Testosterone's Schedule III Status

The Evolving U.S. Regulatory Landscape

THE TESTOSTERONE PROJECT

CognitiveCare

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This report was prepared for The Testosterone Project in response to a Request for Proposal and provides an independent, neutral overview of the legal and policy context for testosterone's federal controlled-substance classification, including evidence commonly cited in current debates and plausible near-term regulatory scenarios.

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Executive Summary

The current regulatory stance often treats testosterone as if it were a high-abuse, recreationally reinforcing intoxicant. The evidence paints a more nuanced picture. Testosterone is an essential medicine with long-standing therapeutic use, a hormone with well-described physiological roles, and a federally controlled substance listed in Schedule III as an anabolic steroid. That classification is not a symbolic label. It shapes how testosterone is prescribed and dispensed, how refills are handled, how care is documented, and how patients experience stigma and access barriers. In practice, scheduling functions as an access system. It can either support stable, medically supervised treatment or introduce friction that disrupts continuity of care.

Testosterone entered Schedule III through a historical pathway that matters for interpreting its fit today. Federal control was designed in an era when public attention focused on athletic doping, youth exposure, and underground steroid distribution. Scheduling aimed to strengthen diversion control and deter non-medical use, while preserving legitimate medical access. The question in 2026 is whether those same tools remain proportionate to the risks we now observe, and whether the Schedule III framework matches testosterone's pharmacology, use patterns, and public health footprint.

Several developments have pushed this question back to the foreground. Clinical prescribing has expanded and diversified, alongside shifts in diagnostic norms, marketing, and professional debate about benefits and risks across patient subgroups. The non-medical environment has also changed. Online marketplaces, informal supply chains, and social-media–driven "optimization" narratives have made information and procurement easier, while complicating traditional diversion-control approaches.

A central point for scheduling-fit is that testosterone does not behave like the drugs that most people associate with controlled substances. Its clinically relevant effects develop gradually over days to weeks. It does not reliably produce rapid intoxication, acute euphoria, or a tight loop of immediate reinforcement that drives frequent redosing and overdose risk. Where non-medical use occurs, it is typically goal-directed. Users pursue longer-term outcomes such as muscularity, performance, or perceived vitality. This pattern is concentrated in specific subcultures rather than broadly distributed across the general population, and national surveillance data on adolescent steroid exposure remain low and have declined substantially over the last two decades. These features do not eliminate risk, but they describe a risk profile that differs in mechanism and tempo from the paradigm that Schedule III is commonly used to manage.

The mismatch also appears when examining what Schedule III controls accomplish in practice. Schedule III regulation exerts its strongest influence over compliant medical actors: clinicians, pharmacies, payers, and patients. Yet much of the non-medical supply that drives harm is increasingly extra-medical, including underground production, counterfeit products, peer networks, and internet-mediated markets. When controlled-substance rules intensify friction in the healthcare system, motivated users can substitute toward illicit channels. Meanwhile, the regulated system absorbs the compliance burden through added documentation, narrower refill windows, delays, and stigma.

Clinical stakes further sharpen the scheduling-fit question. Testosterone deficiency is associated with meaningful health consequences, including reduced bone mineral density and fracture risk, metabolic dysfunction, and elevated cardiometabolic risk in susceptible populations. In therapeutic contexts, testosterone is commonly prescribed to restore physiologic levels under monitoring protocols, not to induce supraphysiologic exposure. Recent federal signals reflect ongoing reassessment of testosterone therapy, and broader public health messaging has increasingly treated testosterone health as relevant to general health and prevention. This creates policy dissonance: a hormone treated as clinically important in health guidance is simultaneously regulated as a Schedule III controlled substance.

Taken together, these facts support a clear conclusion about category fit. Testosterone carries real risks when used at supraphysiologic doses, obtained through illicit channels, or used without medical oversight. Those risks justify oversight and targeted diversion control. The question is whether Schedule III is the right instrument for that job, given testosterone's dominant therapeutic role, delayed reinforcement profile, concentrated and goal-directed patterns of non-medical use, and the limited leverage of Schedule III tools over modern illicit supply chains. The evidence suggests a growing mismatch between the logic of Schedule III and the realities of testosterone use and risk in 2026. In short, testosterone fits poorly in the current Schedule III category.

1. Introduction

Federal drug policy classifies testosterone as a Schedule III controlled substance and, specifically, as an "anabolic steroid" under the Controlled Substances Act (CSA) implementing regulations. Testosterone occupies an unusual place in United States drug policy because it is (1) an essential medicine with long-standing therapeutic use, (2) a drug with a well-documented history of non-medical use in sports, and (3) a federally controlled substance listed in Schedule III. Because scheduling status dictates how medications are prescribed, dispensed, and monitored, testosterone's classification not only acts as a legal label but also directly impacts clinical access, public health surveillance, and diversion-control strategy[1].

Whether testosterone should remain in Schedule III has returned as a central regulatory question. We must ask whether the current controls are still proportionate to the actual risks we see today, and whether they support the CSA's own statutory criteria[2]. This debate is occurring in a medical setting that differs significantly from the one that existed when the Anabolic Steroids Control Act of 1990 was first signed into law. Congress placed anabolic steroids (including testosterone) in Schedule III through the Anabolic Steroids Control Act of 1990 and later refined the statutory framework and definitions through the Anabolic Steroid Control Act of 2004[3].

Several recent developments have increased the salience of the scheduling question. In clinical practice, testosterone prescribing has expanded and diversified alongside changes in diagnostic norms, direct-to-consumer marketing, and evolving professional discussion about benefits and risks across patient subgroups. In parallel, demand for testosterone in gender-affirming care has increased the visibility of access barriers and continuity-of-care risks that can arise when a therapy is regulated as a controlled substance[4,5]. These access arguments have been articulated directly in policy communications, including a 2022 letter led by U.S. Senator Edward J. Markey urging the federal government to consider rescheduling testosterone from Schedule III to Schedule V or descheduling it entirely, framed in part around access to medically necessary gender-affirming hormone therapy[6]. At the same time, the non-medical environment has evolved, with online marketplaces, informal supply chains, and social-media–driven "optimization" narratives accelerating diffusion and complicating traditional diversion-control approaches[7–9].

The current regulatory stance often treats testosterone as if it were a high-abuse, recreationally reinforcing intoxicant. However, the data tells a much more nuanced story. When we look at non-medical use, we do not see the typical intoxication-seeking pattern associated with many controlled substances. Instead, use is largely goal-directed and driven by specific objectives associated with physical performance or aesthetic appearance in relatively small subcultures. The recent national survey of 2024 Monitoring

the Future results show that lifetime steroid use among adolescents remains at or below 1.4%, continuing a steady decline from its peak twenty years ago[10]. Testosterone does not fit the profile of a drug driving a public health crisis of intoxication or rapid-onset reinforcement[10].

The policy question is also sharpened by the medical consequences

Box 1-1. A Shift in Federal Nutrition Policy

In January 2026, USDA and HHS released the *Dietary Guidelines for Americans, 2025–2030*. For the first time in this federal nutrition guidance, the documents explicitly acknowledge "**testosterone health**" as a relevant factor for the general population. The guidelines describe testosterone levels as intrinsically linked to metabolic, musculoskeletal, and cardiometabolic health.

The Policy Dissonance: The discussion in these guidelines emphasizes modifiable factors such as diet quality, healthy weight, and physical activity as main drivers of hormonal health, rather than focusing on misuse or diversion risk. This represents a significant policy signal. A hormone recognized in nutrition guidance as a vital health marker for the general public is simultaneously regulated under drug policy as a Schedule III substance. For patients and clinicians, this contradiction creates policy friction, where a medically necessary hormone is treated with a level of criminal suspicion that is increasingly at odds with the government's own health promotion strategies.

associated with untreated hypogonadism. Research suggests that low testosterone levels are linked to reduced bone mineral density and higher fracture risk[11]. Beyond musculoskeletal health, testosterone deficiency is strongly associated with insulin resistance and development of metabolic syndrome[12]. Similarly, low testosterone levels in men are associated with an increased risk of cardiovascular disease (CVD) whereas, higher endogenous testosterone levels are associated with reduced CVD risk[13,14]. This shows that maintaining physiologic testosterone levels is a systemic health issue instead of an elective enhancement.

The policy friction (Box 1-1) becomes more apparent when viewed alongside federal treatment of other therapeutics with recognized misuse[15]. For example, Gabapentin is not scheduled federally despite documentation of opportunistic misuse and diversion[16]. Likewise, high-impact endocrine therapies such as GLP-1 receptor agonists (e.g., Ozempic) are generally managed through conventional prescription controls rather than CSA-style enforcement mechanisms[17]. This contrasts with the management of testosterone under Schedule III.

Box 1-2. Reassessing the Clinical Record

On December 10, 2025, the U.S. Food and Drug Administration (FDA) convened an ***Expert Panel on Testosterone Replacement Therapy*** (TRT) and opened a parallel public docket (FDA-2025-N-6743)[81]. This forum brought together clinicians, researchers, and federal health officials to review contemporary evidence on the safety and efficacy of TRT.

Key Evolutionary Indicators:

- **Modern Safety Data:** Discussion centered on updated cardiovascular outcome data suggesting that, in appropriately selected men, testosterone therapy does not increase major adverse cardiovascular events (MACE).
- **Essential vs. Lifestyle:** Several experts argued for characterizing testosterone as an essential component of preventive men's health rather than a "lifestyle" drug.
- **Barriers to Care:** Panelists highlighted that Schedule III status, coupled with narrow labeled indications, contributes to persistent patient stigma and administrative burdens for those with clinically significant deficiency.

The Conclusion of the Forum: While the panel did not immediately alter testosterone's labeled indications or its Schedule III status, it served as a determinative indicator that the "status quo" is under review. It formalized a federal process for reassessing the core premises of testosterone's risk-benefit profile. The calls for label modernization and a reconsideration of controlled-substance classification now form a permanent part of the evidentiary record, signaling that the regulatory guardrails of the 1990s may no longer be appropriate for the 2020s.

Changes in prescribing modality and oversight have further reshaped the policy context. In recent years, telemedicine and remote prescribing models have played a pivotal role for controlled-substance regulation. The Drug Enforcement Administration (DEA), working jointly with the Department of Health and Human Services (HHS), has repeatedly addressed the temporary telemedicine flexibilities that allow prescribing of controlled medications without a prior in-person evaluation, extending those flexibilities again effective January 1, 2026 through December 31, 2026, while permanent rules are developed[18–20]. While these telemedicine extensions are not specific to testosterone, they provide temporary relief in accessing standard of care. Still, the Schedule III designation continues to carry a weight of stigma and compliance burden that telehealth alone cannot fix.

Ultimately, testosterone stands as one of the most extensively studied compounds in research literature, its therapeutic parameters and safety profile refined by decades of clinical data[21]. While the public health risks of supraphysiologic exposure and the persistence of illicit supply chains are undisputed, the challenge for modern drug policy lies in balancing these risks against the clinical requirements of a legitimate and expanding patient population. Section 2 sets out the scope and analytic approach used to evaluate this scheduling-fit question under the CSA.

2. Scope of the Article

This article is designed as a documentary-style reference to understand (1) how testosterone came to be controlled as a Schedule III substance, (2) what the evidence base does and does not show about abuse liability, diversion, and public health risk, and (3) how the CSA's eight-factor framework can be applied to testosterone in a transparent and reproducible way[2]. Our aim is to clarify the factual record, summarize the strongest available evidence, identify key uncertainties, and map the ongoing debate onto the statutory criteria that govern scheduling decisions. This orientation is meant to reduce a common failure mode in public discussion, namely treating "testosterone scheduling" as a proxy for broader disputes, while neglecting the specific legal standard and evidentiary questions that scheduling determinations require[2].

To support that purpose, the article follows a documentary and literature review approach and is organized around three linked components. We first outline the regulatory architecture relevant to scheduling and potential reform pathways, then present a historical timeline and narrative account of major legal and regulatory milestones that shaped testosterone's controlled status, including key moments in the development of anabolic steroid controls and subsequent policy refinements, alongside what is known about the practical consequences of Schedule III classification[3]. We then map the current policy viewpoint and the major stakeholder arguments that brought renewed attention to scheduling status. Against that backdrop, we present evidence from literature review and survey across domains relevant to scheduling - including pharmacology and reinforcement; epidemiology of non-medical use; diversion and supply dynamics; dependence and withdrawal phenomena; and health outcomes - while explicitly distinguishing therapeutic from supraphysiologic or non-medical contexts where feasible.

We conclude with a structured CSA eight-factor analysis, organizing evidence under each statutory factor and highlighting where the evidentiary foundation is strong, where it is mixed, and where it remains limited, and we close with forward-looking, non-predictive scenarios describing how policy may evolve depending on emerging evidence and regulatory priorities[2].

Several scope choices are important to state at the outset. This review focuses on U.S. federal scheduling under the CSA and its implementing regulations. We acknowledge that state-level controlled substance rules, prescription drug monitoring programs, payer policies, and professional guidance can amplify or mitigate the real-world impact of federal classification, but those topics are treated only insofar as they affect the practical operation of Schedule III status. We treat "testosterone" as referring to testosterone and its clinically used formulations, while recognizing that scheduling debates often rely on evidence about anabolic-androgenic steroids (AAS) as a broader class[3]. Where class-wide evidence is used, we

identify it explicitly and note limitations in applying those findings to testosterone in particular. We also distinguish sports governance and anti-doping policy from CSA scheduling, while acknowledging that athletic misuse historically influenced public perception and policymaking around anabolic steroids. Finally, we address telemedicine and prescribing modality only insofar as it changes the oversight environment for controlled-substance prescribing and potential diversion risk[18–20].

By grounding the discussion in primary-source documentation, transparent analysis, and the CSA's statutory criteria, this article aims to serve as a durable reference for regulators, clinicians, researchers, and policy stakeholders seeking a deep, context-rich understanding of testosterone's current scheduling status and the directions in which the debate is moving.

3. Methods

3.1 Design and objectives

This article uses a hybrid evidence-synthesis approach that combines (1) documentary legal and regulatory analysis and (2) a scoping review-style evidence map of the scientific and public health literature relevant to scheduling determinations for testosterone under the U.S. Controlled Substances Act (CSA).

Methods were structured to align with established scoping review guidance and reporting standards, with adaptations necessary to incorporate legal and regulatory materials that sit outside conventional biomedical databases.

3.2 Review questions and analytic framework

We framed the project around three regulator-facing questions:

1. **Regulatory history:** What statutory, regulatory, and policy milestones produced and sustained testosterone's classification as a Schedule III anabolic steroid in the United States? [1]
2. **Updated evidence base:** What empirical evidence is available on (a) abuse liability and reinforcement, (b) patterns and prevalence of non-medical use, (c) diversion and supply dynamics, (d) dependence and withdrawal phenomena, and (e) public health outcomes associated with testosterone, with attention to differences between therapeutic and supraphysiologic use contexts?
3. **CSA application:** How does the assembled evidence map to each CSA factor in 21 U.S.C. § 811(c), and where do uncertainties or evidence gaps materially affect scheduling determinations?[2]

3.3 Sources of evidence

3.3.1 Primary legal and regulatory sources

We prioritized primary sources describing scheduling, statutory intent, and implementing controls, including the U.S. Code, the Code of Federal Regulations, Federal Register notices, and government legislative records. This stream also included relevant agency materials (for example, DEA and HHS publications, rulemakings, and dockets) and FDA communications or convenings that shape the broader policy environment for testosterone, recognizing that FDA actions do not themselves determine CSA scheduling[18–20].

3.3.2 *Peer-reviewed scientific literature*

We sought empirical studies relevant to abuse liability, dependence, diversion, prevalence, and public health risk. This included human laboratory studies, observational and pharmacoepidemiologic studies, randomized trials when relevant to safety outcomes, qualitative studies describing use patterns, and systematic or narrative reviews that were methodologically transparent.

3.3.3 *Grey literature and surveillance sources*

To capture real-world signals often used in regulatory assessment, we included grey literature and surveillance sources where they could be evaluated and cited transparently. Examples include official reports, policy statements, and technical documents from governmental or quasi-governmental bodies, as well as data sources used in public health surveillance.

3.4 Search strategy and eligibility criteria

3.4.1 *Documentary search (legal and regulatory record)*

We used targeted searches of government repositories and authoritative legal databases. Search terms included combinations of “testosterone,” “anabolic steroid,” “Schedule III,” “controlled substance,” “CFR 1308.13,” “21 U.S.C. 811,” “eight factors,” and “reschedule” or “deschedule.” Results were limited to materials relevant to U.S. federal scheduling and the operational consequences of Schedule III classification.

3.4.2 *Biomedical and interdisciplinary database search*

We designed database searches to retrieve literature on testosterone’s abuse liability, dependence, diversion, and public health outcomes. Planned databases included MEDLINE (PubMed), Embase, PsycINFO, Web of Science, and Scopus, supplemented by targeted Google Scholar searches for key terms and citation chaining from sentinel papers and major reviews[22]. Searches were designed to capture literature from the inception of modern anabolic steroid policy through the most recent update of the manuscript.

We excluded sources that were not accessible in full text, were purely anecdotal without verifiable provenance, or did not contain information relevant to CSA factors.

3.5 Screening and selection procedures

Screening was designed as a two-stage process: title and abstract screening, followed by full-text review[22]. For documentary sources, screening focused on authenticity, authority (primary versus secondary commentary), and relevance to CSA scheduling criteria[2].

