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Navigating the Regulatory Landscape for Combination Products: An Expanded Review of Regulatory Data, Global Perspectives, and Emerging Challenges

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Abstract: Combination products therapeutic and diagnostic systems that bring together drugs, biologics, and medical devices form one of the fastest-growing segments in modern healthcare. By combining mechanisms of action, these integrated systems can improve clinical outcomes, yet their hybrid nature also creates considerable regulatory complexity. This review offers a structured, critical look at how the U.S. Food and Drug Administration (FDA) regulates combination products, covering statutory definitions, classification systems, primary mode of action (PMOA) determinations, center assignment, designation procedures, and premarket approval routes such as 510(k), PMA, NDA, ANDA, and BLA. It also examines emerging difficulties, including the limits of PMOA-based classification, gaps in post-market surveillance, and the uncertainty surrounding newer technologies such as nanomedicine and AI-enabled devices. A comparison with international systems, the European Commission's framework and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) is included as well. Taken together, the analysis points to a need for more adaptive regulation, closer coordination between agency centres, and greater global harmonization so that both innovation and patient safety can be served.

Keywords: Combination products, FDA regulation, PMOA, drug-device combinations, biologics, regulatory pathways, global harmonization, artificial intelligence, nanomedicine

1. Introduction

Advances in biomedical science have steadily worn away the once-clear lines separating drugs, biologics, and medical devices. Many of today's therapeutic systems now combine several components into a single platform to boost efficacy, safety, and how well patients stick with treatment (1)(2). These hybrid systems – known as combination products – include drug-eluting stents, prefilled syringes, insulin delivery pens, and antibody-drug conjugates (ADCs). By 2023, the global combination products market had reached roughly USD 138 billion, and it is expected to grow at a compound annual rate near 9% through 2030, driven by advances in targeted drug delivery and biologics manufacturing(3).

For all their clinical benefits, combination products raise distinct regulatory problems. Each component can fall under a different regulatory framework, which complicates how the product is classified, evaluated, and ultimately approved. In the United States, the FDA manages this complexity through a coordinated system spanning three centers: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH) (4). The Office of Combination Products (OCP), created under the Medical Device User Fee and Modernization Act of 2002, acts as the coordinating body responsible for classification decisions (5).

This review sets out to critically examine this regulatory landscape, identify its current shortcomings, compare it with international approaches, and suggest directions for future reform.

2. Methodology

A structured literature search was carried out across PubMed, Scopus, and Web of Science. Search terms combined phrases such as "combination products," "FDA regulatory pathways," "drug-device regulation," "PMOA classification," "premarket approval," "510(k)," "BLA," "global harmonization," and "AI medical devices," linked using Boolean operators (AND, OR). Priority was given to studies published between 2015 and 2025 to keep the review current, though foundational regulatory documents were included regardless of publication date(6).

To be included, a source had to address FDA or international regulatory frameworks for combination products, premarket review pathways, or post-market surveillance. Non-peer-reviewed opinion pieces lacking a cited regulatory basis were excluded, as were sources dealing only with single-component products. Primary legal and regulatory material – Code of Federal Regulations (CFR) provisions, FDA guidance documents, and European Medical Device Regulation (MDR) texts – was incorporated directly (7).

The initial search returned more than 400 publications. After applying the inclusion and exclusion criteria and removing duplicates, 52 peer-reviewed studies and 28 regulatory guidance documents remained for synthesis. These were analyzed thematically around classification, premarket pathways, post-market surveillance, international comparison, and challenges posed by emerging technologies(8).

3. Definition and Classification of Combination Products

Under 21 CFR §3.2(e), a combination product is formally defined as one made up of drugs, devices, and/or biological products combined to achieve a therapeutic or diagnostic purpose (9). This definition traces back to Section 503(g) of the Federal Food, Drug, and Cosmetic Act, introduced through the Safe Medical Devices Act of 1990 (1). The FDA recognizes four categories of combination products, each distinguished by how the components are structured, packaged, and labeled (9).

