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PRACTICAL IMPLICATIONSTo advance the development of new treatments, we need to:Increase funding for the National Institutes of Health. Incorporate the patient perspective in product development and allow patient information to be accessed, used, and shared for research.Mitigate the impact that issues related to patent protection have on dormant therapy development. Reduce regulatory duplication and unnecessary delays in institutional review board review.The US Senate is about to pick up the baton passed from the House of Representatives in the race to develop new and better treatments for the millions of Americans with unmet medical needs.1 The race is a marathon: there are many hills and valleys to traverse before the medical innovation legislation arrives at the president's desk for his signature.A fundamental hurdle in this race in the United States is the lengthy and costly development and review process for new products. Different stakeholders have many good, yet different points of view about potential solutions to bringing life-saving cures and treatments to patients faster.RecommendationsFrom the patient perspective, there are 5 core recommendations that would have a significant impact on meeting the clinical needs of people with chronic conditions:1) Increase funding for the National Institutes of Health. Basic science conducted through funding by the National Institutes of Health (NIH) is the lifeblood of research to find new treatments and cures for people with chronic diseases and disabilities. Increasing the funding of NIH through mandatory spending should be a top priority.2) Incorporate the patient perspective in product development. As this column has pointed out before, engaging patients throughout the product development process is critical to ensuring that innovative therapies reach patients faster.2 Many stakeholders are beginning to seek patient input early in the development process with the intent of ensuring that the studies conducted to inform regulatory approval, and eventual clinical use, are capturing information that is highly relevant and specific to the end-users themselves: the patients.To further the use of patient input in drug development and regulation, there needs to be a process under which an entity can submit patient data to be incorporated into the FDA's structured benefit-risk framework. Accompanying guidance would define the types of activities that entities may undergo to seek such input.Another area that warrants further consideration and action from Congress is the current uncertainty and lack of predictability that comes with engaging with patients—particularly from the perspective of biopharmaceutical companies. Because companies often fear their interactions with patients are at risk of being construed as discussions of unapproved medicines or unapproved uses of approved medicines, they are inclined to forgo invaluable input from patients to inform early-stage research decisions, such as clinical trial design. Many companies conduct trials only to learn after their drug is approved that the outcomes they chose to study are of no value or interest to the patients who will take the drug. A more rational approach would be to allow manufacturers to engage patients appropriately in order to inform study design, outcome selection, and other aspects of research and development so that the end product is a drug that is optimally valuable to patients. Clearer guidance and policies are required to encourage these collaborations and to create a more predictable environment for companies to engage patients.3) Mitigate the impact that issues related to patent protection have on dormant therapy development. Bringing promising treatments to all individuals suffering from debilitating and life-threatening diseases remains a critical priority for the patient community. However, existing laws related to patents can discourage investigation of treatments for unmet medical needs, and many promising treatments do not meet the technical requirements of patent eligibility.3,4 Additionally, because patent life runs concurrently with research and development, research into products that take a significantly longer period of time to develop is less likely to occur. The creation of an approval pathway for dormant therapies would remove technical patent requirements that are unrelated to medical promise and would start the period of protection at the point of FDA approval. This pathway would incentivize researchers to pursue the development of drug compounds on the basis of their clinical promise, rather than their patent life.4) Allow patient information to be accessed, used, and shared for research. While privacy is critically important to everyone, people with chronic diseases and disabilities typically consider the benefits of research to outweigh this risk. Therefore, we should grant researchers the flexibility to share data sets, while strengthening the security of data; provide one-time patient authorization for the use of their information; expand appropriate remote access; allow entities collecting data to use it for research; and treat research like other public health activities.5) Reduce regulatory duplication and unnecessary delays in IRB review. The institutional review board (IRB) approval process is a necessary safeguard to ensure appropriate patient protections; however, aspects of the process have proven to be cumbersome and redundant.5 Solutions are needed to create efficiencies and reduce duplications, which will help expedite reviews and ultimately allow research to progress faster.ConclusionsThis critical race to enhance the production of much needed new treatments is a race against time, which is very limited for millions of people living with life-threatening conditions. It can be won, but only by squaring off against what look like insurmountable hurdles to smart public policies. Author Affiliations: National Health Council, Washington, DC.Funding Source: None.Author Disclosures: The author reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.Authorship Information: Concept and design; drafting of the manuscript; critical revision of the manuscript for important intellectual content; supervision.Address correspondence to: Marc Boutin, JD, executive vice president and chief operating officer, National Health Council, 1730 M St NW, Ste 500, Washington, DC 20036-4561. E-mail: mboutin@nhcouncil.org. REFERENCES HR 6: 21st Century Cures Act. 114th Congress (2015-2016). Congress.gov website. . Accessed October 30, 2015.Boutin M. Meaningful patient engagement: can we agree on a framework? Am J Pharm Benefits. 2015;7(1):e25-e26.Roin B. Unpatentable drugs and the standards of patentability, Texas Law Review. 2009;87(3):503-570. 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