GLOBAL BUSINESS MASQUERADING AS SCIENCE
THE HUMAN LABORATORY

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You see here a lady who has nervous problems (slide 1). The year is 1980. She has come to her doctor with nerves or anxiety. Her doctor asks her what her problem is like and she says that she feels bad for a short while in the morning and then the problem clears up but may come back later in the day or perhaps not till the next day. It will have been obvious to both her doctor and to the patient that the problems she had was "nerves", and fortunately we had the perfect treatment for anxiety – we had the benzodiazepine group of drugs.

You see here a further lady with nerves or anxiety (slide 2). Both of these women feature in adverts for the benzodiazepine group of drugs.

In 1980 DSM-III broke up the monolithic concept of anxiety neurosis into a group of anxiety disorders. You can see an advert for one of these new conditions – panic disorder (slide 3). By the end of the 1980's even though panic disorder had been unheard of until a few years before that, and the treatment for panic disorder being advertised here – Xanax, alprazolam – was not available in the United Kingdom, people who came in to see me would tell me that they were having panic attacks. If I asked them what this felt like they would say to me that they felt bad for an hour or two during the morning and it might then clear up and come back later in the day or perhaps not come back for a day or two.

How had the notion of panic attacks entered circulation to such an extent in so short a time that it had come to colour how people saw some of their most intimate problems? Well the media are always keen to hear of good news stories about health care and hearing about this new disorder, panic disorder, programmes appeared about it on the BBC or articles appeared about it in the Times or other newspapers and periodicals. And even though those articles might have said that the best treatment for panic disorder is behaviour therapy, Upjohn, the makers of Xanax were quite happy with the coverage because they knew that simply getting the concept out there into the minds of clinicians and patients would lead to an increase in sales in their drug. This process has since been called disease mongering.

In the next slide you see a further condition created by DSM-III – social phobia or social anxiety disorder as it is now called. What you see here is a booklet written by a World Psychiatric Association Task Force, convened for the purpose. The booklet had been prepared prior to the anticipated launch of moclobemide for social phobia. But Roche did not get licence for this purpose

in the US or in Europe and therefore could not sell social phobia. One hundred thousand copies of this book had been printed off ready to help educate clinicians. The task of educating people about social phobia fell instead to Paxil (paroxetine) and Glaxo SmithKline.

These days if one goes into the health section of book shops in the West there are lots of books on shyness and social phobia and even though these may say that the best treatment for the condition is behaviour therapy or other psychological approaches, again the simple fact of these books being there make people aware of this condition and increase the sales of paroxetine or other SSRI drugs for this condition.

However this process which involves just the same kind of market segmentation that one sees for other consumer goods from sports gear through to automobiles ran into trouble when a crisis blew up about the benzodiazepine group of drugs (slide 5). In the West we became very concerned that this group of drugs could make people physically dependent – they could become hooked to the drugs. The people who did the most to convey this message were probably the companies with a new group of drugs coming to the market – the SSRI group of drugs. In the wake of the benzodiazepine crisis where patients had been seen as being anxious before they now had to be seen as being depressed and the companies helped launch educational campaigns to persuade people that they were depressed. Here in this slide (6) you see an article of mine making just this point around the time of the launch of the major SSRI drugs in Europe.

On the next slide (7) you see an advert for IMS Health who are a secretive organisation rather like to FBI or the CIA but who probably know where Osama Bin Laden actually is in a way that the CIA don't – at least they will know where he is if he is taking drugs. This organisation tracks the prescriptions issued by all physicians for drugs of various sorts from the Pampas of Argentina to the plains of the Mid West in the United States through Europe and onto Japan.

What you see here on the next slide (8) is data on the sales of psychotropic drugs in the United States during the 1990s. You will notice that overall the sales of the benzodiazepine drugs remain the same but the antidepressants increase and cross those of the benzodiazepines in the mid 1990s and have continued to grow thereafter.

In the next slide (9) you see the same picture for the United Kingdom. Sales of the antidepressant barely increased at all in the 1980s but in the 1990s pick up and sales of benzodiazepine tranquillizers or anxiolytics in the 1990s begin to fall and in the middle of the decade the antidepressant market becomes bigger than that of the tranquillizer market.

