Proposed ‘Grant-And-Access’ Program With Price Caps Could Stimulate Development Of Drugs For Very Rare Diseases

ABSTRACT The 1983 Orphan Drug Act created incentives for the development of orphan drugs. Despite its successes, including a substantial increase in new drugs, approved orphan drugs still treat fewer than 5 percent of registered rare diseases. In addition, concerns have arisen about the high prices of many of these therapies, which can cost hundreds of thousands of dollars per patient each year. In this article, we propose a new “grant-and-access pathway,” in which drug developers could opt to compete for federal grants to subsidize the costs of clinical testing. In return for the grant funding, companies would no longer claim orphan drug tax credits and would agree to price caps for marketed products based on the duration and costs associated with drug development, expected market size, and target rate of return. We identify scenarios in which such a policy could provide a net benefit to society.

The Orphan Drug Act of 1983 defined orphan drugs as medications intended to treat disorders that affect fewer than 200,000 people in the United States, including numerous types of cancer, sickle cell disease, and cystic fibrosis. The act created incentives to encourage pharmaceutical companies to develop orphan drugs. These incentives include seven-year market exclusivity for developers of approved orphan products to treat a rare disease or condition, starting from the approval date, and a tax credit of 50 percent of the cost of conducting clinical trials. The Office of Management and Budget estimates that the value of the tax credits has surpassed $400 million per year.

Other incentives include a twenty-year “carry forward” and a one-year “fall back” provision. These provisions allow the pharmaceutical company to apply the tax credit to taxes due for the previous year or to taxes owed for up to twenty years in the future, if the company cannot apply the full tax credit in a single year. In addition, the act contains research and development grants and waived drug application fees for orphan products. Companies may also be eligible for faster review of applications for marketing approval if the products treat rare but life-threatening illnesses, such as late-stage cancers.

The European Medicines Agency—the European Union counterpart of the US Food and Drug Administration (FDA)—adopted similar regulations in 2000. The European agency defines orphan drugs as those intended for conditions affecting no more than 5 in every 10,000 people (under the US definition, the rare condition can affect about 6.5 in every 10,000 people).

The National Institutes of Health’s Office of Rare Diseases lists almost 7,000 rare diseases in the United States, and approximately 250 new rare diseases are described in the literature annually. Together, these diseases affect an estimated twenty to twenty-five million Americans.

Designation of a drug or biologic agent as an orphan product is granted by the Office of Orphan Products Development at the FDA, based on an application submitted by a drug developer.
After a product receives the designation, the developer can submit an application for marketing approval to the FDA. At that point, other FDA offices review the product’s safety and efficacy data for the designated orphan disease. As of May 2012, 399 orphan products had been approved for marketing in the twenty-nine years since the Orphan Drug Act was passed. In contrast, only ten such products were approved in the ten years preceding the act’s passage.

In this article we discuss a subset of orphan products known as “ultra-orphan drugs.” Although there is no such formal category in the United States, other countries define ultra-orphan drugs as those intended for conditions affecting no more than 1 in every 10,000 people. An example of such a drug is alglucosidase alfa, an enzyme replacement therapy that treats Pompe disease, a condition that affects muscle function and occurs in approximately 1 in 140,000 infants and 1 in 60,000 adults.

Despite the apparent success of the Orphan Drug Act, there are concerns that research for rare diseases continues to be underdeveloped, particularly for therapies targeting these ultra-rare conditions. A study of rare diseases found that those conditions affecting 1–5 in every 10,000 people were almost four times more likely to have at least one orphan drug designation than were conditions affecting fewer people. The authors of this study concluded that the current orphan drug legislation is not sufficient to stimulate orphan drug development for exceptionally rare diseases and that new economic incentives will be required.

