

Experts comment on S.2210, the Medical Innovation Prize Fund

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On October 23, 2007 Senator Sanders introduced the Medical Innovation Prize Fund Act of 2007 (S. 2210). The following are comments by experts on innovation and public health, beginning with consumer and public health groups, followed by academic experts:

Comments by consumer and health NGOs

Bill Vaughan, Consumers Union. "As health-care costs continue to spiral, our nation must focus debate on why prescription drugs cost so much. Unfortunately, Congress has never delved into why the process that brings new drugs to market is so insanely expensive, inefficient, and ineffective. Senator Sanders' bill, 'The Medical Innovation Prize Act of 2007,' could at long last begin that debate. The current system is simply not working and is increasingly unaffordable. Our nation spends small fortunes on the latest version of a drug already on the market, while breakthrough research on the key health issues like Alzheimer's and cancer seems to lag. The Senator's prize proposal is worth debate and consideration as a replacement for our current drug-development system."

Merrill Goozner, Author, The \$800 Million Pill: The Truth Behind the Cost of New Drugs. "Research is risky, new drugs are too expensive, and industry focuses far too much of its effort on drugs of minimal medical significance. The prize fund solves all these problems by disconnecting the incentives for generating breakthroughs from the price that individual patients or their insurers must pay. Sen. Sanders has pointed the way toward a new system of financing medical progress in the 21st century."

Buddhima Lokuge, Médecins sans Frontières (MSF). "Study after study is confirming what our field teams have seen for years. Using the price of pharmaceuticals to fund innovation leads to the rationing of essential medicines and the exclusion of low-income populations. At the same time, diseases like TB, for which medical innovation is urgently needed, today are neglected because they primarily affect the poor. There is a growing consensus today that new approaches are urgently needed."

James Love, Knowledge Ecology International (KEI). "The Sanders bill offers a huge change in the business model for drug development – as large as the

change in the business model for network services that we call the Internet. Like the Internet, it would create a culture of abundance in terms of access to knowledge goods. By separating the markets for innovation from the markets for the physical goods, the Prize Fund would ensure that everyone, everywhere, could have access to new medicines at marginal costs. It would dramatically increase incentives to invest in products that improve our lives, and decrease incentives to invest in wasteful and often harmful marketing of 'me too' drugs that do little to improve health outcomes. The bill correctly avoids tying prizes to specific technology solutions, and instead gives drug developers the freedom to use different ways to improve health outcomes. The mechanisms to determine prize valuations will be less complex than those used to justify drug prices or reimbursement. Given the expected costs of health care in the coming years, we need to find ways to control costs. This bill does this in a unique way. It cuts costs and expands access at the same time. As the Internet has proved, when the benefits of change are large, it is possible to change an entrenched but dysfunctional business model."

Ethan Guillen, Universities Allied for Essential Medicines (UAEM). "We applaud Senator Sanders for introducing this innovative legislation. The current intellectual property system has done a great deal of good, but remains flawed, as is demonstrated by the fact that millions still do not have access to life-saving medicines. Universities must join with Senator Sanders in searching for new ways to make the IP system work for those in both rich and poor countries."

Edmund Mierzwinski, Consumer Program Directors, U.S. PIRG. "It is natural for consumers to distrust monopolies, which can even limit access to medicine. The Prize Fund bill, from U.S. Senator Bernie Sanders (I-VT) shows us that we don't have to tolerate monopolies or the abuses of monopoly pricing to stimulate innovation. This innovation without monopolies approach realigns R&D incentives with



consumer interests. With innovation rewarded with prizes rather than monopolies, consumers would benefit from generic drug competition, and low prices. Much of the savings in the bill would be due to the cutbacks in wasteful marketing efforts that now drive costs up. Unlike many proposals for cost control, the prize fund would expand access, while providing enormous savings, and target R&D efforts more effectively.

Mark Cooper, Consumer Federation of America.

