Review Article

From Root to Regulation: The Pharmacognostic Journey of Botanical Drugs in Dermatology

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Botanical remedies have long served as foundational therapies in dermatology, with traditions spanning ancient Egyptian, Ayurvedic, and Chinese medical systems. Recent decades have seen a resurgence of interest in plant-based treatments, driven by both consumer demand and scientific advances. This narrative review examines the pharmacognostic and regulatory trajectory of botanical drugs in dermatology, focusing on case studies of FDA-approved agents including capsaicin (Qutenza®), sinecatechins (Veregen®), and birch bark extract (Filsuvez®). We trace their development from ethnobotanical use to modern clinical trials, highlighting key milestones in safety, efficacy, and standardization. The review also explores near-regulatory candidates, such as Lindioil and bakuchiol, which show promise in treating inflammatory dermatoses. Special attention is given to the U.S. FDA's Botanical Drug Pathway, which outlines distinct challenges related to raw material variability, chemical complexity, and regulatory compliance. Finally, we discuss emerging tools – such as artificial intelligence, synthetic biology, and plant cell culture – that are reshaping the landscape of botanical dermatology. Together, these insights offer a framework for responsibly integrating evidence-based botanicals into future dermatologic care.

1. INTRODUCTION: FROM ANCIENT SKINCARE TO MODERN DERMATOLOGY

For centuries, traditional medicine systems across the globe have relied on botanicals to treat wounds, inflammatory skin conditions, and infections. Ancient civilizations such as the Egyptians, Greeks, and Chinese developed herbal remedies for dermatologic care, as evidenced by the use of aloe vera and honey for wound healing, green tea polyphenols for inflammation, and neem and turmeric for chronic dermatoses.[1-3] Although these remedies continue to influence contemporary practice, their integration into modern medicine has required a scientific and regulatory transformation. The field of pharmacognosy, which systematically studies natural products for medicinal use, has played a crucial role in identifying, isolating, and standardizing bioactive compounds from botanical sources. Many of these phytochemicals exhibit potent antioxidant, anti-inflammatory, and antimicrobial properties.

Nevertheless, widespread clinical adoption of botanical remedies remains limited by challenges such as variability in plant composition, insufficient clinical trials, and difficulties in standardizing extracts. Recognizing this, the U.S. Food and Drug Administration (FDA) introduced the Botanical Drug Pathway in 2004, creating a structured regulatory framework for botanical-derived pharmaceuticals. This initiative, revised in 2016, aimed to facilitate the approval of plant-based drugs by addressing challenges related to composition consistency, quality control, and clinical efficacy.[4, 5]

While only a few botanical drugs have achieved FDA approval, these successes highlight a growing convergence between traditional knowledge, scientific validation, and regulatory innovation. This narrative review explores that trajectory – from ethnobotanical use to pharmacognostic discovery to FDA-sanctioned therapies – while also examining how emerging technologies such as biotechnology and AI are reshaping the future of evidence-based botanical dermatology.

2. MATERIALS AND METHODS

This narrative review was developed through a structured search of PubMed, Embase, Web of Science, and ClinicalTrials.gov (last search: 15 June 2025). Keywords included "botanical drug," "phytomedicine," "dermatology," "FDA approval," "capsaicin," "sinecatechins," "birch bark extract," "indigo naturalis," "bakuchiol." No language restrictions were applied. Reference lists of key articles were hand-searched. Only peer-reviewed primary data, systematic reviews, and regulatory documents were included. Data were synthesized qualitatively; no meta-analysis was performed.

3. RESULTS

3.1. HISTORICAL PATHWAYS OF FDA-APPROVED BOTANICAL DRUGS IN DERMATOLOGY

Before formal regulatory frameworks existed, botanical remedies were shared and preserved through oral tradition and Indigenous languages, ensuring rich, nuanced ethnobotanical knowledge survived across generations. Storytelling, apprenticeships, and rituals functioned as "living libraries," encoding vital details on plant identification, optimal harvest time, preparation methods, dosage, and even contraindications – embedded in local ecological terms that informed safe and effective use.

