EXPLAINER

FDA Regulatory Review:

Pharmaceutical Drugs and Medical Devices

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California Health Benefits Review Program (CHBRP)
University of California

State legislation often references pharmaceutical drugs or medical devices that have undergone FDA review. Aligning bill definitions with federal standards allows state regulators and the California Health Benefits Review Program (CHBRP) to evaluate proposed laws accurately.

The U.S. Food and Drug Administration (FDA) is responsible for ensuring that drugs, medical devices, vaccines, food, cosmetics, and tobacco products marketed in the United States are safe and effective for public use (FDA, 2023). Before a product can reach consumers, it must undergo regulatory review and may require extensive testing. This explainer provides an overview of how the FDA evaluates and approves pharmaceutical drugs and medical devices; clarifies important regulatory terms used by the FDA for both medical devices and pharmaceutical drugs; and explores the major approval pathways, expedited review programs, and key laws that shape the process.

Pharmaceutical Drugs and Medical Devices

Definitions

Federal law defines **pharmaceutical drugs** and **medical devices** using nearly identical language; the primary distinction comes down to *how* the product achieves its intended effect. Both definitions cover products intended to diagnose, cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body—meaning almost every medical product technically meets the baseline definition of a drug. A product is carved out and classified as a device based on its mechanism of action.

Pharmaceutical drugs

- **Statutory definition:** Defined under federal law as any article recognized in an official U.S. pharmacopeia,[1] or any article intended to diagnose, cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body.[2]
- **Core requirement:** Qualifies based on intended use alone, regardless of physical form (e.g., pills, injections, topical creams, or biologics).
- **Primary mechanism:** Achieves its primary purpose through chemical action within the body, or by being metabolized.
- **Key subcategories and exclusions**: Includes small-molecule (chemical) drugs and biological (large-molecule) drugs. Excludes dietary supplements and cosmetics, which are governed separately.

[1] A pharmacopeia is an official reference book that contains quality standards, formulas, tests, and purity requirements for drugs, chemicals, and medicines.
[2] 21 U.S. Code § 321 Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

Medical Devices

- **Statutory Definition:** Defined under federal law as physical equipment, an implant, a lab reagent,[3] or an associated component used in humans or animals. [4]
- **Core requirement:** Must meet the same recognized status or intended-use criteria as a drug (diagnosing, treating, preventing disease, or altering body structures/functions).
- **Primary mechanism:** Achieves its primary purpose through physical, mechanical, or structural means—not through chemical action or metabolic processes.
- **Key subcategories and exclusions:** Encompasses instruments, apparatuses, and certain software, while explicitly excluding specific digital health software.

Regulatory Agencies

Pharmaceutical drug regulatory authority is shared between the FDA's Center for Drug Evaluation and Research (CDER), which focuses primarily on small-molecule drugs, and the Center for Biologics Evaluation and Research (CBER), which regulates biologics. Drugs in both categories must demonstrate safety and efficacy primarily through clinical trials in human subjects (FDA, 2018a).

Medical devices are reviewed by the Center for Devices and Radiological Health (CDRH), and the level of evidence required scales with the device's risk class, ranging from general manufacturing controls for low-risk devices to extensive clinical evidence for high-risk devices (FDA, 2018a). Many devices reach the market by showing they are substantially equivalent to an already-marketed device rather than by running a clinical trial from scratch, a pathway that has no real equivalent for drugs. Substantially equivalent means the device works the same way and produces the same clinical/physiological results as an already-approved device, even if it looks different, is made by a different manufacturer, or uses different materials, as long as those differences do not affect safety or efficacy.

Some products, known as combination products, include both a drug and a device component, such as a prefilled drug syringe (e.g., GLP-1 injectable) or a drug-eluting stent. The FDA assigns these to a lead review center based on the product's primary mode of action.

Categories and Classifications

Drugs: Categories

Drugs are typically grouped into three different categories based on their innovation and marketing status:

1) **New molecular entities (NMEs),** or new drugs, that contain active ingredients that have never before been approved by the FDA.

2) **Generic drugs** are exact chemical copies of another drug that has been determined by the FDA to be safe. They require a prescription and are purchased through a pharmacy.

3) **Over-the-counter (OTC)** drugs that do not require a prescription and may be purchased off-the-shelf in stores.

