



## **Anti-Addiction Medications: Making the Case for Incentives**

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Thanks to Sen. Joseph R. Biden Jr. (D-DE) and like-minded colleagues, we soon may see dramatic new incentives to develop anti-addiction medications (see ADAW, Sept. 23, 1996). While this is encouraging, there are still several steps before it can become a reality: a properly articulated justification, the choice of the right incentives and interested constituencies to speak out.

Because interdiction, treatment and education are less than fully successful, we yearn for a magic bullet to solve the illegal drug problem. The good news is that we are in the midst of a revolution in the medical sciences. Everything is possible, if it has roots in biological processes.

Yet, there does not appear to be great enthusiasm among pharmaceutical and biotechnology companies to develop new anti-addiction medications. Reasons include uncertainty about the size of the market, concerns about payers' willingness to reimburse adequately for ongoing pharmaceutical care; and the lack of a constituency pressing for research.

One of the keys to overcoming this problem is to identify the right types of incentives, so that new activity is stimulated without creating a windfall for activities that would have occurred anyway. Thus far, "ordinary research incentives" – R&D Tax credits, technology-transfer program, patent protection – have been inadequate in stimulating the development of anti-addiction medications.

Congress considered a similar problem in 1982 and adopted the Orphan Drug Act to stimulate research on drugs for small populations. This law incorporated a powerful incentive: up to seven years of market exclusivity for any new orphan indication on a drug. The results have been impressive: about 600 drugs have been designated as orphans and more than 100 of these have been approved for marketing.

The Orphan Drug Act is an example of an "upgraded incentive." Another example is the Food and Drug Administration's fast-track approval system, providing accelerated reviews in AIDS, cancer and other life-threatening conditions. Although this is done for

humanitarian reasons, the effect is to stimulate activity as companies see increased certainty of approval with a relatively smaller investment.

In addition to ordinary and upgraded incentives, there are “extraordinary incentives.” These are designed to dramatically alter investment behavior by significantly adjusting the normal risk/reward/certainty calculation. Extraordinary incentives might take any of several forms:

- Granting a company a one-year patient extension on the product of their choice, in exchange for developing an anti-addiction product.
- Developing an advanced-purchase agreement whereby the government would guarantee a marketplace for a medication.
- Offering a cash bounty for the development of an anti-addiction medication, which is the approach included in the bill introduced last year by Senator Biden.

While Congress has clearly shown an interest in exploring these issues by, among other things, commissioning two Institute of Medicine reports, not much has happened. Biden’s efforts are a great start, but to make further progress two activities need to be undertaken.

- The case for upgraded or even extraordinary incentives must be built systematically.
- Interested constituencies must be brought together to show public support for, and wide-spread understanding of, how anti-addiction medications can play a vital role. This is an area where pharmaceutical companies, police chiefs, physicians, state attorneys general and civil-rights organizations all might find common ground to form a coalition.

Anti-addiction medications are an exciting and feasible approach to lessening our nation’s drug abuse problems. With the right arguments and constituencies, it is possible to get Congress to match incentives to the documented need. There are no reasons why we cannot ask and expect Congress to act to stimulate the research that could make this happen.

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This article is adapted from a presentation to the American Association for the Advancement of Science in February, 1996. ([link to full speech](#))