Table 1: Classification of Combination Products

Type	Description	Example
Single-entity	Two or more components combined – physically, chemically, or otherwise – into one integrated product	Drug-eluting stent
Co-packaged	Two or more separate products packaged together as a single unit	Surgical kit paired with an antibiotic drug
Cross-labelled	Separate products whose labeling references each other and that are meant to be used together	Photodynamic therapy (drug plus light-emitting device)
Investigational	A combination used only in research settings under an IND or IDE	A novel drug-device combination in a Phase II trial

Classification affects far more than which center takes the lead – it also shapes the evidentiary bar, user fee obligations, and post-market requirements that apply to the product (10). Single-entity combination products tend to undergo the most demanding reviews, since their integrated design calls for simultaneous assessment of pharmacological, biological, and engineering properties (11). Cross-labelled products, on the other hand, may be reviewed by separate centers entirely, which brings its own coordination difficulties.

4. Regulatory Framework and Primary Mode of Action (PMOA)

Which center takes regulatory responsibility for a combination product comes down to its Primary Mode of Action (PMOA), defined in 21 CFR §3.2(m) (12). PMOA refers to the single mechanism responsible for the product's most significant therapeutic effect. Once that mechanism is identified, the lead center is the one with the deepest regulatory experience in that area(13)(14) .

When the PMOA is reasonably clear, the FDA assigns the product to CDER for a drug-driven mechanism, CBER for a biologic-driven one, or CDRH for a device-driven one. If the PMOA cannot be pinned down, 21 CFR §3.4(b) supplies a fallback: jurisdiction goes to whichever center regulates products that raise the most similar safety and effectiveness questions [3]. This structure gives the system clarity in principle, but it runs into trouble with products built around multiple, mutually reinforcing mechanisms (15).

4.1 Request for Designation (RFD) and the Pre-RFD Process

Sponsors can formally request a classification decision by filing a Request for Designation (RFD) with the OCP under 21 CFR §3.7 [4]. The OCP must respond within 60 days by statute. A typical RFD includes a description of the product, the sponsor's proposed PMOA, supporting scientific literature, and a recommended center assignment with justification (16). Once issued, the OCP's determination is binding, and it can only be challenged through a formal dispute resolution process (5).

The Pre-RFD process works differently: it is voluntary and non-binding, giving sponsors informal OCP feedback on likely PMOA and center-assignment outcomes while the product is still under investigation. This step reduces regulatory uncertainty considerably, letting sponsors sharpen their scientific case before filing formally. It has proven especially useful for newer biologics-device combinations, such as ADCs built around targeting ligands (17).

5. Premarket Regulatory Pathways

Once classified, a combination product moves into whichever premarket pathway matches its lead center and risk category. Table 2 lays out the main pathways along with the product types they cover, their core evidentiary requirements, and typical review times.

Table 2: FDA Premarket Regulatory Pathways

Pathway	Product Type	Key Requirement	Typical Review Time
510(k)	Low-to-moderate risk devices	Substantial equivalence to a predicate device	~90 days
PMA	High-risk devices (Class III)	Valid scientific evidence of safety and effectiveness	180 days (statutory)
De Novo	Novel low-to-moderate risk devices	Risk-based classification; no predicate required	~150 days
NDA	New drug products	Substantial evidence of safety and efficacy	10–12 months (standard)
ANDA	Generic drug products	Bioequivalence to the reference listed drug	~10 months
BLA	Biological products	Demonstrated safety, purity, and potency	12 months (standard)

The 510(k) pathway, applied to moderate-risk devices, hinges on showing substantial equivalence to an already-marketed predicate device, and in most cases does not call for clinical trials. PMA review, reserved for Class III high-risk devices, demands valid scientific evidence – usually clinical trial data – that establishes reasonable assurance of safety and effectiveness. De Novo offers a risk-based route for novel devices that have no predicate to compare against (18).

Drug-led combination products go through the NDA pathway, which requires substantial evidence of safety and efficacy drawn from adequate, well-controlled studies. ANDA, used for generic drugs, asks only for bioequivalence to the reference listed drug (RLD). BLA, which governs biological products, requires evidence of safety, purity, and potency under 21 CFR §601 (19). Cross-labeled and co-packaged products may need submissions to more than one center, with a single center designated to lead the review.

6. Global Harmonization and International Regulatory Perspectives

How combination products are regulated differs quite a bit from one jurisdiction to the next, which creates real difficulties for sponsors chasing approval in multiple markets at once (20). Comparing the FDA's framework with those used in the European Union and Japan brings out some notable structural differences.

