

the starting point of an analysis, a sign of the need for an analysis, but it should not be the conclusion of an analysis.

### Assembling forms of life

Medicalisation implies passivity on the part of the medicalised. One example is when people claim that disease-awareness campaigns persuade potential customers to “recode” their unease and dissatisfaction in the form of a diagnostic category to extend the market for pharmaceutical products and the remit of medical practitioners. With notable exceptions (children, prisoners, people deemed mentally ill and admitted to hospital under compulsion), doctors do not force diagnostic labels on resistant individuals. And although drug companies use techniques of modern marketing, they do not seek to dupe an essentially submissive audience. Marketing techniques, since the 1950s, have not regarded the consumer as a passive object to be manipulated by advertisers, but as someone to be known in detail, whose needs are to be charted, for whom consumption was an activity bound into a form of life that must be understood.<sup>4</sup> Marketing does not so much invent false needs, as suggested by cultural critics, but rather seeks to understand the desires of potential consumers, to affiliate those with their products, and to link these with the habits needed to use those products. It is this process of mutual construction, the intertwining of products, expectations, ethics and forms of life, that we observe in the development and spread of psychiatric drugs such as those for depression. This process is not a brute attempt to impose a way of recoding miseries, but the creation of delicate affiliations between subjective hopes and dissatisfactions and the alleged capacities of the drug.

Such a medicalisation of sadness can occur only within a political economy of subjectification, a public habitat of images of the good life for identification, a plurality of pedagogies of everyday existence, which display, in meticulous if banal detail, the ways of conducting oneself that make possible a life that is personally pleasurable and socially acceptable. In engaging with these formulae in inventive ways, individuals play their own part in the spread of the diagnosis of depression and shaping new conceptions of the self.

Thus, beyond medicalisation, medicine has shaped our ethical regimes, our relations with ourselves, our judgments of the kinds of people we want to be, and the lives we want to lead. But if medicine has been fully engaged in making us the kinds of people we have become, this is not in itself grounds for critique. Critical evaluation of these heterogeneous developments is essential. But we need more refined conceptual methods and criteria of judgment to assess the costs and benefits of our thoroughly medical form of life—and of those that offer themselves as alternatives.

#### Conflict of interest statement

I declare that I have no conflict of interest.

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## Medicalisation of race

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“Illnesses that seem identical in terms of symptoms may actually be a group of diseases with distinct genetic pathways. This would help explain blacks’ far higher mortality rates for a host of conditions, including diabetes, cancer and stroke.”

“Until now, these gaps have been attributed largely to racism in the healthcare sector and widespread poverty among African-Americans.”<sup>1</sup>

Biotechnology firms have found an unusual and effective way around the problem of confronting the issue of race as a biological category. The strategy does not deal with the notion in a systematic full-scale case-control design, but uses a clinical study that was not intended to test whether race plays any part—only to discover later that the race of the clinical population, however defined, bears some unknown relation to drug efficacy. The reinterpretation of already obtained data sets by racial categories

thereby conveniently circumnavigates the problem of having to define what is meant by race. By sharp contrast, a case-control study that categorised participants according to race would require the researcher to specify the boundaries of the relevant populations. The story of how the first racial drug was approved by the US Food and Drug Administration (FDA) is a remarkable tale of the racialisation of medicine. BiDil (NitroMed, Lexington, MA, USA) is a combination drug (isosorbide dinitrate and hydralazine) designed to restore low or depleted blood nitric oxide concentrations to treat or prevent congestive heart failure. The drug was originally designed without racial specification. But early clinical studies showed no compelling efficacy,<sup>2</sup> and a US Food and Drug Administration advisory panel voted 9 to 3 against approval.<sup>3</sup>

In a remarkable turn of fate, however, one of the investigators looked at the data again, and found that a small sub-sample of African Americans in the original clinical trial seemed to have fared better than did white people.<sup>2</sup> Because the study was not designed to compare efficacy of BiDil in people of different races, a new clinical trial would have had to be approved to investigate such a hypothesis. However, rather than setting up a study design to test this hypothesis, in March, 2001, the FDA approved a full-scale clinical trial, undertaken only in black men and women with heart disease.<sup>4</sup> In June, 2005, after a hearing in which an FDA committee reviewed reports that BiDil was significantly more effective than a placebo, the drug's patent was approved for another 15 years as a race-specific drug.<sup>5</sup> Indeed, the race-specific claim was what made the drug patentable.<sup>6</sup>

The use of black participants only in this BiDil trial is indicative of three problematic assumptions about race and medicine. The first is that African Americans' risk of developing and dying from heart failure is substantially greater than that of white people. An investigation by the Hamline University, St Paul, MN, USA, legal scholar Jonathan Kahn seriously challenges this assertion.<sup>7</sup> Kahn's work shows that claims made by NitroMed, the company that developed BiDil, about the extent of differences in efficacy between black and white people are untrue. Kahn traced the citation sources used to substantiate that claim back nearly two decades, and showed that the difference in mortality between black and white people is not the often quoted 2 to 1, but instead closer to 1.2 to 1.<sup>6</sup>

The second problematic assumption is that BiDil has a greater effect on African Americans than on white people.<sup>7</sup> But as mentioned, none of the clinical trials of the drug were designed to test that hypothesis. By concentrating only on black people, the study by Taylor and colleagues yielded no compelling evidence for this claim. Thus, substantial scaffolding of the BiDil clinical trial is based on non-existent statistical data regarding racial disparities.

