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Health care consumers are contributing their skills, money, and time to develop effective solutions that aren't available on the commercial market.

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BY HAROLD DEMONACO, PEDRO OLIVEIRA, ANDREW TORRANCE, CHRISTIANA VON HIPPEL, AND ERIC VON HIPPEL

Patients are increasingly able to conceive and develop sophisticated medical devices and services to meet their own needs — often without any help from companies that produce or sell medical products. This “free” patient-driven innovation process enables them to benefit from important advances that are not commercially available. Patient innovation also can provide benefits to companies that produce and sell medical devices and services. For them, patient do-it-yourself efforts can be free R&D that informs and amplifies in-house development efforts.

In this article, we will look at two examples of free innovation in the medical field — one for managing type 1 diabetes and the other for managing Crohn's disease. We will set these cases within the context of the broader free innovation movement that has been gaining momentum in an array of industries¹ and apply the general lessons of free innovation to the specific circumstances of medical innovation by patients.

THE LEADING QUESTION

What are the incentives that drive free patient innovation?

FINDINGS

*Patient innovators don't benefit from selling their products and services as producers do.

*Rather, they are self-rewarded by their ability to use and share what they develop.

*For that reason, they are willing to let others copy them for free.

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Example 1: Managing Type 1 Diabetes

In 2013, Dana Lewis, a professional in health communications in her 20s, joined forces with a software engineer and a few other individuals with type 1 diabetes to develop for themselves what the medical device industry had been promising to deliver for decades: an artificial pancreas. As patients, they sought to solve the problem of low overnight blood sugar levels, a common occurrence that can be deadly. They wanted to design a system that could automatically monitor blood sugar levels every few minutes and provide the right insulin dose to keep the number in a healthy range.

Within months, Lewis and her co-innovators designed an artificial pancreas that used computer

code they wrote themselves and off-the-shelf hardware to connect commercially available continuous glucose monitors with commercially available insulin pumps. The device significantly improved Lewis's ability to manage her own blood sugar levels. She and her colleagues decided to make the design available to others online and make their software open source. This was the start of the Open Artificial Pancreas System (OpenAPS) movement.² Today, multiple communities participate in this movement, multiple noncommercial DIY artificial pancreas designs are being shared, and thousands of individuals with diabetes use these DIY systems daily to monitor, manage, and improve their health.

Example 2: Managing Crohn's Disease

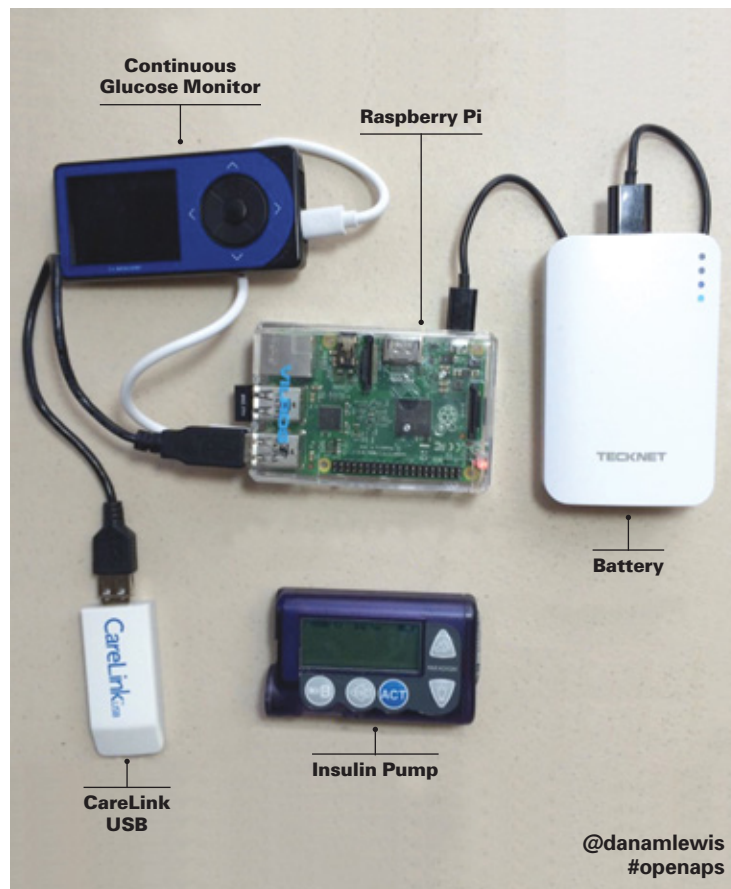
Sean Ahrens, a computer science and business graduate from the University of California, Berkeley, became frustrated in his early 20s that there wasn't any detailed medical information on what he could do to minimize debilitating flare-ups from Crohn's disease. Although several drug treatments for Crohn's existed, all of them had significant toxicities and none was effective for every patient. As a result, many people tried to manage and reduce their symptoms through dietary choices. To fill a resource gap for patients, Ahrens, who was diagnosed with Crohn's when he was 12, created a website in 2011 called Crohnology, where fellow patients were invited to share their experiences regarding interventions and outcomes through an online questionnaire. The site compiled the data so that everyone could see which factors others found troublesome and which were helpful.³ Today, the site has more than 10,000 registered users. Crohn's patients throughout the world have come to find the information invaluable for managing their chronic disease.