"Consumers have an interest in innovation, but also in affordable prices. The current system of granting marketing monopolies for new medicines fails on several counts. Most new drug approvals offer little in terms of therapeutic benefits over existing medicines. Prices for new drugs are very high and increasing at an alarming rate, and very little of what we spend is actually reinvested back into R&D. The monopoly rents collected by the patent holders vastly exceed the costs necessary to provide incentive for innovation. The prize fund approach is a bold proposal to fix a broken system. It provides incentives to innovate through prizes while making drugs available to consumers at prices that reflect the economically efficient and generally low cost of production of generic products. CFA urges the Senate to hold hearings on this innovative and promising proposal to support medical innovation."

Rob Weissman, Essential Action. "The patent monopoly-based system of R&D has proven inefficient at advancing a needs-driven public health agenda. Even by Pharma's estimates, barely more than a sixth of what is spent on drugs is invested in R&D, and the actual amounts may be significantly less. What is spent gets directed to health problems where there is market demand; this sometimes correlates to priority health needs, but often does not. The Medical Innovation Prize Fund suggests an altogether different, market-based system of supporting innovation. It promises to deliver much more bang for the buck, incentivize research in priority health areas currently under-addressed (including but not limited to "neglected diseases" prevalent in poor countries but not rich nations), end wasteful expenditures on marketing, and make medicines dramatically more affordable. These advantages can all be achieved because the prize fund eliminates inefficient monopolies and enables generic competition as soon as products reach the market. Whatever complexities the Medical Innovation Prize Fund approach may engender pale beside the irrational and wasteful complications that we take for granted in the current system of medical R&D.

Dean Baker, co-director, the Center for Economic and Policy Research. "The current system of financing research on prescription drugs through patent monopolies leads to enormous economic waste and leads to a situation in which hundreds of millions of people find it difficult or impossible to pay for the drugs they need. The Sanders bill provides one mechanism for correcting some of the worst problems of this system. Under the bill all prescription drugs could be sold in a competitive market, just like most other products. Without government patent monopolies, the vast majority of drugs could be sold for a few dollars a prescription, as is the case with generic drugs at present. The Sanders bill begins the necessary debate over reforming a financing mechanism that is essentially a relic from the feudal system. It is virtually inconceivable that if we were designing a method for financing drug research from scratch that anyone would opt for the current system of patent monopolies. We should not be stuck with such an inefficient system forever simply because we inherited it from Old Europe."

Professor Brook K. Baker, Health GAP and the Northeastern University School of Law Program on Human Rights and the Global Economy. "The adoption of a prize fund to reward therapeutically targeted innovation and to simultaneously encourage the development of a competitive, low-cost generic market could revolutionize access to medicines in the U.S. and end up saving U.S. insurers, governments, and patients hundreds of billions of dollars for many years to come. However, the proposal will need to be extended globally to ensure that products that receive prizes in the U.S. are not subject to monopoly prices in low- and middle-income countries where innovators are unregulated with respect to their right to file patents abroad. As much as we need a system to increase access to medicines and to lower bloated prices and dysfunctional research and development priorities in the U.S., we need an even more massive effort to transform the international intellectual property regime and to substitute a more rationale international system for energizing targeted innovation and promoting the broadest possible access to affordable medicines."

John S. James, AIDS Treatment News. "This is a very good idea that would end astronomical drug prices, and eliminate the use of patents to block medical research -- while focusing research and development on new drugs that matter for people. Almost all new drugs approved by the FDA would get prize money, with the government's role limited to estimating the comparative worth of the different drugs (using well-known tools like quality-adjusted



years of life saved). Drug patents would still be granted as now, and used to determine ownership for the purpose of awarding the prize money -- but not for stopping potential competitors from producing low-cost generic drugs, or using the patented ideas to create further medical innovations."