Modern pharmacognosy and drug development tap into this orally transmitted wisdom. Researchers in medical anthropology and ethnobotany often begin by consulting traditional healers and analyzing native terminologies and folk taxonomies, which guide the selection of species, extraction techniques, and therapeutic targets. As mentioned before, this culturally informed approach has provided the foundation for the eventual FDA approval of several botanical drugs used in dermatology. By exploring case studies of such botanicals, we can begin to trace and appreciate the progression from community-held knowledge to chemical isolation, clinical trials, and regulatory approval, ultimately paying homage to the enduring importance of oral narratives in contemporary medicine.

3.1.1. CAPSAICIN (QUTENZA® PATCH): CHILI PEPPER FOR NEUROPATHIC DERMATOSES

Capsaicin, the pungent alkaloid found in *Capsicum annuum* L., *C. frutescens* L., and related chili peppers, has played a prominent role in traditional medicine systems across the Americas, India, and Southeast Asia. Historically, healers applied chili extracts both orally and topically to relieve pain, reduce inflammation, and stimulate circulation. In Mesoamerican traditions, ground chili was placed directly onto painful joints and open wounds, believed to "draw out" heat and toxins.[6] In the Ayurvedic tradition, *marich* (black pepper) and *katuvira* (chili) were featured in formulations for rheumatic pain and dermatologic irritation, underscoring the cross-cultural relevance of capsaicin in pain management.

Scientific investigation of capsaicin began in earnest in the late 19th and early 20th centuries, culminating in a landmark discovery in the 1980s: capsaicin's activation of the transient receptor potential vanilloid 1 (TRPV1) channel, a sensory ion channel involved in heat and pain perception.[7] This mechanistic insight opened the door to therapeutic applications targeting peripheral neuropathic pain. Pharmacologically, capsaicin activates TRPV1 receptors on nociceptive neurons, triggering an initial burning sensation followed by reversible desensitization. High-concentration topical formulations (such as 8%) cause defunctionalization of sensory nerve endings by depleting substance P and calcitonin gene-related peptide (CGRP), neuropeptides essential for transmitting pain signals.[8] This allows for sustained pain relief without compromising normal tactile or thermal sensation.

Qutenza®, an 8% capsaicin patch, exemplifies the successful transformation of a traditional botanical remedy into an FDA-approved, prescription-only dermatologic therapy. Approved in 2009 for the treatment of postherpetic neuralgia (PHN) in adults, its indication was expanded in 2020 to include neuropathic pain associated with diabetic peripheral neuropathy of the feet.[9] Clinical efficacy was established through a pooled meta-analysis of seven randomized, controlled trials involving 1,458 participants with PHN or HIV-associated neuropathy (HIV-AN). In these studies, Qutenza® consistently outperformed a low-dose control (0.04%) in reducing pain intensity, with significantly higher rates of ⩾30% and ⩾50% pain reduction, particularly among patients with PHN.[10]

Though its approved indications center on neuropathic pain, its transdermal delivery mechanism renders it directly relevant to dermatologic practice. It is currently used to treat localized neuralgia, diabetic neuropathy, and HIV-AN, and is also prescribed off-label for conditions such as notalgia paresthetica and small fiber neuropathy. Ongoing research is evaluating its potential in chronic pruritus syndromes and chemotherapy-induced neuropathy. The clinical success of Qutenza® underscores the feasibility of translating ethnobotanical knowledge into modern dermatologic therapeutics, provided such agents are accompanied by rigorous mechanistic studies, pharmaceutical standardization, and evidence from well-controlled clinical trials.

