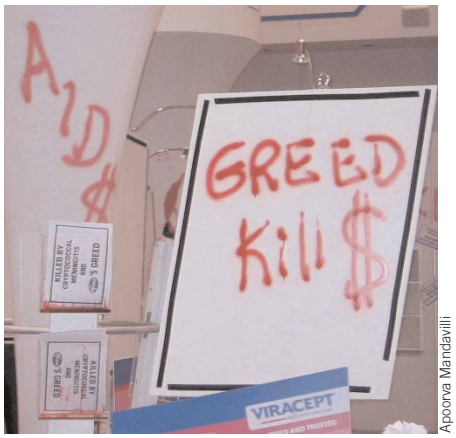
Soaring drug prices send experts scrambling for a fix

Amid intense pressure to reduce skyrocketing drug prices, pharmaceutical and biotech companies are trying to devise models that would give poor countries access to medicine while still covering high drug development costs and maintaining incentives for investors.

Experts say differential drug pricing would transfer some of the financial burden—an estimated $800 million to bring a new drug to market—from the US to other developed nations. Proposals include pricing drugs according to countries' gross domestic product (GDP), or a uniform pricing system in which individual countries would negotiate confidential rebates.

These options are better than price controls, which would ultimately discourage investors and stall drug development, says Judy Lewent, head of Merck's Human Health Asia division. Lewent cites Europe's declining pharmaceutical industry as an example of price caps' negative impact.

Drug prices are higher in the US than in many European countries because the healthcare systems in those countries can negotiate better prices from pharmaceutical companies than can individual American insurers. Critics of differential pricing plans say that countries with effective plans for buying drugs shouldn't be forced to pay more. But changing the way money is allocated to buy drugs could be one solution, says Mark McClellan, former head of the US Food and Drug Administration. McClellan now heads Medicaid, a medical assistance program for low-income US families.



Apoorva Mandavilli

Drug wars: Access to expensive drugs is a contentious issue for diseases such as HIV/AIDS.

Generic drugs are relatively inexpensive and make up the majority of prescriptions in the US—but not in Italy or France. Negotiating cheaper rates for generics in those countries would encourage competition in that market and leave more money to spend on higher-priced medicines, says McClellan.

Representatives at a conference in August at the Massachusetts Institute of Technology (MIT) suggested various new pricing models. Una Ryan, chair of the Massachusetts Biotechnology Council, proposed a scheme where countries with high GDPs would pay higher prices, subsidizing costs for poorer nations. But a potential snag with this is that countries that qualify for cheap drugs could sell them elsewhere, much like the current parallel trade between the US and Canada.

Another option is to have countries pay a uniform price but negotiate confidential rebates, suggests Patricia Danzon, a health care professor at the Wharton School of Management in Pennsylvania. In this system, countries wouldn't know how much their neighbors pay for the same drugs, thus preventing parallel trade. Some researchers doubt it would be possible to maintain confidentiality.

But Ernst Berndt, an economist with MIT's Sloan School of Management, says the model has a sound track record among pharmaceutical companies, which are used to dealing with larger buyers and confidential rebates. The model would be widely applicable to different types of drugs, from medicines for rare orphan diseases to injectable vaccines, he says, but the real hurdle will be convincing countries they are getting a good deal.

Emily Singer, Boston

NIH lab shutdown raises concerns about US prion research

When the US National Institutes of Health (NIH) closed a pioneering prion research lab last month, the timing seemed a bit off.

British researchers had just identified a second case of variant Creutzfeldt-Jakob disease (vCJD) transmitted through a blood transfusion. The UK Medical Research Council is set to launch a trial of potential vCJD treatments, but there are no such trials in the US. A report released last winter by the National Academy of Sciences says the US research program on prion diseases is "small, aging, and inadequately funded."

The NIH quickly responded that the lab's closure is meant to address those concerns, not exacerbate them. The Laboratory for Central Nervous System Studies, founded in the 1960s, was narrowly focused on the transmissibility and infectiousness of prion diseases, says Eugene Major, acting director of basic neuroscience programs at the US National Institute of Neurological Disorders and Stroke.

The agency now wants to develop a broader intramural program that includes research on prion structure and circulation, Major says. "This is the time to look at where the field is going in order to ask the most important questions."

Major notes that lab chief Paul Brown's retirement is just the latest of many exits. The lab's founder, D. Carleton Gajdusek, won a Nobel Prize in medicine for his work tracing the 'kuru' disease in New Guinea to the ritual consumption of human brains. Gajdusek left the NIH in 1997 after pleading guilty to charges of sexually abusing one of many boys he informally adopted during his fieldwork.

His successor, Joe Gibbs, died in 2001. Earlier this year, Brown described himself to the *Wall Street Journal* as "the last living relic" of that team and complained that his lab had no funding. The NIH has not yet decided how it will realign the work done in Brown's lab, but it will probably reflect the agency's new drive for cooperation between various institutes, Major says.

Last month, for instance, scientists began moving into the $261 million Porter Neuroscience Research Center, designed to encourage collaboration. Instead of small, isolated labs, a full third of the center's space is devoted to a large, open lab surrounded by walls of windows. The goal is to have researchers from as many as 11 different institutes work there. NIH officials expect to announce a plan in September to promote the same kind of collaboration among extramural neuroscience researchers.

Over the years, the NIH has increasingly farmed out research on prion diseases to extramural researchers. A review of the agency's grants database turns up 121 grants with the word 'prion' in the title for 2004, compared with 46 in 1994.

Still, it would be helpful to have a central government facility, says neurologist Richard Johnson, who chaired the National Academy of Sciences committee. Individual investigators cannot tackle certain high-risk projects that require infrastructure and long-term support, Johnson notes. Although he is confident that the NIH is moving in the right direction, he says, "It's a different kind of commitment that universities can't provide."

Tinker Ready, Boston