplace and is available without medical supervision (for example, via e-commerce).

⁶For these and further reasons many legal and philosophical accounts of consent view it as a *defeasible* notion, that is to say as a propositional attitude whose ascription may be defeated by any number of different circumstances. It is not possible to state necessary and sufficient conditions for some putative act of consent to be adequate and so to legitimate the action at which it is ostensibly directed; indefinitely numerous conditions may undermine the ascription of consent.

capacities or strenuous conceptions of informed consent, in short because it does **not** rest too much on the fragile structure of the voluntary.

However, ethical reasoning will also fail if it does not engage with a conception of human agency. Ethical arguments, including the arguments of environmental ethics, require an audience who can listen to, understand, accept or reject those claims, and who can choose to act on or flout prescriptions, to endorse or reject recommendations. Whether we think that the fundamental concepts of ethics are those of duty and rights, or those of virtue and vice, we see ethical conclusions as having some normative weight, and as necessarily addressed to agents. Those who criticise and argue against speciesism do not, when one considers their claims with care, deny the importance of agents—although they often fail to say much about agency—nor in all likelihood do they deny the thought that natural agents are to be found wholly or largely among the members of one (human) species. What they deny is that the members of that species should be the sole objects of ethical concern. Anti-speciesism is about non-humans sharing (some of) the claims to welfare and to certain rights of humans; not about them sharing the obligations or virtues of humans. Ethical reasoning—indeed all practical reasoning which does not presuppose that some beings are agents with at least some capacities to understand and to choose, who might at least sometimes give or withhold at least some sorts of informed consent, who might act on its recommendations and prescriptions—will lack audience, influence and point.⁷

Writing in medical ethics may have laid too much weight on human capacities for agency and for practical reasoning, and writing in environmental ethics too little stress on the need for such capacities. But writing in both areas has failed to link accounts of the importance of informed consent to realistic views of agents' actual capacities.

4. Vulnerable Agents and Excess Information

If agency is an indispensable presupposition of serious bioethics and of a proper account of informed consent, closer attention to the capacities of agents, and of the ways in which they can be undermined not only by explicit deceit and duress but by a myriad subtler ways of deflecting and manipulating cognition and choice, will be needed. Yet this sensible aim is elusive. Changes in the nature of the medical information that patients (and others) are asked to grasp and in the ways in which medicine is regulated have escalated the difficulty of securing informed consent. We are faced (and will increasingly be faced) with activities and practices where the amount and complexity of information relevant to many routine decisions exceeds the capacities of human agents, causing problems for any approach to

⁷See Singer (1976), Singer and Cavalieri (1993), Hayward (1997) and O'Neill (1997).

medical ethics which makes informed consent a criterion of permissible action and intervention.

If I am right in this surmise, we are likely to face a deep tension between the limits of available human capacities and the sorts of choices about policies and cases that will actually arise and require justification or rejection. We remain finite, ignorant and vulnerable agents with limited cognitive capacities, limited abilities to choose and limited time: but in medical contexts we face, and will increasingly face, vastly complex ranges of information, organised in the increasingly formalised ways demanded by increasingly intricately structured regulatory processes. Nowhere is this more evident than in those parts of medicine and of life which are most affected by the increasingly complexity and availability of genetic data, and by the increasing variety of ways in which such knowledge may be collected, stored, used and disclosed.

5. Contexts of Consent

A very selective *tour d'horizon* suggests some reasons why the contexts in which consent or dissent might be sought or given are changing in ways that may stretch, strain and perhaps overwhelm individuals' capacities to give informed consent—or dissent.

The requirements for consent to uses of genetic data provide a particularly revealing example of these changes—but not, I think, the only example. Human capacities to consent and dissent are also being stretched, strained and perhaps sometimes overwhelmed by developments that arise not only from the combined revolutions in genetics and informatics, but by other developments within medicine which bring together hugely complex arrays of information and intricate regulatory systems. In the background of all these developments lie profound changes in medical practice; in the foreground there are profound technological changes in the management of information, and specifically of genetic information, and the development of data protection regimes to deal with these complexities.

The changes in medical practice are by now pervasive and well known. Yet much discussion of patient autonomy and informed consent in bioethics—in contrast to some work in the anthropology and sociology of medicine—still proceeds as if the context of informed consent to medical treatment were what is sometimes cosily referred to as 'the doctor-patient relationship'. The model that is assumed, or at least prized, is of a one-to-one relationship between two individuals, the professional and the patient, within which trusting disclosure of information takes place and standards of professional conduct obtain. Doctor and patient show mutual respect; each provides reliable information to the other; the doctor treats the patient's information as confidential; medical decisions are made by the patient on the basis of reliable and comprehensible information supplied by the trusted doctor. In this context the patient's informed consent provides a reasonably plausible indi-

cator that he or she has been treated with respect, and that the decisions made are autonomous decisions.

