

## Causes for Concern and Causes of Action: A Comment on “Pushing Drugs”

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### I. INTRODUCTION

In response to Professor Feldman’s stimulating presentation, *Pushing Drugs: Genomics and Genetics, the Pharmaceutical Industry, and the Law of Negligence*, I have three short comments. In each case, my comments betray a distinctly Anglo-European perspective; and, in each case, they are largely aimed rather modestly at clarification. Let me express my starting point in the form of three sets of questions. First, how are we to understand the concept of “markufacturing” and what is its relevance as pharmacogenetics and its commercial partner pharmacogenomics gather pace?<sup>1</sup> Second, why might the practice of markufacturing represent a cause for concern and, in particular, might Europeans see it as yet another threat to human dignity? Third, if markufacturing is a cause for concern, how far might we need to re-engineer tortious causes of action to cover our concerns?

### II. MARKETS, MARKUFACTURING, AND PHARMACOGENOMICS

Professor Feldman’s starting point is that pharmaceutical companies are now under tremendous pressure to develop the next generation of major drug products. Patents do not last forever; a good portion of patent protection is already mortgaged to finance investment in research and development; the majority of drugs entered for clinical trial fail to get beyond this stage; and, without new products, patents cannot be replenished. Patents and newly developed products thus form a virtuous (vicious?) circle. On both sides of the Atlantic, this scenario rings true. However, the development that Professor Feldman predicts (or, should I say, already observes), namely an increase in the practice of product “markufacturing” is less familiar — or, at any rate, the term of designation that she employs is not a famil-

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1. By “pharmacogenetics,,” I mean the science of understanding how and why the genetic make-up of an individual influences his or her response to particular drugs. By “pharmacogenomics,,” I mean the commercial exploitation of this science and its technology (particularly in the form of tailored drug development). Since this response is largely concerned with the commercial activities of the pharmaceutical industry, from here on, I will simply use the term “pharmacogenomics.”

iar one. To get a handle on the idea of markufacturing, we need to go back to market basics.

It is trite that a market will be moribund unless there is both supply-side and (correlative) demand-side activity. However, a market can be *initiated* on either the supply side or the demand side. In other words, a supplier may speculatively offer goods or services for which it turns out there is a demand; or a demand for goods or services may be articulated, to which a supplier then responds.

As I understand Professor Feldman, what is distinctive about markufacturing is not simply that the market is supply-side initiated but that the supplier also, in effect, constructs the demand side of the market. In principle, we can imagine a spectrum of supply-side activity in relation to the construction of the demand side. At one extreme, the supplier simply puts the product into circulation and hopes that there will be a spontaneous interaction between product and demand-side interest of the kind that is required for the creation of a market.

Some way in from this extreme, the supplier leaves less to chance, informing potential purchasers about the existence and the positive features of the particular product (for example, the advantages of audio-visual digital products over their pre-digital predecessors) and ensuring that, if there is a potential demand, it connects with the product to make a market.

As we move further along this spectrum, marketing and advertising are intensified until we reach the markufacturing extreme, at which point the supplier manufactures both the product to be supplied and the demand-side need. When a product is markufactured, the supplier creates a culture around the product which convinces target purchasers that this is a product they need and must have. Putting the matter in the bluntest of terms, the markufacturing strategy of a pharmaceutical supplier is, first, to market the disease and then to promote the disease-responsive drug.

