Lifestyle drugs: issues for debate

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The past few years have witnessed the release of a number of highly publicized "lifestyle" drugs, such as sildenafil for male erectile dysfunction and orlistat for obesity. Other products have had their indications extended to include situations that usually come under the rubric "lifestyle"; for example, finasteride may now be prescribed for male pattern baldness. The appearance of these new products and the new uses for established drugs have raised a series of issues for physicians, for the health care system in terms of priorities for drug expenditures and for society in general.

Many of the so-called lifestyle drugs are proving highly popular. For instance, within the first 3 months after orlistat was launched in Canada, 78 200 prescriptions for the drug had been written.[1] As these drugs become more widely used, the scope of the debate and its importance will also broaden: What exactly are lifestyle drugs? What are the issues associated with prescribing them? Do they distract attention from other forms of therapy? Are conducting research into lifestyle drugs and including them in drug payment plans the most appropriate ways to be using health care resources?

The first challenge lies in defining lifestyle drugs. Drug companies and patient groups often object to this term on the grounds that it trivializes the conditions that the drugs are designed to treat, although that is not usually the intent. To try to clarify the meaning of the term, a recent report[2] offered 2 definitions. First, the term could be applied to any drug intended or used for a problem that falls into the border zone between the medical and social definitions of health. From this point of view, male pattern baldness could be dismissed as a problem outside the medical sphere, and in this context finasteride would be considered a lifestyle drug. This definition acknowledges that some men who are losing their hair may have a concern but suggests that baldness should not be treated within the health care system. According to the second definition,[2] lifestyle drugs are those intended to treat diseases that result from a person's lifestyle choices. For example, although smoking has serious medical consequences, they are due to the lifestyle that the smoker has chosen. Therefore, a drug such as bupropion for smoking cessation would be classed as a lifestyle drug. According to this definition, such therapy would be offered outside of the medical system, whereas treatment for the consequences of smoking, such as respiratory diseases, would take place within the medical system. Both of these perspectives raise questions that warrant further examination.

The first definition forces us to consider how and where we draw the line between the social and the medical dimensions of health. Last year, SmithKline Beecham received approval to market paroxetine for the treatment of social phobia as defined by the *Diagnostic and Statistical Manual of Mental Disorders*.[3] This disorder can be distressing and disabling for those who suffer from it, limiting their ability to interact with the outside world. But what we now risk, given the cultural acceptance of (and perhaps preference for) an extrovert norm, is an extension of the definition of social phobia to include shyness: a normal character trait of some people who have no psychiatric disease is turned into an abnormality that requires treatment. In the United States a coalition of nonprofit groups, the Anxiety Disorders Association of America (ADAA), which is partially funded by SmithKline Beecham, has built a public awareness campaign for social phobia around the slogan "Imagine Being Allergic to People." This campaign is being orchestrated by SmithKline Beecham's public relations firm, some of the work being done pro bono and the rest being paid for directly by the drug company.[4] In July 1999, as part of this public awareness campaign, the ADAA held a press conference to publicize the findings of a study that purported to quantify the high economic cost of anxiety disorders. The study in question was underwritten by a group of drug manufacturers.[4]

Expanding the definition of what constitutes a treatable medical problem will have a variety of consequences. For example, there may be a change in how general practitioners balance the risks and benefits of pharmacotherapy. No drug is without side effects, but the acceptability of those side effects usually increases with the severity of the illness being treated. What degree of side effects would be acceptable in treating someone who feels too shy? Compared with the other selective serotonin reuptake inhibitors, paroxetine causes significantly more sexual dysfunction.[5] Therefore, as the number of people undergoing pharmacologic treatment for shyness rises, so too will the number with sexual problems. If we redefine treatable medical problems to include normal variants in the population, physicians and patients may become more willing to accept side effects (which might themselves need treatment) that would otherwise be avoided.

On a more fundamental level we must ask whether doctors should even be trying to define and prescribe "normality." In the past some physicians were quite willing to take on this task. Medical journals from the 1960s and 1970s were filled with ads for psychotropic medications showing

young university women away from home for the first time or housewives surrounded by giant vacuum cleaners. These ads implied that the women were suffering from isolation and other forms of mental distress that could be managed pharmacologically. Male doctors responded to the ads and to prevailing societal views by prescribing mood-altering drugs for women, justifying their decisions with comments such as "It's constitutional. The female's nervous system is more sensitive… That's the way the Lord made them" and "females have more time to indulge in neurosis than men."[6] Perhaps prescribing paroxetine for shyness is the new millennium's equivalent of prescribing diazepam for the overwhelmed college student a quarter century ago.

Treating problems that are due to lifestyle choices also has consequences. It appears that, when drug therapy is available, physicians are less willing to consider nondrug treatments, even when there is no evidence that pharmacotherapy is superior.[7] One example is orlistat for the treatment of obesity. Although people taking orlistat lose marginally more weight in the short term than those controlling their dietary intake without pharmaceutical aids (from a starting weight of 100 kg, about 8.9 kg with pharmaceutical aids v. 5.6 kg with placebo over 1 year), there is no evidence that orlistat is any more effective than diet alone in reducing the morbidity and mortality due to obesity.[8] This abandonment of other types of therapy may be due in part to pressure from the pharmaceutical industry in the form of advertising directly to consumers. To continue with the example of orlistat, in 1999 Hoffman – La Roche spent over US$75 million promoting this drug to consumers in the United States.[9] Such levels of advertising are sure to affect patients' requests to their physicians and hence physicians' prescribing practices. Treating conditions such as obesity with drugs may also have negative psychological implications. Some people have speculated that the use of medical interventions may be seen by patients themselves and by others as a form of "cheating," an indication that the person receiving treatment lacks the willpower to change her or his lifestyle.[2] Although it might be expected that such negative psychological connotations would discourage the use of lifestyle drugs, the perceived lack of alternatives would probably override any misgivings.