Prescription drugs are typically regulated by the FDA through the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) process described below, both of which are reviewed and approved for a specific product. OTC drugs are most often marketed under an OTC drug monograph rather than an individual application, as described later in this section. A monograph is a rulebook that sets the conditions, such as approved active ingredients, dosing, and required

[3] A lab reagent is a substance or compound that is added to a system to cause a chemical reaction, or to test to see if one occurs.
[4] 21 U.S. Code § 321 Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act.

labeling, under which an entire category of OTC drug (e.g., sunscreens, antacids, pain relievers) is considered generally recognized as safe and effective (GRASE) (FDA, 2020). Table 1 summarizes the three drug categories.

Table 1. Pharmaceutical Drug Categories, FDA Regulatory Controls, and Pathway to Commercial Market

Drug Category	Risk / Complexity	Nature of the drug	Examples	FDA Regulatory Controls for Safety and Effectiveness	Application Process	FDA Term for Successful Application
New Molecular Entity	High	New chemical compounds never before approved by FDA	New cancer therapies, new vaccines, specialized biologics	Full Clinical	NDA or BLA	"Approved"
Generic Drugs	Moderate	Exact chemical copies of brand-name drugs that have already been proven safe	Acetaminophen, amoxicillin, metformin	Abbreviated	ANDA	"Approved"
OTC Drugs	Low	Well-established ingredients deemed safe for use without a prescription	Aspirin, antacids, acne medications, most sunscreens	General	OTC Monograph	"Marketed"

Source: California Health Benefits Review Program, 2026.
Key: ANDA = abbreviated new drug application; BLA = biologics license application; FDA = U.S. Food and Drug Administration; NDA = new drug application; OTC = over the counter.

Devices: Risk Classes

Medical devices follow a somewhat different pathway from drugs because devices vary greatly in complexity and risk. Devices are initially grouped into one of three classes (Class I, Class II, or Class III) based on their risk profile and must meet certain regulatory standards for safety and effectiveness, also known as regulatory controls, prior to their commercial use (FDA, 2018b). While the process for Class I devices is more administrative, manufacturers of Class II and Class III devices must demonstrate proof the devices meet regulatory controls through specific applications – the 510(k) notification or premarket approval, respectively – as described in the *Application Pathways* section and in Table 2.

Table 2. Medical Device Class Types, FDA Regulatory Controls, and Pathway to Commercial Market

Device Class	Risk	Types of Devices	Examples	FDA Regulatory Controls for Safety and Effectiveness	Application Process	FDA Term for Successful Application
Class I	Low	Devices with minimal potential for harm; generally more simple in design	Bandages, oxygen masks, manual stethoscopes	General	Registration and listing; typically exempt from 510(k)	"Listed" (a)
Class II	Moderate	Complex devices requiring specific performance standards to prevent moderate harm	Powered wheelchairs, infusion pumps, syringes, pregnancy tests, blood pressure monitors	General + Special	510(k)	"Cleared" or "Granted" (De Novo)
Class III	High	Life-sustaining or life-supportive	Implantable pacemakers, breast implants, heart valves	General + PMA	PMA	"Approved"

Source: California Health Benefits Review Program, 2026.
(a) The FDA does not typically use the term "FDA-listed," rather Class I devices that have been registered and are listed for compliance purposes are referred to as "listed."
Key: PMA = Premarket approval.

Regulatory Terminology

The FDA uses different regulatory terminology to indicate how rigorous the testing process was for the product in question. It should be noted that some websites and marketing tactics involve using terminology that is similar to but not officially used by the FDA, which may mislead consumers into thinking their products have been sanctioned by the FDA.

Official FDA Terminology

The application processes referred to in the definitions below are described in more detail in the *Application Pathways* section.

- **FDA-approved:** Drugs and biologics that went through the New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologics License Application (BLA) process, as well as high-risk (Class III) devices approved through premarket approval (PMA) (e.g., new prescription drugs, pacemakers, heart valves, replacement joints).
- **FDA-authorized:** Products – most often drugs, biologics, or diagnostics – that reached the market under an Emergency Use Authorization during a declared public health emergency, rather than through standard approval or clearance.
- **FDA-cleared:** Low-to-moderate risk (mostly Class I and II) devices that reached the market through the 510(k) pathway by demonstrating substantial equivalence to an already-marketed device (e.g., infusion pumps, powered wheelchairs).
- **FDA-granted (de novo):** Novel low-to-moderate risk devices with no device on the market that is substantially equivalent to them, which the FDA classified as Class I or II through the De Novo pathway.
- **FDA-marketed:** Any product that is in commercial distribution and actively supplied in the U.S. market. Consumers must check whether the product holds the status of "FDA-cleared," FDA-granted," or "FDA-approved."
- **Listed:** Class I medical devices that have a registered facility and are listed in the FDA database.