In the next slide (10) you see a very different picture in Japan. Sales of the tranquillizers remain constant through the 1990s. The Japanese did not have a benzodiazepine crisis. Sales of the antidepressants as you see also

remained constant and at a much lower level than the sales of the benzodiazepines.

Which region is out of step? Which region is odd? - the West or Japan? Well the answer is perhaps on the next slide (11) for you see here that in South America, and I can show you similar slides for other regions of Asia and other regions in Africa, sales of the benzodiazepines, of the tranquillizers, remain constant through the 1990s and greatly exceeded those of the antidepressants. Japan and the rest of the world were in step. It was in the West that things were unusual.

The next series of slides shows you a different way to see the same problem. Here in this slide (12) is a lady who was taking Lilly's tranquillizer during the 1960s. This is an advert for a barbiturate.

The next slide (13) shows you an advert for Lilly's antidepressant Nortriptyline in the mid 1960s. What you see here is a much older lady. Depression was a disorder of middle to later years and was quite rare compared to anxiety. If the argument I have just given you is right then what you should see in the adverts in the SSRIs in the 1990s in the West is that the women being treated for depression should become younger and younger and this is what you see. Here is a Prozac woman (14), here is a Faverin woman (15), here is a paroxetine woman (16) and finally here is a Serzone woman (17). She is clearly much younger and in her twenties at the oldest.

When a woman like this came in to see me in the 1990s she would probably have said that she was feeling depressed. If I asked just what it felt like to be depressed, she would have said that she feels bad for an hour or two during the day and then it clears up and may come back later in the day or may not come back for a few days. She is describing the same problem as the very first woman that we saw in this talk but she has a different understanding of what has happened to her.

Finally on the next slide (18) just to show you that I am not sexist here is an advert for an antidepressant featuring a man – this is the husband of the woman you saw earlier.

The next slide shows you the front cover the leading left wing newspaper in the United Kingdom (19). This is from 1997. The World Health Organisation has just said the previous year that depression is the second greatest source of disability on the planet. This article is making the same point that we have all become more depressed. It even says that the British have become a low serotonin people - now you know what happened to the British Empire. But the extraordinary thing here is that no one in the media or in academia wonders how this illness, which had been quite a rare illness until only a few years before, has suddenly become the second most important disorder in medicine. No – psychiatrists instead of questioning these things feel rather pleased that they are now the second most important people in medicine.

What you see in the next slide (20) here is a joke advert made by a group called “Adbusters” for a treatment for compulsive shopping disorder. They thought it was inconceivable that a drug company would ever try to market such an illness but in fact the real joke was when this advert came out Forrest labs were at the time running several clinical trials for citalopram for compulsive shopping disorder. Then the planes hit the World Trade Centre and nobody wanted compulsive shoppers to stop shopping.

On the next slide (21) you see impotence and again this was a disorder where the illness was sold in the first instance rather than the drugs. The disease was mongered.

But this is here to introduce female sexual dysfunction which you see on the next slide (22). You will know that in the West at least there have been great efforts to make FSD into an illness. FSD has arguably however been the pharmaceutical companies Vietnam or perhaps their Iraq in that there was determined resistance from feminists to the notion that FSD should be made into an illness to be treated with pills rather than a state that might respond better to flowers and chocolates and wine.

On the next slide (23) though you see some of the consequences of medicalization of this sort. Here is a book by the Berman sisters, pin ups of the FSD movement. On the slide that follows (24) you see a quote from their website. Here a young mother who has two young and demanding children finds that with everything on her hands she is just not interested in the sexual attentions of her husband and wonders whether there must be something wrong with her. You will see that in the answer given below to her problem, she is told that she should get her serum testosterone levels checked.

Now the point behind this is that for some women this will be the right answer but for most women it probably won’t be the right answer. And with this this change of focus to a focus on sexual functioning in these mechanical terms companies and other proponents of FSD are literally changing – or attempting to change - the meaning of what it means to be in love or to make love.

On the next slide (25) in this sequence you see an advert for paroxetine where this woman says she is really only her true self when she is on the drug. This is astonishing change of affairs. The companies seem to be making a bid to define the very meaning of what it means to be human. The authentic self is the medicated self.