The increasing use of lifestyle drugs raises the question of whether we are trying to homogenize society, consciously or subconsciously. For certain lifestyle problems, medical treatment amounts to an attempt to make people more similar to one another, to eradicate their differences. Remember, for example, the debate that arose a few years ago when Prozac was being prescribed to make people feel "more normal."[10,11]

The question of whether it is acceptable to homogenize society arose in the late 1980s and early 1990s in considering which children should be treated with growth hormone.[12,13] When only pituitary-derived growth hormone was available and supplies were therefore limited, treatment was by necessity restricted to children with documented deficiency of growth hormone. However, once synthetic growth hormone became available in the mid-1980s, consideration was given to prescribing the hormone for normal children of short stature. This situation could only have come about because there is a height bias in our society.[14] Taller people do better at sports, and height also plays an important role in decisions related to employment, politics and choice of marital partners.[13] Short children may be subject to teasing and may have a negative self-image. Despite the difficulties posed by discrimination on the basis of height, the question remains whether doctors have an obligation to solve the problem through medication.

At a more general level, we must ask whether physicians should be trying to deal with social injustices by prescribing drugs to render certain of their patients more similar to the norm (with the net effect of homogenizing the human population) or whether it is up to society to eliminate injustice while retaining the population's heterogeneity. I will use an extreme example to illustrate. Suppose there was a pill that could make everybody's skin colour exactly the same. If everyone took the medication, discrimination on the basis of skin colour would certainly be eliminated. Yet having the "wrong" skin colour can hardly be considered a "lifestyle problem," and eliminating discrimination by erasing our differences can be expected to have profound effects on other aspects of human society.

In terms of economic considerations, there is a real worry that research into lifestyle problems is being driven in a single direction — drug therapy — because that is where the profits lie. At present, the pharmaceutical industry is the single largest direct funder of medical research in both Canada[15,16] and the United States.[17] For example, in Canada the industry contributed $880 million to the total of $2.1 billion in 1998.[15] Through its financial support, the pharmaceutical industry is, to a large extent, determining research priorities, and because of the nature of the industry, research into drug therapy is the type most likely to be funded. To return to the example of social phobia, some research has shown that cognitive behavioural therapy for this condition is just as effective as pharmacotherapy in the short term and probably more effective in the long term.[18] Yet it is unlikely that research funds will be made available to study behavioural therapy. And if researchers know that there is no money to answer certain questions, they may not even bother to ask them. Furthermore, drug companies are heavily promoting products for use in lifestyle problems. In 1999 alone, almost US$325 million was spent advertising just 4 lifestyle drugs (Propecia [finasteride], Viagra [sildenafil], Xenical [orlistat] and Zyban [bupropion]) to US consumers.[9] If research is mainly confined to drug treatment, and drugs are the only form of therapy being publicized through ads, seminars and other publicity, the chances are slim that alternative modalities such as behavioural therapy will be as widely used as they should be.

The issue of which topics receive research funding is only part of the broader question of how society makes de-

cisions about health care priorities. Drug companies have identified lifestyle drugs as a "growth market." The problems these drugs are designed to treat are easily self-diagnosed — we can all see if we are bald or fat — and as the baby boomer generation ages, the number of people looking for these drugs will continue to increase. Drug companies, driven by profit, go where the money is, and the money is not to be found in drugs for diseases of the poor, in either developed or developing countries. For example, during the 25 years before 1998, no new drug treatments for tuberculosis were introduced in the United States.[19] A total of 1223 new chemical entities were commercialized between 1975 and 1997, but only 13 were specifically for tropical diseases and only 4 of these (0.3% of the total) could be considered to have resulted directly from research and development activity of the pharmaceutical industry.[20] Until the World Health Organization initiated its Roll Back Malaria campaign, not 1 of the 24 largest drug companies maintained an in-house research program for this disease, and only 2 had expressed even minimal interest in primary research on malaria.[21]

Because of the potential size of the market for lifestyle drugs, paying for them in unlimited quantities will be very expensive. For example, in June to September 1999, in the first 3 months after orlistat was launched, $7.2 million worth of the drug was sold in Canada.[1] The resources available for health care are limited, so decisions must be made as to where those resources should best be spent. How are those decisions going to be made and by whom? If we as a society decide that lifestyle drugs should be covered through the health care system, then other treatments may not get funded or at least will not get as much funding as they otherwise would have. Decisions will also be needed about who will get the drugs (since almost everyone will want one or more of them) and whether they will be available in unlimited supply.

The need for decisions on how to spend research dollars and on whether lifestyle drugs, especially the expensive ones, should be funded through the health care system may create the impetus we need to start a serious debate on these issues. I would argue that these questions should not be answered only by the pharmaceutical companies, who are looking for profits, or by the medical profession, which is focused on finding solutions to the problems of individual patients, or by the baby boomers, who are looking for their lost youth. We need to find mechanisms whereby all elements of society — government, industry, health care professionals, patients and consumers — can participate in the decisions.[22]

In the near future an increasing number of lifestyle drugs can be expected to reach the marketplace. The debate over how to use and pay for them is going to intensify. A coherent long-term strategy to manage lifestyle drugs entails coming to terms with the issues raised here.

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