Unsanctioned Terminology Used for Medical Devices

- **FDA-registered:** The FDA states this term implies a special status that the FDA does not use. The FDA does register device manufacturing facilities, but registration is not an evaluation or endorsement of a specific product by that manufacturing facility (FDA, 2021).
- **FDA-certified:** The FDA states that some firms sell medical devices alongside "FDA registration certificates" to imply review or approval by the FDA of a device. However, the FDA does not certify medical devices; any product labeling with this terminology is done without sign-off from the FDA. (FDA, 2021).
- **FDA Registration Certificate:** The FDA does not issue certificates of registration to device establishments. Any document presented with this terminology is not an official FDA record (FDA, 2021).

Application Pathways

Pharmaceutical Drugs: FDA Review Processes

New Molecular Entities (New Drugs)

The process below describes the full review pathway for NMEs, the most rigorous of the three drug categories in Table 1. Generic drugs and OTC drugs follow the shorter pathways described in the Generic Drugs and OTC Drugs sections that follow.

For new pharmaceutical drugs, the approval process begins when a drug manufacturer, also known as a sponsor, develops a new compound and presents it to the FDA's Center for Drug Evaluation and Research (CDER) for evaluation (FDA, 2018a). Sponsors must perform initial *in vitro* (testing outside a living thing, e.g., a petri dish) and *in vivo* (testing inside a living organism, e.g., a mouse or human) preclinical research to gather information on the compound (FDA, 2018a). The sponsor submits an Investigational New Drug (IND) application based on these results, which proposes their plan for proceeding with human subjects in the clinical phase (FDA, 2018a). The FDA reviews and verifies these applications.

Biologic drugs[5] require an additional Biologics License Application (BLA) after the IND phase (FDA, 2026). A BLA is submitted to the FDA to obtain approval to market a biological product. It includes evidence from the IND phase demonstrating that the product is safe, effective, and can be consistently manufactured to meet quality standards (FDA, 2026). The distinction matters because biologics are structurally more complex than traditional small-molecule drugs (such as aspirin or ibuprofen), which are chemically synthesized and easier to fully characterize. Because biologics are manufactured in living cells, even small changes in the manufacturing process can affect the final product. Thus, the BLA pathway places extra emphasis on manufacturing consistency rather than only on the finished compound.

Clinical studies for all new small-molecule and biologic drugs typically happen in three phases (FDA, 2018a):

- **Phase 1** emphasizes safety, using 20-80 volunteers to document side effects and how the drug is metabolized (FDA, 2018a).
- **Phase 2** is meant to obtain preliminary data on the drug's effectiveness, using 100+ patients with the disease or illness the drug is meant to treat and a control group given a placebo or a different drug (FDA, 2018a).
- **Phase 3** may use 1000+ patients to gather more information, using the drug in combination with other drugs, testing different dosages, and including participants from a variety of backgrounds.[6]

After the drugs pass the safety and efficacy criteria for the relevant clinical trials, the drug sponsor formally asks the FDA to approve the drug for marketing in the United States with a New Drug Application (NDA) (FDA, 2018a). An NDA includes all animal and human data, analyses of the data, and manufacturing information. A CDER committee reviews the NDA, the drug's labelling to ensure it conveys appropriate information, and inspects the facilities where the drug will be manufactured. For novel or particularly complex products, the FDA may also convene an advisory committee, a panel of outside experts, patient representatives, and consumer representatives, to publicly evaluate the evidence and vote on a recommendation. The vote is non-binding, and the ultimate approval decision remains with the FDA (FDA, 2018a). Once the FDA approves a drug, the sponsor is required to submit periodic safety updates (FDA, 2018a).

Only a small percentage of drugs entering clinical trials (approximately 10–12%) ultimately receive FDA approval. This high failure rate reflects the rigorous safety and efficacy standards the FDA applies.