If we place markufacturing in the context of pharmacogenomics, we can anticipate that the marketing of tailored drug products will add a highly personalised gloss to the culture of need created by suppliers. In other words, markufacturers will generate two mutually supportive messages: targets on the demand side will be persuaded not only that they have certain needs, but also that some particular product is right for them — a case, as it were, of “*you need this*” and “*you need this.*”

On this side of the Atlantic, in a recent report on behavioural genetics,<sup>2</sup> the Nuffield Council on Bioethics picks up on the demand-

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2. NUFFIELD COUNCIL ON BIOETHICS, GENETICS AND HUMAN BEHAVIOUR: THE ETHICAL CONTEXT (2002) [hereinafter NUFFIELD COUNCIL].

side aspects of markufacturing (without using this terminology) by highlighting the phenomenon of so-called “diagnostic spread.” By this, the Council means that there is a tendency to medicalise conditions that, hitherto, have been regarded as lying within the normal range of human behaviour — for example, as the Council remarks, “the producers of new ‘anti-shyness’ drugs, such as Paxil and Luvox, have been accused of applying to normal behaviour, interventions developed for pathological traits.”<sup>3</sup> What is more, individuals who think that they might have General Anxiety Disorder or Social Anxiety Disorder can take an online self-test which sets a suitably low threshold for professional advice to be recommended. The ingredients of this cautionary tale are replicated by the move to promote impotence drugs, such as Viagra, as a response to female sexual anxieties (or, as the drug companies wish to characterise it, the newly recognised medical condition of “female sexual dysfunction”).<sup>4</sup> In both cases, before you can say, “Please write me a prescription,” we find that once normal anxieties are re-classified as pathological and, with the backing of commercial and social pressure, medical intervention is advised.

If we disaggregate markufacturing, and if we look away from the specific case of pharmaceuticals, we might think that Professor Feldman, having coined a new term for dominant supply-side activity in the consumer marketplace, is over-reacting. After all, in the larger consumer marketplace, something very similar to markufacturing has been with us for some time, has it not?<sup>5</sup> As the television-focused consumer society gathered momentum, was it not markufacturing suppliers who oiled the wheels by cultivating consumer need for a range of goods — from white goods (dishwashers, freezers, and the like) through to cosmetics and motor cars? Arguably, some of these markufactured products were inessential; and, beyond any reasonable doubt, some products, such as tobacco and alcohol, had serious adverse effects. Moreover, as we cross the millennium, the revolution in information technology allows for the collection of data about purchasing patterns which then facilitate extremely targeted marketing. Nevertheless, markufacturing (by definition) involves an intensity of supply-side activity that fully justifies taking a hard look at what might go wrong on the constructed demand side, particularly so where we are dealing with the markufacturing of pharmaceuticals; for, not only might pharmaceutical suppliers be trading on a degree of trust (which they might be abusing by markufacturing their products),

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3. *Id.* at 137.

4. See Sarah Boseley, *Drug Firms ‘Invented’ Female Sexual Problem*, *GUARDIAN*, Jan. 3, 2003, at 8.

5. Indeed, in the written version of her paper, Professor Feldman confirms that pharmaceutical companies are now behaving like other makers of consumer goods.

but also, if the product has adverse effects (as many drug products do), we can be looking at very significant harm to the consumer.

Where manufacturing has injurious side-effects, Professor Feldman's thesis is that the supply-side provider/manufacturer (the manufacturer) must assume special responsibility for the harms arising from the market. Why should this be so? Quite simply, I take it, the thinking is that manufacturers should be fixed with this legal responsibility because such harms are no longer the product of a two-sided interaction; they are built into the market by its supply-side creators; so far as manufacturers are concerned, the hazards that they generate are all their own work. Just as producers who put dangerous products into circulation are held legally responsible for the harm caused by their products, manufacturers who create dangerous markets must answer for the consequences of their sales strategy. If we are not to prohibit manufacturing, we get to the challenge presented by Professor Feldman: namely, is the tort system positioned to hold manufacturers fully to account in light of the special responsibility that, as she would argue, they have?