Although the development of any drug is challenging, orphan and especially ultra-orphan drugs present unique difficulties. For these products, patient populations are limited and are typically geographically dispersed, which makes it difficult to recruit subjects for clinical trials. Epidemiological data may be lacking or unreliable, which makes it hard to develop precise estimates of disease incidence and rates of progression and mortality. In addition, appropriate clinical trial endpoints to evaluate treatment response may be unknown, and biomarkers that could serve as intermediate markers of response might not have been previously studied or validated. These challenges in the development of orphan drugs are further complicated by recent changes in the drug industry.

Since the enactment of the Orphan Drug Act, the structure of the drug industry has changed dramatically. Drug discovery and early development occur increasingly in smaller, newer biotechnology firms. These firms often do not have marketed products and must rely on external funding, typically from venture capital or through alliances with larger companies. In addition to financing, larger pharmaceutical and biotechnology companies play a critical role in helping these firms meet the regulatory hurdles for FDA approval and supporting the costly late phases of clinical testing, especially Phase III clinical trials.

Alternative Incentives Needed To Promote Orphan Drug Development

The earliest phases of drug development—from preclinical to proof-of-concept studies—are often referred to as the “Valley of Death.” An estimated 90 percent of drugs do not make it through this period.

Although costs during the early phases of development are generally lower than those during later phases, the risk of failure is higher in the early phases. Because of this substantial risk, smaller biotech firms, start-up companies, and universities face major financial barriers to undertaking early drug development, including relatively high expenditures without a revenue stream from existing products. And, without revenues, they cannot take immediate advantage of the Orphan Drug Act tax credits.

Alternative economic incentives for early-phase clinical testing may help drug developers traverse the Valley of Death, particularly those in academic centers and at small firms. This help is critical because development risk decreases after successful completion of early-phase studies. Although the funding requirements to continue product development become greater, the investment opportunity becomes more attractive to large companies and venture capital firms seeking investment opportunities with higher benefit-to-risk ratios.

Existing Programs

The federal government funds several initiatives to stimulate orphan drug development. The Orphan Products Grants Program, established by the Orphan Drug Act and operated by the FDA, was authorized to receive $30 million a year in funding, but Congress has appropriated only about $14 million annually for this program. The FDA’s Office of Orphan Products Development usually reviews roughly 100 applications for the grants annually and awards 10–15 new grants per year, in addition to funding 60–85 ongoing projects at any given time. Despite limited funding, the program has been used to bring forty-five products to marketing approval.

In addition, the National Institutes of Health’s National Center for Advancing Translational Sciences, established in 2012, administers several programs aimed at supporting the preclinical
and clinical development of drugs for rare diseases. The center’s Therapeutics for Rare and Neglected Diseases program seeks to establish public-private collaborations to improve success during preclinical development of drugs for rare and neglected diseases.

On the clinical development side, the Office of Rare Disease Research collaborates with eight institutes in the National Institutes of Health to administer the Rare Diseases Clinical Research Network. Small Business Innovation Research and Small Business Technology Transfer programs, administered within several federal agencies, encourage small businesses in particular to engage in orphan drug projects that have the potential for commercialization.

Furthermore, the Bayh-Dole Act of 1980 allows academic institutions, small businesses, and nonprofits to benefit from the commercialization of inventions stemming from federally funded research. In addition to these direct subsidies, the FDA offers its assistance to companies in designing clinical studies for orphan drugs.

**THE NEED FOR CHANGES IN PRICING**

Although these efforts indicate that society values biomedical research to search for new therapies for rare diseases, the United States still has a long way to go. Both industry analysts and patient advocates have expressed concerns about the pricing of some orphan products, whose annual costs can reach about $400,000 per patient.

As of 2009 eighteen drugs initially approved for orphan indications had reached blockbuster status—that is, they had annual sales surpassing $1 billion—with their seven years of market exclusivity. In addition, 40 percent of blockbuster drugs that received orphan drug approval had previously been launched under the same brand name for nonorphan indications. This reality shows that in some cases, manufacturers stand to make a substantial profit on orphan products. When more than a third of new drug approvals have an orphan designation, as was the case in 2009, a larger question arises about the cost burden these drugs are imposing on the health care system.