3.6 Quality considerations and synthesis approach

Because the goal was to map and characterize the evidence base rather than estimate pooled effects, we treated this project primarily as a scoping review and evidence map. Consistent with scoping review guidance, we emphasized transparency of inclusion, clear categorization, and explicit identification of evidence gaps[23,24]. Where evidence was used to support high-stakes interpretive claims in the CSA analysis, we performed targeted critical appraisal focusing on internal validity threats (selection bias, confounding, misclassification, and generalizability) and highlighted uncertainty in the narrative synthesis.

4. Regulatory Framework

4.1 The Controlled Substances Act (CSA) scheduling structure

The CSA establishes five schedules (I–V) and links each schedule to specific statutory findings regarding medical use, abuse potential, and dependence liability[2]. For substances placed in Schedules II–V, the CSA requires findings that include accepted medical use and a dependence profile that becomes progressively less restrictive from Schedule II to Schedule V. In particular, the CSA's findings for Schedule III require (A) a potential for abuse less than substances in Schedules I and II, (B) a currently accepted medical use in treatment in the United States, and (C) that abuse may lead to moderate or low physical dependence or high psychological dependence.

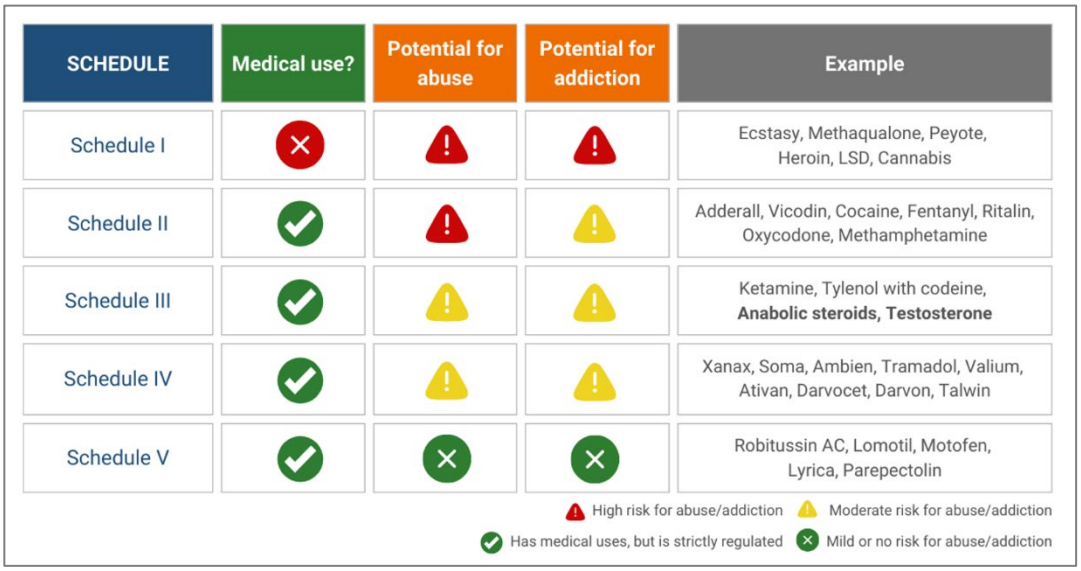

Figure 4-1. CSA Scheduling Structure: Testosterone classified under Schedule III

Scheduling decisions also require consideration of the CSA's eight factors (the "8-factor analysis"), which provide a structured basis for evaluating control, transfer between schedules, or removal from control. These factors include, among other considerations, potential for abuse, scientific evidence of pharmacologic effects, current scientific knowledge, the history and pattern of abuse, scope and significance of abuse, public health risks, dependence liability, and whether the substance is an immediate precursor of another controlled substance

4.2 Authorities and roles in scheduling, rescheduling, and descheduling

Under the CSA, the Attorney General is the statutory decision-maker for scheduling actions, which are implemented through rulemaking and reflected in the schedules in regulation (21 CFR Part 1308)[1]. Proceedings to issue,

amend, or repeal scheduling rules may be initiated in three ways: on the Attorney General's own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of any interested party.

A defining feature of the federal process is the required scientific and medical input from HHS. When the Attorney General proposes to control or reschedule a substance, the CSA requires a request to the Secretary of HHS for a scientific and medical evaluation and a scheduling recommendation. The Secretary's recommendations are binding on the Attorney General with respect to scientific and medical matters, and if the Secretary recommends that a drug not be controlled, the CSA prohibits the Attorney General from controlling it. In practice, this framework creates a two-part process in which HHS provides the medical-scientific assessment and DEA (on behalf of the Attorney General) conducts the scheduling rulemaking and applies the statutory standard through an administrative record[2].

The CSA also specifies the procedural posture for these rules. Scheduling rules must be made "on the record after opportunity for a hearing," using the formal rulemaking procedures referenced in the Administrative Procedure Act. This procedural design is especially relevant for contested scheduling questions because it frames the types of evidence, testimony, and dispute resolution that can enter the administrative record.

4.3 Why testosterone is treated as an anabolic steroid under federal law

Testosterone's Schedule III status is operationalized through the CSA's treatment of anabolic steroids as a category. The statute defines "anabolic steroid" broadly as any drug or hormonal substance chemically and pharmacologically related to testosterone, with specified exclusions (for example, estrogens, progestins, corticosteroids, and dehydroepiandrosterone) and an enumerated list of covered substances. The implementing regulations incorporate this statutory approach by defining "anabolic steroid" in DEA regulations and listing anabolic steroids in Schedule III[1,25].

In the schedule listing itself, 21 CFR § 1308.13 identifies anabolic steroids as Schedule III substances and applies the listing to "any substance meeting the definition of anabolic steroid" as set out in DEA's definitions, including preparations containing covered substances, and includes testosterone by name within the anabolic steroid list[1]. For regulators and policymakers, this structure has two important consequences. First, many debates about testosterone's status implicitly intersect with how anabolic steroids are defined and administered as a class in federal law. Second, evidence used to justify controls may be drawn from class-wide AAS concerns, which makes it especially important to distinguish testosterone-specific evidence from class-wide evidence.

4.4 What Schedule III means operationally for prescribing and dispensing

Schedule III status shapes access and compliance through prescribing, dispensing, recordkeeping, and security requirements that apply to controlled substances. The CSA sets baseline rules for dispensing Schedule III and IV controlled substances that are prescription drugs, requiring dispensing only pursuant to a valid prescription and imposing limits on refills[26]. Specifically, Schedule III (and IV) prescriptions may not be filled or refilled more than six months after the date of issuance and may not be refilled more than five times unless renewed by the practitioner[26,27](Box 4-1). These requirements are mirrored in DEA's implementing regulations[27].

DEA Diversion Control manuals for practitioners and pharmacists summarize these operational rules and related compliance expectations in a form commonly used by regulated entities, including the constraints on refills and the broader responsibilities attached to prescribing and dispensing controlled substances[28,29]. Although such manuals do not replace statutory or regulatory text, they are relevant as interpretive guides that reflect how federal requirements are communicated to registrants and operationalized in practice[28,29].

Box 4-1. Standardized diagnostic confirmation and monitoring elements in prescribing TRT:

- Confirm low testosterone with ≥2 morning measurements before initiation
- Target mid-normal range; measure T after initiation (3–6 months)
- Hematocrit: baseline, 3–6 months, then annually
- Prostate risk evaluation/PSA monitoring for screened populations

Several additional regulatory mechanisms can matter for continuity of care even when the schedule itself does not change. For example, DEA finalized a rule allowing the transfer of electronic prescriptions for controlled substances (Schedules II–V) between DEA-registered retail pharmacies at a patient's request, reducing the need for cancellation and re-issuance by prescribers in certain scenarios[30]. Changes of this type can affect patient access and administrative burden without altering the underlying schedule.

4.5 Pathways for change in testosterone's federal scheduling status

Discussions about keeping, rescheduling, or removing testosterone from Schedule III must be evaluated against the specific legal pathways available under the CSA.

1. **Petition or agency-initiated scheduling action:** Any interested party may petition for a scheduling change, and proceedings may also be initiated by the Attorney General or at the request of the HHS Secretary[31].
2. **HHS medical-scientific evaluation and recommendation:** For actions to control or reschedule, the CSA requires a scientific and medical evaluation and recommendation from HHS, which is binding on scientific and medical matters and can constrain whether control is permissible[31]
3. **DEA rulemaking and administrative record:** Scheduling rules are adopted through formal rulemaking procedures "on the record after opportunity for a hearing," which requires a structured evidentiary record and provides a venue for disputed factual questions[31].
4. **Statutory amendments:** Congress can change the statutory framework directly, including by altering definitions or scheduling provisions, as it has done for anabolic steroids through prior legislation[3,22,32] .

In parallel, "current trends" debates often reference prescribing modality and telemedicine governance because these can affect the practical burden of Schedule III controls. DEA and HHS have recently extended telemedicine flexibilities for controlled substance prescribing while permanent frameworks are developed, and DEA has also proposed rule approaches that would create special telemedicine registrations for prescribing Schedule III–V controlled substances in defined circumstances[19,33]. These developments do not determine testosterone's schedule, but they can influence how stakeholders experience and evaluate the real-world impact of Schedule III status, and they may affect diversion-risk perceptions for Schedule III medications more generally.

5. Substance Overview Relevant to Abuse and Diversion

5.1 Therapeutic and Non-Medical Contexts

Testosterone is an endogenous androgenic steroid hormone with established physiological roles in male sexual development, reproductive function, musculoskeletal maintenance, erythropoiesis, and aspects of neurobehavioral regulation[34–39]. Exogenous testosterone products are approved and prescribed for limited, well-defined medical indications, most notably male hypogonadism diagnosed based on consistent clinical findings and laboratory-confirmed testosterone deficiency[5,40]. In therapeutic settings, administration occurs pursuant to a practitioner's prescription, consistent with approved labeling, and is accompanied by diagnostic confirmation, dosage individualization, and periodic clinical and laboratory monitoring. The intended purpose of therapeutic use is restoration of testosterone concentrations to the normal physiologic range and maintenance of stable systemic exposure, rather than induction of acute pharmacological effects.

By contrast, non-medical use of testosterone occurs outside the bounds of accepted medical practice and is not directed toward treatment of a recognized endocrine disorder. Non-medical use has been documented primarily in contexts related to enhancement of muscularity, physical appearance, athletic performance, or perceived vitality[41–43]. Such use may involve supratherapeutic dosing, concurrent use of multiple AAS, or cyclical patterns of administration. Available evidence indicates that non-medical use of testosterone is predominantly instrumental and goal-directed. Individuals engaging in such use seek delayed functional or aesthetic outcomes rather than immediate intoxication or psychoactive effects.

Diversion of testosterone products occurs through identifiable mechanisms, including prescription misuse, sharing or resale of legitimately obtained products, falsified clinical indications, and acquisition from illicit or counterfeit sources. Epidemiological and enforcement data indicate that diversion and non-medical use are concentrated within discrete subpopulations and specific use contexts[4,44–46]. These patterns differ from substances whose abuse and diversion are characterized by widespread, recreational demand within the general population.

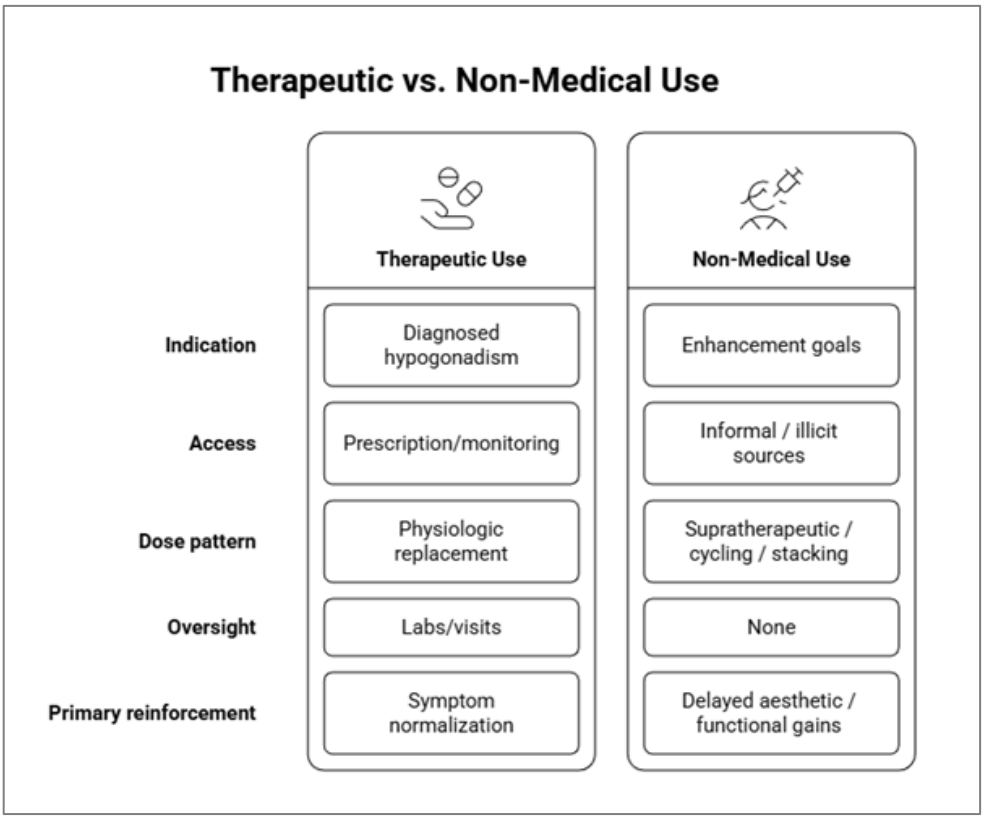

Figure 5-1. Contrasting therapeutic testosterone replacement and non-medical use: differences in indication, access pathway, dosing patterns, monitoring, and intended outcomes

5.2 Reinforcement and Temporal Characteristics

The pharmacological effects of testosterone differ materially from those of substances whose abuse liability is driven by rapid onset of central nervous system effects and immediate reinforcement[5]. Testosterone exerts its primary actions via androgen receptor–mediated mechanisms that result in genomic and downstream physiological changes occurring over days to weeks[4,40,45,46]. Clinical and nonclinical data demonstrate that observable effects related to strength, body composition, libido, and mood develop gradually and are cumulative in nature[47–49].

This delayed onset of effect limits acute reinforcement. Testosterone does not reliably produce rapid euphoria, intoxication, or subjective effects temporally linked to administration. When psycho-behavioral effects are reported, they tend to be variable, indirect, and temporally dissociated from dosing. Reinforcement, where observed, is associated with longer-term outcomes such as changes in physical appearance or functional performance rather than with immediate pharmacologic reward[50–52].

Pharmacokinetic characteristics of approved testosterone formulations further limit abuse liability. These products are designed to provide sustained systemic exposure and to avoid rapid fluctuations in serum concentrations.

Even in cases of non-medical use involving supraphysiologic dosing, effects typically accrue over extended periods rather than producing immediate feedback that would promote frequent redosing or escalation. Patterns of non-medical use, therefore, are more often episodic or cyclical rather than continuous or compulsive[51,52].

Available neurobiological evidence indicates that testosterone does not produce consistent or robust activation of mesolimbic dopamine pathways comparable to substances with high intrinsic abuse potential[45,50]. While hormonal modulation can influence mood and behavior, such effects do not replicate the rapid reinforcement loops characteristic of opioids, stimulants, or sedative-hypnotics[34,41]. Dependence syndromes consistent with classical substance use disorder are infrequently reported and do not represent a defining feature of testosterone misuse[45,46,51].

5.3 Risk Characteristics and Management Considerations

The risks associated with testosterone exposure are well-characterized and largely dependent on dose, duration of exposure, formulation, and individual susceptibility. Documented adverse effects include suppression of endogenous testosterone production, polycythemia, alterations in lipid metabolism, cardiovascular effects in susceptible populations, hepatic effects associated with certain formulations, reproductive consequences, and psychiatric symptoms in a subset of users[4,5,45,50,51]. These effects are biologically plausible consequences of androgen pharmacology and increase in likelihood with supraphysiologic dosing and absence of medical supervision.

In therapeutic contexts, such risks are mitigated through established clinical risk-management practices, including appropriate patient selection, confirmation of diagnosis, baseline and follow-up laboratory monitoring, and dosage adjustments as clinically indicated. These controls are consistent with standard approaches applied to other hormonally active prescription drugs and are reflected in approved labeling and clinical guidelines. When used as directed under medical supervision, testosterone has demonstrated a predictable safety profile.

In non-medical contexts, risk-management challenges arise primarily from the absence of clinical oversight, uncertainty regarding product identity and purity, and dosing regimens that exceed physiological levels. Historical regulatory responses have emphasized targeted enforcement, education, monitoring within organized athletic environments, and control of illicit manufacturing and distribution. Available data does not indicate that testosterone misuse produces patterns of acute toxicity, overdose, or rapid-onset public health crises comparable to substances whose scheduling is driven by immediate psychoactive effects and unpredictable harm[4,44].

6. Historical Record: How Testosterone Came to be Controlled

6.1 Pre-control scientific and therapeutic history

Testosterone was isolated and identified as a biologically active male hormone in the early 1930s following advances in steroid chemistry and endocrinology, with foundational synthesis work subsequently recognized by the 1939 Nobel Prize in Chemistry[53]. By the late 1930s and 1940s, testosterone and early synthetic AAS were rapidly incorporated into clinical medicine for treatment of hypogonadism, delayed puberty, catabolic states, anemia, and certain psychiatric indications, reflecting their acceptance as legitimate therapeutic agents rather than substances of abuse[49,54]. Throughout the 1940s and 1950s, testosterone's medical use expanded within endocrinology and internal medicine, supported by growing physiological understanding of androgen action and without association with intoxication, dependency, or recreational drug culture[55]. By the 1950s, although early anecdotal reports suggested that anabolic steroids could enhance muscularity, their effects were largely underestimated or dismissed in mainstream medical literature, and testosterone continued to be framed principally as hormone replacement therapy rather than a performance-enhancing agent[47,56–58].