However, this model of medical decision-making is obsolete in many forms of medical practice. Complex medical treatment now takes place in hospitals; many professionals have access to patients and their complex records; patients often feel that they are bit-players in crowd scenes. Yet, the relationship is also not best seen as a one-many, patient-professionals relationship. As sociologists of medicine have long pointed out, patients do not (on the whole) appear in splendid isolation: they come equipped with family and friends, dependants and employers, whose ignorance and information, whose enthusiasms and resistance, competence and incompetence, may influence decisions about medical treatment and reproduction.

We have left behind a world of I-thou doctor-patient relationships, and now inhabit one in which the individual patient and the individual doctor draw many others into complex forms of connection. In medicine, as in many other parts of life, we constantly deal with many-many relationships. Nowhere are the implications of this basic and uncontroversial fact about contemporary medical practice stronger than in those parts of life in which genetic data are collected, stored, used and disclosed. However, before turning to the ways in which the management of medical information has been reshaped by technological innovations, it is useful to ask whether there are any more basic peculiarities of genetic information that affect these issues.

6. Is Genetic Information Exceptional?

Genetic information is sometimes characterised as exceptional, and as unlike other medical or personal information. If so, it is urged, it will need distinctive sorts of informed consent. Although this claim does not seem to me to be wholly convincing, it is worth taking seriously.

In speaking of *genetic information*, I set aside discussion of *genetic knowledge* considered in the abstract, such as knowledge claims about the nature and effects of genetic variation, about the respective contributions of genes and environment to specific outcomes or conditions and about the clinical effects of specific genetic variations. The scientific and medical claims that constitute (or aspire to constitute) genetic knowledge are often spoken of as *genetic information*, and metaphors taken from informatics and communication pervade discussions of genetics. We commonly speak of *the genetic code* and of *genetic blueprints* for the construction of organisms. These metaphors drawn from discourses of communication and representation may be misleading in certain ways; but that is not my concern here.

The genetic information at which informed consent is supposed to be directed comprises not genetic knowledge considered in the abstract, but *genetic data that pertain to identifiable persons*, which may be collected, stored or used. Genetic data are personal data; genetic knowledge is impersonal. We currently seek to regulate the acquisition, holding and disclosure of personal information by numer-

ous codes, data protection requirements and professional practices that incorporate requirements for informed consent.

Indeed, at present genetic information about individuals is commonly viewed not just as *personal*, but specifically as *medical* information. It is usually collected by doctors in medical settings, often for medical or reproductive purposes, and is stored, used and disclosed in conformity with professional standards and legal requirements that apply to other medical information. However, genetic information is an unsettling, and in some ways untypical, instance of medical information. We often think of medical information as *intimate* rather than *publicly available*, as *current* rather than *predictive*, and as *individual* rather than *shared by some group*. Perhaps genetic information is distinctive in these or other respects, and should not be viewed as medical information, or even regulated by the standards applied to medical information.

There is some truth to the claims that genetic information is not always intimate, that it does not always have relevance to current conditions, and that it is not individual. First, much loosely genetic information is far from intimate, simply by the fact that those to whom it pertains cannot and do not avoid making it openly and publicly available. Skin colour, height and scores of other genetically based characteristics are simply and obviously visible in daily life, and may even be proudly displayed. Our new focus on the sorts of genetic data provided by DNA tests should not obscure the reality that we all display a great deal of loosely genetic information at all times. While some sorts of genetic information are closely linked to medical and family history information, and so fall within standard understandings of medical information, much genetic information is neither intrinsically intimate nor intrinsically medical.⁸

Secondly, DNA and certain other tests have made it possible to acquire information that pertains not to current but to future medical conditions. Genetic tests may, for example, disclose the presence or absence of genetic variations for which there is currently no other evidence, and provide evidence—sometimes very strong evidence—of susceptibility to specific late-onset disorders, or for carrier status, or for the health prospects of future children. The information that is disclosed by or can be inferred from such test results may be difficult in two familiar senses—intellectually difficult to grasp, and emotionally difficult to accept. However, other categories of personal or medical information also have implications for far future health and for the health of future children, and are also difficult in both senses. Smoking, obesity and exposure to asbestos dust have well known long-term health implications; ‘positive’ HIV test results have well known implications for future children and constitute excruciatingly difficult information.