The third problematic assumption concerns the presentation of data for the age-specific disparities in mortality, for which there is some evidence. In the early spring of 2005, anticipating FDA approval, NitroMed released the following statement:

"The African American community is affected at a greater rate by heart failure than that of the corresponding Caucasian population. African Americans between the ages of 45 and 64 are 2.5 times more likely to die from heart failure than Caucasians in the same age range."<sup>8</sup>

The figures are technically correct, but as I have shown elsewhere, the 45–64 year age-group accounts for only about 6% of deaths from heart failure, whereas people older than 65 years constitute 93.7% of the deaths. Moreover, for people older than 65 years, the differences between African Americans and white people mostly disappear.<sup>9</sup>

Why the focus on race, and what is at stake? Part of the answer almost certainly lies in the role of prospective markets. The original BiDil patent, non-race specific, will expire in 2007. By making the drug race-specific, the patent extends another 13 years giving NitroMed exclusive rights to market the drug until 2020. Yet marketing is only part of the story. The BiDil example also provides an updated chapter in the medicalisation of race. In a classic 1991 study, Michael Klag and his associates<sup>10</sup> showed that, in general, within the African-American community, the darker the skin colour, the higher the rate of hypertension. Klag argued that the correlation between skin colour and hypertension was not biological or genetic in origin, but biological in effect due to stress-related outcomes of reduced access to valued social goods, such as employment, promotion, housing stock, etc.<sup>10</sup> Consistent with this finding, a recently published study by Cooper and colleagues examined prevalence of hypertension in 85 000 participants. Their research compared racial groups; sampling white people from eight surveys completed in Europe, the USA, and Canada, and contrasting these results with those from three surveys undertaken in black people from Africa, the West Indies, and the USA. According to the authors, data from Brazil, Trinidad, and Cuba showed a significantly smaller racial disparity in blood pressure than that in North America. Tellingly, the authors conclude:

"These data demonstrate that the consistent emphasis given to the genetic elements of the racial contrasts may be a distraction from the more relevant issue of defining and intervening on the preventable causes of hypertension, which are likely to have a similar impact regardless of ethnic and racial background."<sup>11</sup>

Despite these clear refutations of genetic racial differences in hypertension, BiDil's approval for use only in black people encourages further racialisation of pharmacology and promotes the view that racial differences in health are attributable to biological causes. For example, the British drug manufacturer AstraZeneca did a large clinical trial in patients with advanced lung cancer to test the efficacy of one of its most promising drugs, Iressa (Gefitinib, AstraZeneca, Luton, UK).<sup>12</sup> First introduced in 2002, more than 45 000 patients have taken the drug worldwide.<sup>11</sup> Iressa works by blocking carcinogenic-cell proliferation. In the original study, the difference between patients given placebo and those taking Iressa was insignificant. When these results were announced, the FDA began a review to assess whether the drug should be pulled from the market. However, when the data were re-assessed by race and ethnicity, scientists found that "Asians" had a 9.5 month prolongation of life on the medication, nearly double the 5.5 month average for the general population. As widely reported in the popular press, AstraZeneca touted the findings as significant, and began their marketing strategies and sales to Asian countries.<sup>12</sup>

The appearance of racialised drugs on pharmacists' shelves only increases the need to attend to the myriad social sources of disparities in morbidity and mortality. Although to turn a profit from fighting racial discrimination is difficult, effective medical care demands continued awareness of the complex social dimensions of diseases, such as hypertension and cancer.

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## If direct-to-consumer advertisements come to Europe: lessons from the USA

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Direct-to-consumer (DTC) advertisements for prescription medications might one day be used in Europe. If some lobbies have their way,<sup>1,2</sup> European doctors and patients will face situations similar to those that have confronted their counterparts in the USA during the 9 years since the US Food and Drug administration relaxed its regulations on pharmaceutical advertising. In the years hence, ever-growing numbers of patients have visited doctors requesting drugs by name after having seen advertisements for drugs, such as antidepressants, antihistamines, antihypertensives, and cosmetic drugs on television, the internet, in magazines, and seemingly everywhere else.

In the event that DTC advertisements cross the Atlantic Ocean, European doctors and patients might take heed of the cautionary tales of American critics who contend that consumer-directed promotions oppose the interests of medicine. Such criticisms often focus on what might be called the intended effects of DTC advertising: namely, that these advertisements effectively induce patients to ask their doctors for specific drugs in ways that effectively encourage doctors to grant these requests. For instance, in a recent study of antidepressant advertising, Kravitz and colleagues<sup>3</sup> suggest that DTC advertising substantially increases brand-specific prescriptions, often for weak indications. And, in *The truth about the drug companies: how they deceive us and what to do about it*,<sup>4</sup> Marcia Angell contends that consumers are “duped” by deceptive advertising practices. Such assertions contribute to more serious concerns that, although drugs undoubtedly

save lives, drug companies extend the markets for their products by manipulating consumers before they arrive at the physician's office.

Critics from the USA, however, have been fairly silent about what might be called the unintended effects of DTC advertising: the ways in which these advertisements challenge assumptions about what being a doctor or a patient means, the assumptions that both parties make about drugs, and the social contexts in which clinical encounters take place. Such effects are not the primary concern of drug companies, yet are no less important for understanding the impact of DTC advertising on medical culture in the USA. For example, fairly little has been said about the effect of patients requesting prescription drugs by name on traditional notions of medical authority, medical communication, or the doctor-patient interaction. Of course, patients have asked for particular treatments since the beginnings of professional medicine. Yet DTC advertisements have changed the ways in which physicians and patients speak and listen to each other. Research suggests that at least 40% of visits in which discussion about a DTC-advertised drug takes place result in a prescription for the advertised drug, and in more than half these cases, physicians claim to have prescribed drugs to accommodate the patient's request.<sup>5</sup> Patients have been emboldened to embrace decisions that were once the sole domain of the physician: selecting the appropriate drug and, by extension, the diagnosis. Physicians, meanwhile, have at times been forced to choose to either concede to or disappoint their