Next we examine whether a new orphan drug approval and pricing pathway could address funding issues and spur greater movement of drugs through the Valley of Death, as well as contributing to the emergence of a sustainable market for affordable therapies, particularly for the rarest diseases.

**A New Strategy**

We propose a strategy that would lower the economic barriers for early-phase drug development, particularly for drug makers that cannot fully benefit from tax credits under the Orphan Drug Act because of a lack of revenues from existing products. Companies applying for orphan drug designation could simultaneously apply to a special grant pool within the FDA or the National Institutes of Health, which would be designed to largely offset clinical development costs.

Companies that received grants would no longer be able to claim orphan drug tax credits. The companies would also agree to adhere to pricing caps for the orphan drugs based on how long drug development took and how much it cost, expected market size, and the target internal rate of return. We refer to this proposed strategy as the “grant-and-access” pathway, in which access refers to patients’ access to affordable drugs.

We built a simple financial model to estimate the company’s “internal rate of return,” similar to the concept of return on investment, expected with drug development when accounting for risk of failure—that is, incorporating the cost of development programs that are unsuccessful as well as those that are successful. The model can be used to compare the differences between investing in the development of an orphan drug under the current pathway versus investing under the proposed pathway.

In this model, we departed from the traditional clinical development process for nonorphan drugs, in which the three phases of clinical testing succeed one another, with decision points at the end of each phase—when pharmaceutical companies decide whether to continue funding clinical development. Instead, we assumed that orphan drugs follow a “bundled” regulatory pathway and that companies have two decision points. At the first, the company must decide whether or not to seek FDA approval. We assumed that the data required to submit an Investigational New Drug application to allow for human testing had already been accumulated.

We considered the following two hypothetical cases: an ultra-orphan drug intended for a 10,000-patient population in the United States, and an orphan drug intended for a 200,000-patient population (Exhibit 1). To estimate development costs, we assumed that clinical testing would last six years. This figure was based on data from the biopharmaceutical industry for new orphan molecular entities, although duration of clinical testing varies across types of drugs. We assumed that FDA review would take another year. And we assumed that the
manufacturer would have seven years of market exclusivity after FDA approval, during which time the drug would generate revenues for the manufacturer.

For the ultra-orphan and orphan drugs, we assumed that 60 patients and 350 patients, respectively, would be necessary for clinical testing, based on typical trial sizes in FDA submissions for orphan drugs. We assumed that clinical testing would cost an average of $100,000 per patient enrolled in the trial—an estimate that is consistent with $39 million in out-of-pocket costs reported by Joseph DiMasi and coauthors for Phase I and Phase II trials when divided by the 350 patients enrolled in clinical testing in the orphan drug scenario.

We then examined how the two hypothetical drugs would have fared under the current pathway (in which the manufacturer receives tax credits but no grants) versus our proposed pathway (in which the manufacturer receives grants but no tax credits and accepts pricing caps). For both pathways, we assumed that the manufacturer earned a net profit of 20 percent of revenues, which is subject to a 35 percent corporate tax rate. For the current pathway, we applied a tax credit equal to the 50 percent of drug development costs that the manufacturer would receive in the first year following FDA approval.

For the main analysis, we assumed that the probability that an experimental orphan drug would ultimately gain FDA approval was 15 percent. We based the percentage on FDA data indicating that 2,594 experimental drugs received orphan drug designation from 1983 to 2012, but only 399 of them, or roughly 15 percent, were approved for sale. Recognizing that this approval rate could be higher or lower across various orphan drug indications, we varied the probability of approval in different scenarios. At an assumed price of $100,000 per patient and a prevalence of 200,000 patients, an orphan drug approved by the FDA that generates $1 billion in annual sales would be used by 5 percent of the affected population in each of its seven years of market exclusivity. This 5 percent market penetration is the usage rate we assumed in our model.