3.1.2. VEREGEN® (SINECATECHINS 15%): GREEN TEA POLYPHENOLS FOR GENITAL WARTS

Green tea (*Camellia sinensis* (L.) Kuntze) has long held a prominent role in Traditional Chinese Medicine (TCM), where it was used not only as a restorative beverage but also as a topical agent for treating burns, inflamed skin, and festering wounds. Ancient healers prepared green tea poultices and compresses to "clear heat" and "eliminate toxins," reflecting a belief in its purifying, anti-inflammatory, and detoxifying properties. Revered across Asia for promoting longevity and internal balance, green tea's dermatologic relevance was deeply intertwined with its broader spiritual and medicinal significance.

In the 20th century, green tea attracted growing scientific attention for its health-promoting properties. Researchers identified a group of polyphenolic compounds, most notably epigallocatechin gallate (EGCG), as the primary bioactive constituents responsible for green tea's antioxidant, anti-inflammatory, and antimicrobial effects.[11] These findings supported long-standing traditional uses and positioned green tea as a serious candidate for pharmaceutical development. Laboratory studies demonstrated EGCG's ability to inhibit viral replication, induce apoptosis in infected keratinocytes, and modulate immune responses, offering mechanistic insight into its potential efficacy in treating cutaneous viral infections.[11]

These discoveries culminated in the development of Veregen®, a topical ointment composed of sinecatechins: a standardized extract of green tea catechins with EGCG as

its principal component. Sinecatechins exhibit antiviral effects through multiple proposed mechanisms, including direct inhibition of human papillomavirus (HPV) replication, stimulation of apoptosis in infected cells, and enhancement of local immune clearance.[12] In addition to its antiviral actions, sinecatechins provide antioxidant protection that may help mitigate oxidative stress and inflammation in affected skin.

Veregen® became one of the first botanical drugs approved under the FDA's Botanical Drug Pathway when it received approval in 2006 for the treatment of external genital and perianal warts caused by HPV.[13] Unlike single-compound drugs, Veregen® required the pharmaceutical development of a complex botanical mixture, demanding rigorous standardization of green tea leaf extracts, batch-to-batch consistency, and reproducibility of chemical composition. Although the precise clinical mechanism remains incompletely understood, in vitro studies suggest that sinecatechins' antioxidant and antiviral properties contribute to their therapeutic effect. Pharmacokinetic data show minimal systemic absorption, with topical application yielding significantly lower catechin exposure than a single 400 mL oral dose of green tea.[14]

Clinical efficacy was demonstrated in two Phase 3 randomized, double-blind, vehicle-controlled trials involving immunocompetent adults with external genital and perianal warts. Participants applied Veregen® 15% ointment three times daily for up to 16 weeks or until complete wart clearance. Across both studies, the median baseline wart count was six, with a median wart area of 51 mm^2. By week 16, 53.6% of patients in the Veregen® group achieved complete clinical clearance, compared to 35.3% in the vehicle group.[14]

While explicitly approved for genital warts, research into the broader dermatological applications for sinecatechins is ongoing. Small studies have explored their use in treating acne vulgaris, rosacea, and photodamage, owing to their combined anti-inflammatory and antioxidant properties. Future studies may expand their role in chronic inflammatory skin conditions and skin aging, but further large-scale trials are needed.

3.1.3. FILSUVEZ® (BIRCH BARK EXTRACT): FDA-APPROVED THERAPY FOR EPIDERMOLYSIS BULLOSA

Birch trees (*Betula* spp.), particularly *Betula pendula* Roth., have long occupied a central place in European traditional medicine, where their bark was widely used in poultices and salves to treat wounds, burns, and inflammatory skin conditions. In Northern and Eastern European folk practices, birch bark was prized not only for its antiseptic and astringent properties but also for its ability to promote wound regeneration and the formation of granulation tissue.[15] Healers often applied salicylate-rich extracts from the bark to chronic ulcers and abrasions – practices that presaged their eventual pharmaceutical development.