The final slide in this sequence (26) shows an advert for Hormone Replacement Therapy, which shows an older woman doing the ironing and almost locked in the attic on the left who has been transformed on the right into a younger woman taking charge in the company boardroom. We all know however what happened to the HRT story - the women who took HRT were not so much likely to take charge in the boardroom as to end up dead prematurely. And women’s capacity to take charge in boardrooms hasn’t come from taking HRT.

We now move on to the next section of the talk, which looks at how companies manage to produce these changes. On this slide you see the increase in the number of articles on depression and antidepressants in periodicals like Vogue during the 1980s and 1990s (27). These drugs remember had been available from the 1950s but there were very few articles on this rare illness depression or its treatment. This is the kind of thing that you might expect. What you won't expect is on the next slide (28), which is that exactly the same thing happens in the academic literature. Even though the drugs have been available from the 1950s there were very few articles on antidepressants or depression and it is only during the 1980s that these articles begin to appear.

What is happening here is not a conspiracy so much as both the academic and lay media want good news stories about health. It has become impossible to write good news stories about the benzodiazepines and anxiety and when these big trees in the jungle get cut down other trees have a chance to spread.

How do companies help them sprout? Well as you see here in the next slide (29) that if you had happened to write as I did an article thirteen years ago which mentioned one drug favourably the company can requests thousands of reprints of this article. If I had written a really good article, which didn't mention a drug I would have been very lucky to get two or three hundred reprint requests for the article.

What you see on the next slide after this (30) is back in 1996 or so if I had had the money to pay to go to this expensive meeting I would have been able to go and be taught by people from Lilly or Pfizer or Merck how to set up patient groups to lobby for a particular drug. There has been a recognition by the companies that when marketing new drugs that may not be any better than old drugs but that cost much more than the old drugs, one very useful weapon is to mobilise patient groups to demand access to a treatment.

None of this will probably surprise you but the next few slides may surprise you. What you see here is the cover of the Hasting Centre report for Spring 2000 (31). This is probably the premier bioethical journal in the world. This issue contains a series of articles on Prozac. Two of the articles say that it is not a good idea that Prozac be used indiscriminately for people other than people who are depressed. Two more articles say that if people who are not depressed find themselves helped by Prozac what is the problem?

The fifth article asks the reader to wake up and realise that all of this is about the share price of Lilly and that articles have been ghost written and data concealed in order to boost the sales of Prozac just the way that any other corporation would attempt to boost the sales of its product. There is little interest in the actual health of anybody who may be taking it. It turned out that the Hasting Centre received a substantial donation annually from Lilly. We found out about this because following my article in this copy of the Hastings Centre report Lilly cancelled their donation to the Centre.

On the next slide you see a book Prozac Backlash (32). This book by Joseph Glenmullen advocates using psychotherapeutic approaches rather than drugs for nervous problems. Many of you here will not necessarily agree with this advice. What you would be interested here is the series of reviews of the book in the next six slides (33-37). You don't need to read the reviews in detail just notice the names of the authors of these reviews who all come from very prestigious institutions in the United States. I am not saying for one minute that these authors did not fully believe everything they wrote about this book but this brings out something interesting. All of these reviews went to the Boston Globe in Boston when the book came out and to News Day in New York when the book came out and in the case of Boston they were sent from Lilly's PR agency in Boston and in the case of News Day they were sent by Lilly's PR agency in New York.

And you will see in this covering letter (slide 38) from Robert Schwadron of Chamberlain Communications, Lilly's PR agency in New York that he can arrange for interviews with independent researchers from the medical community who will say just the opposite to what the book is saying if News Day is interested. How this man can arrange for interviews with independent researchers is an interesting issue.

On the next slide you see the logo for Chamberlain Communications, which is a target (39). This is something that interests me as I found that Chamberlain has targeted me in the past and this was before I lost my job in the University of Toronto.

We are in the kind of world illustrated by the book on the next slide (40) which is a world where Big Oil and Big Tobacco can create consumer groups who advocate for the product and have experts on stream who will come out and give views that are the opposite to the views which some expert has put forward about global warming or other hazard related to the company's product. To Big Oil and Big Tobacco you now need to add Big Pharma.