During the 1960s, testosterone esters and related anabolic steroids were widely available by prescription, regulatory oversight focused on safety and labeling under the evolving authority of the U.S. FDA, and no federal abuse-control classification applied to these agents[59]. Even in the early 1970s, major medical and sports medicine bodies continued to debate or downplay anabolic efficacy, and testosterone was not viewed through the lens of substance abuse or addiction. This prolonged pre-control period—spanning roughly four decades from the 1930s through the mid-1970s—demonstrates that testosterone's scientific discovery, therapeutic establishment, and regulatory acceptance occurred well before the emergence of sustained non-medical misuse or policy concerns related to abuse and diversion[59–61].

6.2 Emergence of athletic and non-medical misuse

Non-medical use of testosterone and other AAS emerged gradually and in parallel with developments in organized sport rather than through recreational drug culture, with early anecdotal indications appearing as early as the 1930s–1940s, when androgenic substances were reportedly administered to select athletes in pre-war Europe, although without systematic documentation[54,59–61].More substantive evidence of athletic misuse became apparent in the 1950s, notably following reports of testosterone use among Soviet weightlifters at the 1952 and 1956 Olympics Games, and subsequently in the United States after 1954,

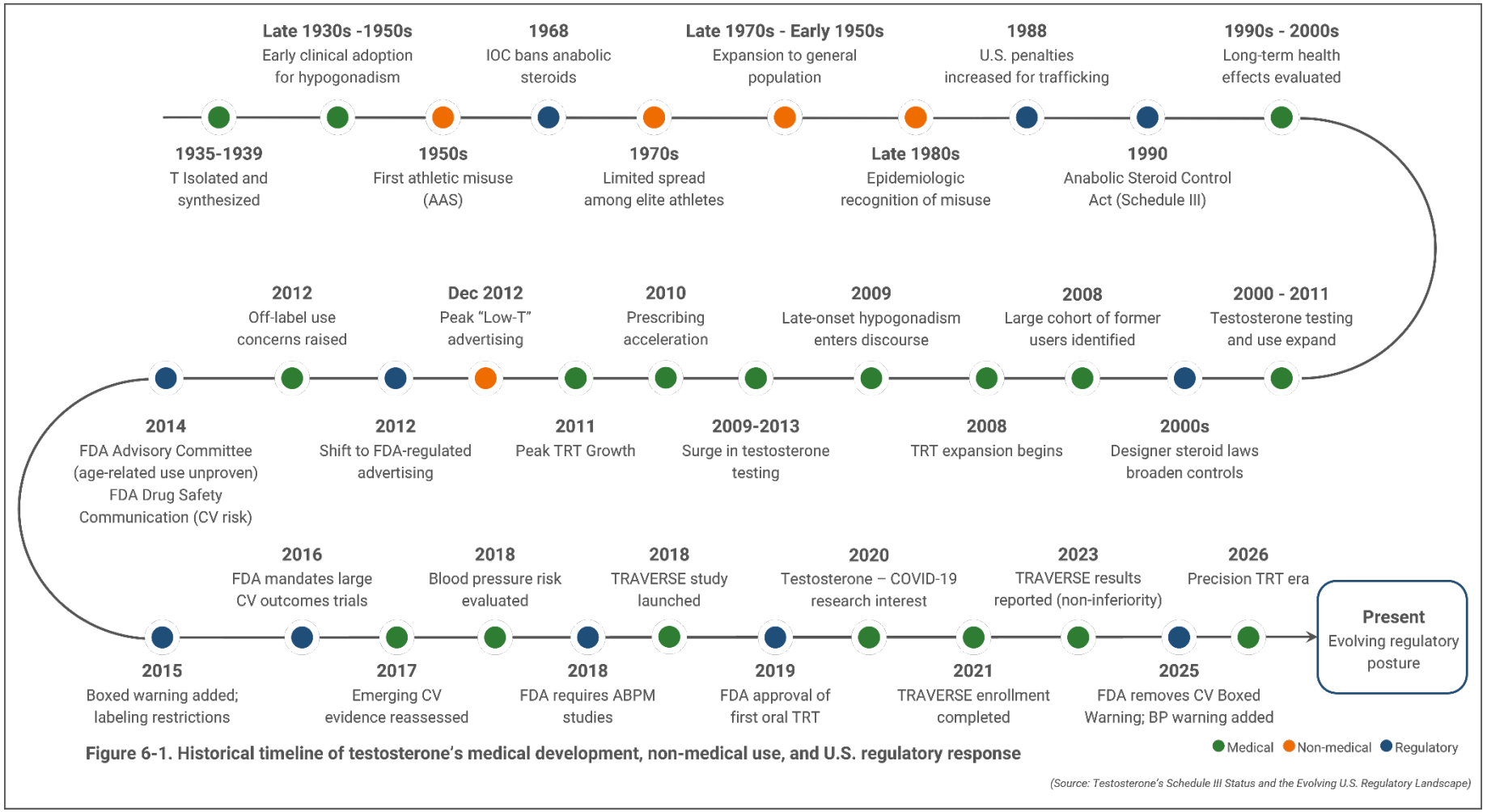

Figure 6-1. Historical timeline of testosterone's medical development, non-medical use, and U.S. regulatory response

(Source: Testosterone's Schedule III Status and the Evolving U.S. Regulatory Landscape)

when American weightlifters were exposed to androgen use practices observed internationally[62–65].

Throughout the 1960s, non-medical testosterone use expanded within elite athletics and strength-based sports, occurring alongside limited scientific skepticism regarding its efficacy and minimal regulatory scrutiny. By the late 1960s and early 1970s, increasing recognition of performance enhancement led to formal responses within sport, including the 1967 International Olympic Committee (IOC) publication of its first prohibited substances list and the 1974 IOC ban on anabolic steroids, reflecting growing concern about fairness and athlete health rather than addiction or intoxication[66,67].

During the 1970s and 1980s, systematic state-sponsored doping programs—most notably within the former German Democratic Republic—demonstrated large-scale, organized use of testosterone derivatives, often without informed consent, further elevating international awareness[68]. In parallel, by the 1980s, non-medical use expanded beyond elite athletes into bodybuilding and recreational fitness communities, facilitated by underground manufacturing, informal distribution networks, and self-directed dosing practices such as “cycling” and “stacking,” as documented in emerging psychiatric and epidemiologic literature[61,69].

Importantly, throughout this period and continuing into the 1990s, misuse remained predominantly goal-directed and episodic, aimed at delayed outcomes such as muscularity and performance; even as dependence-like syndromes were increasingly described, these were understood to differ mechanistically and temporally from classical drug abuse models[44,62,64,70–73].

This historical pattern underscores that the emergence of testosterone misuse was shaped by evolving athletic, cultural, and institutional pressures over several decades, rather than by intrinsic intoxicating properties or rapid reinforcement comparable to traditional drugs of abuse[74,75].

6.3 Legislative response and Schedule III placement

Federal legislative control over testosterone emerged in response to accumulating concerns regarding non-medical use, athletic doping, and diversion rather than evidence of classical addictive potential. The policy attention intensified during the mid-to-late 1980s as reports of widespread AAS use among athletes and recreational bodybuilders became more visible in the United States and internationally. Congressional hearings conducted in the late 1980s documented the growth of underground steroid distribution networks, adolescent exposure, and health consequences associated with supraphysiologic dosing, while also acknowledging testosterone’s longstanding accepted medical use.

These developments culminated in the enactment of the Anabolic Steroid Control Act of 1990, which amended the CSA to explicitly define anabolic steroids as a distinct category and place them, including testosterone and its esters, into Schedule III, effective November 29, 1990[59,76]. Legislative records from this period indicate that Schedule III placement reflected a determination that testosterone possessed recognized medical utility and a lower potential for abuse relative to Schedule I or II substances, while still warranting controls to address diversion, illicit trafficking, and non-medical distribution. Unlike substances scheduled based on acute intoxication, overdose risk, or strong psychoactive reinforcement, testosterone was scheduled primarily to facilitate monitoring of supply chains, restrict non-prescribed access, and deter misuse in sports and youth populations. Implementation authority was assigned to the DEA, which applied standard Schedule III regulatory mechanisms, including registration, recordkeeping, and prescribing requirements, without reclassifying testosterone as a narcotic or intoxicant drug.

Medical literature from the early 1990s emphasized that this legislative action was policy-driven and preventive in nature, aimed at curbing emerging misuse trends while preserving clinical access, rather than a response to demonstrable patterns of compulsive drug use or widespread public health crises associated with acute toxicity or addiction[77].

6.4 Post-scheduling expansions and market adaptation

Following placement of testosterone and other AAS into Schedule III under the Anabolic Steroid Control Act of 1990, both legitimate medical markets and non-medical supply chains adapted in distinct and predictable ways throughout the 1990s and 2000s. In the immediate post-scheduling period of the early 1990s, enforcement efforts focused on curtailing diversion from legitimate pharmaceutical sources and disrupting emerging underground distribution networks, while clinical use of testosterone continued largely uninterrupted within endocrinology and urology. By the mid-to-late 1990s, illicit markets increasingly shifted toward non-prescription sources, including international manufacturing and gym-based distribution networks, as documented by law-enforcement and epidemiologic surveys, while patterns of misuse remained largely cyclical and goal-directed rather than recreational. During the late 1990s and early 2000s, pharmaceutical innovation accelerated within the regulated market, with development and approval of transdermal gels, patches, longer-acting injectable esters, and later implantable formulations designed to improve pharmacokinetic stability, adherence, and safety for therapeutic users.

Concurrently, non-medical users adapted by adopting self-directed dosing regimens, internet-mediated procurement, and increasingly sophisticated information exchange regarding “cycling”, “stacking”, and post-cycle recovery, reflecting behavioral adaptation to scheduling controls rather than

expansion of demand. By the mid-2000s, epidemiological data indicated that while lifetime prevalence of anabolic steroid exposure had increased modestly in some populations, particularly among recreational fitness communities, misuse did not diffuse broadly into the general population nor exhibit escalation patterns associated with classical drugs of abuse. Instead, misuse remained concentrated within defined subcultures and continued to be shaped by delayed performance and appearance outcomes.

Internationally, during the 2000s, regulatory heterogeneity persisted, with some jurisdictions maintaining prescription-only models without formal scheduling and others aligning with U.S. controls, reinforcing that market dynamics were driven by policy design and enforcement intensity rather than by intrinsic intoxicating properties of testosterone. Overall, post-scheduling experience through the late 2000s demonstrates that Schedule III placement altered distribution pathways and compliance behavior but did not transform testosterone into a substance characterized by widespread recreational abuse, acute public health crises, or compulsive use patterns.

6.5 Safety and regulatory milestones shaping today's context

From the early 2000s, safety and regulatory evaluation of testosterone increasingly emphasized population-level prescribing trends and long-term outcomes, coinciding with a marked rise in legitimate androgen prescribing documented between 2001 and 2011, during which testosterone use among U.S. men over 40 increased more than threefold, driven largely by transdermal formulations and expanded clinical recognition of hypogonadal symptoms[78]. This expansion prompted heightened regulatory scrutiny in the mid-2010s, culminating in the 2015 FDA safety communication addressing potential cardiovascular risks and the introduction of boxed warnings, followed in October 2016 by FDA-mandated class-wide labeling updates explicitly distinguishing medically supervised testosterone therapy from supraphysiologic anabolic steroid abuse and adding warnings related to abuse and dependence based on published literature and case reports[79].

During the 2010s, DEA continued to refine the anabolic steroid control framework through administrative actions, including the 2012 scheduling of prostanozol and methasterone, reinforcing that regulatory control remained anchored to chemical relatedness to testosterone rather than new findings of intoxicating potential. The COVID-19 public health emergency (2020–2022) represented a significant inflection point, during which temporary DEA telemedicine flexibilities allowed initiation and continuation of testosterone therapy without mandatory in-person evaluation, generating substantial real-world evidence that access expansion did not result in increased diversion or misuse[18,19]. In June 2020, DEA further clarified regulatory boundaries by designating certain low-dose estrogen–methyltestosterone combinations as exempt anabolic steroid products, underscoring a differentiated, formulation-specific approach to risk[20]. Scientific reassessment accelerated in

the early 2020s informing a major regulatory inflection in February 2025, when FDA formally recommended removal of the cardiovascular boxed warning from testosterone product labeling[80].

Subsequently, in December 2025, FDA-convened expert panels publicly urged modernization of testosterone labeling and indications, citing scientific evidence demonstrating lack of increased prostate cancer risk, improved metabolic outcomes in appropriately selected patients, and the growing mismatch between Schedule III stigma and modern clinical practice[81]. These discussions explicitly identified testosterone's-controlled status as a policy legacy of 1980s–1990s doping concerns, rather than reflection of present-day abuse liability, and emphasized the need to preserve diversion controls while reducing barriers to legitimate care, including telemedicine access.

Collectively, regulatory activity from 2000 through 2025 reflects an incremental evolution toward precision risk management—distinguishing therapeutic use, enhancement-driven misuse, and illicit anabolic abuse—rather than escalation of abuse signals. It also emphasized that misjudging of testosterone is shaped by improved safety evidence, refined clinical governance, and access considerations instead of emerging patterns of intoxication, overdose, or compulsive use.

6.6 Evolution of testosterone formulations and delivery systems

Testosterone was first isolated in 1935 and chemically synthesized soon thereafter[53]. The first therapeutic formulation, testosterone propionate, was introduced in 1937 and established injectable administration as the initial delivery approach. During the 1940s and early 1950s, continued clinical use revealed the need for longer-acting preparations. This led to the introduction of testosterone cypionate and testosterone enanthate between 1951 and 1953, which allowed extended dosing intervals and improved therapeutic practicality. For several decades, injectable esters remained the principal formulation used in clinical practice. A major shift occurred in 1995, with approval of the first transdermal testosterone patch, enabling non-injectable, daily hormone replacement. This was followed in 2002–2003 by approval of transdermal testosterone gels, which further expanded outpatient use and improved serum testosterone stability[82]. From 2003 onward, additional delivery systems were developed, including oral testosterone undecanoate formulations designed to reduce first-pass hepatic metabolism, as well as nasal and buccal formulations intended to offer alternative routes of administration[82–85]. By 2025, testosterone was available in injectable, transdermal, oral, nasal, and buccal forms. These formulation developments consistently aim to improve pharmacokinetic control, safety, and patient adherence. They reflect evolution toward physiologic hormone replacement rather than toward rapid-onset or intoxicating drug effects.

7. Implementation Aftermath: What Schedule III Changed in Practice

7.1 Prescribing and Dispensing Friction and Compliance Burden

The most immediate implementation effect of Schedule III classification for testosterone and related AAS has been the intensification of regulatory friction within lawful medical prescribing and dispensing systems, instead of a demonstrable reduction in non-medical demand. Across policy analyses, legal scholarship, and clinical literature, Schedule III controls are shown to have redistributed administrative burden toward clinicians, pharmacies, and payers operating in regulated settings, while leaving dominant illicit supply channels largely unaffected[46,86–89].

7.1.1 Regulatory compliance burden in clinical practice

Schedule III placement subjected testosterone prescribing to the CSA framework. This included DEA registration, recordkeeping obligations, refill limits, inventory controls, and audit exposure. Policy sources note that these controls were largely borrowed from substances with acute psychoactive effects and higher intrinsic abuse liability. This occurred despite testosterone's gradual onset, peripheral pharmacology, and long-standing therapeutic use[90]. As a result, compliance obligations expanded sharply without corresponding gains in targeting non-medical use. Clinical literature consistently notes that testosterone therapy is predominantly managed in primary care, endocrinology, and urology settings. Treatment is more commonly long-term treatment than episodic prescribing[89]. Schedule III requirements increased documentation requirement and perceived professional risk in these settings. This encouraged conservative prescribing practices that emphasized regulatory defensibility over individualized clinical judgment.

7.1.2 Diagnostic ambiguity under enforcement pressure

Prescribing friction was further amplified by scientific uncertainty around diagnostic thresholds for testosterone deficiency. This was particularly evident in older men and in patients with multiple comorbidities. Multiple reviews show that serum testosterone levels correlate imperfectly with symptom burden and therapeutic response[91–93]. As a result, categorical distinctions between "appropriate use" and "misuse" are difficult to operationalize[89,94]. Despite this ambiguity, Schedule III classification imposed binary enforcement logic onto a clinically uncertain domain. FDA safety communications issued beginning in 2014 clarified that "age-related hypogonadism" is not an approved indication. These communications were intended as labeling guidance rather than prohibition[95]. However, Schedule III status converted regulatory caution into de facto restriction. Clinicians, pharmacies, and insurers interpreted diagnostic ambiguity as legal exposure.

This dynamic promoted defensive prescribing, treatment discontinuation, and narrower eligibility criteria, independent of demonstrated misuse.

7.1.3 Pharmacy and payer amplification

Dispensing friction extended beyond prescribers to pharmacies and payers. Pharmacists assumed increased gatekeeping responsibilities under Schedule III oversight. Many defaulted to heightened scrutiny, refill delays, or additional verification to reduce enforcement risk[90]. Policy analyses characterize these actions as precautionary and not evidence based. They reflect regulatory uncertainty over identified diversion. Payer policies further amplified these effects. Due to Schedule III classification, insurers applied utilization-management frameworks originally designed for substances with higher abuse liability. These included prior authorization, repeated laboratory verification, specialist referral requirements, and narrow diagnostic definitions[79,89]. Such controls were frequently imposed even when inconsistent with clinical guidelines. Application varied widely across payers and jurisdictions. The result was uneven access rather than standardized oversight.