Under the current system, drug companies set a drug’s price to achieve rates of return high enough to justify the risk of investing in the drug’s clinical testing. For example, at the assumed annual treatment price of $100,000 per patient and a 15 percent probability of receiving FDA approval, the orphan drug provides an internal rate of return of 20.7 percent. In contrast, the return for the ultra-orphan drug indication barely reaches 2.7 percent with an assumed 15 percent probability of approval (Exhibit 2).

When multiple projects are competing for funding, the rational decision is to fund the project with the highest expected rate of return. In other words, investors will prefer to fund the development of the orphan drug rather than the ultra-orphan drug. This calculation illustrates the dynamics of a system in which some orphan drugs seem to represent an attractive investment, but a large majority of ultra-orphan drugs do not.

In the absence of a robust grant program, the ultra-orphan drug developer in our example would need to increase drug prices to $329,000 per patient for an annual course of treatment to yield a 20 percent rate of return. In comparison, a grant program that would cover, for example, 75 percent of the development costs—equivalent to $4.5 million in our example—would give the ultra-orphan drug developer a 20 percent return at a treatment

**EXHIBIT 1**

**Assumptions About The Development And Sale Of Two Hypothetical Drugs**

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Ultra-orphan drug</th>
<th>Orphan drug</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEFORE FDA APPROVAL</strong></td>
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<td></td>
</tr>
<tr>
<td>Number of patients in clinical testing</td>
<td>60</td>
<td>350</td>
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<tr>
<td>Cost per patient in clinical testing</td>
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<td>$100,000</td>
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<td>Total cost of clinical testing</td>
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<td>$35 million</td>
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<tr>
<td><strong>AFTER FDA APPROVAL</strong></td>
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<td></td>
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<tr>
<td>Size of target population</td>
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<td>200,000 patients</td>
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<tr>
<td>Patients treated per year</td>
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<td>10,000 patients</td>
</tr>
<tr>
<td>Annual sales</td>
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<tr>
<td>Annual net profit before tax (20% of sales)</td>
<td>$10 million</td>
<td>$200 million</td>
</tr>
</tbody>
</table>

**SOURCE** Authors’ model. **NOTE** FDA is Food and Drug Administration.

**EXHIBIT 2**

**Internal Rate Of Return Under The Current Pathway For Orphan And Ultra-Orphan Drugs**

![Graph showing internal rate of return under the current pathway for orphan and ultra-orphan drugs.](http://content.healthaffairs.org/)

**SOURCE** Authors’ calculations. **NOTE** Calculations assume estimated clinical testing costs of $35 million for orphan drugs and $6 million for ultra-orphan drugs.
price of $84,750 per patient—roughly one-fourth of the cost estimated under the current pathway.25

In this scenario, the expected cost to the FDA grant program per approved drug is approximately $30.0 million ($4.5 million divided by a 15 percent probability of success). Given the difference of $244,250 in annual per patient costs between the grant-and-access pathway and the current pathway, if just 123 patients were treated every year, the cost of the grant program would be more than offset by savings to society from the lower drug prices. If 500 patients were treated per year, as we assumed in our model for the ultra-orphan drug scenario, the societal savings from the grant-and-access pathway, defined as savings from the lower drug prices minus grant costs, would be approximately $92.1 million per year for every drug approved using this mechanism.

Exhibit 3 shows the results for both the orphan and nonorphan drug scenarios at varying levels of grant support.

**Discussion**

Drug development has undergone a profound transformation in the years since the Orphan Drug Act was enacted. Innovation is increasingly undertaken by small biotechnology firms and universities, which later license their novel molecules to large pharmaceutical companies for late-phase development and marketing.