On the next slide (41) you see some of the kind of information that I got when I made a freedom of information request to Eli Lilly some years back. You will see that they arranged to have people in the audience when I speak to keep an eye on the kinds of things that I say and they actively consider suing me based on the kinds of things that I say.

Now how about this slide here (42). Some years ago I was asked to participate in a symposium about one of the new drugs. I agreed to do so and shortly afterwards had an email which said the things that you see here and it said that the company was delighted that I was taking part in the meeting and attached was my article. I was very surprised at this, as when I agreed to take part in the meeting I knew I would have to write an article but I knew pretty well what I wanted to write. I had an even bigger surprise when I read the article that was written for me. This was quite a good "Healy" article. It was full of "Healy" references and made the kinds of points that I often make. If someone who thought they knew my work was asked to look through a few

of my articles and pick out the article that I hadn't written they possibly would not have picked this one out.

I wrote back to the company as you see in the next slide (43) and said that I was happy to write my own article and indeed I did so and sent it to them and they replied as you see here that this was quite a good article but that there were some important commercial points in the first article and that they would organise for someone else to become the author of that first article.

So what you see in the next slide (44) is the article that I did write for this meeting and what you see in the slide afterwards (45) is the article that had been written for e and they both appear side by side in the same journal supplement. And interestingly this is quite a symbol, the author of the ghost written Healy article is Siegfried Kasper, the Professor of Psychiatry in Vienna. This was where Freud come from – so this really is something of a Freudian slip.

On the next slide (46) you see a portfolio of articles, which were being coordinated for Pfizer by a communications group based in New York called Current Medical Directions – CMD. If you go into CMD's website what you find is the following in the next slide (47). And if you go into the portfolio as you see on the next slide (48) you find things like this – There was a list of articles for Sertraline (Zolot) we used for depression and for anxiety and in the elderly and in the young and for instance PTSD, Post Traumatic Stress Disorder as you see here. What you see on the right is that it says that this paper has been completed in the case of one of the papers and in the case of the other paper it also says that it has been completed and they say that one of these papers will go to the New England Journal of Medicine and the other to JAMA. These are the premier journals in the field. One in fact does appear in JAMA and the other appears in the Archives of General Psychiatry. But the really interesting thing is over on the left where you see that even though the papers have been completed they say "Author TBD". Tbd means, " Author to be determined". The articles have been written but no one knows who the authors are going to be just yet until the company decides who it will be useful to have as the authors.

On the next slide (49) you see some research that we undertook based on this portfolio of articles. We looked at what journals these articles subsequently appeared in and who their authors were and the rate at which these articles were cited afterwards compared with all other articles on Sertraline in the world literature over the same time period. What you see is that the articles being coordinated for Pfizer by CMD appeared in journals that had a two times greater impact factor than the articles that weren't being coordinated by CMD. The authors on the CMD coordinated articles had on average twice as many published articles to their name as the authors on the non CMD coordinated articles.

The key thing is this - when presented with an article that appears in the New England Journal of Medicine authored by the Professor of Psychiatry in Harvard talking about the results of a trial with a drug does the field regard

this as proper science or does it regard it as simply as an advert? The answer appears to be that it seems to regard it as proper science because we cite these articles at a three times greater rate than we cite the articles that have not been coordinated for Pfizer by CMD.

But if you look at the next slide (50) at the articles in the portfolio you see that these almost exclusively relate to Pfizer's areas of marketing interest. None of them are address the very real scientific questions that there are in this field, which these drugs throw up.

What you see on the next slide (51) is just the opposite. In the case of articles that are saying good things about drugs it appears that often the authors have to do no work at all. They simply have to agree to have their name added to the article. In the case of an article which contains information about hazards to do with drugs what you see here is the editor of the BMJ saying that they won't be able to publish my article even though it has gone through the peer review process and been approved for publication. It took eighteen months for this article to finally appear. This regularly happens with articles that I write.

Does it make a difference if articles are ghostwritten? Well if you look at the published articles on Paxil, Prozac and Zolot and at the suicidal acts and completed suicides that happened in the clinical trials of these drugs that got them on the market what you see here on this slide (52) is the actual point during the trial where the suicidal acts happened. These acts happened during the wash out phase of the trial when the person had been removed from previous drugs before they entered the randomised phase of the trial. Acts also happened during the randomised phase of the trial where you would expect more to happen on the drug than on the placebo simply because there are more patients randomised to drug than to placebo. Some acts also happened after the randomised phase was over.