Academics and Other Experts

Burton A. Weisbrod, John Evans Professor of Economics, Northwestern University: "Senator Sanders' bill addresses the seriously-flawed current system in the pharmaceutical marketplace. It breaks the link between the incentives for pharmaceutical firms to undertake R&D on new and more effective drugs, and their incentives for pricing those drugs--and breaking that link is critical. The basic economic problem is that R&D is extremely expensive, but producing their end result, "pills," is not. Under current law the only way the high cost R&D can be made profitable is to charge prices for pills that vastly exceed the tiny cost of producing them. The result is the high prices that consumers face for drugs that are increasingly essential, especially for an aging population, and the increasingly common evidence of some consumers being priced out of the market. The fundamental reform that is called for is to separate the incentive for developing effective new drugs from the incentive to produce low-priced pills. This is exactly what Senator Sanders' bill, for a Medical Innovation Prize Fund, would do, and this approach has much to be said for it. The bill poses problems of implementation, but major "prizes" have been used to promote innovation in many other contexts, and as a replacement for our current patent-based monopoly-pricing system the prize-fund approach has vast potential. Its goals of strengthening incentives for both new drug development and for pricing policies that broaden access to those drugs are attainable."

Steven Shavell, Director, John M. Olin Center for Law, Economics, and Business and Samuel R. Rosenthal Professor of Law and Economics, Harvard University. "Senator Sanders' proposed new legislation to replace the system of exclusive marketing rights for drugs with a system of prizes may constitute a great win-win policy for consumers and for the drug industry. Under the Sanders' plan, consumers would benefit greatly and immediately. Consumers would no longer pay sky-high prices for new drugs, because drug developers would no longer have monopolies and would not be able to charge what the market will bear. All new drugs would be like today's generic drugs - their prices would be driven down by competition among many drug producers. A developer of a new drug would still

benefit, however. The developer would receive a reward from a government prize fund that could equal or exceed what it obtains today if it holds a patent. Moreover, drug companies would be free to improve and modify any drugs without permission from patent holders. Hence, consumers would benefit from more versions and improvements of new drugs than they do today.

Kevin Outterson, Associate Professor of Law, Boston University. "Our current biomedical R&D system is unfair and inefficient. R&D is increasingly driven by marketing rather than medical need. Drug companies finance R&D from consumers, health plans and governments through high-priced patented medicines. The Medical Innovation Prize Fund Bill is a serious attempt to simultaneously provide access to all drugs at generic prices, while increasing the effectiveness of drug R&D. Prizes for innovation is an old idea, but deserves serious study again as a possible replacement for our deeply flawed current system."

James Boyle, William Neal Reynolds Professor of Law and co-founder of the Center for the Study of the Public Domain at Duke Law School. "There is a long, distinguished and successful history of using prizes as incentives for innovation. Prizes have successfully encouraged advances ranging from methods of determining longitude in the 18th century, to private, manned space flight in the 21st. Some prizes have stipulated that the invention must be offered to the public free of patent rights -- allowing widest possible use because competition drives the price down to generic levels. Representative Sanders' bill daringly extends this notion to the drug patent system with the aim of producing medical innovation while slashing costs and avoiding some of the heart-wrenching moral dilemmas presented by the high prices of patented pharmaceuticals. At the same time, the Bill contains provisions that would encourage the production of medicines in areas that the market will not serve, particularly drugs that treat diseases of the global poor, or that treat "orphan diseases" affecting comparatively few individuals. Personally, I do not support the idea that we completely replace our current drug patent system with the prize fund. I would rather experiment with supplements and additions to our current system, gather data, and reinforce what has been proven to work empirically. But I think that Representative Sanders' Bill, by focusing us on the possibility of other ways of producing innovation, has the possibility of spurring a hugely valuable national debate on the subject. In addition, I think that parts of this Bill -- particularly those dealing in the areas where the patent system will not work to encourage innovation, such as producing

medicines for tropical diseases -- would be ideal places to begin the experiment.”