7.1.4 Telehealth and access contraction

Telehealth expansion revealed a parallel mechanism of access contraction tied to Schedule III compliance requirements. Controlled-substance prescribing rules restricted the remote initiation and continuation of testosterone therapy. These restrictions created access instability even when clinical appropriateness was not in dispute. Legal and policy scholarships show that Schedule III status is intersected with state-level regulatory variation and gender politics. This interaction generated disproportionate barriers for transgender patients and for rural populations who rely on telemedicine[96]. As with payer-driven restrictions, these effects resulted from cumulative regulatory layering rather than from the pharmacologic risk profile of testosterone itself.

7.1.5 Limited diversion impact

Across policy and epidemiological sources, there is little evidence that increased prescribing and dispensing friction reduced non-medical anabolic steroid use. Non-medical users primarily obtain products through illicit markets that bypass clinical and pharmacy systems altogether[71,97]. As a result, Schedule III controls concentrated regulatory burden on compliant medical actors. Dominant misuse pathways remained structurally intact. This pattern is consistent with broader critiques of prohibition-oriented drug policy[98,99].

7.2 Diversion-Control Tools and Their Real-World Effect

Schedule III placement of testosterone and related AAS was justified in part by the expectation that enhanced diversion controls would reduce non-

medical use. Post-implementation evidence shows a persistent mismatch between where regulation is applied and where diversion actually occurs[4,45]. Policy analyses, criminological studies, and public-health literature indicate that Schedule III diversion-control tools had limited effect on availability or prevalence. Instead, these controls contributed to displacement, substitution, and market adaptation[5,45,95].

7.2.1 Assumptions underlying diversion control

Schedule III diversion control relies mainly on supply-side medical gatekeeping. This includes prescription requirements, refill limits, pharmacy recordkeeping, and enforcement actions targeting prescribing irregularities. This model assumes that a substantial share of non-medical use originates from diverted prescriptions or pharmacy leakage. Epidemiological and ethnographic evidence consistently contradicts this assumption. Historical and current reviews show that most non-medical AAS users obtain products through extra-medical channels. These include peer networks, gyms, underground laboratories, internet sellers, and cross-border supply chains[61,71]. As a result, diversion controls focused on clinical settings exert leverage primarily over compliant prescribers and pharmacies. They do not meaningfully affect the environments where misuse is most prevalent. Policy scholarships describe this pattern as structural misalignment. Enforcement pressure is applied where oversight is easiest, not where misuse is most concentrated[97].

7.2.2 Market adaptation and displacement

Rather than constraining availability, Schedule III controls coincided with market adaptation and diversification. Criminological analyses describe the modern steroid marketplace as decentralized and low barrier. Production and distribution models are resilient to prescription-based enforcement[97]. As regulatory scrutiny increased around scheduled compounds, suppliers and users migrated toward alternatives. These included steroid precursors, misbranded dietary supplements, and later selective androgen receptor modulators. Many of these products circulated outside established scheduling frameworks[100,101].

This substitution effect mirrors patterns observed in broader drug control policy. Analyses of steroid precursor regulation show that partial scheduling often reshuffles product categories rather than reducing use. Manufacturers make incremental chemical modifications to remain outside statutory definitions[102]. From a diversion perspective, the result is regulatory arbitrage rather than scarcity.

7.2.3 Sport-based enforcement as a diversion analog

The limited effectiveness of Schedule III diversion tools parallels long-standing failures in sport-based anti-doping regimes. Despite increasingly sophisticated testing and severe sanctions, prevalence estimates consistently

exceed detection rates. This indicates that enforcement functions primarily as a sentinel or symbolic deterrent rather than a suppressive mechanism[98,103]. Athletes and recreational users adapt through timing strategies, cycling, masking agents, or migration to undetectable compounds. These behaviors closely resemble illicit market adaptation under drug scheduling.

Policy critiques note that zero-tolerance and prohibition-oriented models privilege visibility over effectiveness. They produce cycles of detection and evasion rather than sustained behavior change[98,99]. Applied to testosterone regulation, diversion control has followed a similar pattern. Formal oversight increased, but demand and supply remained intact.

7.2.4 Enforcement outcomes and public-health tradeoffs

From a public-health perspective, diversion controls under Schedule III redistributed risk rather than reduced it. Lawful access was constrained while illicit markets remained adaptive. This encouraged non-medical users, and some medically excluded patients, to rely on unregulated products with uncertain potency, purity, and dosing[72,104]. Several authors note that this undermines opportunities for harm reduction, education, and medical monitoring [46,95]. Policy analyses also observe that trafficking enforcement is episodic and geographically uneven[46]. Such actions produce temporary disruptions rather than durable supply reduction[97]. This pattern reflects broader “war on drugs” dynamics. Intensified enforcement correlates weakly with long-term prevalence but strongly with market sophistication and concealment[97,98].

7.3 Unintended Consequences: Illicit Sourcing Displacement and Continuity-of-Care Issues

Beyond its limited effect on diversion, Schedule III classification of testosterone and related AAS produced predictable unintended consequences. These consequences reshaped risk distribution and disrupted legitimate medical care. Across public-health, criminological, legal, and clinical literature, two effects occur. The first is displacement toward illicit sourcing. The second is erosion of continuity of care for lawful patients. Together, these outcomes show how prohibition-oriented controls can magnify harm, even when they are intended to reduce it.

7.3.1 Displacement toward illicit and unregulated markets

A central unintended effect of Schedule III controls has been the redirection of demand away from regulated healthcare and toward illicit markets. Policy and epidemiological sources show that testosterone demand did not decline after scheduling. Demand persisted across medical, functional, and enhancement contexts. Access instead shifted to decentralized supply networks that operate outside clinical oversight[97,104]. Criminological studies describe a highly adaptive steroid marketplace.

Underground laboratories, international suppliers, and peer-to-peer networks provide readily available alternatives to prescription products[97].

When regulatory friction increases in medical settings—through prescriber hesitation, pharmacy scrutiny, or payer denial—users with ongoing demand migrate to these markets. This displacement does not necessarily reflect increased risk awareness. Users often view illicit sourcing as more reliable, accessible, and autonomous once regulatory barriers rise. Multiple authors note that this mirrors broader drug-control dynamics and prohibition rarely eliminates use and instead externalizes it[98,99]. In the context of testosterone and AAS, this has increased exposure to counterfeit products, supraphysiologic dosing, polypharmacy stacking, and contaminated or mislabeled compounds[71,72].

7.3.2 Risk redistribution rather than risk reduction

Public health analyses consistently indicate that Schedule III controls redistributed harm instead of reducing it. Tightening access to pharmaceutical-grade testosterone under medical supervision increased the relative appeal of illicit formulations. These products often have uncertain purity and potency. Reviews of health outcomes among non-medical AAS users identify cardiovascular, hepatic, endocrine, and psychiatric risks[7] . These risks are exacerbated by unmonitored dosing and lack of follow-up[72,104]. Policy sources emphasize that such harms are dose- and duration-dependent rather than intrinsic to testosterone itself[4,44].

The resulting displacement undermines harm-reduction opportunities by severing contact between users and healthcare systems capable of screening, counseling, and mitigating adverse effects. Several authors contrast this outcome with the stated public-health rationale of scheduling. They argue that control mechanisms focused on visibility and deterrence can deepen concealment and concentrate risk[98].

7.3.3 Continuity-of-care disruptions in legitimate populations

Parallel to illicit displacement, Schedule III implementation produced measurable continuity-of-care disruptions for patients with legitimate clinical needs. Clinical and policy literature documents increased prescribing scrutiny, payer restrictions, and pharmacy gatekeeping. These forces led to therapy interruptions, delayed initiation, and inconsistent dosing, even when patients met accepted clinical criteria[79,89].

Diagnostic ambiguity further amplified these effects. Where testosterone deficiency thresholds remain contested, Schedule III enforcement encouraged conservative defaults. Clinicians declined to prescribe, discontinued therapy, or required repeated testing without clear clinical indication. Policy analyses note that such interruptions are not medically neutral. Hormone fluctuations can worsen symptoms, reduce adherence, and erode patient trust in healthcare systems[105,106]. Certain populations were

disproportionately affected. Transgender health scholarship shows that controlled-substance status interacted with state regulation, telehealth limits, and gender-political dynamics to destabilize access for transgender men and gender-diverse patients[96]. Rural patients and those reliant on telemedicine experienced similar disruptions. These discontinuities stemmed from regulatory layering instead of clinical contraindication.

7.3.4 Feedback loop between disruption and illicit use

Policy sources also describe a feedback loop between continuity-of-care disruption and illicit sourcing. Patients who face repeated administrative barriers or abrupt therapy interruption may seek continuity through non-medical channels. This is more likely when symptoms recur or worsen. Once outside regulated care, re-engagement becomes less likely due to stigma, fear of disclosure, or prior negative experiences. This phenomenon is well documented in sport policy and drug-use literature[4,62,66,75]. Punitive approaches reduce transparency and push behavior underground[98,99]. Applied to testosterone regulation, unintended consequences accumulate. Regulatory burden reduces lawful access. Reduced access increases illicit sourcing. Illicit sourcing raises health risk while further distancing users from care.

7.4 Where State and Payer Rules Amplify or Differ

Although Schedule III classification establishes a federal baseline, its practical effects are unevenly amplified by state law and payer policy. This amplification produces variability that exceeds statutory intent. Policy, legal, and clinical sources consistently show that downstream implementation, rather than the federal schedule alone, determines real-world access, continuity of care, and compliance burden.

7.4.1 State-level amplification and variability

States differ widely in how they operationalize controlled-substance oversight for testosterone. While CSA scheduling is uniform, states add requirements through prescription drug monitoring programs, licensing rules, telehealth statutes, and enforcement priorities. Legal analyses note that these layers often treat testosterone as interchangeable with other Schedule III substances, despite its distinct clinical role and abuse profile[97]. In some jurisdictions, heightened monitoring and narrow interpretations of “medical necessity” have increased prescriber caution and caused episodic access disruptions, even without evidence of diversion or misuse[46]. In other states, enforcement focuses primarily on trafficking, resulting in fewer effects on routine medical care[97].

The outcome is geographic inequity. Patients with similar clinical profiles experience different access outcomes based on state policy rather than medical need. These differences are especially evident in telehealth[33,107]. State controlled-substance rules, sometimes aligned with broader political

initiatives, have limited remote initiation or continuation of testosterone therapy. This has disproportionately affected rural patients and transgender populations who rely on telemedicine for specialty care[96]. These variations stem from state interpretation and enforcement, not from changes in federal scheduling.

7.4.2 Payer rules as de facto regulators

Payer policy represents the most significant point of amplification. Insurers frequently incorporate Schedule III status into utilization-management frameworks that exceed federal requirements. Common measures include prior authorization, repeated laboratory thresholds, specialist-only prescribing, and strict diagnostic criteria[79,89]. Policy analyses note that payers treat Schedule III designation as a risk proxy. They use it to justify administrative controls designed for substances with higher abuse liability. These controls often persist despite evidence that medical diversion contributes little to non-medical use. As a result, medical decision-making shifts from clinicians to administrative processes. Variability across plans produces inconsistent patient access.

Importantly, payer amplification operates independently of state enforcement intensity. Even in jurisdictions with permissive prescribing environments, insurer rules can narrow eligibility, delay initiation, or interrupt continuity of care. This divergence shows that the most restrictive effects of Schedule III are often private sector mediated and not through public law.

7.4.3 Interaction effects and cumulative burden

State and payer rules rarely operate in isolation. Their interaction creates cumulative burden, where moderate federal control becomes stringent in practice. A clinician may be federally authorized to prescribe testosterone and licensed at the state level yet still be constrained by payer denial or pharmacy refusal. Policy sources identify this regulatory layering as a key driver of care discontinuity, patient and clinician frustration, and migration toward out-of-system alternatives[97,98].

From an implementation perspective, these amplifications do not reflect coordinated risk management. Instead, they result from independent actors responding to regulatory signals in risk-averse ways. The resulting heterogeneity complicates oversight, obscures accountability, and weakens the connection between regulatory intent and real-world outcomes.

8. Current landscape: What is Being Proposed and Why

8.1 Stakeholder Map

Multiple stakeholders influence federal policy on testosterone's Schedule III status. Federal agencies play central roles; the DEA enforces controlled substance laws and has authority to add or remove anabolic steroids under the CSA (with HHS input), as seen when it scheduled new steroid compounds in response to abuse trends[108]. The Department of Health and Human Services (HHS), through agencies like FDA, provides scientific and medical evaluations for scheduling decisions and oversees drug labeling and safe use. Notably, the FDA has acted on testosterone safety evidence in recent years (e.g. updating class labeling in 2016 to warn of abuse risks)[109], and convened an expert panel in 2025 to revisit testosterone therapy indications and warnings[81,110].

Congress also influences; anabolic steroids including testosterone were placed into Schedule III by acts of Congress (the Anabolic Steroids Control Acts of 1990 and 2004) in response to concerns about misuse in sports and youth[108]. Congressional interest persists; for example, a 2022 letter led by Senator Markey urged federal authorities to consider rescheduling testosterone, citing access barriers in transgender care[6]. At the same time, some lawmakers have focused on combating steroid abuse in sports (e.g. past hearings on doping in professional baseball) and, more recently, on restricting gender-affirming hormone use in minors at the state level[111]– illustrating the diverse political perspectives around testosterone.

Professional and civil society stakeholders also shape the landscape. Medical professional societies such as the Endocrine Society and American Urological Association (AUA) develop clinical guidelines for testosterone therapy and often engage in policy discussions. These groups emphasize evidence-based use (e.g. the Endocrine Society's clinical guideline for male hypogonadism), and they have signaled concern that excessive regulation may hinder patient care. For instance, experts at a recent FDA panel (including endocrine and urology specialists) argued that treating testosterone as a controlled substance contributes to stigma and under-treatment of legitimate pat[110].

The American Medical Association (AMA) and specialty societies have also advocated to preserve access to testosterone for indicated medical uses, including gender-affirming therapy, in the face of regulatory or legislative restrictions. On the other hand, anti-doping organizations such as the U.S. Anti-Doping Agency (USADA) support strict controls on testosterone and other anabolic steroids. USADA has commended DEA scheduling actions and pushed for faster regulation of new steroid analogues to protect sports integrity and public health[112]. From USADA's perspective, testosterone's Schedule III status is a crucial tool to deter abuse and penalize illicit suppliers,

even as they acknowledge challenges in keeping pace with emerging black-market compounds[112].

The rise of telehealth providers and industry groups is a newer factor. Online clinics and telemedicine platforms (some specializing in "low T" treatment or gender-affirming care) have become major prescribers of testosterone. Trade organizations like the American Telemedicine Association (ATA) have lobbied for flexible prescribing rules, noting that current Schedule III requirements (such as the Ryan Haight Act's in-person exam mandate) can impede access for those in remote or underserved areas [1]. During the COVID-19 public health emergency, DEA temporarily waived the in-person rule for controlled substances, and telehealth stakeholders mobilized to keep those flexibilities for testosterone[19,20].

In 2023, hundreds of providers and patients (including Planned Parenthood's gender health leaders) submitted comments urging DEA to allow tele-prescribing of testosterone without an initial in-person visit, emphasizing that testosterone is a non-narcotic Schedule III drug with low abuse potential in medical context[113]. These telehealth advocates argue that requiring in-person visits would be a "catastrophic" barrier for many patients, particularly transgender men who may live far from knowledgeable providers[113].

Patient advocacy groups are likewise influential. Organizations focused on transgender health (e.g. the World Professional Association for Transgender Health and U.S. transgender rights groups) highlight how controlled-substance rules exacerbate stigma and access problems for gender-affirming hormone therapy. Surveys indicate many transgender individuals avoid medical settings due to anticipated discrimination[6], and advocacy letters have stressed that Schedule III controls (DEA registration requirements, etc.) further shrink the pool of trans-friendly providers[6]. These groups support revisiting testosterone's status to reduce what they view as a "criminalization" of essential medicine for trans people[6].

Finally, variations at the state level provide context. While states generally mirror the federal Schedule III classification for testosterone, some have taken additional measures. For example, a few states implemented steroid education and testing programs in high school athletics (Pennsylvania requires school districts to ban steroid use, and Virginia imposes athletic participation bans for students caught using steroids)[114,115]. Meanwhile, a recent wave of state laws restricting gender-affirming care (including testosterone for minors)[111] reflects how access to testosterone can become entangled in state-level policy debates, separate from the CSA schedule itself.

All these stakeholders – federal agencies, Congress, medical societies, telehealth and industry groups, anti-doping bodies, patient advocates, and state authorities – contribute to a complex policy landscape, each bringing

different priorities (from preventing abuse and diversion to ensuring equitable access) that inform the discussion on maintaining or changing testosterone's scheduling.

8.2 Arguments for Maintaining Schedule III

Proponents of retaining testosterone as a Schedule III controlled substance emphasize several evidence-based concerns centered on abuse prevention, diversion control, and public health protection.