The early innovators often struggle for funding to advance novel therapies past the proof-of-concept stage. The incentives originally envisioned for such innovators through the Orphan Drug Act are out of reach for many of these small companies and universities: Tax credits have little influence on firms that have not yet generated any revenue. Moreover, current incentives appear to steer development toward a few profitable areas, such as oncology, while research on the large majority of other orphan diseases remains underdeveloped.20

Our proposed grant-and-access pathway represents a rate-of-return regulation similar to the United Kingdom’s Pharmaceutical Price Regulation Scheme, which is an agreement between the Association of the British Pharmaceutical Industry and the UK government that sets a ceiling on companies’ profits as a function of sales of patented drugs purchased by the National Health Service. A major difference is that our proposed policy is limited to specific drugs whose developers choose to take advantage of the pathway in return for the grant support, whereas the UK scheme caps profits at the company level with no associated grants for development. Our model demonstrates that for companies choosing the grant-and-access pathway, an orphan drug candidate could represent an attractive investment, even with pricing caps on marketed products and in the absence of tax credits.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Level of grant support</th>
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<tbody>
<tr>
<td></td>
<td>0%</td>
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<tr>
<td><strong>ORPHAN DRUG</strong></td>
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<tr>
<td>Price cap per patient</td>
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<tr>
<td>Total subsidy</td>
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<tr>
<td>Savings from lower drug prices</td>
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<tr>
<td>Net savings to society</td>
<td>0</td>
</tr>
<tr>
<td><strong>ULTRA-ORPHAN DRUG</strong></td>
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<tr>
<td>Price cap per patient</td>
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</tr>
<tr>
<td>Total subsidy</td>
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<tr>
<td>Savings from lower drug prices</td>
<td>0</td>
</tr>
<tr>
<td>Net savings to society</td>
<td>0</td>
</tr>
</tbody>
</table>

**Source** Authors’ calculations. **Notes** Calculations assume a target internal rate of return of 20 percent when varying the amount of grant support, a 15 percent chance that a drug will be approved by the Food and Drug Administration, and clinical testing costs of $35 million for each orphan drug and $6 million for each ultra-orphan drug. M denotes millions of dollars.
people who prefer less government involvement in funding drug development.

The Affordable Care Act is an example of a recent legislative effort that allows drug developers to choose the incentive scheme that best fits their particular needs. The act offers the option of twelve-year market exclusivity for biologics (as opposed to the current seven-year exclusivity under the Orphan Drug Act) or a tax credit, but not both.

For an ultra-orphan drug developer that rejects the tax credit but seeks twelve-year exclusivity, our model suggests that its internal rate of return at the assumed revenue price of $100,000 per patient is still only 7.3 percent. That is well short of a rate of return that would typically be attractive to investors. The shortfall suggests that prices of more than $100,000 per year per patient would be necessary to provide an adequate return, unless a mechanism such as the grant-and-access pathway proposed here were implemented.

The extent to which drug developers would opt for the grant-and-access pathway if it were available is uncertain. Larger companies with adequate resources to fund clinical development and smaller companies that are successful in attracting venture funding would be least likely to commit to a price cap and pursue this pathway. However, we would expect that other smaller biotech firms, universities, and private research institutes would be likely to choose the pathway.

If the competitive funding component were implemented, the applications for grants would need to be assessed. The FDA’s existing Orphan Products Grants Program could be expanded or could collaborate with the National Institutes of Health’s Office of Rare Disease Research to take on this task. To avoid continuing to fund unsuccessful projects, progress would have to be monitored using specified timelines and benchmarks.

We propose that the Internal Revenue Service be responsible for setting price caps. Because the agency currently processes financial information on research and development costs to administer orphan drug tax credits, it would be well suited for this role. Drug prices could be set according to a predetermined formula based on the duration and cost of clinical development; the number of patients eligible for treatment, information that is available in the application submitted to the FDA for orphan drug designation; and a given internal rate of return that could be set by Congress.