Scientific interest in birch bark intensified in the late 20th century, as pharmacognosists isolated triterpenes such as betulin, lupeol, and betulinic acid and identified their role in modulating inflammation and wound repair. These compounds were shown to enhance key regenerative processes, including keratinocyte migration, fibroblast activation, and cytokine signaling.[16] Building on these insights, researchers developed a standardized birch bark extract with consistent triterpene content, designed for therapeutic use in conditions where normal wound healing is compromised.

This development culminated in Filsuvez®, a topical gel composed of a dry extract from *Betula pendula* bark, standardized to deliver betulin, lupeol, and other bioactive triterpenes. Filsuvez® acts by stimulating keratinocyte migration and inhibiting NF-κB signaling, thereby reducing inflammation and accelerating re-epithelialization. It also supports extracellular matrix remodeling, which is crucial for effective wound closure in fragile or blistering skin.[16] These properties made it a promising candidate for treating epidermolysis bullosa (EB), a group of rare genetic skin disorders characterized by chronic, slow-healing wounds.

In 2022, Filsuvez® received FDA approval for the treatment of partial-thickness wounds in patients aged six months and older with junctional and dystrophic forms of EB.[17] This landmark approval, the first for a drug specifically targeting EB-related wounds, was based on the results of the EASE trial, a Phase III randomized, double-blind, vehicle-controlled study that demonstrated statistically significant improvements in wound closure compared to placebo.[18] Developers faced the dual challenge of demonstrating efficacy and ensuring batch-to-batch consistency of a multi-component botanical product in a pediatric orphan disease population.

Although Filsuvez® is currently approved only for EB, its underlying mechanisms suggest broader potential in chronic wound care. Early studies are exploring its use in diabetic ulcers, venous leg ulcers, and burns, where impaired healing remains a clinical challenge. The success of Filsuvez® has also renewed interest in triterpene-rich botanicals for regenerative dermatology, offering a template for future botanical drug development targeting complex skin conditions.

3.2. ON THE HORIZON: BOTANICALS WITH NEAR-REGULATORY POTENTIAL

3.2.1. LINDIOIL (INDIGO NATURALIS): ANCIENT REMEDY FOR PSORIASIS

Indigo naturalis, a deep-blue powder derived from plants such as *Indigofera tinctoria* L., has long been revered in TCM for treating inflammatory skin conditions. Historical texts, including those from the Song Dynasty, describe its use in managing what were classified as "hot" or "toxic" skin disorders – descriptions that likely encompassed modern-day psoriasis, eczema, and dermatitis.[19] Typically applied in combination with other "cooling" herbs, indigo naturalis was used to alleviate redness, scaling, and itching, the hallmarks of chronic inflammatory dermatoses.

Modern scientific interest in indigo naturalis was sparked by clinical observations in Taiwan and mainland China, where topical applications produced notable improvements in psoriatic lesions. This led to the identifica-

tion of active compounds such as indirubin and tryptanthrin, both of which display anti-inflammatory and antiproliferative properties. In particular, indirubin is the most extensively characterized, acting through dual mechanisms: inhibition of cyclin-dependent kinases, which curbs keratinocyte hyperproliferation, and suppression of key inflammatory cytokines such as IL-17 and TNF-α that drive psoriatic immunopathogenesis.[20] Further studies have shown that indirubin reduces proliferative markers such as Ki67 and PCNA while inducing G_0/G_1 cell cycle arrest, thereby modulating keratinocyte differentiation and providing additional mechanistic rationale for its antipsoriatic effects.[21,22] Recent comprehensive reviews also highlight its broader impact on modulating inflammatory pathways through the IL-23/STAT3 and NF-κB signaling axes, reinforcing the potential of indigo naturalis in treating both proliferative and inflammatory dermatoses.[23]

Building on this pharmacological insight, researchers developed Lindioil®, a refined topical preparation of indigo naturalis standardized by indirubin content. In a randomized, double-blind, dose-ranging trial, Lindioil® formulations containing 200 µg/g of indirubin achieved a 69.2% mean reduction in Psoriasis Area and Severity Index (PASI) scores after 8 weeks of treatment. Notably, 57% of participants reached PASI 75 and 30% achieved PASI 90, while no serious adverse events were reported during the 20-week evaluation period.[24] These findings affirm both the efficacy and short-term safety of indirubin-rich preparations in managing plaque psoriasis.