8.2.1 Risk of Abuse and Dependence

Testosterone is the prototypical anabolic steroid, and its non-medical use in supraphysiologic doses has well-documented harm. Abuse of testosterone (often in combination with other AAS) is associated with severe adverse effects on multiple organ systems – including cardiovascular complications (hypertension, arrhythmias, heart failure), cerebrovascular events, hepatic toxicity, endocrine disruptions, and psychiatric effects[108,109]. Clinical literature and case reports have recorded outcomes such as myocardial infarction, stroke, liver failure, aggression/"roid rage", depression, and withdrawal syndromes in chronic abusers[108,109]. These effects can be life-threatening; long-term steroid abusers have an estimated mortality rate two to three times higher than age-matched controls[116].

Importantly, while medically supervised testosterone therapy typically uses moderate replacement doses, illicit users may take doses 10–100 times higher than therapeutic levels, greatly amplifying risks[116]. There is also evidence that anabolic steroids can engender dependence in a substantial subset of users. One review found about 30% of illicit AAS users develop a dependence syndrome – continuing steroids despite physical or psychosocial harm, and experiencing withdrawal symptoms (fatigue, low mood, irritability, etc.) upon cessation[41]. Though the dependence mechanism differs from classic addictive drugs (steroids don't cause acute intoxication or euphoria), the compulsive use pattern is well-recognized in both humans and animal models[61].

Given these data, advocates for Schedule III maintain that testosterone meets the CSA's criteria of a substance with significant abuse potential and dependence liability. They view the current controls as proportional to these risks and worry that loosening control could lead to increased unsupervised use with attendant health consequences. The evidence supporting serious harm from non-medical testosterone abuse is strong (derived from case series, epidemiological studies, and mechanistic research) and largely uncontested[116]. By contrast, evidence on testosterone's abuse potential under medical use is more nuanced (patients treated for hypogonadism generally do not exhibit drug-seeking behavior), but Schedule III advocates stress that the scheduling must account for abuse in any context, not only clinical settings.

8.2.2 *Diversion and Illegal Trafficking*

Another key argument is that Schedule III status is an essential tool for controlling diversion of testosterone to illicit markets. Despite being a natural hormone, testosterone can be misused as a performance-enhancing drug, and there remains a sizable black market for anabolic steroids in the U.S. and internationally[116]. Supporters of the status quo note that DEA scheduling makes it illegal to manufacture, distribute, or possess testosterone without a prescription, thereby enabling law enforcement to prosecute trafficking networks and underground labs. For example, scheduling facilitated actions against "rogue" anti-aging clinics and online steroid vendors in the past, since distributing testosterone outside of authorized channels is a federal crime.

DEA officials and anti-doping advocates point out that without Schedule III designation, enforcement would be largely limited to FDA regulatory mechanisms (e.g. pursuing misbranded or unapproved drugs) which lack the swift punitive teeth of the CSA. Indeed, USADA and others have warned that the regulatory process struggles to keep pace with the continual emergence of new steroid products and precursor chemicals marketed as supplements[112]. They argue that maintaining stringent controls on known substances like testosterone is critical to "hold the line" while broader efforts to curb novel enhancers continue. Although illicit availability of testosterone persists (via gyms, online forums, etc.), advocates believe it would be yet more widespread absent Schedule III controls. They cite data that anabolic steroids remain "readily available" in some fitness circles despite regulations[116], interpreting this not as a failure of scheduling but as evidence that constant vigilance is required.

In their view, diversion control feasibility would worsen with decontrol: authorities might find themselves unable to interdict large imports of steroid powder or bulk hormone if testosterone were no longer a controlled substance. Here the evidence is mixed – we have documentation of ongoing black-market activity[116], but it is inherently difficult to quantify how much scheduling suppresses that activity.

Nonetheless, past experience with over-the-counter steroid precursors (like androstenedione before the 2004 law) showed that unscheduled anabolic agents could be sold broadly, reaching young consumers and athletes until regulatory action caught up[112]. Proponents of Schedule III often invoke this historical lesson, asserting that keeping testosterone in Schedule III is a preventative measure to avoid repeating a cycle of proliferation-then-prohibition that occurred with prohormones.

8.2.3 *Public Health and Deterrence*

Finally, arguments to maintain Schedule III highlight public health benefits and the precautionary principle. From this perspective, the inconvenience imposed on legitimate users is outweighed by the need to deter misuse and signal the seriousness of the drug's risks. Epidemiological data indicate that

lifetime prevalence of anabolic steroid use among U.S. males is roughly 6% (with even higher rates in certain subgroups such as weightlifters and law enforcement)[116]. Although surveys suggest most non-medical users are adult men seeking cosmetic or strength gains (rather than competitive athletes)[116], the health outcomes of this misuse impact society via increased healthcare burden (cardiac events, psychiatric complications, etc.) and potential spillover effects like increased aggression and violence linked to steroid abuse[108]. Those in favor of retaining strict control note that deterrence is an explicit goal of the CSA scheduling system.

Classifying testosterone in Schedule III (alongside substances like ketamine and certain opioids) communicates that it has moderate-to-high abuse potential and is not a routine medication. This, they argue, may dissuade casual abuse by adolescents or gym-goers who might otherwise view testosterone as benign. Some supportive evidence comes from historical trends. After the enactment of the 1990 Anabolic Steroids Control Act and related educational efforts, steroid use among high-school teens appeared to decline in the 1990s[117]. While causation is hard to prove, the timing aligns with intensified enforcement and anti-steroid messaging. Current disapproval of steroid abuse among youth is relatively high, which advocates partially attribute to the substance's controlled status and the stigma that carries[118].

In terms of enforcement practicality, Schedule III status also allows for tighter monitoring of legitimate distribution (through required record-keeping, limits on refills, and state prescription drug monitoring programs). Proponents contend that these measures make it easier to spot unusual prescribing or dispensing patterns that could indicate diversion, thereby bolstering public health surveillance. They acknowledge that no system is foolproof – illicit steroid use remains an underground problem – but argue that removing testosterone from control would send the wrong signal and remove safeguards, potentially leading to a resurgence of overt "body-building supplement" type sales or higher teenage experimentation.

In summary, the case for maintaining Schedule III is grounded in strong evidence of harm from abuse, clear if qualitative evidence of continuing diversion risk, and a precautionary stance given the uncertainties. Advocates concede that legitimate medical users face some burden, but they view those burdens as manageable through existing mechanisms (e.g. streamlined scheduling of refills, telemedicine extensions) without fundamentally altering the drug's legal classification. Areas of uncertainty that they highlight include how to best thwart the black market (acknowledging that scheduling alone is not sufficient) and how to balance enforcement with ensuring patients in need still get therapy – issues they believe can be addressed via targeted policy tweaks rather than descheduling.

8.3 Arguments for Rescheduling or Descheduling

On the other side, stakeholders favoring a change to testosterone's scheduling (either moving it to a less restrictive schedule or removing it from control entirely) focus on evidence of undue burdens, evolving science, and misalignment between anabolic steroid controls and modern medical practice.

8.3.1 Access Barriers and Healthcare Burden

A primary argument is that Schedule III status imposes disproportionate barriers on patients who legitimately need testosterone, thereby harming public health more than protecting it. Because testosterone is controlled, every prescribing clinician must maintain a DEA registration (with associated fees and regulatory obligations), which some providers – especially those in smaller or resource-limited practices – opt not to do[6]. Advocates for change point out that this shrinks the pool of available prescribers. Indeed, one analysis noted some physicians forego DEA registration to avoid costs or scrutiny, meaning otherwise qualified providers (e.g. primary care doctors in rural areas) might not offer testosterone therapy at all[6]. By *descheduling* testosterone, these administrative barriers would disappear, potentially enabling more providers (including general practitioners and community clinics) to treat conditions like hypogonadism or gender dysphoria without navigating controlled-substance requirements[6].

Another access issue is prescription logistics. Schedule III drugs face tighter limits on refills (maximum 5 refills or 6 months' supply per prescription) and cannot be dispensed without a valid prescription. While these are safety measures, in the case of a lifelong therapy such as hormone replacement, they necessitate more frequent doctor visits or telehealth consultations for renewals, adding cost and inconvenience. During the pandemic, exemptions allowed telemedicine initiation of controlled substances; however, absent those, a patient on testosterone typically must see a provider in person initially (per the Ryan Haight Act) and regularly follow up for refills. For stable patients, this is seen as unnecessary friction.

Telehealth providers report that requiring even one in-person visit can be prohibitive for individuals in rural or underserved areas[113]. For example, transgender men in areas without local gender-affirming clinics might have to travel long distances or face long wait times for an appointment, delaying care. Commenters to DEA have warned that an in-person requirement would "prevent many patients from accessing hormone therapy entirely"[113]. Those favoring rescheduling note that testosterone is *not* a narcotic or acute CNS depressant; it's a long-term hormone therapy, so the risk of immediate harm from a telehealth initiation is low. This view is backed by clinicians who have safely managed thousands of patients' testosterone via telemedicine during COVID with no rise in adverse events or abuse noted[113]. Thus, they argue, the

blanket controlled-substance tele-prescribing rules are ill-suited to testosterone and exacerbate healthcare disparities.

Overall, the evidence for access barriers is qualitative but compelling: surveys and advocacy reports document instances of patients discontinuing needed therapy due to regulatory hurdles[6], and the dramatic expansion of patients accessing testosterone under the telehealth flexibilities underscores how many were previously underserved[113]. This argument acknowledges uncertainty in quantifying how many more patients would benefit if testosterone were easier to prescribe, but it points to clear *signals* of unmet need under the status quo.

8.3.2 Stigma and Appropriateness of Control

Another contention is that treating testosterone as a controlled substance contributes to stigma and may no longer be scientifically justified. Unlike psychoactive drugs of abuse, testosterone does not produce an immediate "high" or impairment; its misuse involves slow, cumulative physiological changes[42,45,86,119]. Advocates for change posit that the CSA framework, designed for substances like opioids or stimulants, is a blunt instrument when applied to a hormone with legitimate therapeutic uses. They note that other endocrine therapies (estrogen, thyroid hormone, insulin, etc.) are not scheduled and yet abuse of those is minimal – suggesting that medical supervision, not the criminalization, is what ensures safe use[21,120]. In expert forums, clinicians have argued that testosterone's Schedule III classification is outdated and rooted in 1980s–90s doping panic more than current medical reality[110]. For instance, a panel of urology and endocrine experts convened by FDA in late 2025 unanimously urged the agency to "discontinue treating testosterone as a controlled substance," citing the view that it "creates unnecessary barriers to care [and] contributes to stigma" around men's health[81]. They pointed out that many men with genuine hypogonadism are reluctant to seek treatment because being on a "steroid" carries social stigma or self-image issues, which are reinforced by its legal status[110]. Similarly, transgender advocates note that labeling testosterone as a controlled substance implicitly pathologizes it, feeding into narratives that gender-affirming hormones are illicit or inherently dangerous. This stigma, they argue, not only discourages some patients from continuing therapy but can also subject them to additional scrutiny at pharmacies or during travel (testosterone is sometimes scrutinized by law enforcement if not properly labeled, etc., causing stress for patients who rely on it).

Proponents of rescheduling often emphasize that evidence of harm in medical contexts is low. They distinguish the non-medical abuse (bodybuilders taking huge doses, often illegally procured) from the typical patient usage (moderate dosing, prescribed by a physician). The latter, they argue, has a safety profile more akin to unscheduled medications. Notably, testosterone is one of the few medications that is both a naturally occurring hormone and scheduled; advocates question whether its dependence liability

truly warrants Schedule III. They point to research indicating that therapeutic testosterone does not cause addiction or craving – patients do not escalate their doses uncontrollably under medical supervision, and any "dependence" is physiological (the body's reliance on external hormone) unlike the psychological addiction seen with narcotics[51,121].

A Planned Parenthood clinician testified that in years of treating trans patients, she has "not seen a patient abuse or intentionally misuse prescribed testosterone," underscoring that its addictive potential in the medical setting is essentially nil[113]. Such testimonials, while anecdotal, align with the pharmacology: testosterone does not activate reward pathways like drugs of abuse. In terms of evidence, the argument that testosterone's controlled status causes stigma is difficult to quantify but supported by consensus opinions of clinical experts[110] and patient reports. And the lack of classical addictive properties is well-supported by endocrinology texts (testosterone's effects are not acute or intoxicating).

These points lead rescheduling proponents to argue that Schedule III may be a category error for testosterone – grouping it with drugs that have far more misuse of the "get high" variety, and thereby over-regulating it relative to its true risk when used appropriately.

8.3.3 Recent Evidence and Risk-Benefit Reassessment

Perhaps the most significant recent development bolstering calls for change is new clinical evidence clarifying testosterone's safety profile. Historically, concerns about risks such as prostate cancer stimulation or cardiovascular events in older men were factors that made regulators cautious about testosterone use. However, studies have largely *not* confirmed these feared risks under proper medical use. The landmark TRAVERSE trial, a 5,200-patient, multi-year randomized trial mandated by the FDA, found that testosterone therapy in hypogonadal men did not increase the incidence of major adverse cardiac events (MACE) or prostate cancer compared to placebo. In fact, the trial met criteria for non-inferiority on cardiovascular outcomes, effectively refuting earlier signals from smaller studies that had suggested testosterone might elevate heart attack or stroke risk[122,123]. Likewise, no uptick in prostate malignancies was observed; testosterone did not behave as a carcinogen in that large sample. As a result of this evidence, in February 2025 the FDA removed a longstanding black-box warning about cardiovascular risk from testosterone product labeling[110].

Professional guidelines are following suit in updating recommendations. This shift in the risk-benefit understanding is crucial. Advocates for descheduling argue that much of the justification for strict controls hinged on worst-case assumptions about health dangers, which now appear less applicable for medically managed patients. With testosterone's safety in appropriate populations affirmed (or at least much better defined), the question is raised: *if* the drug is reasonably safe under medical supervision

and not prone to abuse in that context, do the onerous controls still make sense? They contend that regulators should recalibrate policy to match current evidence – which shows significant health *benefits* of testosterone therapy for many patients (improvements in symptoms of hypogonadism, bone density, mood, etc.) and manageable risks[110,123].

Additionally, the risk of untreated or undertreated hypogonadism is itself a public health issue (e.g., links between low testosterone and diabetes or mortality were noted by experts[110]). From this vantage, reducing barriers to treatment would yield net health gains. Rescheduling to Schedule V or descheduling would also align the U.S. with some international practices – for instance, in many European countries, testosterone is prescription-only but not on a controlled drug schedule, reflecting a judgment that general prescription controls suffice.

Advocates highlight that misuse trends have also evolved. While steroid abuse remains a concern, a growing share of the problem has shifted to novel substances like SARMs (Selective Androgen Receptor Modulators) and designer steroids not explicitly scheduled. They argue that law enforcement should focus on those emerging threats, while testosterone itself, being well-studied and medically indicated, could be regulated in a manner similar to, say, growth hormone (a prescription drug with misuse potential, managed through regular prescription oversight and doping controls, but not scheduled under the CSA).

Removing or loosening CSA controls on testosterone would not mean an absence of regulation – the FDA would still regulate it as a prescription drug, and sports bodies would still ban non-prescribed use – but it would remove the criminal law element for possession and streamline the prescribing process. Supporters cite letters and petitions which argue that rescheduling/descheduling would further public health goals, by exempting testosterone from telemedicine restrictions and expanding the provider base, without spurring a surge in abuse[6]. They also note a potential unintended consequence of strict control. Patients who cannot obtain legal prescriptions may turn to the black market (ordering unregulated testosterone online or via gyms)[6]. This is already a documented phenomenon in the transgender community and among men who feel stigma seeing a doctor – they self-medicate with illicit testosterone when access is obstructed[45,124]. Descheduling, it is argued, would reduce this *leakage* into unsafe channels by making legitimate access easier, thus actually reducing public health risks from contaminated or improperly dosed products.

The evidence behind some of these claims is variable. The TRAVERSE trial and FDA actions provide *strong, high-quality evidence* that prior risk concerns (CV, prostate) are mitigated, while the link between descheduling and improved access or reduced black-market use is more speculative (logical arguments supported by case reports, but no direct trials). Advocates readily

admit that careful monitoring would be needed after any policy change, to ensure abuse rates don't climb. However, they maintain that the status quo also has glaring gaps – given the thriving underground steroid culture despite Schedule III, it's unclear that keeping testosterone controlled is containing that problem effectively[116].

In summary, the pro-change position is that *on balance*, current evidence favors a more permissive regulatory approach: testosterone therapy offers important health benefits, its risks under medical use are lower than once thought, and its Schedule III status imposes tangible costs (restricted access, stigma, and administrative load) that are not adequately justified now. They call for a data-driven reevaluation and suggest that even a move to Schedule V (denoting low potential for abuse) or an outright descheduling would be consistent with the scientific and clinical record. Areas of uncertainty – such as the long-term cardiovascular effects in populations not studied in TRAVERSE (e.g. younger women/trans men, for whom data are still accruing) – are acknowledged, but proponents argue these can be managed through medical vigilance and do not necessitate a criminal-law approach. Crucially, they stress that changing the schedule would not mean condoning steroid abuse; it would mean refocusing control measures on truly dangerous usage (via sports anti-doping programs, education, and targeted enforcement) rather than broadly applying punitive controls to a medication that many patients need. This perspective seeks testosterone's scheduling realignment in the interest of patient care and regulatory coherence.

8.4 Signals to Watch

Looking ahead, several observable developments can indicate whether policy attention is consolidating around maintaining, modifying, or revisiting testosterone's Schedule III status. This subsection does not project outcomes. Instead, it identifies the specific procedural venues and evidence channels through which scheduling questions typically advance (or stall), including petitions and legislative activity, agency dockets and rulemaking, shifts in clinical consensus, and real-world enforcement and public health data.