### III. CAUSES FOR CONCERN

It falls to the relatively infant discipline of bioethics to evaluate proposed applications of new developments in human genetics. Until fairly recently, bioethics has amounted to something of a dialogue between utilitarian and human rights perspectives. So, for example, Baroness Mary Warnock, speaking some ten years ago, at a symposium on the challenges (both ethical and legal) presented by the rapid developments in modern genetics, summarised our options in the following way:

Technology has made all kinds of things possible that were impossible, or unimaginable in an earlier age. Ought all these things to be carried into practice? This is the most general ethical question to be asked about genetic engineering, whether of plants, animals or humans. The question may itself take two forms: in the first place, we may ask whether the benefits promised by the practice are outweighed by its possible harms. This is an ethical question posed in strictly utilitarian form. . . . It entails looking into the future, calculating probabilities, and of course evaluating outcomes. "Benefits" and "harm" are not self-evidently identifiable values. Secondly we may ask whether, even if the benefits of the practice seem to outweigh the dangers, it nevertheless so outrages our sense of justice or of rights or of human decency that it should be prohibited whatever the advantages.<sup>6</sup>

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6. Baroness Mary Warnock, *Philosophy and Ethics, in* GENETIC ENGINEERING: THE NEW CHALLENGE 67 (Clive Cookson et al. eds., 1993).

Generalising and simplifying this guidance, we can evaluate new developments or proposed practices *either* by reference to utilitarian (harm-benefit) criteria (if our calculations indicate a balance of harm over benefit, we should definitely not proceed; but if the assessment indicates a balance of benefit over harm, then the particular development or practice should be regarded as ethically clean (and the law should take up a permissive position)) *or* by asking whether a new development (or proposed practice) “outrages our sense of justice or of rights or of human decency” (if it does not, we should pronounce the particular development or practice ethically clean; but, if we are so outraged, we should reject the proposal even if it means that we will have to forego certain perceived benefits).

Such a bifurcation is probably over-simplistic. For example, there are important differences between those utilitarians who operate with short-term rather than medium-term or long-term time-frames; a number of quite different deontological theories might find a home somewhere in the realm of justice, rights, or human decency; and there are strategies for blending utilitarian and deontological perspectives — for example, in the way that some interpret the hugely influential value framework for bioethics constructed by Tom Beauchamp and James Childress<sup>7</sup> — as well as pluralistic approaches that belie any simple bifurcation between utilitarian and deontological perspectives.

Nevertheless, there is more than a grain of truth in the idea that developments in fields such as human genetics tend to provoke debates in which promoters of the particular technology implicitly appeal to utilitarian considerations (especially on the benefit side of the calculation) while their opponents invoke deontological criteria of the kind represented by respect for justice, rights, or human decency. Of course, where the harms associated with a particular development transparently outweigh any possible benefits, the proposal will not get to first base — such is the case, for example, in the current state of the art, with human reproductive cloning. However, if the technology improved to the point where reproductive cloning in humans was perfectly safe and reliable, and where there were no discernible “harms” to offset the “benefits” (such as psychological harm in families), whatever opposition remained would come from the side of those concerned with justice, rights, or human decency.

While bioethics has been in its infancy, the overwhelming concern of the non-utilitarians has been to assert the importance of individual

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7. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (3d ed. 1989). For an indication of the influence of this work, see, e.g., RAANAN GILLON, *PHILOSOPHICAL MEDICAL ETHICS* (1986).

human rights, particularly individual rights to autonomy and privacy. Watershed declarations, such as those at Nuremburg and Helsinki, underline that the rights of individuals must not be subordinated to the supposed advance of science or medicine or to the interests of society; and, in both research and clinical settings, the importance of informed consent (reflecting the right of autonomous choice) has been loudly proclaimed.<sup>8</sup> For those who have grown up to take bioethics seriously, it will be natural enough to think that we should also take rights seriously. And, if we think that respect for human rights follows from respect for human dignity, then we will go back to this dignitarian premise when we make our last stand against the utilitarians. In Europe, though, there are signs that this configuration of secular bioethics is undergoing a significant change; specifically, that in place of a two-sided contest between utilitarian and human rights perspectives, we are moving towards a three-cornered contest in which these founding protagonists are joined by a new “dignitarian alliance” (for whom the protection of human dignity is the unifying and overriding value).

