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# FDA Approves Breakthrough Cholesterol Pill That Cuts “Bad” Cholesterol by Nearly 60%—What You Need to Know

By bestfolkmedicine · 06/11/2026 · 10 min read



**A major development in heart health has arrived: the U.S. Food and Drug Administration has approved a new once-daily pill capable of dramatically lowering LDL, commonly known as “bad” cholesterol. In clinical trials, the medication reduced LDL levels by as much as 59%, potentially offering a powerful new option for millions of adults struggling to control their cholesterol.**

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For decades, doctors have relied heavily on statins and other medications to manage dangerously high cholesterol. More recently, injectable treatments have provided another option for patients who need additional reductions.

Now, a new medication called **Lipfendra (enlicitide)** is changing how one of these advanced treatments can be delivered.

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Instead of requiring injections, patients may be able to achieve substantial cholesterol reductions with a daily tablet.

But how does this medication work, who could benefit, and what should people know before considering it?

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## A New Era in Cholesterol Treatment

In July 2026, the FDA approved Lipfendra, developed by pharmaceutical company Merck, as the first oral medication designed to inhibit a protein called PCSK9.

The approval represents an important development because PCSK9 inhibitors have traditionally been administered by injection.

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These medications work differently from statins, targeting a biological mechanism that affects how efficiently the liver removes LDL cholesterol from the bloodstream.

Lipfendra is approved for adults with high LDL cholesterol, including those with an inherited condition known as heterozygous familial hypercholesterolemia.

It is intended to be used alongside appropriate dietary habits, physical activity, and other cholesterol-lowering treatments when needed.

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For patients who have difficulty reaching their cholesterol targets with existing therapies, the new pill provides another treatment option.

## What Makes This New Pill Different?

To understand why the FDA approval is significant, it helps to understand how cholesterol moves through the body.

Cholesterol is a waxy substance that plays an essential role in building cell membranes, producing hormones, and supporting numerous biological processes.

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The problem develops when excessive amounts of LDL cholesterol circulate in the bloodstream.

Over time, LDL particles can enter artery walls and contribute to the formation of fatty deposits called plaques.

This process, known as atherosclerosis, can narrow arteries and increase the risk of heart attacks and strokes.

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### The Role of the PCSK9 Protein

The liver plays a central role in regulating cholesterol levels.

Specialized structures called LDL receptors help remove LDL particles from the blood.

However, a naturally occurring protein called PCSK9 can promote the destruction of these receptors.

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When fewer LDL receptors are available, the liver becomes less efficient at clearing LDL cholesterol.

Lipfendra works by blocking PCSK9.

This allows more LDL receptors to remain available, helping the liver remove greater amounts of LDL cholesterol from circulation.

The result can be a substantial reduction in LDL levels.

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Unlike statins, which primarily reduce cholesterol production in the liver, PCSK9 inhibitors increase the body's ability to clear LDL cholesterol.

These different mechanisms explain why the medications can be used together.

## Clinical Trials Reveal Nearly 60% LDL Reduction

The FDA's decision was supported by two randomized, double-blind, placebo-controlled clinical trials involving a combined 3,207 adults with elevated LDL cholesterol.

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Participants were receiving maximally tolerated statin therapy, providing researchers with an opportunity to evaluate the additional cholesterol-lowering benefits of Lipfendra.

The results were substantial.

In the first study, involving adults with established cardiovascular disease or a high risk of developing it, Lipfendra produced an average LDL reduction of approximately 56% compared with placebo after 24 weeks.

In a second study involving patients with heterozygous familial hypercholesterolemia, the reduction reached approximately 59%.

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These figures represent treatment effects compared with placebo, not a guarantee that every patient's cholesterol will fall by the same percentage.

### What Does a 59% Reduction Actually Mean?

Consider someone whose LDL cholesterol measures 160 mg/dL.

A 59% reduction would mathematically bring that level to approximately 66 mg/dL.

Such a change could be clinically meaningful, particularly for people with cardiovascular disease who require substantial LDL lowering.