8.4.1 Formal Petitions or Legislative Proposals

One signal is the appearance of a formal administrative petition to DEA or an explicit legislative proposal in Congress. At present, there is no public record of a DEA petition to deschedule testosterone. Congressional engagement is visible through oversight and correspondence; for example, the 2022 letter led by Senator Markey asked DOJ, HHS, and DEA whether rescheduling or descheduling should be considered, citing access concerns in transgender care[6]. Additional letters, hearings, or introduced bills that directly address testosterone's schedule placement (rather than broader anabolic-steroid enforcement) would be notable procedural developments. Continued committee attention to controlled-substance access or hormone-therapy policy could also shape the agenda, even absent legislation.

8.4.2 *Agency Dockets and Rulemaking*

A second signal is activity in ongoing or new agency dockets that shape the oversight environment for testosterone. One major channel is DEA's telemedicine prescribing rule development. Following the COVID-era waivers, DEA and HHS have extended temporary telemedicine flexibilities while refining permanent rules, with extensive stakeholder input that frequently cited testosterone access[113]. In January 2025, DEA announced a proposal for Special Telemedicine Registrations intended to allow prescribing of Schedule III–V medications without an initial in-person exam under defined conditions[20,33]. Separately, FDA's engagement with testosterone policy provides another venue where scientific and clinical framing of risk, benefit, and appropriate use is debated, even though FDA actions do not themselves determine CSA scheduling[81,110].

8.4.3 *Enforcement and Public Safety Trends:*

A third signal is movement in clinical guidance and real-world indicators of use and misuse. Updates to authoritative guidelines (e.g., Endocrine Society, AUA) in response to emerging evidence can influence how regulators interpret "current state of scientific knowledge" and medical utility. In parallel, enforcement and surveillance data — including trends in illicit steroid seizures, diversion investigations, and epidemiologic indicators of non-medical use — can shape perceptions of public health risk and feasibility of control[116]. Sports-doping events may also affect public attention to anabolic steroids, even when the legal standard for CSA scheduling remains distinct. Together, these channels (guidelines, surveillance, enforcement, and public salience) constitute the main empirical "signal surface" through which the scheduling conversation evolves.

9. CSA 8-Factor Analysis

The CSA sets forth an eight-factor framework intended to guide scheduling and rescheduling decisions through a comprehensive evaluation of abuse liability, pharmacological effects, and public health considerations (Figure 9-1). This analysis is designed to be cumulative, drawing on clinical, epidemiological, behavioral, and regulatory evidence rather than any single metric of risk. In this section we have attempted to examine testosterone's abuse potential and societal impact in the context of ongoing scheduling debate[81].

Although most of the aspects of testosterone's history and abuse have been discussed in detail in earlier Section 5 and Section 6, we have summarized it here again from the perspective of CSA factor analysis framework.

Figure 9-1. CSA 8-factor analysis (Section 201 (c), [21 U.S.C. § 811 (c)])

9.1 Actual or Relative Potential for Abuse

Assessment of the actual or relative potential for abuse requires evaluation of observed patterns of use, motivations for non-medical consumption, reinforcing psychoactive properties, and population-level behaviors. As summarized in (Table 9.1), the accumulated clinical, epidemiological, psychiatric, and forensic literature demonstrates that testosterone and other androgens exhibit a distinct abuse profile that differs fundamentally from substances with high intrinsic abuse liability.

9.1.1 Patterns and Motivations of Non-Medical Use

The available scientific literature indicates that non-medical testosterone use is predominantly purposeful and outcome-oriented, characterized by deliberate dosing strategies intended to enhance muscle mass, strength, physical appearance, athletic performance, or perceived functional capacity rather than to produce acute psychoactive effects. Patterns of use commonly involve structured regimens such as cycling, stacking, and timing of administration to maximize desired physiological outcomes or reduce detection risk. These behaviors reflect calculated, goal-driven decision-making and are not consistent with compulsive, binge, or intoxication-seeking use patterns typically associated with substances possessing a high potential for abuse[41,42,125].

9.1.2 Reinforcing Effects and Psychoactive Properties

A key determinant of abuse liability under CSA Factor 1 is the presence of reliable, reinforcing psychoactive effects. The available literature indicates that testosterone does not produce consistent acute euphoria, intoxication, or rapid reinforcement comparable to opioids, stimulants, or sedative-hypnotics (Table 9-1). Any reported reinforcement is typically delayed and outcome-based, emerging from gradual changes in physical performance, appearance, or mood over weeks to months of exposure. Psychiatric effects such as euphoria, irritability, or mood elevation have been documented primarily under supraphysiologic dosing conditions and are variable, dose-dependent, and not consistently observed across users (Table 9-1), thereby limiting testosterone's capacity to function as a primary reinforcer in the general population[41,42,61].

9.1.3 Dependence and Continuation of Use

Literature acknowledges that dependence may develop in a subset of users, particularly among individuals engaging in long-term, high-dose AAS use (Table 9-1). Prevalence estimates, however, consistently indicate that most users do not meet criteria for dependence, even following repeated cycles of exposure. When continued use does occur, it is most often attributed to secondary physiological mechanisms, such as anabolic steroid induced hypogonadism, or to underlying psychosocial vulnerability, rather than to craving or intoxication-seeking behavior. Notably, relapse or ongoing

use is frequently characterized as an attempt to self-manage withdrawal-related symptoms or perceived functional decline, further distinguishing testosterone from substances whose reinforcement is driven primarily by acute neurochemical reward[42,86–88,120,124].

9.1.4 Population-Level Patterns and Illicit Market Dynamics

At the population level, lifetime prevalence of testosterone or AAS use remains modest when compared with substances commonly associated with high abuse liability. The literature further indicates that restricted medical access and existing regulatory barriers are primary contributors to illicit sourcing and black-market distribution, instead of intrinsic demand for psychoactive or intoxicating effects[45,87,88,119,120]. As a result, observed non-medical acquisition pathways appear to reflect systemic access constraints rather than elevated abuse potential inherent to testosterone itself[126].

9.2 Scientific Evidence of Pharmacological Effects

Where CSA Factor 1 evaluates patterns and motivation for misuse, CSA Factor 2 focuses on the scientific evidence of pharmacological effects, including mechanism of action, dose–response characteristics, central nervous system effects, and temporal features relevant to abuse liability. In contrast to substances whose abuse potential derives primarily from rapid central nervous system reinforcement, the pharmacology of testosterone and other androgens reflects slow-onset, peripherally mediated effects with limited direct psychoactive reward, a distinction that contextualizes the abuse profile described in Factor 1.

9.2.1 Mechanism of Action and Primary Biological Targets

Testosterone exerts its primary effects through binding to the androgen receptor, a ligand-activated nuclear transcription factor widely expressed in skeletal muscle, bone, reproductive tissues, and other peripheral targets[62,127]. Following receptor binding, testosterone androgen receptor complexes translocate to the nucleus and regulate transcription of androgen-responsive genes involved in protein synthesis, erythropoiesis, and sexual differentiation. These genomic mechanisms require sustained exposure, with physiological effects that take days to weeks rather than minutes or hours. Although non-genomic androgen receptor–associated signaling pathways have been described, these pathways are secondary and are not associated with rapid dopaminergic activation comparable to substances with high abuse liability[62,128].

Source	Population Studied	Primary Motivation for Use	Pattern of Use	Reinforcing / Psychoactive Effects	Dependence Characteristics	Factor 1 Interpretation	Ref.
Historical reviews of AAS use	Athletes, bodybuilders, recreational users	Physical performance, body image	Cyclical, planned	Delayed, outcome-based	Occurs in a subset	Abuse is instrumental rather than intoxicating	[42]
Anabolic-Androgenic Steroid Dependence: An Emerging Disorder	Long-term AAS users	Performance, physique maintenance	Structured cycles	Minimal acute reward	~25–33% meet dependence criteria	Moderate, context-dependent abuse potential	[41]
Androgen Abuse in Athletes	Elite & amateur athletes	Ergogenic advantage	Cycling, stacking	Inconsistent psychoactive effects	Not universal	Abuse driven by competition rather than reward	[125]
Doping with Testosterone and Impact on Health	Athletes, non-athlete users	Muscle and strength enhancement	Variable, strategic	No consistent euphoria	Secondary physiological dependence	Limited intrinsic abuse liability	[43]
Long-Term Effects of AAS Abuse	Fatal case reports	Chronic enhancement use	Long-term high-dose	None described	Not characterized as addiction	Severe outcomes reflect cumulative misuse, not abuse drive	[129]

Medical Consequences of AAS Doping	General & athletic populations	Performance and appearance	Planned, cyclical	Outcome-driven	Secondary endocrine effects	Abuse shaped by context and access	[128]
Self-Medicated Testosterone Replacement	Non-prescribed TRT users	Symptom relief, functional restoration	Near-physiologic, structured	No intoxication	Fear of hypogonadal symptoms	Illicit use does not equate to abuse	[126]
Testosterone Abuse and Affective Disorders	High-dose AAS users	Performance, mood regulation	High-dose misuse	Variable, dose-dependent	~12–15% dependence	Abuse risk limited to vulnerable subgroups	[130]
Use and Misuse of Testosterone in Sport	Elite athletes	Competitive advantage	Strategic, detection-aware	Non-reward-driven	Not framed as addiction	Regulatory pressure shapes misuse	[62]
Use, Misuse and Abuse of Testosterone and Other Androgens	General population & gym users	Physical & psychological benefits	Cycling, stacking	Delayed reinforcement	~32% dependence among AAS users	Moderate abuse potential, non-uniform	[44]

Table 9-1. Evidence Mapping for Actual or Relative Potential for Abuse (CSA Factor 1) of Testosterone and Other Androgens

9.2.2 *Central Nervous System Effects and Reinforcement*

Testosterone crosses the blood–brain barrier and may influence central nervous system function through direct androgen receptor binding or indirect estrogenic effects following aromatization. Controlled human studies indicate that effects on mood, cognition, or behavior are inconsistent, dose-dependent, and not reliably reinforcing[41,130]. Unlike opioids, stimulants, or sedative hypnotics, testosterone does not consistently activate mesolimbic dopamine pathways in a manner associated with acute reward or intoxication. Reported affective changes, including euphoria, irritability, or aggression, are observed primarily at supraphysiologic doses, display substantial inter-individual variability, and lack the predictable onset and offset dynamics characteristic of substances with high abuse potential. Collectively, these features are consistent with delayed, outcome-based reinforcement patterns identified under CSA Factor 1.

9.2.3 *Dose Response Characteristics and Temporal Profile*

Testosterone demonstrates a graded dose response relationship for its anabolic and androgenic effects, with physiologic replacement therapy restoring endocrine function toward normative ranges and supraphysiologic exposure producing amplified peripheral effects on muscle mass and strength[21]. Across both therapeutic and non-medical contexts, these effects accrue gradually over time, thereby limiting testosterone's capacity to serve as an immediately reinforcing agent. In addition, the pharmacokinetic properties of commonly used formulations, particularly long-acting ester preparations, are characterized by slow absorption and sustained plasma exposure rather than rapid concentration spikes, further reducing abuse liability relative to substances associated with acute psychoactive reinforcement.

9.2.4 *Tolerance, Withdrawal, and Pharmacological Dependence*

Chronic exogenous testosterone suppresses endogenous hypothalamic-pituitary-gonadal axis function, leading to reduced gonadotropin secretion and decreased endogenous testosterone production. Upon discontinuation, some individuals experience transient hypogonadal symptoms, including fatigue, depressive mood, and sexual dysfunction[128]. These effects reflect predictable physiological adaptation rather than neurochemical craving or compulsive drug-seeking behavior. Although tolerance to certain peripheral effects may occur, dose escalation is generally directed toward overcoming anabolic plateaus rather than recapturing psychoactive reward, further distinguishing testosterone from substances whose pharmacology directly reinforces compulsive escalation.

9.2.5 *Regulatory Context and Emerging Consensus*

Consistent with this pharmacological profile, recent FDA communications and scientific reviews released in February 2025 have reevaluated the risk characterization of testosterone replacement therapy, formally distinguishing

medically supervised TRT from earlier frameworks that implied elevated abuse or dependence risk[80]. These determinations reflect increasing regulatory recognition that, when used within therapeutic parameters, testosterone does not exhibit pharmacodynamic features associated with high abuse liability and that prior risk assumptions were not supported by clinical evidence. Although regulatory determinations are distinct from CSA scheduling criteria, this updated FDA assessment further supports the conclusion that testosterone's pharmacological effects are not aligned with substances characterized by rapid reinforcement, intoxication, or high abuse potential.

9.2.6 Integration With Abuse Liability Assessment

Collectively, the scientific evidence indicates that testosterone's pharmacological effects are predominantly genomic, peripheral, and slow in onset, with central nervous system effects that are inconsistent and context dependent. The absence of rapid euphoria, reliable intoxication, or direct activation of reward pathways limits abuse potential attributable to pharmacology alone and is consistent with real-world patterns of use described under CSA Factor 1.

9.3 State of Current Scientific Knowledge

CSA Factor 3 requires assessment of the current state of scientific knowledge regarding the substance, including chemistry, pharmacology, clinical use, patterns of misuse, and areas of uncertainty. In the case of testosterone and other androgens, scientific literature is extensive, mature, and multidisciplinary, encompassing endocrinology, pharmacology, psychiatry, sports medicine, epidemiology, and regulatory science. Importantly, this body of knowledge has evolved substantially over the past two decades, leading to clearer distinctions between therapeutic use, misuse, and abuse.

9.3.1 Chemical and Biological Characterization

Testosterone is a well-characterized endogenous steroid hormone synthesized primarily by the testes and, to a lesser extent, by the adrenal cortex and ovaries[44,128]. Its molecular structure, metabolic pathways, receptor interactions, and downstream genomic effects have been extensively described for several decades[62]. Synthetic testosterone esters and other androgens likewise possess well-defined chemical and pharmacokinetic profiles, with established differences in absorption, distribution, metabolism, and elimination. This extensive chemical and biological characterization separate testosterone from many substances evaluated under the CSA, for which abuse potential must often be inferred from limited or emerging data rather than from a mature and well-developed scientific evidence base[44,128].

9.3.2 *Clinical Knowledge and Therapeutic Use*

Clinically, testosterone replacement therapy is an established treatment for male hypogonadism, supported by randomized controlled trials, long-term observational studies, and published clinical practice guidelines. The therapeutic objectives, dosing ranges, formulation selection, monitoring strategies, and safety profiles of TRT are well delineated within the medical literature, and recent regulatory reassessments have further refined its benefit risk framework by emphasizing appropriate patient selection, physiological dosing, and longitudinal monitoring. Of direct relevance to CSA evaluation, the clinical literature does not characterize therapeutic testosterone use as producing intoxication, euphoria, or behavioral reinforcement patterns typical of substances with high abuse liability; rather, therapeutic effects are gradual, restorative, and mechanistically linked to correction of an underlying endocrine deficiency[37,47–49].

9.3.3 *Scientific Understanding of Misuse and Abuse*

In parallel with clinical knowledge, the scientific understanding of non-medical testosterone use has continued to evolve. Current reviews consistently distinguish among therapeutic use that is evidence based and clinically supervised, misuse involving medical or quasi-medical use without clear indication or appropriate oversight, and abuse characterized by illicit, supraphysiologic use for performance or cosmetic purposes. Epidemiologic studies indicate that most non-medical users engage in structured, time-limited regimens and are primarily motivated by anticipated physical or functional outcomes rather than by pursuit of psychoactive reward. When dependence syndromes are observed, they are increasingly interpreted as secondary phenomena, commonly associated with endocrine suppression, prolonged high-dose exposure, or underlying psychological vulnerability and not with primary pharmacological reinforcement[4,44,62,73].

9.3.4 *Neurobiological and Behavioral Evidence*

From a neurobiological perspective, the available evidence does not support classification of testosterone as a substance that produces strong or consistent activation of central reward pathways. Unlike agents that directly participate in dopaminergic signaling, testosterone's effects within the central nervous system are indirect, variable, and highly dependent on dose, contextual factors, and individual susceptibility. Although animal studies have identified androgen-related behavioral effects, their translational relevance to human abuse liability remains limited. In contrast, human laboratory and clinical investigations do not demonstrate predictable self-administration driven by acute reward[124,126,131–133].

9.3.5 *Population-Level and Regulatory Knowledge*

At the population level, prevalence estimates for testosterone and AAS use are relatively stable and well characterized. Present literature increasingly emphasizes the influence of the regulatory environment, access

to medical care, and sociocultural factors in shaping patterns of misuse. Illicit markets and self-directed use are widely interpreted as downstream consequences of access barriers and inconsistent clinical practice rather than as indicators of intrinsic abuse potential. This evolving understanding is also reflected in updated regulatory positions, including recent safety communications and re-evaluations of earlier risk assumptions. Although regulatory determinations are distinct from CSA scheduling decisions, they nonetheless illustrate the maturation of the scientific evidence base regarding testosterone's pharmacology and real-world patterns of use[134,135].

9.3.6 Knowledge Gaps and Ongoing Research

Despite the breadth of the existing evidence base, certain gaps remain. These include limited data on the long-term outcomes of sustained supraphysiologic androgen exposure, optimal management strategies for anabolic steroid–induced hypogonadism, improved identification and characterization of potentially vulnerable subpopulations, and clearer differentiation between misuse and abuse within epidemiologic surveillance systems. Importantly, these gaps primarily relate to risk management, clinical practice, and public health monitoring, rather than to unresolved questions regarding the fundamental mechanisms of abuse liability.