The General Practice of Free Consumer Innovation

What is striking about both of these cases is that neither commercial medical producers nor the clinical care system offered a solution that these patients urgently needed. Motivated patients stepped forward to develop solutions for themselves, entirely without commercial support.⁴

A DIY ARTIFICIAL PANCREAS

The artificial pancreas that type 1 diabetes patient Dana Lewis and her co-innovators developed for themselves used an off-the-shelf microcomputer to connect commercially available continuous glucose monitors with commercially available insulin pumps.



Free innovation in the medical field follows the general pattern seen in many other areas, including crafts, sporting goods, home and garden equipment, pet products, and apparel.⁵ Enabled by technology, social media, and a keen desire to find solutions aligned with their own needs, consumers of all kinds are designing new products for themselves. (See “About the Research.”)

Consumers innovate and diffuse their innovations in ways that are very different from producers, and it is important to understand the differences. (See “Consumer Versus Producer Innovation,” p. 84.) Unlike traditional producers, who start with market research and R&D, free innovation begins with consumers identifying something they need or want that is not available in the marketplace. To address this, they invest their own funds, expertise, and free time to create a solution. Rather than seeking to protect their designs from imitators, as commercial innovators do, we found that more than 90% of consumer innovators make their designs available to everyone for free. What’s more, they let other people test and improve on the initial design and make the new version available for free as well. Once a design is fully developed, it gets diffused still further, allowing consumers to make their own noncommercial copies, and allowing producers to commercialize the designs without having to license them from the consumer innovators.⁶

You might wonder why individuals would bother to invest time and money in innovations without any expectation of being paid for either their labor or their product designs. The answer is simple: Consumers who innovate are attracted by the personal benefits, such as the opportunity to use their innovations and the fun and learning they gain from the process of developing them. They also get satisfaction from

SHARING CROHN’S DISEASE INFORMATION GLOBALLY

Through Crohncology.com, Crohn’s disease patients around the world can share their knowledge and experiences and learn how treatments have worked for others. Contributors are asked to create a timeline of their personal health and treatments used. They also can ask and reply to research questions and participate in studies. Crohncology.com shares the collective knowledge with contributors and noncontributors alike.

TOP MEDICATIONS	Remicade	★ ★ ★ ↓	2,698 people
	Prednisone	★ ★ ★ ★	4,783 people
	Imuran	★ ★ ★	2,355 people
TOP DIETS	No Beer	★ ★ ★ ★	2,348 people
	No Dairy	★ ★ ★ ★	2,010 people
	No Spicy Food	★ ★ ★ ★	1,936 people
TOP SUPPLEMENTS	Vitamin B12	★ ★ ★ ↓	2,536 people
	Vitamin D	★ ★ ★ ↓	3,165 people
	Probiotics	★ ★ ★ ↓	3,095 people

SOURCE: CROHNOLOGY.COM

sharing their innovations with people with similar needs.⁷ In other words, they are *self-rewarded*.