Thirdly, and perhaps most interestingly, the information provided by genetic

⁸This suggests that appeals to ‘genetic privacy’ will be of scant help in these debates; they point to a problem, not a solution.

tests is intrinsically not just individual but familial. By the nature of the case, genetic information pertains not just to an individual but also to his or her ‘blood’ relatives. It is therefore unsurprising that treating genetic information as *straightforwardly individual* produces some strikingly unsettling results. Consider somebody with an identical twin who discovers a genetic characteristic that the twin shares but knows nothing about, or a young person who has a positive Huntington’s test, thereby establishing that a still asymptomatic parent will have the condition. In these cases obtaining information may have been handled as a strictly individual decision, subject only to individual consent, but the decision has given one individual knowledge of the genetic make-up of another who has not sought it and has not consented to being tested, indeed who may have chosen not to seek the information. Yet even here there are analogous cases outside genetics: HIV status and shared exposure to pathogens create shared medical problems—although not in this case problems that are shared only with ‘blood’ relatives.

Clearly these three features of genetic data, and particularly the third, put pressure on the idea that obtaining informed consent from one individual provides the central justification for seeking or using such data. Some commentators have tried to deal with the reality that genetic information is not wholly individual by arguing that relatives should have a right to a say in deciding whether the information should be collected or stored or used, or to whom it should be disclosed, or perhaps even a right to insist that it be sought or not. Alternatively one might argue that related individuals have a conditional right to insist that *if* genetic information pertaining to them is acquired it also be imparted, or not imparted, to them. However, familial versions of informed consent could not be instituted without obstructing individuals who for medical or other reasons seek information about their own genetic status, yet lack familial consent to do so.⁹

The fact that genetic information is not solely individual also bears on practices in reproductive medicine, including paternity testing and the use of new reproductive technologies. It used to be said that motherhood was a matter of knowledge and fatherhood a matter of opinion. That age-old bit of cynicism is now simply false: paternity and non-paternity can be a matter of knowledge (except where the putative father has an identical twin). Moreover, acquiring genetic information in order to determine paternity and non-paternity is no longer fully controlled or controllable by the individuals most affected. Already state agencies may require DNA tests to settle disputes about child support, or about eligibility for immigration.¹⁰

⁹Some UK patient groups for serious single-gene diseases are keen to view genetic information as belonging to families—yet although in the UK individuals are urged to share information with relatives ‘if appropriate’, they are not legally required either to seek relatives’ permission to obtain information that is relevant to those relatives, or to share information they have obtained, or on the other hand to keep information they have obtained to themselves. Genetic information is thereby viewed as quasi-individual. See Nuffield Council on Bioethics (1993) and Advisory Committee on Genetic Testing (1997).

¹⁰In the UK DNA tests may be required by the Child Support Agency to settle who should pay child support for a particular child.

We will no doubt soon read about a busy-body who seeks to determine the paternity of an unrelated child by acquiring saliva samples and arranging for DNA testing, to which no (putative) parent has consented. Genetic information that settles disputes about paternity may be emotional and economic dynamite for families: relationships to parent, partner or child may be transformed, even destroyed, by acquiring or disclosing information that challenges assumptions on which a family have based their lives.

Despite these suggestive examples, it is clear that genetic data are not wholly different from other data collected for medical purposes. However, this is because much other medical and personal information is also public rather than intimate (my cough and my limp are there for all to hear or see), also relevant to future and not only to current health (my obesity or my smoking may affect my far future) and also often shared rather than strictly pertaining to a single individual. Yet even if 'genetic exceptionalism' is false as a *general* claim about the distinctiveness of genetic data, these data provide a particularly rich and challenging example of the real problems for any approach to bioethics that lays great weight on individual informed consent. Some of the new uses of these data are indeed exceptional.