9.4 History and Current Pattern of Abuse

CSA Factor 4 examines the historical emergence, evolution, and present-day patterns of abuse, including who uses the substance, under what circumstances, and whether abuse patterns have intensified, stabilized, or changed over time. We have discussed the historical context and pattern of use at length in Section 6. For testosterone and other androgens, the historical record reveals a distinct and highly contextualized trajectory of misuse, shaped less by pharmacology and more by medical practice, athletic culture, and regulatory developments.

9.4.1 Historical Emergence of Non-Medical Use

The non-medical use of testosterone first emerged in the mid-20th century, initially within legitimate medical practice and later within elite athletic settings. During the 1940s through the 1960s, testosterone and related compounds were prescribed for a wide range of indications, including fatigue and depressive symptoms, before the establishment of modern endocrine diagnostic criteria. Subsequent diffusion into competitive sport, particularly strength- and power-oriented disciplines, was driven by demonstrated anabolic efficacy rather than by pursuit of psychoactive or intoxicating effects. State-sponsored doping programs in the latter half of the 20th century, most notably in Eastern Europe, represent a historically unique and extreme pattern of androgen misuse characterized by systematic, externally directed administration, frequently without athlete autonomy and motivated by political and competitive objectives rather than individual drug-seeking behavior. Although these programs significantly influenced early

perceptions of androgen abuse, they are not representative of modern patterns of non-medical use at the population level[61,74].

9.4.2 Expansion Beyond Elite Sport

By the late 20th and early 21st centuries, testosterone misuse expanded beyond elite sport into recreational bodybuilding and non-competitive settings. Epidemiologic evidence indicates that most users were no longer professional athletes but individuals motivated by physical appearance, occupational performance, or perceived quality-of-life benefits. This transition marked a shift from institutionally driven doping practices to largely self-directed, goal-oriented use. Importantly, this broader uptake was not accompanied by the emergence of widespread intoxication-seeking behavior; instead, users commonly adopted structured regimens, such as cycling and stacking, informed by peer networks and informal knowledge systems, reflecting planned and intentional patterns of use rather than impulsive consumption[136,137].

9.4.3 Modern Patterns of Abuse

Current patterns of testosterone misuse are characterized by heterogeneity rather than progressive escalation. Available data indicate that use remains concentrated within specific subpopulations, including gym-affiliated individuals, certain athletic cohorts, and individuals self-directing hormone therapy outside formal medical supervision. Initiation most commonly occurs in early adulthood rather than adolescence, a pattern that contrasts with many substances associated with high abuse liability. Additionally, use is typically episodic or time limited rather than continuous or progressively escalating. Modern-day misuse also increasingly overlaps with self-directed testosterone replacement, particularly in settings where access to consistent medical care is perceived as limited or restrictive. This overlap complicates conventional distinctions between misuse and abuse and highlights the need for contextualized interpretation within CSA evaluations[4,88,137].

9.4.4 Illicit Markets and Regulatory Influence

The history and current pattern of testosterone abuse are closely intertwined with regulatory frameworks governing access and distribution. Periods of increased restriction of legal access have been temporally associated with the expansion of illicit supply chains, including underground laboratories and online distribution networks. The emergence of these markets appears to reflect displacement of supply rather than an increase in intrinsic demand and parallels patterns observed with other medically used substances subject to heightened regulatory control. Notably, innovations in androgen misuse, such as the development of designer compounds or alternative administration routes, have been driven primarily by efforts to avoid detection or circumvent access barriers rather than by attempts to enhance psychoactive effects[88,137].

9.4.5 *Stability and Absence of Escalating Abuse Trends*

Unlike substances with high abuse liability, testosterone has not exhibited progressive escalation in population-level abuse over time. Prevalence estimates have remained relatively stable across decades, and literature does not demonstrate a widespread transition from intermittent or time-limited misuse to compulsive use within the broader population. Although adverse outcomes are clinically relevant, they are largely concentrated among individuals engaging in long-term, high-dose exposure rather than reflecting a generalized or escalating pattern of abuse[138].

9.5 *Scope, Duration, and Significance of Abuse*

CSA Factor 5 evaluates the extent (scope), temporal characteristics (duration), and public health relevance (significance) of abuse. In the case of testosterone and other androgens, available evidence indicates that misuse occurs within defined and relatively stable subpopulations, is typically episodic or time-limited, and does not constitute a widespread or escalating abuse phenomenon when assessed at the population level.

9.5.1 *Scope of Abuse*

The scope of testosterone abuse remains limited relative to substances associated with high abuse liability. Population-based surveys consistently report low single-digit lifetime prevalence in the general population, with higher concentrations confined to specific subgroups such as competitive athletes, recreational bodybuilders, and individuals engaging in self-directed hormone use. Importantly, most users fall outside traditional substance use disorder populations and rarely present through addiction treatment pathways. Globally, patterns of misuse exhibit geographic variability that correlate more strongly with differences in sports culture, medical access, and regulatory environments than with intrinsic pharmacological appeal. The absence of widespread initiation beyond these contexts suggests that testosterone does not exert a broad population-level pull characteristic of substances with high abuse potential[88,137,138].

9.5.2 *Duration of Abuse Episodes*

The duration of testosterone abuse episodes is most commonly finite and intermittent rather than continuous. Non-medical users typically engage in time-limited cycles of use, followed by periods of abstinence, with discontinuation often occurring after attainment of predefined physical or functional goals. Although a subset of individuals progresses to longer-term or repeated cycles, particularly within bodybuilding contexts, this trajectory does not represent the predominant pattern of use. In contrast to substances with high abuse liability, there is little evidence that initial experimentation with testosterone reliably evolves into chronic, compulsive use across the general population. Where prolonged exposure does occur, it is generally the result of intentional continuation rather than loss of control and is often

accompanied by structured strategies aimed at managing anticipated physiological consequences[41,137].

9.5.3 *Significance of Abuse*

From a public health perspective, the significance of testosterone misuse differs qualitatively from that of substances traditionally prioritized under CSA scheduling. Although serious adverse outcomes are well documented, they are largely concentrated among individuals engaged in long-term, high-dose exposure and are not uniformly distributed across all non-medical users. Moreover, testosterone misuse has not been linked to hallmark indicators of public safety impact, such as acute intoxication–related accidents, overdose epidemics, or large-scale diversion–driven morbidity. Available emergency department utilization and mortality data do not exhibit patterns consistent with substances recognized as having high societal abuse impact. Accordingly, the primary clinical and public health relevance of testosterone misuse resides in chronic health risks and secondary endocrine consequences, which are more appropriately addressed through medical monitoring, education, and access to care rather than through punitive control-oriented approaches[4,44,73].

9.5.4 *Temporal Trends and Stability*

The scope and significance of testosterone misuse have remained relatively stable over time, without evidence of exponential growth or diffusion into new high-risk populations. Observed shifts in patterns of misuse, including the transition from elite sport doping to recreational or self-directed use, reflect redistribution of existing behaviors rather than expansion of abuse. Notably, increased regulatory stringency has not been accompanied by proportional reductions in misuse prevalence but has instead correlated with changes in sourcing and supply channels. These trends further support the interpretation that the scope and public health significance of testosterone misuse are primarily shaped by access dynamics and regulatory context rather than by intrinsic pharmacological abuse drive[134,137].

9.5.5 *Integration With Prior CSA Factors*

When considered in conjunction with CSA Factors 1 through 4, the scope, duration, and significance of testosterone abuse support a consistent and internally coherent narrative. Abuse remains limited in scope and concentrated within identifiable subpopulations, duration of use is typically episodic or intentional rather than compulsive, and the broader societal impact is modest and non-acute, lacking the defining features of substances associated with a high public health burden[88,138,139].

9.6 Risk to Public Health

CSA Factor 6 considers whether use or abuse of the substance poses a significant risk to public health, including acute toxicity, indirect harm, and societal impact. In the case of testosterone and other androgens, available evidence indicates that public health risk is context-dependent and largely confined to specific patterns of long-term or supraphysiologic misuse, rather than representing a broad, acute population-level threat.

9.6.1 Nature of Health Risks

The health risks associated with testosterone misuse are well characterized and predominantly involve cardiovascular strain among long-term, high-dose users, suppression of endogenous endocrine and reproductive function, and the emergence of psychiatric symptoms in susceptible individuals. These risks are strongly dose- and duration-dependent and are not uniformly observed across all users. Importantly, testosterone does not produce acute intoxication associated with overdose fatalities, respiratory depression, or rapid functional impairment, further distinguishing it from substances associated with high immediate public health risk[42,87,119,140,141].

9.6.2 Absence of Acute Harm Signals

Unlike substances with high abuse liability, testosterone misuse has not been associated with episodic overdose crises, surges in emergency department presentations driven by acute intoxication, or widespread incidental harm to third parties, such as impairment-related accidents. Adverse outcomes, when they occur, typically develop gradually, creating opportunities for early intervention, clinical monitoring, and risk-mitigation strategies[119,142–144].

9.6.3 Public Health Interpretation

From a public health perspective, testosterone misuse represents a chronic and manageable clinical concern rather than an acute societal hazard. The primary risks are most effectively addressed through improved medical supervision, patient education, enhanced surveillance, and expanded access to care, rather than through control strategies designed for substances characterized by rapid intoxicating effects and acute public safety threats.

9.7 Psychic or Physiological Dependence Liability

CSA Factor 7 evaluates the degree to which a substance produces psychological (psychic) or physical (physiological) dependence. The evidence indicates that testosterone and other androgens have limited psychic dependence potential and contextual physiological dependence.

9.7.1 Psychic Dependence

Testosterone lacks the defining characteristics associated with strong psychic dependence, including consistent acute euphoria, rapid onset of reinforcing psychoactive effects, and predictable craving driven by activation of reward circuitry. Accordingly, compulsive drug-seeking behavior is uncommon and is largely confined to a limited subset of individuals with pre-existing psychological vulnerabilities or body-image–related disorders. Most users do not self-identify as addicted and rarely present for clinical care with primary substance-use complaints[42,45,88,119,120,145].

9.7.2 Physiological Dependence

Physiological dependence may occur following prolonged exogenous testosterone exposure as a result of suppression of the hypothalamic–pituitary–gonadal axis. Discontinuation can be associated with transient symptoms, including fatigue, depressed mood, or sexual dysfunction, which reflect reversible endocrine adaptation rather than a toxic withdrawal syndrome. Importantly, the presence of physiological dependence does not inherently necessitate continued misuse; many individuals discontinue use with appropriate medical support or transition to supervised therapeutic management[21,42,86,87,119].

9.8 Immediate Precursor Status

CSA Factor 8 assesses whether the substance is an immediate precursor of a controlled substance and whether its control is necessary to prevent illicit manufacturing. Testosterone does not meet criteria for immediate precursor status.

9.8.1 Chemical and Regulatory Considerations

Testosterone is not an essential intermediate in the synthesis of other controlled substances in a manner that would warrant scheduling based on precursor status. Its chemical synthesis, distribution, and metabolism are well defined and do not pose risks of diversion for downstream illicit drug production.

9.9 Summary

The historical development of testosterone demonstrates that its placement under federal control occurred in response to evolving patterns of non-medical use rather than to evidence of an immediate or inherent abuse liability. As set forth in the CSA, determinations regarding scheduling are required to consider a defined set of factors related to pharmacology, patterns of use, public health impact, and dependence potential. The historical record summarized in Table 9-2 provides necessary context for evaluating these factors in a manner consistent with the statute.

CSA Factor	Criterion	Evidence Summary	Integrated Interpretation
Factor 1	Actual or relative potential for abuse	Non-medical use is predominantly instrumental (performance, appearance, symptom relief); lacks consistent acute psychoactive reward; dependence occurs in a minority and is context-dependent	Limited intrinsic abuse potential
Factor 2	Scientific evidence of pharmacological effects	Slow-onset genomic and peripheral actions via androgen receptor; inconsistent CNS effects; absence of rapid reinforcement	Pharmacology poorly aligned with addictive reinforcement
Factor 3	State of current scientific knowledge	Extensive, mature literature across endocrinology, psychiatry, sports medicine; clear distinctions between use, misuse, and abuse	Well-characterized substance with clarified risk profile
Factor 4	History and current pattern of abuse	Historical misuse shaped by medical practice and sport culture; current patterns stable, structured, and context-driven	No escalating abuse trajectory
Factor 5	Scope, duration, and significance of abuse	Limited population scope; episodic or intentional use; serious harms confined to long-term high-dose users	Restricted scope and modest societal impact
Factor 6	Risk to public health	No intoxication crisis or overdose pattern; risks are chronic, dose-dependent, and predictable	Public health risk manageable and non-acute
Factor 7	Psychic or physiological dependence liability	Low psychic dependence; physiological dependence reflects reversible endocrine suppression	Conditional, non-compulsive dependence
Factor 8	Immediate precursor status	Not a precursor to other controlled substances	Not applicable

Table 9-2. Summary Matrix of CSA 8-Factors for Testosterone

10. What Happens Next: Scenarios and Decision Triggers

The future of testosterone's scheduling cannot be predicted with certainty. Regulators, however, typically move through a limited set of legal and administrative pathways whose operational consequences are reasonably specifiable. Building on the current landscape summarized in Section 8 (stakeholders, arguments, and active policy venues), this section presents three neutral "what-if" scenarios that illustrate how different balances could be struck between access and diversion control. These are not forecasts. They are structured depictions of plausible pathways under existing legal authorities. We conclude with cross-cutting decision triggers such as procedural and evidentiary developments that would tend to precede movement toward any of the scenarios.

10.1 Scenario A: Retain Schedule III with Refined Guardrails

In this scenario, testosterone remains a Schedule III controlled substance, but targeted regulatory adjustments ("guardrails") are implemented to address access frictions while preserving core diversion controls. Instead of a wholesale change in legal status, the DEA and other authorities would use administrative tools to fine-tune how Schedule III requirements apply to testosterone. For example, permanent telehealth allowances could be established so that patients can continue to receive testosterone therapy without an initial in-person exam – a flexibility many providers and advocates have urged for non-narcotic Schedule III medications like testosterone[113]. The DEA is already pursuing a rulemaking for *Special Telemedicine Registration* that would allow remote prescribing of Schedule III–V drugs under defined conditions, a move explicitly intended to balance access and diversion concerns in the post-pandemic era. By finalizing such rules (or Congress enacting a similar carveout), regulators could make permanent the telehealth practices that proved workable during COVID-19.

Other guardrails could include formulary-level exemptions or exclusions for certain low-risk testosterone products. The CSA grants DEA authority to exempt specific *compounds, mixtures, or preparations* of anabolic steroids if they "do not present any significant potential for abuse" due to their formulation or delivery mechanism[146]. In fact, DEA has used this process to exempt certain combination products (e.g. estrogen-androgen tablets for menopause) from control on the grounds that added ingredients make them undesirable to steroid abusers[146]. Applying this logic, regulators might identify particular testosterone formulations with inherently low diversion appeal – for instance, an implant or an estrogen-combined therapy – and relax requirements for those products.

Additionally, documentation streamlining measures could be pursued. This might involve adjusting record-keeping or refill rules to reduce burden on patients and providers. For example, Schedule III prescriptions are currently limited to 6 months' validity with up to five refills, necessitating regular doctor visits[147]. While those limits are set by federal regulation, DEA could explore mechanisms (or support legislation) to allow longer prescription durations for testosterone specifically, provided safety is monitored. During the pandemic some patients were allowed 90- or 100-day supplies of medications by mail, but testosterone was often excluded due to its controlled status[147]. Scenario A envisions finding ways to mitigate such exclusions going forward.

10.1.1 Regulatory pathway

These changes could largely be accomplished through agency rulemaking and guidance rather than new legislation. DEA, in consultation with HHS, would promulgate rules (e.g. the telemedicine special registration) or issue orders under existing authority (e.g. exempting a product via 21 C.F.R. §1308.33). The CSA would continue to classify testosterone in Schedule III, so no statutory reclassification is needed – only tailored adjustments in its implementation. Coordination with FDA and state boards might be involved for aligning any formulary exemptions or pharmacy dispensing policies, but Congress would not have to act as long as agencies stay within their delegated powers.

10.1.2 Operational effects

By retaining Schedule III, this scenario maintains the status quo tools for preventing abuse and diversion. Law enforcement would still be able to investigate and prosecute unauthorized manufacture or distribution with the full weight of CSA penalties, a central point for those concerned about illicit steroid markets. At the same time, refined guardrails would improve patient access and administrative feasibility at the margins. Permanent telemedicine authority, for instance, would ensure that patients (such as those in rural areas or under gender-affirming care) are not forced into costly travel or interrupted therapy due to an in-person visit requirement. Streamlined prescribing (longer refill periods or clarified exceptions for testosterone) would reduce the frequency of provider visits and pharmacy trips, alleviating what many see as unnecessary friction for chronic therapy. These changes, while incremental, could meaningfully decrease delays and drop-offs in care. Importantly, they do so without relaxing the core schedule – meaning pharmacies would still track testosterone in inventory, prescribers would still need a DEA registration, and prescriptions would still be monitored via state PDMPs as controlled substances.

The hope among proponents is that targeted tweaks can resolve pain points (telehealth access, paperwork burden) without undermining diversion control. Enforcement bodies should find this scenario highly feasible: it

demands no retraining or overhaul of current systems, only some updated procedures (for example, enabling a new telehealth registry or recognizing an exempt product in the scheduling tables).

10.1.3 Stakeholder alignment

Scenario A is most consistent with stakeholders who favor retaining Schedule III while modernizing implementation to reduce access frictions — particularly around telemedicine and renewal logistics — without removing diversion and enforcement tools (see Sections 8.2; 8.3.1; and 8.4.2)[113]. It also aligns with the general approach of using targeted exemptions or mechanism-level adjustments where statutory authority permits[146].