Table 3: International Regulatory Comparison – Combination Products

Criterion	FDA (USA)	EU MDR/IVDR	PMDA (Japan)
Classification Basis	Primary Mode of Action (PMOA)	Device-centric; drug component governed by EMA	Integrated review; PMDA coordinates with MHLW
Lead Agency	FDA (CDER, CBER, or CDRH)	Notified Body plus EMA consultation	PMDA under MHLW oversight

Approval Timeline	90 days (510(k)) to 12 months (BLA)	Variable; often 12–18 months	12 months (standard review)
Post-Market Surveillance	FAERS and MAUDE (fragmented)	EUDAMED (centralized EU database)	JADER (Japanese Adverse Drug Event Report)
AI/Digital Device Policy	SaMD framework plus predetermined change protocols	MDR Annex I; MDCG guidance on AI	Dedicated SaMD review office; guidelines issued 2023
Harmonization Body	IMDRF, ICH	IMDRF, EMA network	IMDRF, ICH (founding member)

Under EU MDR 2017/745, combination products with a device component are treated primarily as medical devices, and the drug component must go through mandatory consultation with the European Medicines Agency (EMA) (21). This device-first approach differs sharply from the FDA's PMOA-based assignment, and it can mean the same product is classified one way in the United States and another way in Europe (22). An antibiotic-coated orthopedic implant, for instance, may be treated as drug-led under FDA rules yet as a device under EU MDR, subject to EMA consultation (23).

Japan's PMDA takes a more integrated route, reviewing the drug and device components at the same time under the oversight of the Ministry of Health, Labour and Welfare (MHLW) (24). The United States and Japan are both founding members of the International Council for Harmonisation (ICH) and the International Medical Device Regulators Forum (IMDRF) (25). The United States held the IMDRF chair in 2024, and Japan took over the role in 2025.

Even with these harmonization efforts, real gaps remain in clinical data requirements, post-market surveillance capacity, and how AI-enabled devices are treated (26). These differences add to development costs and slow patient access in some markets. Bringing classification principles closer together, along with mutual recognition of clinical evidence, remains an important unmet goal.

7. Discussion

7.1 Regulatory Challenges

Several structural and emerging issues complicate the regulation of combination products, spanning classification methodology, post-market surveillance infrastructure, and the integration of newer technologies.

PMOA Limitations in Multi-Mechanism Products: The PMOA framework was built with products that have one clearly dominant mechanism in mind. But many of today's combination products – drug-eluting bioresorbable scaffolds, targeted nanoparticle therapeutics, cell-drug-device combinations – can produce comparably significant effects through several pathways operating at once. When that happens, determining the PMOA becomes genuinely contested, often stretching out RFD review or triggering disputes between FDA centers over jurisdiction. A 2022 OCP analysis found that roughly 14% of RFD submissions needed inter-center consultation because of PMOA ambiguity, adding an average of 45 days beyond the statutory 60-day window (9).

Fragmented Post-Market Surveillance: Safety monitoring after approval is complicated by the fact that drugs and biologics are tracked through the FDA Adverse Event Reporting System (FAERS), while devices are tracked separately through the Manufacturer and User Facility Device Experience (MAUDE) database (27). A product combining both a drug and a device can generate safety signals in each system without those signals ever being pulled together for analysis, delaying recognition of systemic problems. The 2019 concerns over paclitaxel-coated balloon catheters illustrate this well: early adverse events were scattered across both databases before regulators pieced together a consolidated signal (28).

Artificial Intelligence-Enabled Combination Products: Diagnostic devices powered by AI and paired with drug delivery systems are a fast-growing category [65,66]. The FDA's Software as a Medical Device (SaMD) framework, along with its 2021 AI/ML Action Plan, gives regulators a starting point, but neither was built specifically for products where AI makes real-time dosing decisions. Open questions remain around how algorithm updates should be handled after approval, what counts as a "significant change" requiring resubmission, and how AI decision-making should be validated across different patient populations. Japan's PMDA has moved further on this front, establishing a dedicated SaMD review office and issuing specific guidance in 2023 (29)(28).

Nanotechnology-Based Combination Products: Nanomedicine products – liposomal drug systems, nanoparticle-antibody conjugates – raise classification problems because their mechanism of action can

differ fundamentally from that of their bulk-material equivalents. Current PMOA definitions do not really account for size-dependent biological effects that alter pharmacokinetics, bio distribution, and immunogenicity. Doxil was approved in 1995 as the first nano-drug, and roughly 700 health-related nanomaterial products exist today , yet a full regulatory framework built specifically for nanomedicine combination products remains a work in progress (30).