If you look at the published literature however this is not what you would learn about where these acts happened. What you would see is what is on the next slide (53), which is that all of these other suicidal acts now appeared to have happened during the placebo phase of the trial making it look as if there is no risk from active treatment when in fact there is. Active treatment has a two and a half fold increased risk of completed suicide and suicidal acts compared with placebo.

Now look here. This is News Week on World Mental Health Day some four years ago now running an article on teenage depression (slide 54). At this stage you must know what is happening. Some pharmaceutical company must have a drug close to being launched for teenagers who are depressed – in fact three companies have – Lilly, Pfizer and Glaxo Smith Kline. So the public is being told about the good news. We now have new pills that will help treat teenagers who are depressed so that they don't go on to alcoholism, drug abuse, career failure, divorce and suicide.

This slide 55 shows you quotes from some of the articles on Sertraline and Paroxetine from the clinical trials of these drugs when given to children. You see they repeatedly say that the drug is safe and effective when in actual fact if you look over on the right hand side here the figure 9% - this refers to 9% of the children who are depressed in this trial going on to a suicidal act on the drug. And if you look at this trial here Keller Wagner and colleagues with its 5.4% rate of suicidal acts on Paroxetine you have here what should be one of the most famous trials in all of medicine – as you will see. But more generally what we now know is that in the case of these drugs this is the greatest divide in all of medicine between what the scientific literature says on the one hand and what the raw data says on the other hand.

But look at study 329 here (slide 56) - the authorship line has some of the biggest and best-known names in American psychopharmacology. These are all signing up to say that the drug is safe and effective. However what you see in the next two slides (57, 58) is three years beforehand, a year after trial 329 finished Glaxo SmithKline had decided that this and a further trial show that their drug did not work for children who were depressed. The company is faced with the issue of how to handle all this. They decided that they couldn't readily show the data to the FDA. They also decide that it wouldn't be commercially acceptable to say that the drug hadn't worked.

This ultimately provoked a crisis about SSRI drugs making children suicidal. When this crisis happened, the American College of Neuropyschopharmacology who once prided themselves on their independence from industry and their reliance on data produced this report saying there really was no problem (slide 59). Here are the members of the task force and these included the authors of quite a few of the articles that you have seen earlier including some authors from Study 329 (slide 60). What you would be interested to see here is that these authors in fact did not even write the task force report. This was written by GYMR who are a PR agency based in Washington DC and as you see from the website here (slide 61) are successful because "we know how to take the language of science and medicine and transform it into the more understandable language of health".

So where does this leave us? Well this is a page from the British Medical Journal (slide 62). Most people looking at this see an advert on the left hand side and think if only there weren't adverts in Journals like the BMJ. If only doctors didn't get free pens and free cups and trips to conferences everything in medicine would be OK. However the real problem is the infomercial on the right. I don't know that this particular trial isn't a very good trial but lots of trials that look just like this will in fact be adverts and more potent and effective adverts than the advert that you see on the left. More dangerous adverts than the advert that you see on the left. Some years ago pharmaceutical companies took clinicians at their word when they said that they were really only influenced by the evidence and they have since then been in the business of controlling the evidence.

This next slide makes the point that at some point there must be a clash, a fundamental clash between marketing and science (63). What companies are

in the business of doing is to try and get you to think Hoover rather than vacuum cleaner, to think Coca Cola, to think brand. This is not part of science.