10.2 Scenario B: Reschedule to Schedule IV or V with Risk-Mitigation Measures

Scenario B envisions a formal rescheduling of testosterone to a lower CSA schedule (IV or V), coupled with complementary measures to manage residual risks through means other than strict scheduling. This outcome would acknowledge that testosterone's abuse potential, as weighed against its medical uses, no longer warrants the constraints of Schedule III. By moving it to Schedule IV or V, regulators would be signaling that testosterone has a more limited potential for abuse and dependence relative to higher-scheduled substances. Notably, some policymakers have already suggested reclassifying testosterone to Schedule V (or even removing it entirely) to reduce access barriers[6]. Under Scenario B, that suggestion is realized in part – testosterone is downgraded on the schedule but not removed from control[86,119,124].

10.2.1 Regulatory pathway

Rescheduling can be accomplished either administratively or through legislation. Administratively, the CSA allows the DEA to transfer a drug between schedules (or remove it) if new evidence on the statutory scheduling factors emerges[148]. Typically, this process would start with an HHS scientific and medical evaluation, including an updated eight-factor analysis, followed by a DEA rulemaking proposing the schedule change. An HHS recommendation in favor of Schedule IV or V would carry considerable weight (similar to how a recent HHS recommendation prompted DEA to reconsider cannabis's schedule in 2023). Barring administrative action, Congress could act directly. Since anabolic steroids including testosterone were originally scheduled by statute (the Anabolic Steroids Control Act of 1990, as amended in 2004), Congress could pass a law amending that act to reclassify testosterone.

In practice, an administrative route is more likely for rescheduling. It would involve publishing a proposed rule in the *Federal Register*, taking public comments, and then issuing a final rule moving testosterone to the designated schedule. This scenario therefore hinges on a formal reevaluation

of the evidence by federal authorities, potentially triggered by advocacy petitions or evolving scientific consensus.

10.2.2 Operational effects

Reclassifying testosterone to Schedule IV or V would relax several regulatory constraints on prescribing and dispensing. The concrete impact would depend on which schedule is chosen. A move to Schedule IV (home to many sedatives and anxiolytics) modestly lowers control but still subjects the drug to most controlled-substance rules (including the federal limit of 5 refills/6 months per prescription, similar record-keeping, and the requirement for a DEA-registered prescriber). A move to Schedule V – the category for substances with the lowest abuse potential – would be more significant. Schedule V medications (e.g. certain codeine cough syrups) are "not subject to any federal limits on prescriptions or refills"[147], meaning a testosterone prescription could be valid for a full year or more with refills as needed, just like a typical non-controlled prescription. Doctors would still need DEA registration and pharmacies would still log the drug, but the onerous refill timing and supply restrictions could be lifted. This translates to fewer doctor visits for stable patients and more flexibility in how pharmacies dispense testosterone (potentially allowing 90-day supplies, mail-order fulfillment, etc., without special exemptions).

For patients, especially those on lifelong therapy, this reduced hassle is not trivial – it could lower costs and improve continuity of care. From an access standpoint, Schedule V classification in particular would largely equalize testosterone with unscheduled prescription hormones in terms of routine logistics[147]. It's important to note that rescheduling alone does *not* automatically change telemedicine rules (since those apply to all controlled substances). However, if testosterone is seen as less prone to abuse (especially in Schedule V), DEA and state boards might be more amenable to flexible telehealth treatment even absent a special federal carveout. In parallel, this scenario features additional risk-mitigation measures outside of scheduling to ensure diversion and misuse remain in check. Regulators could mandate or encourage enhanced prescriber education (for instance, CME modules on safe testosterone prescribing and recognizing non-medical use). They could leverage Prescription Drug Monitoring Programs (PDMPs) by requiring that any testosterone prescription be reported and perhaps flagging unusual high-dose or multi-prescriber patterns for review – effectively using data to catch potential abuse cases.

Another idea is practitioner certification or guidelines adherence. While testosterone would become easier to prescribe, professional bodies might establish certification programs or clinical criteria to guide appropriate use (e.g. ensuring prescribers evaluate patients for hypogonadism according to best practices before initiating therapy). These measures would act as guardrails to compensate for the looser legal status. Enforcement against black-market trafficking would continue, albeit under slightly lower schedule

penalties. Unlawful distribution of testosterone (without a prescription) would remain a federal crime, but as a Schedule IV/V substance, the penalties for offenders could be somewhat reduced. Law enforcement could still seize illicit shipments and prosecute dealers, but they might rely more on tracking *sources* (e.g. rogue clinics or importers) and less on pursuing individual users, since possession of a lower-schedule drug often carries lighter consequences.

10.2.3 Stakeholder alignment

Scenario B reflects a compromise posture. It incorporates arguments that Schedule III may overstate testosterone's relative abuse risk in medically supervised contexts and imposes disproportionate administrative burdens (Section 8.3), while preserving controlled-status tracking and enforcement mechanisms emphasized by stakeholders concerned about diversion, misuse, and deterrence (Section 8.2)[110]. The degree of alignment varies by whether the rescheduling endpoint is IV or V, and by the scope of accompanying risk-mitigation measures.

10.3 Scenario C: Deschedule and Rely on Prescription-Drug Controls

Scenario C represents the most sweeping change. Testosterone is removed from the federal controlled substance schedules entirely, to be regulated henceforth like a conventional prescription drug. In this outcome, the CSA would no longer classify testosterone or other anabolic steroids containing testosterone as controlled substances. Oversight would revert exclusively to FDA authorities (for product approval, labeling, and post-market surveillance) and to standard medical practice regulation (state medical boards, pharmacy laws, etc.). Testosterone would still require a prescription – it would not be available over-the-counter but it would be treated similarly to hormones such as estrogen or thyroid medication, without the extra layer of DEA-imposed restrictions.

Descheduling has been proposed by some stakeholders who argue that the CSA framework is both unjustified (given testosterone's therapeutic importance and relatively low acute abuse potential) and counterproductive (given the barriers and stigma it creates) (see Section 8.3.2). Indeed, the recent FDA-convened expert panel in December 2025 urged regulators to "discontinue treating testosterone as a controlled substance," contending that the Schedule III designation creates unnecessary hurdles and stigma around a medication that many patients legitimately need[81].

Under Scenario C, testosterone would join the list of unscheduled prescription substances, and the Anabolic Steroids Control Act would no longer apply to it.

10.3.1 Regulatory pathway

Descheduling a substance outright is a serious step, but it is legally feasible via the same CSA process that allows for rescheduling. DEA, upon a scientific and medical evaluation from HHS, can remove a drug from the schedules if it finds that the drug does not meet the criteria for control (for example, if it no longer has a significant abuse potential or danger to public health relative to unscheduled drugs)[148]. In practice, such a move would require very robust evidence and likely a strong endorsement from health authorities. One can envision HHS (through FDA, NIH, etc.) conducting a thorough eight-factor analysis and potentially concluding that while testosterone can be misused, the risks can be managed through ordinary prescription controls rather than criminal scheduling.

The political and interagency hurdles would be high, DEA tends to be cautious about decontrol, and completely removing a drug from CSA scheduling is extremely rare and can implicate international treaty obligations[147]. Still, it is within the Attorney General's authority (delegated to DEA) to initiate a rulemaking to decontrol. Alternatively, Congress could pass legislation carving testosterone out of the controlled substance lists. This could involve amending the CSA's anabolic steroid definition in 21 U.S.C. §802(41) to exclude certain forms of testosterone, or repealing its inclusion entirely.

Given that Congress proactively scheduled testosterone in 1990, a legislative fix is conceivable if there is sufficient consensus (for example, a future "Testosterone Access Act"). However, legislative action might also come with strings (such as conditions or alternative regulatory measures for testosterone distribution). Overall, Scenario C's pathway would likely require clear alignment between HHS, DEA, and Congress that medical and scientific justifications exist to warrant descheduling – essentially a policy decision that the harms of controlling testosterone now outweigh the benefits.

10.3.2 Operational effects

Descheduling would have profound operational impacts on access, risk management, and enforcement. On the access side, many of the friction points that patients and providers currently face would disappear virtually overnight. All licensed physicians, not just DEA-registered ones, could prescribe testosterone, expanding the pool of potential prescribers (e.g. more general practitioners or clinic staff could treat hypogonadism without obtaining a DEA license). Prescriptions could be issued for longer durations with refills per usual medical practice (often up to 12 months), freeing patients from the 6-month renewal cycle and frequent pharmacy visits.

Telemedicine would become far simpler: the special restrictions of the Ryan Haight Act would no longer apply, so a patient could be evaluated and managed entirely via telehealth if clinically appropriate, just as they could for any non-controlled medication. This change directly addresses one of the

core concerns about Schedule III status – that requiring in-person visits or other hoops for testosterone has prevented some patients from receiving care. With descheduling, a provider in a telehealth platform could legally prescribe testosterone across state lines (subject only to standard state telemedicine rules, not DEA waivers). Pharmacies could dispense and even mail testosterone without the extra record-keeping and signature requirements of controlled substances.

Overall, the administrative simplification would be dramatic: obtaining testosterone would be akin to obtaining an antibiotic or an asthma inhaler in terms of process. From a patient perspective, this likely means greater continuity (fewer disruptions due to paperwork), reduced stigma at the pharmacy counter (testosterone would no longer trigger controlled-drug protocols), and potentially lower costs (some providers charge extra fees for controlled-substance management which would no longer be relevant).

The flipside is that diversion control would shift to alternate mechanisms. Without CSA scheduling, unlawful trafficking in testosterone would not carry the same specific criminal penalties. Instead, the primary legal safeguard is that testosterone remains a prescription drug, so any distribution without a valid prescription is a violation of the Food, Drug, and Cosmetic Act (FDCA) and/or state pharmacy laws. Enforcement against diversion would thus rely on FDA regulatory actions, customs enforcement, and professional discipline rather than DEA raids. For example, if large quantities of illicit testosterone were imported or produced, authorities could pursue the sellers for distributing an unapproved/misbranded drug, but they could no longer charge "possession with intent to distribute a controlled substance." Such FDCA prosecutions are usually less severe and less immediate, which could challenge enforcement feasibility for stopping black-market operations quickly.

To counterbalance this, Scenario C would employ alternative diversion-control strategies. One key strategy is strengthened product labeling and tracking. FDA could require prominent labeling on testosterone products to warn against non-medical use (similar to boxed warnings) and to affirm that dispensing without prescription is illegal. More tangibly, the Drug Supply Chain Security Act (DSCSA) now mandates serialization and electronic tracking of prescription drugs; this can be leveraged to detect and intercept counterfeit or diverted testosterone in the supply chain. Manufacturers and pharmacies would track shipments, making it harder for illicit product to intermingle with legitimate channels [149,150].

Another strategy is anti-counterfeiting measures – ensuring that legitimate testosterone medications have identifiers (holograms, barcodes) that allow users and law enforcement to verify authenticity, thereby discouraging use of black-market versions. *Sports doping enforcement* would continue through separate channels: even if testosterone is no longer a

controlled substance, organizations like WADA, USADA, and professional leagues will still ban its use without a therapeutic exemption. In fact, one can argue that doping prevention has increasingly become a specialized realm, using biological passports and testing to catch cheaters rather than relying on criminal law.

For everyday public health, the assumption in Scenario C is that the medical system's standard controls are sufficient to manage testosterone's risks. Doctors would prescribe it when appropriate and counsel patients on proper use; pharmacists would guard against inappropriate refills or suspicious prescriptions (as they already do for many drugs); and misuse for bodybuilding purposes would be addressed through education and the existing illegality of dispensing without a prescription.

Supporters of descheduling contend that this approach would *reduce* overall harm: by making legitimate access easier, it could shrink the demand for underground steroids and thereby reduce the prevalence of dangerous, unregulated products (see Section 8.3.3). They note that many current abusers obtain testosterone from illicit sources precisely because the legal pathway is cumbersome or stigmatized; if that barrier is removed, more individuals might go through proper medical channels, where they can be monitored. Empirical data on this point are limited (it is challenging to predict how user behavior shifts), so it remains a hopeful assumption of this scenario.

10.3.3 Stakeholder alignment

Scenario C aligns with stakeholders who argue that testosterone's controlled status is misaligned with recent clinical practice and that ordinary prescription-drug oversight (rather than CSA scheduling) is the appropriate regulatory layer (Sections 8.3.2-8.3.3)[110]. It is least aligned with stakeholders who view Schedule III as essential for deterrence and trafficking enforcement (Section 8.2), and it therefore tends to require stronger interagency and political consensus to be plausible as a pathway.

10.4 Leading Indicators and Decision Triggers

The signals summarized in Section 8.4 become decision triggers when they cross a procedural or evidentiary threshold that initiates (or materially constrains) a scheduling pathway. The most consequential triggers are typically the following:

10.4.1 Agency scientific reviews or formal recommendations

A trigger occurs when HHS (including FDA as appropriate) produces a formal scientific and medical evaluation explicitly framed for scheduling purposes and transmitted to DEA, or when DEA publicly initiates an updated eight-factor review for testosterone. These steps move the issue from public debate into a process with defined statutory milestones under 21 U.S.C. §

811(c)[2]. Expert-panel discussions may shape framing, but formal interagency recommendations or a DEA rulemaking notice are more decisive procedural thresholds[110].

10.4.2 Rulemaking that resolves major access frictions without rescheduling

A trigger occurs when DEA finalizes telemedicine mechanisms that materially reduce access barriers for Schedule III–V prescribing under enforceable conditions (e.g., special registration or equivalent). Such a resolution can shift attention toward implementation-level reform consistent with Scenario A, without requiring reclassification[33,113]. Conversely, if final rules reintroduce stringent in-person requirements that materially disrupt continuity of care, the unresolved friction can function as a trigger for intensified rescheduling advocacy, even though it does not determine the appropriate outcome.

10.4.3 Congressional action beyond correspondence

Letters and hearings are signals; a trigger occurs when Congress introduces, advances, or enacts legislation that directly amends the anabolic-steroid scheduling framework (e.g., reclassifying testosterone, creating carve-outs, or redefining coverage). Such steps change the feasible policy set irrespective of agency preferences and may accelerate or preempt administrative pathways[6,108].

10.4.4 Empirical inflection points in misuse, diversion, or health outcomes

A trigger occurs when surveillance, pharmacoepidemiology, or enforcement data show a sustained shift that materially alters the "risk" or "control feasibility" assumptions used in the eight-factor analysis — for example, documented increases in diversion harms tied to medical channels, or evidence that the predominant illicit market has shifted away from pharmaceutical testosterone toward other compounds, changing the practical leverage of Schedule III classification[116]. The relevant threshold is typically sustained change with clear policy relevance, not a single datapoint.

10.4.5 Professional consensus statements that directly address scheduling-relevant premises

Guideline updates become a trigger when they explicitly speak to premises central to scheduling deliberation. For example, clarifying therapeutic risk-benefit in a way that shifts the "public health risk" narrative, or directly stating that current controls impede appropriate care (or, alternatively, remain necessary). While not dispositive, such statements can materially influence how regulators interpret "current state of scientific knowledge" and accepted medical use within the CSA framework[110].

In conclusion, the fate of testosterone's Schedule III status will be guided by a mix of such signals. As of early 2026, the policy landscape is in flux – DEA's telehealth rules are pending, HHS has engaged via an expert panel, and

advocacy continues from multiple directions. Regulators will be reading these indicators: a recommendation letter here, a dataset there, a public petition, or a nod from the medical community. Any one development is unlikely to trigger a change overnight, but together they will shape a narrative about whether the current classification “works” or needs adjustment. The debate on testosterone’s scheduling is ultimately a test of how evidence and values translate into policy – and the coming months and years will reveal which signals carry the day.

11. Conclusion

Testosterone's Schedule III status reflects its dual role in federal policy. It is an established therapy with accepted medical use, and it is also treated as an anabolic steroid under a framework built to address non-medical use and diversion. Any reassessment therefore turns on proportionality under the CSA criteria and the eight-factor analysis, not on broad judgments about testosterone as a category.

The evidence summarized in this review consistently differentiates supervised therapeutic use from non-medical use patterns. The most serious harms are more closely associated with high-dose, prolonged, and poorly monitored use, often alongside stacking and other co-use practices. This distinction does not eliminate risk in medical settings, but it clarifies where risk concentrates and what kinds of controls are most directly relevant.

Several uncertainties remain central to scheduling judgments. Diversion pathways are not quantified with precision across settings, which complicates attribution of harm to prescription versus extra-medical sources. Practical restrictiveness also varies because federal scheduling interacts with state rules, PDMP practices, pharmacy policies, and payer controls. These layers can shape access and oversight as much as the schedule itself.

This review does not recommend a scheduling outcome. It supports a structured approach that aligns the regulatory burden with the mechanisms most likely to reduce the harm of concern. That approach benefits from clear definitions, especially around "abuse" in this context, which is often goal-directed and not primarily driven by acute intoxication. Clarity here improves how evidence is weighed across abuse potential, dependence liability, and public health risk considerations.

Any change in testosterone's classification would move through established pathways, including petitions and eight-factor review, HHS medical-scientific evaluation and recommendation, DEA rulemaking, or congressional amendment. Separately, implementation-level actions, including telemedicine rules for controlled substances, can materially alter access and oversight without changing the schedule. These adjacent policy moves can influence stakeholder pressure and perceived need for rescheduling.

Testosterone's current status is best understood as a policy inheritance that can be evaluated against modern conditions. A durable path forward is a transparent application of the CSA criteria that states assumptions explicitly, distinguishes use patterns that drive risk, and ties regulatory controls to measurable public health goals.

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