Enhancing Life or Eradicating Ugliness?: Lifestyle Drugs

By Jeannette Yeznach Wick

In the earliest decades of the 19th century, people developed dental caries frequently. They knew the pain of a toothache, and dentists used what are now considered rudimentary, even barbaric, tools to fill cavities and pull teeth. The perfect bite was more the exception than the rule. Over the decades, interventions spurred controversy. Communities resisted fluoridation of water, and people grumbled that the investment of thousands of dollars for braces was money wasted for cosmetics. Today, we know that fluoridation has reduced the incidence of cavities significantly, braces improve overall oral health while they improve self-esteem, and dental disease can be correlated to poor nutrition and systemic disease.

Managed care (or any person or group charged with determining pharmaceutical resource allocation) is in the midst of a similar debate. Traditionally, pharmacy benefits have dealt with treatments that were frankly medical. Now, new drugs offer unforeseen results, and a broader array of outcomes. They target conditions that seem more cosmetic (and maybe recreational) than medical. Their benefit is that they make the people who use them happy or more comfortable, but they also have risks and so are available only by prescription. Depending on who’s discussing them, drugs might be described as cosmetic, life-enhancing, recreational, convenience, quality-of-life, discretionary, or (most commonly) lifestyle drugs. Third-party payers must now balance responsible allocation of scarce resources with the pressure to create a product attractive to stakeholders (or that makes stakeholders attractive).

The Journal of Managed Care Pharmacy spoke to eight stakeholders in the debate over prescription drug coverage and asked them to discuss drugs that stimulate debate. These representatives and the stakeholder group they represent are listed in Table 1.

**Definition**

The first comprehensive English language dictionary was compiled in 1928, after 70 years of information collection. Its editors listed all known words and then struggled with precise definitions. Medicine is looking for a definition for a group of drugs, but without the benefit of a standard word or phrase to start. When stakeholders were asked to define lifestyle or quality of life drugs, reactions varied from outright objection to the term to rather vague descriptions of it.

Some stakeholders said that they disliked the term entirely because all drugs affect lifestyle or quality of life. An antibiotic, for example, relieves discomfort and allows people to resume normal activity. Migraine headaches disrupt lifestyle without threatening lives. Yet drugs used to treat migraines are never considered to be lifestyle drugs when deciding whether to include them in coverage. Brian Sweet, of WellPoint Pharmacy Management, says that his firm does not have a formal description of lifestyle drugs—the term is used more often by clients during drug policy discussions. WellPoint tends to avoid the term because there are difficulties defining exactly what it means. Sweet suggests that there are better ways to distinguish amongst categories of drugs. He cites symptomatic relief, chronic or acute conditions, or potentially life-threatening events as better measures.

Most stakeholders emphasized that every drug should be evaluated on its own merits and that the line between life enhancing and outright cosmetic is sometimes blurry. Consider an antifungal used to treat a nail fungus. In a teenager, it may be cosmetic. For immunocompromised people, antifungal treatment may save lives.

Most stakeholders had no formal definition for this group, but were able to describe them generally. Several informal definitions are similar, but not identical:

- A drug that if not taken, does not result in additional health risk.
- Drugs that are not medically necessary.
- Drugs that confer no health benefit are not indicated for any medical condition, and have no medical indication.
- Treatments that increase patient satisfaction, but without which they could live.
- Drugs that are discretionary in nature.
- Drugs that are used to treat indications that are personal choice rather than illness, or to treat problems that lie at the margins of health and wellness.