Elsewhere, I have written at some length about two conceptions of human dignity.<sup>9</sup> Whilst one account (“human dignity as empowerment”) underlies the human rights perspective which has been so important in the formative years of bioethics, the other (“human dignity as constraint”) is the gathering point for the dignitarian alliance. To repeat, the reason why the latter is an important entrant into the bioethical arena is that it challenges the wisdom of both utilitarianism and dignity-based human rights. Expressing this third perspective in communitarian terms, we would say that human dignity is a good, which must not be compromised by our actions or practices, and that any action or practice that compromises the good is unethical irrespective of welfare-maximising consequences (contrary to utilitarianism) and regardless of the informed consent of the participants (contrary to human rights thinking). Thus, even if, say, human reproductive cloning could be supported by utilitarians and tolerated by human rights theorists, if the dignitarian alliance regards such a practice as compromising human dignity, it will be treated as off limits.

Perhaps the emergence of the dignitarian alliance owes something, as Gregory Stock puts it, to “European sensitivities,”<sup>10</sup> in which case it might be credible only within certain bioethical circles. Moreo-

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8. See, e.g., RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986).

9. See, e.g., Roger Brownsword, *An Interest in Human Dignity as the Basis for Genomic Torts*, 42 WASHBURN L.J. 413 (2003).

10. GREGORY STOCK, *REDESIGNING HUMANS: OUR INEVITABLE GENETIC FUTURE* 13 (2002).

ver, so long as bioethics is a secular discipline, this particular articulation of human dignity might yet fall away as quickly as it has asserted itself. After all, it is a mere thirty years since philosophers could write that human dignity “seems to have suffered the fate of notions such as virtue and honor, by simply fading into the past.”<sup>11</sup> Nevertheless, there are at least two reasons for thinking otherwise.<sup>12</sup>

One reason is that neither utilitarian nor human rights perspectives give much support to the interests of conservatism, constancy, and stability. When human dignity as the underpinning of human rights has acted as such a dynamic and progressive force for change, it might seem incongruous to enlist this same idea in defence of the status quo. Yet, as the pace of biotechnology accelerates, we should not underrate the felt need to find a way of registering our concern that we should at least have the opportunity to hang on to those parts of the human condition that are familiar and reassuringly “human.” Rather obviously, the notion of “human dignity” fits this particular bill. The other reason for thinking that the dignitarian alliance might be in for the longer run is that there are some forms of biotechnology that impact directly on humans, but which are not readily engaged by the human rights perspective. One such example is research on human embryos; and, not surprisingly, therefore, we find the dignitarian alliance pitted against the utilitarians in the debates about stem cell research that are now reverberating around the world.<sup>13</sup>

Turning to manufacturing, what kind of concerns might we have and are they captured by utilitarian or human rights perspectives? Or is this one of those emerging cases, such as embryonic stem cell research or the patenting of human gene sequences,<sup>14</sup> in which we must rely on the new dignitarianism to register our deepest concerns?

First, what are our particular concerns about the manufacturing of new drug products? Some of our concerns are those that we might already have about any drug product, in particular that the drug might not work (and thus disappoint expectations), or that it might have adverse side-effects and cause harm to the user, or that, even if the product does not cause harm to the user, the user has nonetheless taken the drug without being fully informed as to its possible adverse consequences. Over and above such common concerns, however, we might see manufacturing as occasioning new and unwarranted anxieties; for, unless target consumers are made to feel anxious about their

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11. Michael Pritchard, *Human Dignity and Justice*, 82 *ETHICS* 299, 299 (1972).

12. See also Roger Brownsword, *Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the ‘Dignitarian Alliance’* 17 *NOTRE DAME J.L. ETHICS & PUB. POL’Y* 15 (2003).