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However, individual responses vary depending on genetics, other medications, baseline cholesterol levels, and underlying health conditions.

It is also important to distinguish between lowering cholesterol numbers and demonstrating fewer heart attacks or strokes.

Although LDL cholesterol is a well-established cardiovascular risk factor, a dedicated outcomes trial is still evaluating whether Lipfendra itself reduces major cardiovascular events.

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Results from that trial are expected in 2029.

## Why This Approval Matters for People Who Struggle With Statins

Statins remain among the most extensively studied medications for reducing cardiovascular risk.

For many people, they successfully lower LDL cholesterol and reduce the likelihood of heart attacks and strokes.

However, not everyone achieves their recommended cholesterol target with statins alone.

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Some individuals have inherited conditions that cause exceptionally high LDL levels.

Others may experience side effects or need additional medication because their cardiovascular risk is particularly elevated.

Previously, doctors could prescribe injectable PCSK9 inhibitors, including evolocumab and alirocumab, for eligible patients.

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While these medications are effective, some people dislike injections or find them inconvenient.

A once-daily oral alternative may make this type of treatment more accessible and easier to incorporate into a routine.

Nevertheless, Lipfendra does not automatically replace statins.

Doctors must consider the patient's overall cardiovascular risk, medical history, existing treatments, and response to therapy before selecting an appropriate medication.

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## What Are the Possible Side Effects?

As with any prescription medication, safety is an important consideration.

In the clinical trials reviewed by the FDA, Lipfendra was generally well tolerated.

In the first trial, adverse reactions occurred at similar frequencies among participants receiving Lipfendra and those receiving placebo.

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In the second trial, diarrhea and dizziness were among the adverse reactions reported more frequently with the medication than with placebo.

The percentage of participants who discontinued treatment because of adverse reactions was comparable between the treatment and placebo groups.

These findings are encouraging, but they do not mean the medication is free of risks.

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Long-term safety monitoring remains important, particularly as more patients begin using the treatment outside clinical trials.

People should review the full prescribing information with their healthcare professional, including dosing requirements, possible adverse reactions, and precautions.

## Is Lower Cholesterol Always Better?

For people at elevated cardiovascular risk, lowering excessive LDL cholesterol is a central strategy for preventing atherosclerotic disease.

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Multiple large clinical trials involving different cholesterol-lowering medications have demonstrated that reducing LDL can substantially decrease cardiovascular events.

However, treatment goals are individualized.

A person with no history of cardiovascular disease may have different recommended LDL targets than someone who has already experienced a heart attack.

Patients with established coronary artery disease, diabetes, familial hypercholesterolemia, or several cardiovascular risk factors may require more intensive treatment.

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Doctors also consider age, blood pressure, smoking history, family history, and other relevant medical information.

The goal is not simply to produce the lowest possible laboratory number.

It is to reduce overall cardiovascular risk using treatments supported by medical evidence.

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## Can Natural Lifestyle Changes Still Make a Difference?

Absolutely.

The development of powerful cholesterol-lowering medications does not make healthy lifestyle habits less important.

Diet, exercise, smoking cessation, sleep, and weight management remain essential components of cardiovascular prevention.

For some individuals, lifestyle changes may provide sufficient improvements to manage mildly elevated LDL cholesterol.

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Others, particularly those with inherited conditions or significant cardiovascular disease, may require medication despite maintaining healthy habits.

Several everyday strategies are supported by cardiovascular research.

### 1. Eat More Soluble Fiber

Soluble fiber can help reduce LDL cholesterol by influencing cholesterol and bile acid metabolism in the digestive system.

Good dietary sources include:

- Oats and oat bran
- Beans and lentils
- Apples and pears
- Psyllium husk
- Certain vegetables and seeds

Regularly including soluble fiber as part of a balanced diet may contribute to modest improvements in LDL cholesterol.

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### 2. Replace Saturated Fats With Unsaturated Fats

The type of fat consumed can influence blood cholesterol levels.

Replacing some saturated fats with unsaturated fats may help reduce LDL cholesterol.