Now let me take you to a final example

Just as with any other corporations trying to market goods from sports gear to automobiles, pharmaceutical companies use focus groups in an attempt to establish what are the unmet needs of the market place. In the case of psychiatry, the focus groups typically focus on the opinions of psychiatrists. Some years ago it became clear that a series of unmet needs clustered around the concept of bipolar disorder. The field – that is, other psychiatrists and mental health workers - were prepared to believe that bipolar disorder could affect up to 5% of the population; that it was an unacknowledged and unresearched disorder; that antidepressants might not be good for this disorder; that treatment might be better focused on the use of a mood stabiliser; and that patients through a process of self monitoring could be helped. (slide 64)

This research coincided with the introduction in the West of Depakote as a mood stabiliser (65). This anticonvulsant drug, which in the form of sodium valproate had been available from the mid 1960s and had been shown in France to be potentially helpful in manic depressive illness from the mid 1960s, had been reformulated by Abbott Laboratories in the form of a semi-sodium valproate salt. Abbott claimed this salt formed a more stable solution that sodium valproate. This trivial distinction between the two compounds was sufficient to enable them to take a patent out on the new compound. This gives you some indication of how much the patent laws have tilted toward company interests and away from an emphasis on a reward for genuine novelty that offers a clear benefit to the community.

Depakote was introduced in 1995 by the FDA after trials which showed that this very sedative agent could produce beneficial effects in the treatment of acute manic states. Any sedative agent can produce some demonstrable benefits in the treatment of acute manic states, so this was not surprising.

Depakote, however, almost immediately was advertised as a mood stabiliser (66). Had it been advertised as being prophylactic for manic depressive disorder it is almost certainly the case that FDA would have had to rule the advert as illegal as the prophylactic effect had not been demonstrated. The term mood stabiliser however had no precise clinical or neuroscientific meaning and as such was not open to legal action in the same way. Depakote quickly became known as a mood stabiliser even though there had not at the time, and have not since, been any studies that prove it to be prophylactic for manic depressive illness.

The next slide shows you the increase in frequency of the articles citing the new term mood stabiliser in their titles (67). From being a term hardly heard before 1995, a few years later it is found in the titles of over a 100 articles per year. This term is a new brand. And in addition the illness, manic-depressive

disease, was rebranded and around this time became known as bipolar disorder.

What you see on the next slide is that this new term was quickly adopted by a range of other anticonvulsant and antipsychotic drugs with olanzapine, quetiapine and risperidone passing themselves off as mood stabilisers (68). This is despite the fact that this word still has no precise clinical or neuroscientific meaning. However the field as part of its unmet need desperately seems to need mood stabilisers. Both clinicians and patients are happy to endorse the concept.

In addition to launching themselves as mood stabilisers, Lilly and Janssen the makers of olanzapine and risperidone have used what are now the standard company marketing tricks. First, they create a series of patients literatures and website materials aimed at telling people more about this disorder. You see on the next slide (69) one such patient leaflet for Zyprexa and also a booklet on what patients might need to do to stay well (70). Note the disease is being marketed here rather than a medication.

Among the recommendations in this book from Lilly shown in slide (71) are:
1/ that bipolar disorder is often a life long illness needing life long treatment,
2/ that symptoms come and go but the illness stays,
3/ that people feel better because the medication is working,
4/ that almost everyone who stops taking the medication will get ill again and
5/ that the more episodes you have the more difficult they are to treat.

This is almost precisely the same message from the self guide for people with bipolar disorder sponsored by Janssen Pharmaceuticals shown in slide 72

Which says (73) *'the right medicine at the right time: medicines are crucially important in the treatment of bipolar disorders. Studies over the past 20 years have shown without a shadow doubt that people who have received the appropriate drugs are better off in the long term than those who receive no medicine*.'

If studies had shown this over the past 20 years there would be a number of drugs licensed for the prophylaxis of bipolar disorder when in fact until recently there were none. Lithium was the only drug that had demonstrable prophylactic efficacy but even this had not received a license from the FDA.

More to the point as slide 74 shows all studies of life expectancy on antipsychotics show a doubling of mortality rates on treatment compared to the non-treated state and this doubling increases again for every extra antipsychotic drug that the patient takes. Patients taking these show a reduction of life expectancy.

To date all studies of the prophylaxis on bipolar disorder with mood stabilisers such as Depakote, Zyprexa and Risperdal show a doubling of suicidal act risk on active treatment compared to patients being treated with placebo.

Valproate and other anticonvulsant mood stabilisers are among the most terategenic in medicine. Therefore the statement above from these companies goes beyond being misleading to being close to duplicitous.

A further aspect of the marketing of the drugs has relied heavily on lists of writers, poets, playwrights, artists and composers who have supposedly been bipolar. Material from Kay Jamison 'Touched by Fire' has been widely reproduced. To look at some of these lists you would think that almost all major Western artists of the 19th and 20th Century had been bipolar, when in fact very few if any of these had manic-depressive disease (75).