13. See Roger Brownsword, *Stem Cells, Superman, and the Report of the Select Committee*, 65 *MOD. L. REV.* 568 (2002).

14. See Roger Brownsword, *The Relatin Opposition Revisited*, 9 *JAHRBUCH FÜR RECHT UND ETHIK* 3 (2001).

“condition,” they are unlikely to feel the need to address it, let alone purchase a drug product that seems to be designed for this very purpose. In other words, once we see through markufacturing we might be concerned that the supplier of the problem-solving product is also the author of the problem. Finally, where markufacturing is applied in a pharmacogenomic context, there might also be a concern that the advantages of tailored drugs can only be enjoyed by those who have undertaken genetic testing, which, in turn, might impinge on privacy interests.

This catalogue of particular itemised concerns does not, however, quite do justice to a more fundamental concern that we might have with markufacturing. For, there is a sense in which markufacturing is more objectionable than the sum of its objectionable parts.<sup>15</sup> If we think that it is morally axiomatic that humans should treat one another as ends (with, as Kant would say, intrinsic dignity) and not simply as means, then markufacturers clearly, and systematically, violate this principle. Markufacturers need the participation of consumers to create a market for their product. However, the way in which markufacturers relate to consumers seems to be not merely instrumental but instrumental without respecting the dignity of consumers. Markufacturing involves the manufacturing of both product and consumer need; and, in this latter respect, consumers are not respected as ends. On this view, we should be concerned not just that markufacturing is irresponsible, or that it builds markets on inauthentic needs, but that it fails to relate to consumers in the way that humans owe it to respect one another.

If this is the landscape of our concerns, how much of it is captured by a utilitarian perspective? Utilitarians will focus on concerns about safety, on possible product benefits and possible harm to users. They will also take account of the benefits to be secured both through good product information and pharmacogenomics as well as the possible distress occasioned by anxieties arising from diagnostic spread. And, utilitarians will at least pay lip-service to the Kantian principle, albeit in the form of counting the interests of everyone, markufacturers and consumers alike.

On this analysis, what is problematic about utilitarianism is not so much that it has an incomplete view of the set of concerns (all consequences are material) but that it calculates and balances positive and negative consequences as though they are equal units. For the utilitarian, there is no privileging, for instance, of the right to know or the

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15. In light of Professor Feldman's written paper, I am confident that this is a highly significant point and one on which we agree. However, whilst I am thinking about developing the point outside a framework of negligence liability, Professor Feldman, for the time being at least, is focused on placing negligence liability in the larger setting of markufacturing activities.

right not to know, of the right to give an informed consent or the right to privacy, and so on. There is also no special protection against adverse drug effects: if the drug is known to bring some small relief to the vast majority of users but also to cause great harm to a tiny minority of users, utilitarians may well calculate that, in aggregate terms, the benefits outweigh the harms — in which case, in principle at least, the drug is justifiably marketed.

If the drug is markufactured, the same pattern of reasoning applies. Markufacturers may well be aware that in constructing their market, they will occasion some serious harm to product users; or they may do this irresponsibly, not really caring about or considering the foreseeable negative effects. However, if all things considered, the beneficial consequences (including the beneficial consequences on the *supply* side) outweigh the negative effects (the disutilities), the utilitarian will judge that supplying the product is ethical. Moreover, whether or not the law should (as Professor Feldman argues) take a distinctively tough line on the responsibility of markufacturers for the damage they cause, is a matter that utilitarians would approach in precisely the same way. Instating such a remedial regime might increase utility overall; if so, it should be done; if not, it should not. In sum, then, it seems to me that, in principle, utilitarians have the measure of markufacturing and pharmacogenomics, but the worry is that they are applying the wrong moral metric and, thus, will misguidedly endorse these practices in light of their promised benefits.