As a point of reference for the rate of return, recent estimates indicate that the cost of capital ranged from 17.7 percent for companies whose most advanced drug candidates were still in the preclinical development phase to 13 percent for companies with drugs in more advanced phases of development. The higher cost of capital faced by companies whose drugs had not yet moved into clinical testing reflects higher failure rates during the early phases of drug development. The internal rate of return set by Congress would have to be higher than the cost of capital to make drug development attractive to investors.

If the annual revenues of a drug that had won FDA approval were to surpass projections because the number of patients actually treated with the drug for the orphan disease surpassed the expected number used in the formula to determine the drug’s price cap, a windfall tax could be imposed on the company.

Although we are not suggesting that the grant-and-access pathway be funded with redirected tax credits currently provided under the Orphan Drug Act, it is useful to consider the potential effects of funding this pathway at an equivalent level to the current pathway. The tax credits are valued at $400 million per year, an amount that could provide approximately $4.5 million in funding—the 75 percent of development costs in our ultra-orphan example—for almost ninety new drug development programs per year. If the 15 percent FDA approval rate holds over the long term, approximately thirteen new ultra-orphan drugs could be developed on an annual basis.

That number is similar to the rate of about fourteen orphan drugs approved per year since the Orphan Drug Act became law, but the proposed pathway would have the added benefit to society of lower drug prices.

CONCLUSION Additional analyses of our proposed policy changes and alternatives put forward by others, including an extension of existing tax credits to “angel” or venture capital firms to encourage investment, are necessary before any new legislation is considered. In addition, administrative flexibility at the FDA and initiatives at the National Institutes of Health’s Office of Rare Diseases with regard to appropriate study design and biomarker development for rare diseases could also reduce risks to investors and accelerate orphan drug development.

For instance, even if a promising biomarker that is a drug target has yet to be validated through the monitoring of long-term clinical outcomes, the FDA could grant conditional approval for a drug that targets the biomarker. The agency could then require the drug’s manufacturer to prospectively collect the information after approval that would be necessary to validate the biomarker.

The proposed grant-and-access pathway has the potential to foster innovation for ultra-orphan diseases, leveling the playing field for
drug developers so that all of them could benefit, whether or not they currently have revenues. The new policy would provide a net benefit to society by stimulating the development of novel drugs for the rarest diseases, while reducing financial barriers that limit access to treatment.

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NOTES


19 Roos JC, Hyry HI, Cox TM. Orphan drug pricing may warrant a competition law investigation. BMJ. 2010;341:c6471.


24 We assumed that a generic alternative would be available after the seven-year exclusivity period and that the original developer would therefore receive no revenues from the orphan drug after that period. We chose $1 billion in sales to represent an orphan drug with blockbuster sales, equivalent to 5 percent of the patient population spending $100,000 each on the drug.

25 For simplicity, costs in this section are not discounted to take into account the time value of money. Since the $4.5 million from the grant program would not all be paid in year 1 but would be spread out over the seven years of development, the actual total cost of the program would be lower than $4.5 million, or equivalent to the sum of the amounts paid each year discounted by the cost of capital. The internal rate of return, on the other hand, is by definition calculated taking into account the time value of money.
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In this month’s Health Affairs, Ana Valverde and coauthors advance a proposal for a new innovation and regulatory pathway that could stimulate investment in affordable drugs to treat very rare diseases. Under their proposed “grant-and-access” pathway, drug developers could compete for federal grants to subsidize the costs of clinical testing; once grants were obtained, these developers could no longer claim orphan drug tax credits and would also agree to price caps for marketed products. The authors suggest that this approach could appeal to academic institutions and smaller developers and identify scenarios in which such a policy could provide a net benefit to society.

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Reed received a doctorate in pharmaceutical health services research from the University of Maryland and completed a two-year postdoctoral fellowship in the Pharmaceutical Outcomes Research and Policy Program and the Center for AIDS Research at the University of Washington.