Perhaps the bluntest of all, Frederick S. Mayer of Pharmacists Planning Services, San Rafael, Calif., says, lifestyle drugs are...
TABLE 1  Stakeholders in the Discussion on Lifestyle Drugs

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<tr>
<th>Stakeholder Category</th>
<th>Representative</th>
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<tr>
<td>Employee Benefits Manager CEO</td>
<td>Christopher V. Goff, J.D., MA, President and CEO, Employers Health Purchasing Corporation of Ohio, North Canton, Ohio</td>
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<tr>
<td>Health Plan Marketing Director</td>
<td>Scott Averill, Vice President of Marketing and Sales, Health Alliance Plan, Detroit, Michigan</td>
</tr>
<tr>
<td>Health Plan Medical Director</td>
<td>Bernie Mannsheim, M.D., Senior Vice President and Medical Director, Coventry Health Care, Bethesda, Maryland</td>
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<tr>
<td>Pharmacy Benefit Manager Clinical Pharmacist</td>
<td>Brian Sweet, B.S. Pharm., M.B.A., Vice President, Clinical Services, Wellpoint Pharmacy Management, Grand Island, New York</td>
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<tr>
<td>Pharmaceutical Company Executive</td>
<td>Myron Holubiak, former president of Roche Pharmaceuticals, currently President and CEO, i-PhysicianNet, Princeton, NJ</td>
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<tr>
<td>Employee Benefits Consultant</td>
<td>Connie Perry, Pharm.D., Assistant Vice President, Aon Consulting Employee Benefits Consulting Group, Chicago, Illinois</td>
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<tr>
<td>Public Provider</td>
<td>Ron Gottrich, Manager, Drugs and Medical Devices Programs, Department of Public Health, Springfield, Illinois</td>
</tr>
<tr>
<td>Patient Advocate</td>
<td>Frederick S. Mayer, R.Ph., M.P.H., President, Pharmacists Planning Service, Inc., San Rafael, California</td>
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“drugs that managed care doesn’t want to pay for.” Others agree. One source indicates that “managed care is not going to allow some of these … drugs to be purchased, and manufacturers will develop marketing campaigns to circumvent the system.” Still others point out that not paying for lifestyle drugs is as common outside of managed care as within it.

Only two stakeholders had formal definitions. Christopher Goff, J.D., M.A., of the Employers Health Purchasing Corporation of Ohio, provided this definition: “Products that improve one’s perceived quality of life without improving medical outcomes or reducing overall health care costs.”

Connie Perry, Pharm.D., of Aon Consulting, said that they define lifestyle drugs as those that are not life sustaining, but life enhancing.

So what are these drugs? The answer depends on a number of factors including the indication for the drug, the location of the patient or payer, availability of alternative treatments, and the cost. Table 2 lists drugs that are sometimes considered lifestyle drugs.

When stakeholders reviewed the list, there was disagreement among them about which of them were medically necessary and which were purely cosmetic. Ron Gottrich, manager of the drugs and medical devices program for the Illinois Department of Public Health, indicated that the state’s Medicaid drug program, administered by the Department of Public Aid, does not cover anorectics or cosmetics, and until recently, smoking cessation products weren’t covered. Many private plans do cover these products and more, however.

The debate is many-sided, and profoundly unscientific. Arguments include more than medical research; emotion, politics and finance also impact decisions. The term “medicalization” has been crafted to describe the propensity for health care professionals to take ownership of a lifestyle problem by defining it as a condition either in the manufacturer’s marketing campaign, or at the policy making level, or at the direct care level. Critics claim that managed care plans have provided little to no education to patients and prescribers about the differences between treatments that are useful, and those that are unnecessary.

Lifestyle Drugs: Profit or Expense?

For manufacturers, lifestyle drugs represent giant untapped markets of potential profit. The availability and kind of lifestyle drugs is increasing exponentially, and often profit driven. Some accuse industry of cold-bloodedness—focusing only on profitable diseases and conditions, supported by statistics like this: From 1975 to 1997, only 13 of 1223 new medications listed treatment of tropical diseases that plague the Third World as indications.

When drugs are not medically necessary, drug development’s companion is marketing. Industry campaigns may try to redefine illness in stakeholder’s minds, or use direct-to-consumer marketing to stimulate demand. Branding and marketing generate the perception of quality and brand loyalty, generate positive perceptions about safety, and remind patients to refill prescriptions.