Yet despite these promising results, no indigo naturalis-based product has obtained FDA approval. Regulatory obstacles stem largely from the complexities of botanical standardization: indigo naturalis contains a chemically diverse mixture of constituents that can vary significantly between batches. Additionally, concerns about hepatotoxicity, especially in crude or inconsistently processed formulations, highlight the need for rigorous quality control and long-term safety data.[25] Nevertheless, indigo naturalis represents a compelling candidate for future regulatory advancement, pending multicenter Phase III trials and enhanced extract standardization.

Today, indigo naturalis continues to be used extensively in East Asian dermatologic practice and is gaining traction in Western contexts as a steroid-sparing alternative. Beyond psoriasis, preliminary studies suggest broader applications in other inflammatory dermatoses, laying the groundwork for future therapeutic expansion.

3.2.2. BAKUCHIOL: A BOTANICAL RETINOL ANALOG IN THE MAKING

Bakuchiol, a meroterpene compound later isolated from the seeds and leaves of *Psoralea corylifolia* L. is commonly known as Babchi and traces its origins to Ayurvedic medicine and TCM, where the whole plant was long employed in the treatment of skin disorders such as vitiligo, leprosy, and inflammatory dermatoses.[26] In these traditional systems, oil-based preparations of Babchi were applied topically, often in conjunction with sun exposure, to stimulate pigmentation and promote skin healing. While bakuchiol itself was not identified until much later, its presence in these formulations likely contributed to their therapeutic efficacy. These practices underscore the enduring ethnopharmacological relevance of *P. corylifolia* in managing pigmentary imbalance and cutaneous inflammation.

In recent decades, bakuchiol has re-emerged in dermatologic science as a compelling botanical analog to retinol. Despite being structurally unrelated to retinoids, it exhibits similar functional activity. This was first substantiated in 2014 through gene expression profiling, which demonstrated bakuchiol's ability to regulate dermal extracellular matrix components, such as collagen and elastin, while avoiding the irritancy commonly associated with retinoic acid derivatives.[27] As interest in plant-based, well-tolerated skincare alternatives surged, bakuchiol garnered significant attention in the cosmeceutical sector.

Mechanistically, bakuchiol exerts its anti-aging and anti-inflammatory effects by modulating pathways involved in skin architecture and immune signaling. It promotes the expression of collagen types I and III and elastin while suppressing matrix metalloproteinases (MMPs), enzymes implicated in dermal degradation. Additionally, it downregulates pro-inflammatory cytokines like IL-6 and TNF-α and exhibits antimicrobial activity against *Cutibacterium acnes*, supporting its emerging role in acne treatment.[28] Furthermore, clinical trials have shown that bakuchiol, unlike retinoids, does not induce photosensitivity or significant skin irritation, making it a suitable option for patients with sensitive or reactive skin.[29]

Although bakuchiol is widely used in over-the-counter skincare products, it has not yet been evaluated under the FDA's Botanical Drug Pathway. Its current regulatory status as a cosmetic ingredient limits claims of therapeutic efficacy, yet its strong safety profile and growing clinical evidence suggest it could transition into prescription dermatology with further study. Key developmental challenges include establishing standardized extraction methods, ensuring compound stability in topical formulations, and conducting large-scale, randomized controlled trials to meet regulatory benchmarks.

Presently, bakuchiol is featured in numerous formulations targeting photoaging, hyperpigmentation, and acne. Clinical comparisons with retinol have shown equivalent efficacy in reducing fine lines and pigmentation, with superior tolerability, making it a favorable alternative for individuals who cannot tolerate retinoids. As research continues, bakuchiol may be positioned as a leading plant-derived agent in evidence-based botanical dermatology.