7.2 Case Studies

Drug-Eluting Stents (DES) – PMA Pathway

Drug-eluting stents pair a metallic coronary scaffold (the device) with an antiproliferative drug coating, making them one of the earliest and most thoroughly studied combination products. The FDA classified them as device-led, placing them under CDRH while the drug component is governed through a drug master file. Early DES generations – the CYPHER sirolimus-eluting stent tested in the SIRIUS trial and the TAXUS paclitaxel-eluting stent tested in TAXUS-IV – showed marked reductions in restenosis (31). It was the clinical evidence required under the PMA pathway that helped identify late stent thrombosis risk during long-term follow-up, which then drove design changes in second-generation DES. This example shows how much value strong clinical evidence adds when reviewing high-risk, device-led combination products.

Antibody-Drug Conjugates (ADCs) – BLA Pathway

Antibody-drug conjugates attach a cytotoxic drug payload to a monoclonal antibody through a chemical linker, producing a targeted cancer therapy. Even though the linker and payload behave somewhat like a delivery device, the PMOA is treated as biologic-led because of the antibody's targeting role, which puts these products under CBER or CDER and requires BLA submission. Kadcyla (ado-trastuzumab emtansine), approved in 2013, was the first ADC cleared for solid tumors. Enhertu (fam-trastuzumab deruxtecan) received accelerated approval in December 2019 on the strength of the DESTINY-Breast01 trial. By 2025, the FDA had approved 15 ADCs, and BLA submissions for these products require full characterization of all three parts – antibody, linker, and payload – within a single quality, safety, and efficacy framework(32).

Insulin Delivery Pens – NDA Pathway

Prefilled insulin pens are co-packaged drug-device products where the therapeutic effect comes mainly from the insulin itself. That places them on the NDA pathway under CDER, with CDRH weighing in on the device side. A recurring regulatory issue has been ensuring consistent drug delivery performance across different pen devices used with the same insulin formulation. FDA guidance on Container Closure Systems for Packaging Human Drugs and Biologics, together with device-specific human factors guidance, sets standards for dose accuracy, needle penetration depth, and usability testing. This case shows that even when the lead center is obvious, co-packaged products can still require coordinated review across multiple centersin (33).

7.3 Critical Perspective and Recommendations

The regulatory framework in place today reflects decades of gradual refinement, and it has made possible the approval of many clinically important products. Even so, it was built for an era of simpler, more discrete products, and it is showing strain as products grow more complex. Three reforms would help. First, the FDA should set up a formal Combination Product Advisory Committee with standing representation from CDER, CBER, and CDRH, plus outside scientific and patient advocates, to offer structured input on PMOA questions for novel product types before sponsors file a formal RFD. That would ease inter-center disputes and give sponsors earlier certainty. Second, the FDA should build a unified post-market surveillance platform that brings together and cross-references safety signals from FAERS and MAUDE. A combined database, similar in concept to the EU's EUDAMED system, would make it easier to catch safety problems that arise from interactions between drug and device components. Third, a dedicated regulatory pathway is needed for AI-enabled combination products – one that stands apart from both the SaMD guidance and conventional drug pathways. That pathway should address predetermined change control protocols, requirements for monitoring real-world performance, and standards for algorithmic transparency.

8. Conclusion

Combination products now occupy an important and growing space in healthcare, delivering therapeutic capabilities that no single category drug, biologic, or device could achieve alone. The FDA's regulatory framework, built around PMOA-based classification, center assignment, and established premarket pathways, has given this space meaningful structure, enabling the approval of major products such as drug-

eluting stents, antibody-drug conjugates, and closed-loop insulin delivery systems. That said, the framework's limits are becoming harder to ignore as product complexity outpaces the system built to regulate it. PMOA ambiguity in multi-mechanism products, fragmented post-market surveillance, and the lack of dedicated pathways for AI-enabled and nanotechnology-based products are specific, fixable gaps. International divergence in regulatory approach adds a further layer of complication for sponsors seeking approval across multiple markets. Closing these gaps will take three coordinated efforts: structural changes within the FDA to improve coordination between centers and build a unified surveillance system; new regulatory pathways designed specifically for emerging technologies; and continued engagement through IMDRF and ICH to align classification principles and mutually recognize clinical evidence across borders. None of this is about loosening regulatory standards it is about making sure the system keeps pace with innovation, protecting patients while still getting genuinely transformative therapies to them without unnecessary delay.

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