Generic Drugs: The Abbreviated New Drug Application (ANDA)

Most prescriptions filled in the United States are generic drugs, which follow a different pathway from the NDA process described above. Rather than repeating the preclinical and clinical trials, a generic manufacturer submits an Abbreviated New Drug Application (ANDA), demonstrating that its product is bioequivalent to an already-approved "reference listed drug," meaning it delivers the same active ingredient, at the same dose, into the bloodstream at essentially the same rate and extent (FDA, 2025b). Because the FDA already evaluated the reference drug's safety and effectiveness, the ANDA process relies on that existing record rather than requiring it to be re-established from scratch. The ANDA pathway was created by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which was designed to encourage competition and lower prescription drug costs (FDA, 2025a).

[5] Biologics requiring a BLA can include vaccines, blood products, gene therapies, tissues, and recombinant therapeutic proteins (FDA, 2026).
[6] Once a drug is approved by the FDA and is made available to the public, the safety of the drug may continue to be evaluated by researchers through Phase 4 trials. These trials are done in an effort to generate additional information about the drug, such as optimal use and other benefits (NIH, 2025).

Over-the-Counter Drugs

OTC drugs are regulated through OTC drug monographs. A monograph is a rulebook that sets the conditions, such as approved active ingredients, dosing, and required labeling, under which an entire category of OTC drug (e.g., sunscreens, antacids, pain relievers) is considered generally recognized as safe and effective (GRASE) (FDA, 2020). If a product complies with the applicable monograph, it can be marketed without FDA pre-approval of that specific product. Some OTC products, particularly first-of-their-kind ingredients or "Rx-to-OTC switches," still go through the NDA process (FDA, 2020).

Medical Devices: FDA Review Processes

Class I

All classes of devices must follow what are known as General Controls, which set baseline standards for labeling, facility registration, device listing, adverse event reporting, and good manufacturing practices. For most Class I devices, compliance requires only registering the facility and listing the device in the FDA's public online database. However, if a Class I device plays a critical role in preventing health impairment or carries a potential risk of illness or injury, then the manufacturer must submit a 510(k) notification to the FDA (FDA, 2025b). For example, medical gloves require 510(k) clearance to verify biocompatibility and leak resistance, as defects can cause direct harm (FDA, 2024).

Class II

In addition to General Controls, Class II devices must pass Special Controls, which are typically device-specific and dictate exactly what performance standards or safety tests must be met or passed to be considered safe. Special Controls also include postmarket surveillance requirements, patient registries, special labeling requirements, premarket data requirements, and general regulatory guidelines (FDA, 2018b). To prove compliance with Special Controls, manufacturers submit a 510(k) notification, which requires proof that the device is substantially equivalent to a legally marketed device that is not subject to the premarket approval process described below.

Class III

The other, more rigorous pathway is known as the Premarket Approval (PMA) process (FDA, 2018b). PMA is the FDA's most stringent review pathway and is required for most Class III, high-risk devices or devices that cannot demonstrate substantial equivalence for the 510(k) process (FDA, 2018b). PMA requires extensive scientific evidence through clinical trials that show the device is safe and effective, and evidence that its benefits outweigh its risks (FDA, 2018b).

Typical Review Timeline

The FDA review process timelines vary significantly depending on the pathway, product complexity, and whether expedited review designations apply. For policymakers and stakeholders, understanding these timelines is critical when evaluating legislation that references FDA approval status or funding for regulatory processes. Table 3 provides typical review periods across common approval routes.

Table 3. Typical Timelines of FDA Review Pathways

Pathway	Timeline	Notes
NDA / BLA (standard)	~10 months	Standard review
NDA / BLA (priority)	~6 months	Fast-tracked
510(k)	90 days (a)	Most common for devices
PMA	180 days (b)	Most rigorous device pathway
EUA	Days to weeks	Emergency-only, expedited

Source: California Health Benefits Review Program, 2026; FDA, 2019; FDA, 2022a; FDA 2025c.
(a) The FDA states the goal to make a decision for a 510(k) application is 90 FDA days.
(b) The minimum period of review is 180 days. The process may take months or years longer depending on whether the FDA requests additional information from the applicant.

Expedited and Non-Standard FDA Review Pathways

Pharmaceutical Drugs

The FDA also offers several programs intended to speed the development and review of some drugs. For the first four pathways below, the final terminology used for a drug that successfully completes review is the same as it would be under standard review — for example, a drug that received Accelerated Approval still carries a final status of "FDA-approved." Emergency Use Authorization is the exception: it is not part of the standard approval track, and drugs reaching the market this way carry the distinct status of "FDA-authorized" instead.