Heart-healthy options include olive oil, avocados, walnuts, almonds, and other nuts.

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Reducing excessive amounts of butter, fatty processed meats, and other foods high in saturated fat may also support healthier cholesterol levels.

### 3. Include Foods Rich in Plant Sterols

Plant sterols and stanols are naturally occurring compounds found in small amounts in nuts, seeds, legumes, and vegetable oils.

They can reduce cholesterol absorption in the intestine.

Certain foods are also fortified with plant sterols.

When consumed in appropriate amounts, these compounds may provide a modest LDL-lowering benefit.

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### 4. Stay Physically Active

Regular exercise supports cardiovascular health in several ways.

Physical activity can improve blood pressure, insulin sensitivity, cardiovascular fitness, and overall metabolic function.

Although exercise alone may have a relatively modest effect on LDL cholesterol, its broader heart-health benefits are substantial.

Adults are generally encouraged to aim for at least 150 minutes of moderate-intensity aerobic activity each week, with additional muscle-strengthening activities.

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### 5. Avoid Smoking and Manage Other Risk Factors

Smoking damages blood vessels and increases the risk of cardiovascular disease.

Quitting tobacco, maintaining healthy blood pressure, managing diabetes, and addressing excess body weight when appropriate can all improve long-term cardiovascular outcomes.

These actions remain valuable regardless of whether a person takes cholesterol-lowering medication.

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## Does the New Pill Mean Statins Will Become Obsolete?

Despite the excitement surrounding Lipfendra, statins are unlikely to disappear from cardiovascular treatment.

Statins have decades of clinical evidence demonstrating that they reduce heart attacks, strokes, and cardiovascular deaths in appropriately selected patients.

They are also widely available, relatively inexpensive in generic form, and familiar to healthcare professionals.

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Lipfendra offers a different mechanism of action and may provide additional LDL lowering when existing treatment is insufficient.

Its role in clinical practice will depend on factors such as cost, insurance coverage, long-term safety, physician recommendations, and future cardiovascular outcomes research.

The most appropriate treatment will continue to depend on individual patient needs.

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## One Important Question Researchers Still Need to Answer

The most significant unanswered question is whether Lipfendra's dramatic LDL reductions will translate into fewer heart attacks, strokes, and cardiovascular deaths.

This distinction matters because a medication can improve a laboratory marker without necessarily demonstrating every expected clinical benefit.

Other PCSK9 inhibitors have already shown cardiovascular benefits in large outcomes trials, providing strong scientific support for targeting this pathway.

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However, results from those medications cannot automatically substitute for direct outcomes evidence involving Lipfendra.

A larger clinical trial is underway to investigate these questions, with results anticipated in 2029.

Until then, the FDA approval establishes Lipfendra as an effective LDL-lowering therapy, while its specific effects on major cardiovascular outcomes continue to be studied.

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## Final Thoughts: A Promising Development, but Not a Miracle Cure

The approval of Lipfendra represents a meaningful advance in the treatment of high cholesterol.

For the first time, adults who need substantial LDL reductions have access to an oral PCSK9 inhibitor, offering an alternative to the injectable medications previously used to target this pathway.

Clinical trial reductions of approximately 56% to 59% are impressive, particularly among patients already receiving cholesterol-lowering treatment.

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However, the medication should not be viewed as a replacement for healthy habits or as a universal solution for cardiovascular disease.

Heart health depends on several interconnected factors, including blood pressure, blood sugar, smoking status, physical activity, nutrition, genetics, and overall metabolic health.

**The biggest takeaway is simple: managing high LDL cholesterol is becoming more achievable, but prevention, personalized treatment, and long-term cardiovascular care remain essential.**

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For people who have struggled to control their cholesterol despite appropriate treatment, this new medication may offer another important option to discuss with their healthcare provider.

**Medical Disclaimer:** This article is for educational and informational purposes only and should not be considered medical advice. Lipfendra is a prescription medication and should be used only under the supervision of a qualified healthcare professional. Never start, discontinue, or change cholesterol-lowering medications without consulting your physician.

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