For employers and payers, the drugs that rest at the fringes of established medicine are a dilemma. It often appears that patients’ demands, driven by longer life spans, new technology, and greater expectations, is unsatisfiable.
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says, “Before, employers had only a broad interest in expenditures for the drug benefit. Now, these drugs are a bigger issue all the time. Employers want to know how much they are spending on lifestyle drugs all the time.” Scott Averill agrees, saying, “Right now, drugs are the issue for employers and payers. They are looking at anything they can do to mitigate expense.” Increases in health care costs could cause employers to forgo benefits like salary increases, and exclusion of some medications may cause employees to select more expensive plans. When employers offer multiple plans and employees receive sufficient information about each plan to evaluate the formula, inclusion of some drugs may motivate employees to select certain (and sometimes the more expensive) plans. Perry refers to this as “adverse selection.”

Expansive formularies, according to Chris Goff, are attractive to potential employees, and a factor in attracting or retaining qualified employees in a tight market. There is a need for unbiased information before good policies can be developed. Other sources agree, and go further to say that lifestyle drugs may decrease absenteeism and increase productivity.

Managing Lifestyle Drugs

So what is the relief, and can policy decisions at the uppermost organizational level translate to the direct care level? Opinions vary. Some believe that certain types of relief are nominally obligatory and can be rationed by a willingness to wait or a willingness to pay. Other plans restrict payment to only those treatments that restore normal capacity, and still others establish policies that are more inclusive than exclusive. Brain Sweet indicates that payment mechanisms depend on the type of benefit and the population served. The goal should be an attempt to be a comprehensive, affordable benefit that meets the dynamic needs of both member and employer groups. Members differ in their assessment of medications, and Wellpoint has constructed different coverage policies to address those differences.

The concept of rationing—using measures to curtail access that, according to the deciding body, enhance effectiveness in an efficient, equitable, ethical, or beneficial way—is understood by most stakeholders, with the debate centering on how decisions must be made. It is here that all stakeholders agree: The process must include everyone. If there is uncertainty about what constitutes legitimate demand, then policy will have to be established that denies some people some prescription drugs that they want.

Choices must be value based, and examine which drugs benefit members in the most substantive fashion. For example, a drug used to treat people with HIV that affects 20,000 members may be considered more valuable than a drug costing the same but used to reduce body mass index in only 200 members.

Possible solutions abound. Some plans use multi-tiered copayments, others use complex and refined allocation policies that as a result require prior authorization capabilities, and still others simply exclude some drugs from coverage altogether. Mayer, a consumer advocate, concurs with others that these are hard choices. He cites the example of smoking cessation. Many plans exclude smoking cessation products, but 48 million Americans smoke, and 3,000 children start smoking every day. With the adverse consequences of smoking well known, he believes that smoking cessation products fall on the medically necessary side of the fuzzy line.

Location, Location, Location

Some stakeholders were quick to point out that this issue is one of philosophy, and culture. Perry uses the example of oral contraceptives (OCs); she finds that depending on the area of the country and the predominant culture, OCs may or may not be considered lifestyle drugs. And consider this: In Japan, fluoxetine (Prozac) is considered a lifestyle drug. How will society regard drugs for shyness or the new substance P inhibitors which don’t necessarily relieve depression, but offer a pick-me-up?

The continuum from obligatory care to discretionary care is long, and the boundary where one becomes the other is grey.

Gender As An Issue

Others acknowledge that some gender issues have been exposed, especially since sildenafil (Viagra) was introduced. Perry says that sildenafil created an unpredicted, explosive situation. Its visibility and marketing raised women’s awareness of what was available to men in terms of reproductive health. Prior to its introduction, she says that payers didn’t necessarily consider gender issues.

Chris Goff also speaks eloquently about gender issues, referring to a William M. Mercer, Inc., study revealing that regardless of the cost of oral contraceptive pills, the cost of unintended pregnancy is greater. A recent federal court ruling in Seattle, Washington, stipulated that excluding a class of drugs used only by women from a generally comprehensive drug plan discriminates against women by providing them with less coverage than is offered to men.

Mayer also cites this legal case, incidentally filed by a female pharmacist against Bartell Co.