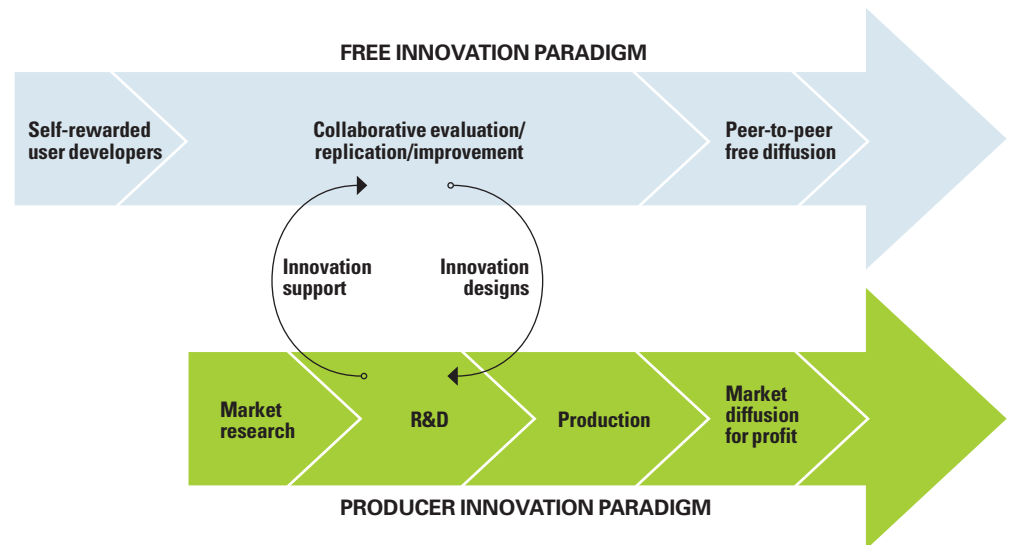
As different as the consumer and commercial paradigms are from each other, they are complementary rather than opposing. Indeed, research shows that consumers, producers, and society at large are best served when both paradigms are used simultaneously.⁸ Producers can benefit from consumer innovation by adopting consumer product designs developed and tested by consumers for free; consumers benefit from producer-developed modules for DIY projects such as Raspberry Pi micro-computers and also from producer-developed innovations that serve mainstream needs. And, of course, society as a *whole* benefits when consumer

ABOUT THE RESEARCH

We studied the extent and nature of innovation by medical patients via two types of research. First, working with academic colleagues around the world, we conducted nationally representative surveys in 10 countries.¹ We used these surveys to determine the nature and frequency of all types of consumer-driven product innovations, including those in the medical field. Next, we conducted both qualitative and quantitative research to learn more about medical-product innovation development in particular. The studies, including surveys and face-to-face discussions with groups of collaborating patient innovators, allowed us to deeply understand critical field-specific issues. These issues include the strong desire by medical patient innovation groups to find ways to design and ethically conduct valid clinical trials to test the medical effects of their innovations.

CONSUMER VERSUS PRODUCER INNOVATION

The approach consumers use to develop products for themselves, based on the free innovation paradigm, differs greatly from the producer innovation paradigm. Rather than seeking to protect their designs from imitators, most consumer innovators make their designs available to everyone for free. Producers, by contrast, develop what they can protect from imitators and sell at a profit. As indicated by the curved arrows, free innovators sometimes use commercially available products in their solutions, and producers sometimes use designs developed by free innovators.



SOURCE: E. VON HIPPEL, FREE INNOVATION, 2017

and producer innovators focus on what they do best and most efficiently.⁹

Applying the Ideas of Consumer Innovation to Health Care

Surveys show that medical-device development by patients is taking place on a massive scale. In nationally representative surveys conducted from 2010 to 2015 in the United States, the United Kingdom, Japan, Finland, Canada, and South Korea, approximately 1 million individuals reported that they had developed medical innovations to serve their own needs in the three years preceding the surveys.¹⁰ Although the basic practices underlying free consumer innovation apply across sectors, innovators must make adaptations for their own personal and market environments. In the case of patient innovation, the most important adaptations have to do with ensuring safety and supporting free diffusion.

When a medical product that meets patient needs is available on the market, patients often prefer to buy that product rather than developing their

own or copying another patient's free design. However, if a solution isn't available commercially and the need is urgent, many try to design and build their own product. Things patients need may not be profitable to produce for reasons including the following:

- Thousands of rare diseases are chronic and challenging for patients to manage on a long-term basis. In many instances, the diseases afflict relatively few patients and represent markets that are too small for producers to profitably serve.
- Often, even when a large number of patients have the same need, producers don't have sufficient incentive to innovate because there's no good way for them to profit from the type of solution that's needed. Crohn's disease offers a case in point. As useful as it may be for Crohn's patients to manage and reduce their symptoms through diet, getting companies to invest in the clinical trials is a hard sell. They would want to recoup the costs via patented food products or other measures.

- Even if an innovation can be protected and is potentially profitable, the regulations governing clinical trials tend to make it costly and slow for producers to get approvals. For example, in the United States, getting Food and Drug Administration approval for a device of low or moderate risk takes an average of 10 months. Approvals for high-risk devices — such as an artificial pancreas — could take four to five years and cost \$75 million.¹¹ As demonstrated by the history of the patient-developed artificial pancreas, patient innovators (whose noncommercial activities are exempt from FDA regulation) may be able to develop and produce something in a matter of weeks or months, at very little cost.