One of the key aspects of the marketing has involved the use of mood diaries, shown in slide 76. These break up the day into hourly segments (77) and ask people to rate there moods on a rating scale that for example typically goes from +5 to –5. Here in slide xx scores on the Lilly sponsored mood diary scale for example include at +2 - being very productive, doing things to excess such as phone calls, writing, having tea, smoking, as well as being charming and talkative. You score a + 1 if your self-esteem is good, you are optimistic, sociable and articulate, make good decisions and get work done. Minus 1 involves slight withdrawal from social situations, less concentration than usual and perhaps slight agitation. Minus 2 involves feelings of panic and anxiety with full concentration and memory and some comfort in routine activities. Most normal people during the course of the week will probably cycle between at least +2 and –2. And that's almost precisely the point – once you map this out all of you will show a bipolar variation in your moods and what is this but bipolar mood disorder in embryonic form (slide 78).

A further point behind the input of measurement to the problem comes from the example of the weighing scales (79). As I have outlined in The Creation of Psychopharmacology, the emergence of eating disorders in the West coincided in the 1870s with the emergence of weighing scales. There was an increase in frequency in eating disorders in the 1920s and this parallels a much wider public availability of weighing scales and also the emergence of norms for weight that began to change our ideas of what is beautiful. In the 1960s you have an explosion of eating disorders and you also have the development of smaller bathroom scales that every home could have. This I believe illustrates some of the power of measurement – how figures from one area of our lives can come to dominate our lives.

A final aspect of the marketing of all these disorders involves the marketing of risk (80). This is true for the marketing of depression and bipolar disorder as well disorders like osteoporosis, hypertension and others. In the case of osteoporosis, as you see here companies typically will do something like present pictures of a country's or region's top model looking her best in her mid- to late- 20s and juxtapose that image with the image of the same person as she might look during her 60s or 70s with osteoporosis. On the one hand a beautiful woman, on the other a shrunken crone. The message is 'one can never be too safe'. If one wants to retain beauty and vitality it is probably best to start treatment early.

In the case of mood disorders the classic risks that are marketed are the risk of suicide, alcoholism, divorce, career failure etc. (81)

All of the above come together in this classic direct to consumer advert for bipolar disorder made by Lilly soon after Zyprexa has been licensed for mania. This features disease mongering, the marketing of risk and the use of mood scales. Lets look at it – slide 82.

The upshot has been to produce a change to the situation (slide 83). Until recently manic depressive illness was a rare disorder in the Japan involving 10 per million new cases per year or 1,200 new cases per year at its current level of population. This was a disorder that was 8 times less common than schizophrenia. In contrast bipolar disorder is now is thought to affect 5% of the population – that is 6 million Japanese. It is as common as depression and 10 times more common than schizophrenia.

Until very recently manic depressive illness was not thought to start before the teenage years. It quite rarely had its onset in the earliest years of puberty but more often than not happened in mid to later pubertal years and often later in persons in their 20s or 30s.

Theodore Ziehen (84), writing in the early years of the 20th century established the view, against some opposition, that is was possible to have the onset of the illness during the teenage years. This remained the standard view for close to 100 years. But in the last few years in the United States things have changed.

The clearest indictor of the changing picture came with the publication in 2000 of The Bipolar Child by Papolos and Papolos (85). This sold 70,000 hardback copies in the course of half a year. Newspapers throughout the United States reported increasingly on the diagnosis of bipolar disorder in children as young as 2 years old.

A series of books began to appear such as My Bipolar Roller Coaster Feelings Book (86). These books come with mood diaries for children as you see on the next slide (87)

One of the most startling books in this area is Brandon and the Bipolar Bear (88). In this we are introduced to Brandon, who typical of these children shows 3 features – a fear of the dark and nightmares, temper tantrums, and moods that go from giddy to tearful several times during the day – a normal child you might think but Brandon is brought to Dr Samuel (89, 90, 91).

Dr Samuel tells Brandon, 'You have bipolar disorder'.