3.3. REGULATORY FRAMEWORK: KEY ELEMENTS OF THE FDA BOTANICAL DRUG PATHWAY

The U.S. FDA's Botanical Drug Pathway holds plant-derived mixtures to the same statutory standard of "substantial evidence of efficacy and safety" that applies to conventional small-molecule and biologic products, while layering on extra chemistry, manufacturing, and controls (CMC) requirements to manage the natural variability of living raw materials. The 2016 *Botanical Drug Pathway* describes five checkpoints: (1) Discovery/Pre-Investigational New Drug

Table 1. FDA Botanical Drug Development Timeline

Development Stage	FDA Focus for Botanicals	Typical Timeline
Discovery / Pre-IND	• Authenticate species; archive voucher specimens • Define cultivation/harvest controls • Develop pilot chemical-fingerprint QC when active constituents are unknown • Summarize prior human use (may shorten non-clinical tox)	≈ 3–5 yrs
IND & Early Clinical (Phase 1–2)	• Submit full BRM → drug-product CMC package • Limited tox if long human-use record • Establish batch bridging by fingerprint QC rather than a single marker • Conduct dose-finding / proof-of-concept studies	≈ 2–4 yrs
Phase 3 (Pivotal)	• ≥1 adequate, well-controlled trial (or 1 + confirmatory evidence) • Multi-batch clinical bridging to show therapeutic consistency • Late-phase CMC upgrades (process validation, stability)	≈ 3–4 yrs
NDA Submission & FDA Review	• Held to same "substantial evidence" standard as synthetic drugs • Lock raw-material controls and QC specifications • Post-marketing PV plan • Review timelines: 6 months (priority), 10 months (standard); extra cycles if CRL issued	0.6–1 yr (1+ yr if CRL)
Post-Marketing (Phase 4)	• Ongoing GMP/QC inspections • Adverse-event and lot-consistency reporting • Supplemental studies for new indications	Ongoing

Abbreviations: IND, Investigational New Drug; BRM, Botanical Raw Material; CMC, Chemistry, Manufacturing, and Controls; QC, Quality Control; Tox, Toxicology; NDA, New Drug Application; PV, Pharmacovigilance; CRL, Complete Response Letter; GMP, Good Manufacturing Practices.

(IND), (2) IND with Phase 1–2 studies, (3) Pivotal Phase 3, (4) New Drug Application (NDA) review, and (5) Post-marketing surveillance. This pathway offers flexibility when no single "active" constituent can be isolated (See Table 1). For example, sponsors may submit a reduced toxicology package if extensive prior human use is documented, and they may rely on a chemical-fingerprint profile plus a bioassay in lieu of a single-marker potency test for early batches.

These concessions rarely shorten the overall timeline, however, because each development stage still demands batch-to-batch therapeutic consistency across a multi-component mixture. Industry surveys estimate 10–15 years from discovery to approval for most new therapeutics, and the three dermatology botanicals profiled in Section 2 (Veregen®, Qutenza®, and Filsuvez®) all landed squarely in that range, underscoring that prior traditional use does not exempt botanicals from the full arc of evidence-based drug development.

5. DISCUSSION

5.1. THE FDA BOTANICAL DRUG PATHWAY: CHALLENGES AND OPPORTUNITIES

While the FDA's Botanical Drug Pathway provides a clear regulatory process, successfully advancing a botanical mixture from traditional use to approved drug presents distinct challenges not faced by synthetic pharmaceuticals. The complexity of plant-derived therapeutics lies not in the absence of a framework, but in the difficulty of meeting its standards using inherently variable natural materials. Environmental factors such as soil composition, seasonal variation, and harvest conditions can significantly alter a plant's phytochemical profile, complicating efforts to ensure batch-to-batch consistency. Moreover, the historical roots of many botanicals in traditional medicine often mean a lack of modern, placebo-controlled clinical trials, leaving sponsors with limited evidence upon which to build their investigational programs. These scientific gaps must be bridged through rigorous standardization, innovative manufacturing approaches, and often, de novo clinical development.