Jeremy Bentham, the founding father of utilitarian thinking, famously dismissed a belief in natural rights as nonsense on stilts. From the perspective of human rights thinking, this was a fatal error and utilitarianism, despite the modern shift from act to rule-utilitarianism, has never quite recovered. The fatal flaw in utilitarianism is, quite simply, that it does not take rights seriously. If, contrary to utilitarian reasoning, we do take rights seriously, what will we make of markufacturing? In general, rights theorists scan the landscape for autonomy and welfare-enhancing benefits and for rights-violating infringements. On the benefit side, if we take the claims made for pharmacogenomics at face value, rights theorists will be attracted by the prospect of tailored drugs that work for particular identified individuals. The privacy interests of individuals will need to be protected but, subject to this qualification, this is a gain — tailored drugs give us an option that we did not previously have. With regard to rights infringement, there will be particular concern that markufacturing fails to respect the autonomous decision-making capacity of consumers. This is not to advocate paternalistic protection for users who are liable to be damaged by the next generation of drug products. Rather,

rights-theory advocates that pharmaceuticals should be marketed in a way that facilitates the making of unforced (free) choices and that ensures that such choices are made on an informed basis. To some extent, these goals may be aspirational, but markufacturing gives cause for concern in both respects. Again this is something that the Nuffield Council on Bioethics has picked up:

If genetic tests and corresponding genetic, medical or environmental interventions relevant to traits in the normal range are developed, it is important to consider how such tests and interventions may be made available. . . . [I]t may turn out that individuals are left to make decisions about whether to make use of tests or interventions without the involvement of health professionals.

. . . .

. . . Without appropriate safeguards, consumers may be at risk of exploitation through misleading marketing practices. This is particularly likely in novel areas of science, where most people will not be well placed to make informed judgements. . . .

. . . .

. . . [W]e consider that the issues raised by tests for behavioural traits and other traits that exhibit normal variation require specific attention. The questions addressed by these tests include very sensitive areas of personal and family vulnerability, and there is considerable potential for exploitation of the anxieties and aspirations of members of the public in an area where the science is not well understood. This danger is particularly important since both tests and interventions might be applied to children without their consent.<sup>16</sup>

Predictably, these concerns lead the Council to recommend that the provision of self-tests of this kind should be “stringently monitored and regulated as necessary.”<sup>17</sup>

Thus far, markufacturing does not seem to be the kind of development that cannot be adequately critiqued from a utilitarian or rights perspective and that has at least some European bioethicists reaching for the idea that human dignity is compromised. If markufacturing were aimed at encouraging one of the practices forbidden by the dignitarian alliance, this would be another matter, but markufacturing itself does not look like a prime target. There is, however, an aspect of markufacturing in the context of pharmacogenomics that might catch the eye of the dignitarians.

Let us suppose that research into the aging process discloses a genetic element that can be retarded by a tailored drug regime.<sup>18</sup> For the most part, markufacturing would be pushing at an open door in sowing the seeds of the idea that aging (and death) is a problem, and that taking steps to delay the process is something that we need to do

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16. NUFFIELD COUNCIL, *supra* note 2, at 146-47.

17. *Id.* at 147.

18. *Cf.* STOCK, *supra* note 10.

if possible. From most practical viewpoints, the opportunities for sharp practice in relation to age-postponing drugs — or life-extending or health-enhancing prescriptions — is too obvious to require comment.<sup>19</sup> However, for the dignitarian alliance, the objection might be that we simply should not artificially interfere with the natural span of human life, whether by shortening it (as with euthanasia and its variants) or by extending it. In other words, from a new dignitarian perspective, manufacturing life-extending products, even if the products are fit for their claimed purpose, is not a path that we should tread. To repeat, however, it is not manufacturing as such that provokes claims about the value of human dignity being compromised; rather, it is the dignity-compromising product that is being manufactured that is the focus of concern.