'Bi…What?' asks Brandon. (92)

'Bipolar disorder,' repeated Dr Samuel. 'You see, the way we feel is controlled by chemicals in our brain. In people with bipolar disorder these chemicals can't do their job right so their feelings get jumbled inside. You might feel

wonderfully happy, horribly angry, very excited, terribly sad or extremely irritated, all in the same day. It's very scary and confusing sometimes. It can be so confusing inside that living seems too hard'.

'I think I got bipolar because I'm bad,' mumbled Brandon.(93)

'Listen to me,' said Dr Samuel, 'Many children just like you have bipolar disorder. They come to see me so that I can try to help them. It doesn't mean that you are bad! You are a good boy with an illness that makes you feel bad inside. ' (94)

'If I didn't get bipolar from being bad, then how did I get?' he asked.

'How did you get your green eyes and your brown hair?' asks Dr Samuel.

'My mama has green eyes,' Brandon said looking at his mother. 'And your daddy has brown hair,' said his mother as she ran her fingers through his soft hair. 'It's the same with bipolar disorder. You can inherit it. Somewhere else in your family may have it too. Many other children have also inherited it from their families.'

'Will I ever feel better?' sighed Brandon.

'That's the good news,' smiled Dr Samuel. 'I will do my best to help you feel better. There are good medicines to help people with bipolar disorder. You can start taking one right away. You can also come back to visit me again soon. (95)

I want you to promise to take your medicine when your mama tells you'. Brandon hugged his bear as hard as he could. 'I promise!' he said. He was sure he heard his bear say 'Me too!'

American experts it seems are now prepared to consider the diagnosis of bipolar disorder in very young children. In The Bipolar Child (96) there are indications that Dr Papolos and others are prepared to make the diagnosis even earlier *'while my daughter was in the womb, she kicked so hard and often that I had very little rest…. Much of the time it felt that she was in a fight-rolling and tumbling around and then, when she was born she kept all the other babies up with her screaming.' (97)*

'I too noticed signs that this was an extra spirited child. In fact, while I was pregnant I thought 'Uh-ah, the baby is angry again'. These kicks would last for an hour as I doubled over in pain.'

'At 14 weeks, the sonographer and obstetrician were unable to get a picture of Ian's face and could not sample to amniotic fluid due to constant unpredictable activity'.

Far from academic reigning in this hysteria, you see here a clinical trial of Risperdal and Zyprexa in child with an average age of 4 – so some of the

children will be 2 and 3 years old - these are some of the most toxic drugs in all of medicine. (98). Who are these researchers – these are from Harvard University. And they recruit their patients to studies like this with adverts on television like this one (99)

So in my final slide you see here the Human Laboratory (100). The common perception is that drugs are made in company laboratories. This is wrong. Companies make chemicals but we are the laboratories in which modern drugs are made. There is an immediate and less immediate sense to this. In a very physical sense, drugs cannot come into being unless we as healthy volunteers and later as patients in clinical trials agree to take them to see what happens. Without this participation by the community, there is no drug.

Our willingness to participate in these studies was borne out of the global calamity of World War, when conditions of scarcity mandated the development of the first controlled trials. We participated on the basis that taking risks might injure us but would benefit a community that included our friends, relatives and children. We did so for free. At first this worked and extended the compass of human freedom from the epidemics and other scourges to which our ancestors had been subject for millennia.

But now this data freely given is sequestered by corporations who market selected parts of it back to us under the banner of science. This business model has made these corporations the most profitable on the planet. The process is one that increasingly appears to jeopardize the health and well being of our friends, relatives and children.

In a less immediate and less physical sense companies take our inner aspirations and fears and mould these into a strategy designed to get us to consume drugs more faithfully than we would do if we were living in a totalitarian regime and were ordered to consume.

And the same process, by which they effect this compliance, has now begun to interfere with our very conception of who we are just as much as any developments in neuroscience might do. Companies once affected our experience by delivering us from disease but now their capacities to control our experience seem to be escalating in inverse proportion to their ability to deliver us from new diseases, and instead their strategies appear to be infecting formerly healthy experiences.

For this reason, and because our civilization appears threatened by fundamentalisms whose appeal lies in a message that we have lost sight of some of the most important things about being human, the process that delivered us to this shore deserves investigation.