7. Informatics and Genetics

The second respect in which the collection and use of medical, and in particular genetic, information have changed is driven not only by developments in medical practice but by changes in information technology. We face a future in which the scientific knowledge provided by the human genome project is likely to be integrated into a technology of genetic testing, in which multi-testing may become technically routine and cheap, and in which the storage and handling of very large amounts of genetic data about individuals may be feasible, cheap and useful. As these technologies are introduced, obtaining data not only about the presence or absence of a specific genetic variation in some individual but about individual genetic profiles would become a realistic possibility. Such assemblage, storage and use of large arrays of genetic data is a striking example of the new technical possibilities for collecting and holding large arrays of varied types of personal, including medical, data.¹¹

The collection of large arrays of personal data is not peculiar to genetics. Medical practice is already based on holding patient information in electronic form, a practice that has greatly enlarged the number of persons who can have access to confidential information about a given individual. It is said that in an average British NHS hospital 52 people have legitimate access to a patient's file. The figure is unlikely to be particularly accurate: but it at least dramatises the problem. Some

¹¹Multiple sorts of information can of course be linked in one data bank. For example, health, genetic and genealogical data are linked in the Icelandic *DeCode* project.

doctors now consciously do not record certain sorts of sensitive information in what they (rightly) no longer view as genuinely confidential files. It already is proving hard to sustain traditional conceptions of the confidential collection, storage, use and disclosure of genetic and medical data in the real context of ordinary medical practice, which is now so profoundly different from any cosy one-to-one doctor-patient relationship. So far the standard response to problems that arise for individual patients who are called upon to give informed consent to proposals to obtain, store and use massive amounts of complex information has been to create more elaborate institutional safeguards. Yet for individuals this institutional complexity may make it harder rather than easier to provide informed consent, since consent would have to be directed not only to the data to be obtained and stored and to their future uses, but to the institutional structures and safeguards under which the data are to be held.

These changes will be even more striking if pharmacogenetics develops in the ways in which its proponents hope. Already leaders of the pharmaceutical industry speak of a future in which cheap multi-testing makes it possible to hold very extensive data about each individual's genetic make-up, with the hoped-for benefit that more precisely targeted drugs could be developed and prescribed. If this future became the basis for medical practice, comprehensive genetic testing of individuals would become routine; large arrays of genetic data would be held for each individual; genetically targeted pharmaceuticals would reduce inappropriate prescription and (supposedly) lower drug costs; some drugs presently banned because they produce harm for a minority of patients might be used for others whom they would benefit. Analogous revolutionary prospects are held out for the forensic use of genetic databases, with the thought that suspects could be quickly and reliably cleared or charged if databases of individual genetic profiles were built up.

In a world within which genetic data were held for these and related purposes, with safeguards appropriate to the various purposes, any claim that informed consent by individual patients could provide the key to acceptable action would I think prove radically implausible. Genetic information on this scale would be held on a smart card or in a central database. Any hope that such information was private would have to depend less on professional codes governing the action of individual doctors and more on intricate regimes of data protection. Any thought that individuals could determine how such information should be held and used would prove implausible if the complexity of the information exceeded what individuals can grasp or interpret. Any thought that individuals could understand their genetic profiles and decide just which data they would disclose to which others or for which uses looks implausibly demanding. Yet any thought that such information would be so unimportant to the world at large that no control on its use or dissemination is needed wilts in the face of the facts. Medical data, and in particular genetic data, are of value not only to individuals and their families, and to those who provide their medical treatment, but to varied third

parties. For example, insurers,¹² employers¹³ and the police¹⁴ are all likely to view such information as valuable, and differing data protection regimes might prove important for each of these and for many other uses.

8. Trustworthy Institutions and Informed Consent

From the point of view of individuals who are working out whether to give or withhold informed consent, complex regulatory systems can look more like another hurdle than a safeguard. The difficulties will grow as genetic data become more and more readily available, and as the construction of electronic databases combining genetic, medical and other information becomes more and more feasible. Individuals could not be expected to develop an adequate grasp of their own genetic information, or to give any but the most general—that is, minimally informed—consent to the collection, storage, uses or disclosure of parts of that information. It will take determination and discrimination to find realistic ways to secure genuine, legitimating informed consent in the face of these developments.

One suggested way forward might be to think of informed consent as having two quite distinct stages. We may have increasingly to distinguish seeking *public consent to systems* for collecting, storing, using and disclosing data from seeking (a necessarily limited degree of) *individual consent to particular acts* of collecting, storing, using or disclosing data about individuals.¹⁵ Individuals cannot be expected to perform heroic, indeed impossible, cognitive feats of consent and dissent, and yet consent achieved by overwhelming an agent's cognitive capacities provides no genuine justification. However, if it could be shown to be acceptable to seek forms of public legitimation for systems of using personal data, then the demands placed on individual consent procedures might be reduced. The construction of background institutions that secure decent standards in medical and scientific practice

¹²The likelihood that medical and specifically genetic information might be so used by insurers has been made quite clear in debates about a supposed 'right to underwrite', that is to use all and any information with actuarial implications as a basis for setting premiums. Even outside the US, in parts of the world where commercial medical practice is uncommon, insurers are keen to insist that they have a right to the disclosure of any pertinent genetic information in setting life insurance premiums. For the UK debate see Association of British Insurers (1997) and Human Genetics Advisory Commission (1997).