#### IV. CAUSES OF ACTION

If the common law is to offer remedies to the victims of manufacturing, what kind of claims would it need to make available? The obvious claims that would be brought forward are (i) that the product does not work or (ii) that the product has caused harm because it was not manufactured properly or (iii) that the product has had adverse side-effects about which there was not a proper warning. Beyond such claims, however, it might be argued that manufacturers have a responsibility (iv) for creating a culture of drug dependency or (v) for manipulatively interfering with the autonomy of (i.e., instrumentalising) others. How would such claims register in the law?

Let us suppose, first, that the product is given a hard sell and that it does not live up to the claims made for it. In such a case, contract might well be the answer. For instance, in the well-known English case of *Carlill v. Carbolic Smoke Ball Co.*,<sup>20</sup> the manufacturers of the smoke ball promoted their product in very strong terms, saying that they would pay a handsome reward to any person who, despite using the smoke ball as prescribed, still caught influenza. The Court of Appeal held that Mrs. Carlill, having acted on the manufacturers' marketing script, was entitled to the advertised reward as a matter of contract law. Although Mrs. Carlill's contract claim was a bit shaky, the court clearly wished to send out a message to copywriters to mod-

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19. See James Meek, *Public 'Misled by Gene Test Hype,'* GUARDIAN, Mar. 12, 2002, at 9, for reported concerns about genetic tests being sold direct to consumers through the Body Shop chain stores. The tests, developed by Sciona, a company based in England, are aimed at detecting various polymorphisms. According to this report,

[o]n the basis of the tests and a lifestyle quiz, [Sciona] offers "genetically tuned" advice on what subscribers should and should not eat and drink. Sciona claims that by matching lifestyle to their unique genetic profile, as detailed by the company, subscribers — who pay an annual fee of £120 — will achieve a higher level of general health.

*Id.*

20. [1893] 1 Q.B. 256 (C.A. 1892).

erate the claims made for consumer products.<sup>21</sup> Again, to take a contemporary example, those consumers who are paying £120 per annum to get “genetically tuned” advice on what they should and should not eat and drink, with a view to improving their general health,<sup>22</sup> would look, in the first instance, to a contractual claim if they found that their health was not enhanced in the terms promised. Following such examples, if manufacturers oversell their products, disappointed users might be able to construct a claim for damages based on a contractual warranty or misrepresentation. It is true, of course, that if pharmacogenomics lives up to its promise, tailored drugs should work very much better for their selected users but, at the same time, the very idea of bespoke drugs raises expectations and makes failure less easy to excuse.

If the complaint about the drug is not so much that it does not work but that it has adverse side-effects, then this looks more like a tort or product liability claim. In England, legal action is being contemplated against the British manufacturers of Seroxat<sup>23</sup> which, like Prozac, is within the SSRI (selective serotonin reuptake inhibitor) group of drugs.<sup>24</sup> The now well-publicised complaint about Seroxat is that it has under-advertised side-effects, particularly concerning aggression and dependency. In relation to the latter, there is likely to be argument about whether the drug is in any sense addictive, or whether it is addictive in the strict sense, and in consequence whether there has been a failure to give a proper warning.<sup>25</sup> In relation to the former, there is likely to be extended argument, case-by-case, about causation. This is not to say that claimants can never win such arguments; but it certainly signifies that claimants face an uphill struggle as they enter the tort system. However, there is nothing new here and manufacturing does not add to claimants’ difficulties in bringing familiar types of negligence or product liability claims. Maybe, though, Professor Feldman thinks that, where a claim is made in a manufacturing context, there should be a regime of liability that is even more strict than that which applies in product liability. Perhaps, for example, manufacturers should be held liable even where it was not possible for them to anticipate the damage that they would cause. Certainly, to argue that those who irresponsibly promote a culture of dependency should be

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21. For the full story of the case and its follow-up, see A.W.B. Simpson, *Quackery and Contract Law: The Case of the Carbolic Smoke Ball*, 14 J. LEGAL STUD. 345 (1985).