Frederick M. Abbott, Edward Ball Eminent Scholar, Professor of International Law, Florida State University College of Law. "There is wide acknowledgment that the system intended to promote innovation in the pharmaceutical sector is broken, as perhaps best reflected in the November 2006 Report by the Government Accountability Office to Congress on New Drug Development in the United States. There are good reasons for trying to separate the way in which research and development of new drugs is rewarded from the prices ultimately charged those drugs. The current innovation system, based almost solely on patents, encourages sales of high priced drugs and high sales volumes, even though this may not be what is in the best interests of patients and public health. Prizes are an important alternative mechanism for promoting innovation that may be particularly useful in the field of medicines. With the establishment of prizes based on addressing important public health needs - whether cancer treatment, an HIV-AIDS vaccine or a cure for diabetes - researchers would be encouraged to tackle fundamental public health problems, and could be handsomely rewarded for doing that. Prices of new drugs could then fall proximate to production costs. There may not be a single solution to the innovation and access problems confronting the pharmaceutical sector, but the proposal to establish prizes as an alternative incentive mechanism deserves serious consideration as a solution in a variety of settings where innovation and access are both essential. It is important to begin to evaluate the merits and feasibility of prize funds, whatever role they may ultimately play in the total mix of pharmaceutical innovation policies."

Professor Arti Rai, Duke University School of Law. "Senator Sanders' bill offers an intriguing mechanism for targeting R&D incentives towards drugs that achieve significant health improvements over existing medicines. Under the bill, the magnitude of the prize would be directly proportional to how much the drug improved health. In theory, a system of universal health insurance in which insurance companies made decisions about covering drugs based on good information about benefit-cost ratios could achieve the same result. But we are very far from such a system. The battle for universal coverage has been waged and lost many times. And unbiased information about health benefits is an under-produced public good. We need more study to evaluate whether or not patent monopolies should be replaced with prizes. In the near term, the place to begin experimentation with prizes is neglected diseases, where little if any

research is motivated by patents."

Aidan Hollis, Associate Professor, Department of Economics, University of Calgary. "The fundamental question to be asked about this bill is whether it will accelerate the rate of pharmaceutical innovation. The mechanism being used is sound: innovators earn more money the greater the health impact of their new drug. Under the current system, in contrast, firms are often rewarded very richly for innovations with relatively small effects on population health, and not enough for more important innovations. Since the Sanders bill ties the reward to the innovator directly to measurable health effects, the incentives for innovation are exactly right. Companies with a great pipeline of therapeutically valuable products should love this bill, because it promises them an opportunity to make a lot of money – and companies with a pipeline full of products which are marginally effective (but which they were planning to market heavily) will hate this bill. One criticism that can't be made of this bill is that the rewards to innovation aren't adequate. That is only a complaint that 0.6% of GDP is not a big enough share to spend on pharmaceutical innovation. If that is the concern, then all that is required is to set aside a larger share. A question that naturally arises is why there should be such special treatment of pharmaceutical innovation. There are two reasons for this: first, the pharmaceutical market in some respects functions very poorly because the people who consume are typically poorly informed about what they consuming and don't choose it – doctors choose for them. And the doctors who choose don't pay the price of the medicine – that is typically split between the consumer and the insurer. Thus the market does not provide the same incentives for performance as other markets. Second, pharmaceuticals are unusual in that what is valued can be measured, independent of price, as an impact on health. While measures of health impact of a drug are imperfect, they are meaningful. It is much harder to measure the value of other types of innovation. Drug companies with weak product pipelines will certainly claim that this bill introduces too much government interference into the pharmaceutical market. That is also a canard. Governments already interfere very substantially in pharmaceutical markets as insurers and regulators. The proposed mechanism in the bill will force pharmaceutical firms to compete to earn their share of the prize fund by developing products which have great therapeutic value. The government's role is limited to estimating therapeutic value. I hope that other governments, including Canada's, will be so forward-looking as to introduce similar legislation."