Perry addresses this issue directly; she encourages clients to cover new drugs if other similar drugs or procedures are already reimbursed. Thus, a plan that cov-

### TABLE 2 Drugs Sometimes Classified as Lifestyle

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<th>Drugs</th>
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<td>Anabolic steroids</td>
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<td>Bedwetting prevention</td>
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<td>Botulism toxin</td>
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<td>Cognition enhancing drugs</td>
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<td>Erectile dysfunction treatments</td>
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<td>Growth hormone</td>
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<td>Hair growth agents</td>
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<td>Infertility drugs</td>
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<td>Morning after pills</td>
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<tr>
<td>Nail fungus treatments</td>
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<tr>
<td>Non-sedating antihistamines</td>
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<tr>
<td>Oral contraceptive pills</td>
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<tr>
<td>Smoking cessation products</td>
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<tr>
<td>Topical anti-aging agents</td>
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<tr>
<td>Weight loss products</td>
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<tr>
<td>Oral influenza shortening agents</td>
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ERS RU-486 and abortion would be encouraged to include OCs as a preventive measure. On the specific issue of sildenafil, a good policy is that if sexual counseling, penile implants or other drugs have been reimbursed in the past, sildenafil should be available after gender equity, safety and cost issues are assessed.

Safety, Cost, and Confidentiality

Safety and cost are certainly driving forces, leading most plans back to rationing. Most plans do not allow members unlimited coverage of "expensive blue pills," or similarly high cost medications and others use screening devices to ensure that safety issues are addressed from the start. Myron Holubiak states that limitations do not only apply to lifestyle drugs; if a plan uses scientific data to establish how often colonoscopies are needed to provide a measure of safety to a population, but a person at high risk wants a colonoscopy more often, should the pool pay?

There will no doubt be increasing member contributions for drugs in general and lifestyle drugs specifically.

Finally, issues of confidentiality were raised among stakeholders. Holubiak believes that confidentiality expectations are greater when lifestyle drugs are used than with other drugs. Plan members may be less willing to reveal that they are using a drug to grow hair, cure impotence or remove wrinkles than to treat hypertension or diabetes. With confidentiality in general under the gun, this is a major consideration.

Coming To Consensus

Stakeholders agree in general that there is no universal answer to issues surrounding lifestyle drugs. Every stakeholder agreed that input from all parties is essential, and that insurers should not have to pay for purely cosmetic medications. Ron Gottrich says that since public agencies must ensure appropriate use of scarce resources, he doesn’t envision increased availability of many lifestyle drugs in the public sector. Scott Averill, however, indicated that the plan for which he works serves a unionized organization with few fiscal problems and strong member influence. Many lifestyle drugs are included under certain circumstances. Myron Holubiak sums it up well: These decisions must be community decisions.

Summary

When conditions are not life-threatening or treatments offer only neutral or tentative benefit, there will be discussion, debate and rationing. Proper use of the specific drug may define coverage. It is also likely that drugs and treatments that seem to be lifestyle agents at one level, such as smoking cessation and obesity drugs, may in the long run offer hidden benefits and important improvements, such as dental interventions cited at the beginning of this article. Over time, we will know more about each of the agents. Like the mother of any who has a limited budget, we will have to ask, “Do we want it? Do we need it? Do we absolutely need to have it?” after clarifying allocation principles and priorities. Individual members will have to determine if the potential benefits of drugs that are not covered are worth higher co-payments or paying for them directly. This issue, regardless of the name used to describe it, will be around for a while.

Richard Russo, a fiction writer of growing fame, recently released a new book, Empire Falls. He describes the people of Empire Falls as normal people with all the usual blemishes and warts, unlike people in certain parts of California where he understands they have “eradi- cate ugliness.” It remains to be seen if drugs and technology will indeed eradicate ugliness, or if improvements that now seem cosmetic will lead to better overall wellness.

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10. Interview with Fred Mayer, R.Ph. M.PH., President, Pharmacists Planning Service, Inc., San Rafael, California.
12. Interview with Connie Perry, PharmD, Assistant Vice President, Aon Consulting Employee Benefits Consulting Group, Chicago, Illinois.
13. Interview with Ron Gottrich, Manager, Drugs and Medical Devices Programs, Department of Public Health, Springfield, Illinois.
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