One or more of these constraints can inhibit the commercial provision of many things that patients need. This makes the free patient innovation system a critical resource that must be recognized and supported.

Supporting Patient Innovation

Would-be patient innovators grapple with important questions about legality and safety, what the future of patient innovation looks like, and how the DIY system can be supported and improved. We address these questions here.

Is it legal for patients to develop and diffuse DIY medical innovations? Different countries have different laws regarding patient-developed innovations, although many Western countries follow similar guidelines. In the United States, freedom for patients to innovate is firmly rooted in the country's legal traditions. Under the U.S. Constitution's Fourth Amendment, which enshrines the right to privacy, citizens may create medical innovations at home and use them on themselves. This right is protected whether others consider an innovation to be effective or ineffective or its use wise or unwise. The First Amendment, moreover, protects the right to free speech, thereby

entitling people to tell the world about their innovations and to share details about designs and their use.

In addition, the Commerce Clause of the U.S. Constitution and the governing statutes of federal regulatory agencies such as the FDA restrict agencies from regulating noncommercial activity.¹²

Is patient innovation safe? It's important to acknowledge that safety is not guaranteed. For example, a software coding error in the design of an artificial pancreas could lead to dangerous miscalculations in a patient's insulin dose. Such an error would be far more serious than, say, erroneously advising a Crohn's patient to avoid drinking beer. Offsetting this sort of risk is the fact that very few patient-created medical innovations fall into the highest FDA risk category.¹³

Even in cases where there are significant safety risks, we think it would be a mistake for governments to limit patient innovation. In our view, there are two compelling reasons to encourage it.

First, the proper way to evaluate the dangers of patient innovation is to compare the risks patient DIY devices pose with the harm patients suffer when no such innovation exists. Consider again the artificial pancreas. Once building one became technically possible, it was hard to overlook the fact that the *lack* of an FDA-approved commercially available product contributed to the deaths from hypoglycemia of thousands of people with diabetes and a worsened quality of life for thousands more suffering from the disease.¹⁴

In other words, when patients innovate to address medical problems unserved by commercial solutions, we may well see that their innovations provide a net gain rather than a loss in safety and quality of life for the whole population of affected patients. We expect safety will improve further as low-cost clinical trial methods are developed to enable patient communities to test their own innovations, utilizing



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similar ethical standards to those used by hospitals and universities for clinical research involving human subjects. (See “Low-Cost Clinical Trials by and for Patients.”)

Second, as already noted, individual patients have the legal right to make their own choices, and these rights are very broad. By way of comparison, extreme sports are widely recognized as risky — those who participate in them can face injury or even death. Yet, in the name of personal freedom, society doesn’t ban people from taking part in extreme sports. Similarly, some patient innovators will develop devices that could be seen as overly risky. But society shouldn’t use that as an excuse for banning patient innovation.

What does the future of patient innovation look like? The ability of patients to develop new medical products to serve their own needs is growing, and we expect the system to become stronger over time for several important reasons. First, the DIY design tools that patient innovators need are becoming cheaper and increasingly capable. People with fairly rudimentary engineering skills can acquire powerful design software that can run on an ordinary personal computer either for free

or for very little money. Second, the materials and tools used to build products from DIY designs are also becoming both cheaper and increasingly capable. For example, the original DIY artificial pancreas system design used a microcomputer that sells for about \$30 today. Newer DIY solutions don’t require a special-purpose computer at all, instead using smartphones and specially designed apps.¹⁵ Third, the search and connection functions of today’s internet enable patients — even those with extremely rare diseases — to find others with similar problems throughout the world. Patients and caregivers can collaborate online to build DIY projects. Indeed, thousands of patients have found their way to the OpenAPS and Crohnlology websites, and many people have contributed their technical skills.

How can the free grassroots patient innovation system be supported and improved? We believe that patients, medical product and service producers, and government regulators should all support the patient innovation system and help it develop in medically and socially valuable directions. How can this be done?

At present, the early stages of the patient innovation process seem to be working well. It can

LOW-COST CLINICAL TRIALS BY AND FOR PATIENTS

As we have noted, the FDA does not have jurisdiction over noncommercial patient innovation and diffusion. Therefore, it can’t force patient innovators to invest in trials to assess the safety and efficacy of their innovations before diffusing them. However, patients themselves are likely to be interested in learning about any experiments that have been conducted before they personally adopt a DIY innovation. Fortunately, very low-cost approaches exist and are being developed to make it practical for patients — both individuals and groups — to carry out high-quality, ethically appropriate trials. Many of them involve a trial design called “n of 1,” in which trials are of a single patient, or “aggregated n of 1” for multiple patients.