¹³At present there is very little use of genetic testing by employers in the UK, although the Ministry of Defence tests military aircrew for sickle cell trait. With the validation of more DNA tests and lower costs, employers could have more reason to use genetic tests, including multi-tests, with the hope of screening out employees who would have foreseeably raised risks of ill health. On the other hand, both employers and employees might have reason for employees to take tests that could identify rare susceptibilities to be harmed by minimal exposure to substances that are without implications for most people and cannot be effectively eliminated from the work place. For discussion see *The Implications of Genetic Testing for Employment* (Human Genetics Advisory Commission, 1999).

¹⁴Home Office consultation, July 1999.

¹⁵A two-stage consent process of this sort was used for the Icelandic *DeCode* project; there has been criticism of the way in which the first, public stage was conducted.

might be used to frame and provide a warrant for the particular procedures for which individual consent was sought. Requests for 'consent' that lack a trustworthy background—for example, requests to 'choose' among incomprehensible options, or to evaluate proposals whose structure is wholly opaque, or to fill in relentlessly detailed forms—may be ethically bogus and legitimate nothing.

The construction of *trustworthy institutions* is a vast task. It is obstructed rather than implemented by fantasies that individuals can provide informed consent to options of great complexity, and by assumptions that the improved regulation will by itself guarantee trust. Trustworthy institutions need not dictate the details, but they must provide accessible reasons for individuals to rely on institutions and the practices they permit. Any realistic, ethically acceptable and politically feasible approach to building trustworthy institutions and practices would have to make sure that individuals were presented with assessable propositions for their consent or dissent. It would have to offer individuals simple and realistic ways of checking that what they consent to is indeed what happens, and that what they do not consent to does not happen. Its proponents would have to accept that the burden of proof for the ethical acceptability of a data protection system is neither that some professionals can convince one another that it is effective, nor merely that popular support has been expressed, but that it provides a way for those who consent to the use of genetic data they provide can call those in charge of data to account. This is genuinely difficult. It cannot be done by proliferating small print, which few people have the time and specialist knowledge to read, understand or dissect; nor by setting up systems of reporting or questioning that are not feasible for individuals to use.

These considerations can be summarised in two necessarily gestural conclusions. The first is that bioethical debate will have to become more political, and to take fuller cognisance of the realities of the contemporary world, its technologies and its institutional possibilities. Otherwise no adequate account can be taken either of the implications of the prospective availability of so much genetic information, or of increased capacity to collect, store, transmit and disseminate personal genetic data, or of the ethical fragility of individualistic conceptions of informed consent unsupported by trustworthy institutions.

My second conclusion is that trustworthy institutions will have to incorporate user-friendly ways by which individuals can check whether what is done to the data they consent to make available accords both with publicly agreed systems of data protection and with the content of the consent they have given. Checking procedures need to be ready to hand and easily useable, although they will rarely be used if they successfully create trust. To achieve this is no easy matter: we are all too aware that 'the audit society' has created a plethora of onerous requirements in the name of securing accountability and yet that mistrust has grown almost as fast as structures of accountability. Trust is not achieved by constant official examination, monitoring, appraisal, assessment, audit or investigation, but by

secure knowledge that there are feasible procedures by which individuals can check on what is done.¹⁶

The philosophical and practical agenda that arises from these requirements is, I believe, very large. We shall need to develop more plausible views of agency that fit the complex information culture that is coming into existence. We shall need a better account of the agency of collectivities, including regulatory bodies, and of the responsibilities that are and are not assignable to such institutions. We shall need to take a more systematic view of the conflicts of interest between individuals and the bodies that are interested in genetic data, acknowledging not only the interests of businesses and bureaucracies but also the sometimes less well recognised interests of professions and campaigning groups, who may prefer to think of themselves as selfless. We shall need to scale our demands for individual informed consent to less exorbitant views of human cognition and human choosing, and less absurd views of the time available to ordinary people.

Acknowledgements—A preliminary version of this paper was presented as the Greenwall Lecture to the American Society for Bioethics and Humanities in October 1999. I am grateful for useful comments from many participants, and in particular to Thomas Murray for sharpening my views on genetic exceptionalism.

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