R Street

Free markets. Real solutions.

EXPLAINER

Governing Institutions and Contraception

November 2026

Introduction

Over half of reproductive-age women in the United States use some form of contraception, with medical products like hormonal pills and long-acting reversible devices (e.g., intrauterine devices, hormonal implants) among the most common. However, contraceptive needs vary based on factors like medical needs, side effects, affordability, and personal preference—all of which can change throughout a person's life. Nearly one quarter of contraceptive users would choose a different method if they could use any available option. Cost also remains a barrier, especially for uninsured and low-income women.



Whether consumers can choose and obtain contraceptives that meet their needs depends partly on the institutions governing their development and distribution. In the United States, federal governing agencies like the U.S. Food and Drug Administration (FDA) establish the legal and regulatory framework that shapes which contraceptive options are researched and developed and which products reach the market. Meanwhile, state governments determine how those products are provided (i.e., prescription or over the counter) and how consumers can obtain them.

Developing New Contraceptives

Although regulatory pathways vary between pharmaceuticals, newly developed contraceptives generally follow a similar path before reaching consumers. Manufacturers start by researching and developing a potential product. The company must then conduct studies and clinical trials to gauge the product's safety and effectiveness and submit the resulting evidence to the FDA.

These clinical trials generally progress through three phases prior to approval:



Following clinical testing, manufacturers submit their data to the FDA for review. The agency then evaluates whether the available evidence demonstrates that the contraceptive's benefits outweigh its risks. It also establishes labeling requirements and determines whether the product requires a prescription or can be sold over the counter. If the product is approved, then the manufacturer may begin to produce and market it according to the FDA's labeling, manufacturing, and quality-control standards.

Institutions influence nearly every step in this often lengthy and expensive process. The Congressional Budget Office estimates the average research and development cost for a new drug ranges from less than $1 billion to greater than $2 billion, including spending on products that never reach the market. The intent is to ensure that all approved contraceptives meet established quality and safety standards.

Contraceptive Products on the Market

While FDA approval determines which new contraceptives may enter the U.S. market, approval does not end institutional oversight. For example, companies must continue to comply with the agency's Current Good Manufacturing Practices (CGMP), which establish standards for production, quality control, recordkeeping, sanitation, and facility inspections.

The FDA also monitors adverse-event reports and other safety information through post-marketing surveillance. Because some adverse events become apparent only after a much larger population uses the product, the agency can use post-marketing surveillance to identify these risks and respond by updating product labeling, communicating new safety information, and requiring additional studies. In rare cases, the agency may even reevaluate whether a product should remain on the market.

Beyond general regulations, producers benefit from predictable institutional rules. Developing a new contraceptive often requires years of research and substantial financial investment. Clear regulatory expectations reduce uncertainty by helping firms understand the evidence, manufacturing standards, and approval requirements necessary before bringing a product to market.

Decisions affecting producers ultimately shape consumer choice. Regulations that influence development costs, approval times, and product availability can affect which contraceptives reach the market as well as how quickly consumers can access them.

Regulating Channels of Contraceptive Access

In addition to product development and manufacture, U.S. institutions regulate access to different contraceptives based on risk level and method of use.

- Short-acting barrier methods (e.g., condoms): Widely available over the counter for all ages
- Rules vary among hormonal methods
  - "The Pill": Typically requires a prescription
  - Long-acting methods (e.g., intrauterine devices or implants): Must be prescribed, inserted by a trained professional

These differences reflect efforts to balance access with safety; however, they also affect the ease with which people can obtain different types of contraception in practice.

Prescription requirements determine whether consumers must meet with a healthcare provider before using a particular contraceptive. These requirements are often based on how much medical supervision is necessary for safe use, which can vary between available methods. Contraceptives that the FDA determines can be used safely without provider supervision may be sold over the counter, which reduces barriers to access by eliminating the need for an appointment and reducing the time and cost required to obtain them.

Insurance policies affect contraception affordability by determining which methods are covered and what consumers must pay out of pocket. Federal and state coverage requirements can reduce these expenses, while coverage exclusions, cost sharing, and utilization-management rules can make particular methods more difficult or costly to get.

States themselves regulate the availability and accessibility of contraceptive options within their borders. Policies governing pharmacist prescribing, extended supply, telehealth, and provider scope of practice can either limit or expand access, depending on their structure.

For example, several states allow pharmacists to prescribe certain contraceptives after receiving specialized training and screening. Expanding pharmacist prescribing can increase access by lowering the need for more appointments, especially in areas experiencing provider shortages or in contraceptive deserts.

Because these policies differ between states, two people with the same needs might face different levels of access depending on where they live. This variation exemplifies the key role regulatory policies play in shaping contraceptive access.

Conclusion

Governing institutions influence almost every step of contraceptive access, from how the products are developed and approved to how they are prescribed, paid for, and obtained. But while these rules help protect consumers and provide clear expectations for producers, they can also add costs, delays, and other barriers. As a result, a contraceptive's availability on the market does not always ensure easy access to it.

Authored by: Lindsay Heck, Research Assistant, Healthier Communities

For more information, contact:

Stacey McKenna
Associate Director and Resident Senior Fellow
Healthier Communities
smckenna@rstreet.org

Courtney Joslin
Head of Right by Women and Resident Fellow
Healthier Communities
cjoslin@rstreet.org