To illustrate, consider Adam Brown, who has type 1 diabetes and writes about diabetes for an online journal. He wanted to know whether to adhere to a low-carbohydrate diet or whether his blood sugar levels could be managed equally well on a high-carbohydrate diet with carefully timed doses of insulin. If the latter were true, he and other people with diabetes could include more high-carbohydrate treats in their diets. Brown decided to conduct his own n-of-1 trial. As a first step, he went on a low-carbohydrate diet for two weeks, carefully monitoring his meals and their timing. He also monitored his blood sugar levels every few minutes (using a personal continuous glucose monitor) and recorded the insulin doses and the times. Then he went on a two-week higher-carbohydrate diet and made the same measurements. Comparing the two diets, Brown found that while his long-term average blood sugar levels (as measured by the A1C test) were nearly the same on both diets, the low-carb diet helped him keep his hourly blood sugar levels within a safe range more easily, which is what counts for long-term health.

Brown published an account of his personal experiment, including his methods and findings, on the diaTribe.org website, which is aimed at people with diabetes.ⁱⁱ Sharing the information allowed other people to copy the experiment. To the extent that others add their data to a common database, it can be configured into the evidence base for an aggregated n-of-1 nonblinded multipatient trial, which can then be analyzed by expert patients and/or by professionals.ⁱⁱⁱ



The economic reality is that commercial producers and medical service providers will never be able to deliver everything patients need. Innovative patients can fill many of the gaps if they are properly supported.

leverage the same tools and systems used for consumer innovation in other fields — everything from open-source software development to hardware hacking in maker spaces. However, clinical testing and certain aspects of free diffusion are unique to medical innovation. These elements require special attention and improvement, and that's where innovating patients, commercial producers, and governments can all play a role.

Improving clinical testing. In the case of clinical trials, patient innovators cannot simply adopt FDA gold-standard trial designs. These designs — including randomized double-blind placebo-controlled trials — are generally too expensive for patient communities to conduct on their own. However, less elaborate designs can produce high-quality results at much lower cost and in less time.¹⁶ Support for improvements here would involve creating websites and tool kits to provide guidance to patients who have little knowledge of trial design, appropriate privacy and safety standards for trial participants, and statistical analysis (much as other websites help software development newbies set up open-source projects with pretested tools and procedures). Such tool kits are being developed by DIY patient communities and offered by commercial sites like ProofPilot¹⁷ to support both commercial and community experimentation.

Improving diffusion. Since patient innovations are exempt from FDA regulation only if they are diffused noncommercially, patients must make their own noncommercial copies from free designs. Given this restriction, how can noncommercial diffusion be simplified to make innovations more accessible to individuals who lack technical skills?

We see some promising opportunities in taking advantage of increasing openness of government-approved medical devices to DIY attachments and in the increased availability of commercial off-the-shelf, open-source components suitable for DIY

projects. Consider the artificial pancreas project. In 2013 commercial medical devices such as continuous glucose monitors and insulin pumps were designed to protect the data these devices collected on patients, using encryption. Patients didn't have access to their data because the assumption was that only doctors would understand it and have use for it. As a result, innovators had to find ways to hack the devices to gain access to their own patient data, overriding the producer's intent. Today, device makers have incentives to make their interfaces open so that they can be a valued part of DIY systems.¹⁸

As the benefits of patient-developed innovations become increasingly evident, many new types of specialized platforms and services to support free diffusion are likely to emerge. For example, Patient Innovation, a nonprofit online platform devoted to facilitating the evaluation and sharing of innovative solutions developed by patients with any disease, is available for free.¹⁹ It complements special-purpose platforms like OpenAPS and Crohnology.

AS THE FREE PATIENT innovation system expands and strengthens over time, we expect to see greater complementarity between it and the commercial medical innovation systems. Patients, medical product and service producers, and government regulators all have vital roles to play in supporting the free patient innovation system and helping it develop in medically and socially valuable directions. The economic reality is that commercial producers and medical service providers will *never* be able to deliver everything patients need. Innovative patients can fill many of the gaps if they are properly supported. A richer set of available medical innovation options will benefit patients, commercial medical caregivers, producers, and society at large.

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