- **Fast Track** designation is granted to drugs intended to treat serious conditions and address unmet medical needs, meaning the FDA will perform more frequent communication with the drug sponsor (FDA, 2022b).
- **Priority Review** shortens the FDA review goal for an NDA from the standard ten months to six months (FDA, 2022b).
- **Accelerated Approval** allows drugs for serious conditions to be approved earlier based on a surrogate endpoint – a laboratory measurement, physical sign, or other measure that is thought to predict clinical benefit but not measuring it directly (FDA, 2022b).
- **Breakthrough Therapy** designation expedites the approval process for drugs with findings that suggest a clear advantage over available therapy, typically measured by clinical findings indicating a significant effect on serious symptoms of the disease or irreversible morbidity (FDA, 2022b).
- **Emergency Use Authorization (EUA)** allows for the use of unapproved medical drug or device (or an unapproved use of an already-approved drug or device) during a declared public health emergency, when there is no sufficient approved alternative and the drug or device's potential benefits have been deemed to outweigh the risks. An EUA is tied to a public health emergency and remains in effect until either the FDA ƒ individual authorizations, or the U.S. Department of Health and Human Services determines that the underlying circumstances for the emergency declaration have ceased. The FDA can revise an EUA during the public health emergency (FDA, 2017).

Medical Devices

Humanitarian Device Exemption

A Humanitarian Device Exemption (HDE) is a special pathway for devices that treat or diagnose disease or conditions affecting no more than 8,000 people in the United States per year, a threshold raised from the original 4,000 by the 21st Century Cures Act in 2016 (FDA, 2025d). Because it may be difficult or impractical to collect the extensive clinical evidence normally required, the FDA allows these devices to be marketed if the probable benefit appears to outweigh the risks.

De Novo Devices

The De Novo classification is an FDA pathway for novel low or moderate risk medical devices for which there are no existing substantially equivalent devices (FDA, 2018b). Through a risk-based review, the FDA may classify these devices as Class I or II, allowing them to be marketed and potentially serve as predicate devices for future 510(k) submissions. A predicate device is an already-approved device used as a comparison point. New devices can demonstrate substantial equivalence to a predicate device to obtain faster 510(k) clearance. These pathways and requests cost additional fees on top of standard application fees depending on the specific pathway and the size of business making the request (FDA, 2026).

Breakthrough Devices

The Breakthrough Devices Program, established by the 21st Century Cures Act in 2016, was established in an effort to speed the development and review of devices that provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. To qualify as a Breakthrough Device, a device must meet this primary criterion and at least one of the following criteria:

1) Represent a breakthrough technology.

2) Have no FDA-approved or FDA-cleared alternatives.

3) Offer a significant advantage over existing FDA-approved or FDA-cleared alternatives.

4) Device availability is in the best interest of patients (FDA, 2026a).

Breakthrough Device designation is not tied to a specific device class – it can apply to devices reviewed under 510(k), PMA, or De Novo, whichever pathway the device would otherwise require. Sponsors request the designation before submitting their marketing application (e.g., 510(k) or PMA applications), and if granted, receive more frequent FDA interaction and priority review. The designation does not change the underlying safety and effectiveness standard; a breakthrough device is still cleared, approved, or granted through its normal pathway, simply on an expedited basis. Devices that receive the Breakthrough Device designation and may be sold on the commercial market are referred to as “authorized for marketing.”

Application Fees

Pharmaceutical Drugs

Application fees are authorized under the Prescription Drug User Fee Act (PDUFA). Drug sponsors pay fees at the application stage, plus an additional annual program fee, regardless of whether the sponsored product is a small-molecule drug or a biologic (FDA, 2026).

For the 2027 fiscal year, applications requiring clinical data carry a roughly $4.6 million fee, applications that do not require clinical data run about $2.3 million, and the annual program fee is roughly $417,000 per sponsor; exact figures are set annually under the Prescription Drug User Fee Act and are published on FDA.gov (FDA, 2026). While FDA application fees are substantial, preclinical and clinical drug development typically costs $1–3 billion overall, meaning FDA fees represent a small fraction of total development investment.

See the Appendix for more information on the PDUFA and why the FDA collects application fees.

Medical Devices

Medical device application fees are authorized under the Medical Device Use Fee and Modernization Act (MDUFMA). The cost of a medical device application varies widely depending on the pathway, application type, and whether the sponsor is considered a small business (FDA, 2026).