22. See *supra* note 19.

23. In the United States, this drug is marketed under the name of Paxil.

24. See Sarah Boseley, *800 Hooked on Drug Seek Legal Action*, GUARDIAN, Sept. 16, 2002, at 11; Sarah Boseley, *Drug Inquiry Thrown Into Doubt Over Members’ Links With Manufacturers*, GUARDIAN, Mar. 17, 2003, at 1-2.

25. In England, the Medicines Control Agency, which regulates pharmaceuticals, is being pressed to act on the evidence of these reported side-effects. See *id.*

held legally responsible for the consequences of that dependency seems to me to be not in the least an irrational response.<sup>26</sup> Similarly, if the difficulty for claimants<sup>27</sup> is establishing the necessary causal link between markufactured drug and, say, aggressive behaviour, why not adopt the *res ipsa loquitur* presumption and put the burden on the markufacturer to show absence of cause?<sup>28</sup>

What, though, about claims that seem to be distinctively associated with the larger wrong perpetrated by markufacturing? Markufacturing, as we have said, simply does not pay due respect to those who are channelled towards participating as consumers of the product. Even if there is no physical or psychological injury as a result of consuming a markufactured drug, it might be complained that (as some civilian lawyers in Europe might put it) the personality interests of consumers have been violated. To address such a violation through the tort system, however, seems ill-conceived. The point about markufacturing is not that it occasionally infringes the personality interest, but that it does so *systematically* and pervasively. In principle, each and every consumer, actual or potential, is wronged. On this view, therefore, we might contemplate tort-based awards for violation of the personality interest *on top of*, say, claims for physical or psychological injury. However, to allow claims for violation of the personality interest simpliciter would be to invite the largest class action of all time. The tort system is not ready for this; and nor should it be; rather like slavery, markufacturing is a case for general public regulation not occasional private law redress.

## V. CONCLUSION

I started with three questions. What is markufacturing? To what kinds of concerns does markufacturing give rise? And, how far does the tort system need to be re-modelled to take account of these concerns? The answers that I am somewhat tentatively formulating suggest that I should send Professor Feldman the following letter from Europe.

Markufacturing, understood as supply-side creation of the demand-side of the market, is not a new phenomenon. Nevertheless, in the context of pharmaceuticals and pharmacogenomics, we should not be complacent about such a practice and Professor Feldman is abso-

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26. Cf. Deryck Beyleveld & Roger Brownsword, *Impossibility, Irrationality, and Strict Product Liability*, 20 *ANGLO-AM. L. REV.* 257 (1991). And, on the attribution of legal responsibility generally, see PETER CANE, *RESPONSIBILITY IN LAW AND MORALITY* (2002).

27. This applies equally to two classes of claimants: (i) those who are taking the drug; and (ii) those who have been injured by the drug-taker.

28. As I understand Professor Feldman's paper, she adopts something like this doctrinal ploy through references to *Sindell v. Abbott Laboratories*, 607 P.2d 924 (Cal. 1980).

lutely right to put the tort regime on notice. Although the particular concerns to which markufacturing of drugs gives rise can be captured reasonably well by traditional bioethical perspectives, we should not lose sight of the wood for the trees. The overwhelming concern about markufacturing is that it violates the dignity of humans. However, the sense in which human dignity is violated is not that propounded by the new dignitarian alliance, but that which underpins the modern human rights tradition. In other words, markufacturing is incompatible with what I would call human dignity as empowerment (not human dignity as constraint). Some of the concerns to which markufacturing gives rise can be covered by well-established contract and tort causes of action; but, if, as Professor Feldman insightfully suggests, we want to underline the special responsibilities of markufacturers (the message being “markufacture at your peril”), then a tailored regime of liability seems to be required — for designer drugs, there would be designer liability. Finally, if we wish to respond to the systematic neglect of human dignity (personality) represented by the practice of markufacturing, then this seems to me to be a suitable case for European-style regulation rather than U.S.-style litigation.