For the 2027 fiscal year:

- A 510(k) application will have a standard fee of $28,653 and a reduced small business fee $7,163 (FDA, 2026).
- A PMA application will cost a standard rate of $636,732 and a small business fee of $159,183 (FDA, 2026).
- Sponsors are also required to pay the annual device reporting fee; in 2027 these fees will be $22,286 for standard businesses and $5,572 for small businesses (FDA, 2026).

See the Appendix for more on MDUFA and why the FDA collects these fees.

Post-Market Surveillance

FDA oversight does not end at approval. Once a drug or device is on the market, the FDA continues to monitor its safety through mechanisms that apply to both drugs and devices.

- **MedWatch** is the FDA's safety information and adverse event reporting program. Health professionals, manufacturers, and consumers can use it to report suspected adverse events, product quality problems, or use errors involving drugs, biologics, or devices; manufacturers and certain user facilities are required to report certain events, while reporting by consumers and health professionals is voluntary (FDA, 2026).
- **Recalls** remove or correct a marketed product that may be defective or pose a health risk. Most recalls are voluntary actions taken by the manufacturer, sometimes at the FDA's request, though the FDA has authority to mandate a recall for certain products.

Conclusion

This explainer is designed to support policymakers and stakeholders in navigating the FDA's regulatory processes and terminology when working on legislation related to pharmaceutical drugs and medical devices. Terms like "FDA-approved," "FDA-cleared," or "FDA-authorized" carry specific regulatory meanings, as each aligns with a different review pathway and set of standards. Choosing precise language helps ensure that bills are implemented smoothly and as intended, avoiding potential ambiguity around a law's scope. Understanding these distinctions can help ensure legislation aligns closely with how these regulatory pathways function in practice.

Appendix: Law Related to FDA Regulatory Review

The Federal Food, Drug, and Cosmetic Act is extensive and broadly governs the FDA approval process for both drugs and devices (FDA, 2014). The agency also follows regulations in the Code of Federal Regulations for reviewing drug applications and uses internal Manuals of Policies and Procedures to standardize its review process (FDA, 2014).

One important law shaping the modern FDA approval process is the Prescription Drug User Fee Act (PDUFA), first passed in 1992 (FDA, 2026b). PDUFA allows the FDA to collect fees from pharmaceutical companies when they submit applications for new drugs and biologics (FDA, 2026b). These fees help fund additional FDA staff and resources, allowing the agency to review applications more efficiently and reduce approval times (FDA, 2026b). PDUFA also created new drug designations, most notably Priority Review, with the goal of giving accelerated access to new medications for serious illnesses (FDA, 2026b). The Medical Device User Fee and Modernization Act (MDUFMA) passed in 2002 serves a similar purpose (FDA, 2026c). MDUFMA requires that medical device companies pay fees upon submitting an application to market a device in the U.S (FDA, 2026c).

The FDA Modernization Act of 1997 was a major reform law designed to make the FDA's regulatory processes more efficient. It expanded patient access to experimental treatments, created a public clinical trials database, allowed limited distribution of scientific information about off-label uses, simplified certain food safety regulations, and established the De Novo classification pathway, among other changes to the FDA's operation. The FDA Modernization Act 2.0, passed in 2022b, removed the mandate for animal testing in the drug development process.

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, created the modern generic drug (ANDA) pathway described earlier. It allows generic manufacturers to rely on a brand-name drug's existing safety and efficacy record rather than repeating clinical trials, in exchange for certain patent protections for brand-name drug makers (FDA, 2025b).

The 21st Century Cures Act, signed into law in 2016, is a more recent reform aimed at accelerating medical product development. Among other provisions, it directed the FDA to develop a framework for using real-world evidence, data drawn from sources like electronic health records and patient registries rather than traditional clinical trials, to help support new drug indications and satisfy post-approval study requirements (FDA, 2026).

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About the California Health Benefits Review Program (CHBRP)

Drawing on the experience and assistance of multi-disciplinary faculty, researchers, and analysts based at the University of California, CHBRP provides the California Legislature with timely, independent, and rigorous evidence-based analyses of introduced health insurance benefits-related legislation. Most frequently, CHBRP analyzes proposed health insurance benefit mandates (e.g., mandates to cover a test, treatment, or service, such as continuous glucose monitors). For more about CHBRP's 60-day analysis process, see the resource Academic Rigor on a Legislature's Timeline.

To read any of the bill analyses CHBRP has completed, see the Completed Analysis page on CHBRP's website. In addition to analysis of introduced legislation, CHBRP produces other publications including several annually updated resources, as well as issue briefs and explainers.

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