Notably, the few botanical drugs that have achieved FDA approval share a critical feature: each has been able to meet the agency's CMC requirements by establishing reproducible chemical fingerprints and ensuring batch-to-batch consistency. Qutenza® relies on a single purified alkaloid (capsaicin), Veregen® employs a catechin-rich extract standardized to epigallocatechin gallate, and Filsuvez® uses a triterpene-rich birch bark extract with well-defined marker compounds. In contrast, many promising botanicals, such as indigo naturalis or bakuchiol, remain in pre-approval stages due to challenges in standardization, variability in active constituents, or the absence of large-scale Phase III data. This distinction underscores that regulatory success in botanicals depends as much on pharmaceutical rigor as on therapeutic potential. In practice, this means that FDA approval has thus far been limited to botanicals where either a single active compound can be tightly quantified or a reproducible chemical and chromatographic fingerprint can be validated across production batches.[30]

Beyond scientific hurdles, economic considerations present additional obstacles. Pharmaceutical companies often prefer synthetic molecules, which offer stronger intellectual property protections and more predictable manufacturing scalability. By contrast, botanical mixtures, being complex and widely accessible, are more challenging to patent and commercialize, thereby reducing incentives for investment.

Biotechnology offers promising solutions to these long-standing challenges. Advances in synthetic biology, plant tissue culture, and AI-driven compound discovery are facilitating the standardization and development of botanical therapeutics. These technologies enable the precise identification, optimization, and mass production of bioactive plant compounds, mitigating variability and enhancing

scalability. Synthetic biology allows for microbial production of plant molecules under controlled conditions, while plant tissue culture produces uniform botanical material independent of environmental influences. AI-driven platforms accelerate the identification of promising phytochemicals from ethnobotanical records, offering a modern pathway for the rediscovery and validation of traditional remedies.[31]

Despite these advances, the path from root to regulation remains long and resource-intensive. Successful examples like Veregen® demonstrate feasibility but highlight the continued need for interdisciplinary collaboration between ethnobotanists, pharmacologists, clinicians, and regulatory experts to bring new botanical therapies into clinical practice.

5.2. THE FUTURE OF BOTANICAL DERMATOLOGY

The future of botanical dermatology stands at a pivotal intersection of traditional knowledge and cutting-edge science. Rather than relying solely on anthropological pathways, emerging approaches now harness artificial intelligence and machine learning to accelerate ethnobotanical discovery. These tools mine digitized historical medical texts, biological databases, and phytochemical libraries to identify plant-derived compounds with anti-inflammatory, antimicrobial, or regenerative potential – already catalyzing the development of new candidates for acne, aging, and chronic inflammatory dermatoses. This digital revolution is bolstered by initiatives such as those undertaken by the Royal Botanic Gardens, Kew – the world's largest botanical garden – where extensive efforts are underway to digitize herbarium specimens and archival botanical data for global scientific use.[32] By linking traditional use records with validated taxonomic and pharmacological data, these efforts provide a foundational infrastructure for algorithmic discovery and sustainable drug development. Simultaneously, advances in biotechnology – including synthetic biology, microbial fermentation systems, and plant cell culture – are overcoming longstanding challenges related to raw material variability, thereby enabling the scalable and controlled production of standardized bioactive compounds. Together, these innovations are transforming botanical dermatology into a more precise, reproducible, and accessible field rooted in both ethnomedical heritage and modern biomedical science.

As interest in natural treatments continues to grow, the dermatologic community must also confront the ethical and ecological responsibilities of botanical drug development. Ensuring the sustainability of plant sources, protecting endangered species, and fostering equitable benefit-sharing with Indigenous and local knowledge holders are not optional add-ons but essential components of a responsible future. Regenerative cultivation methods and transparent supply chains can help align botanical innovation with broader goals of environmental and social stewardship.

From ancient poultices to modern pharmacotherapy, the evolution of botanical dermatology reflects a profound continuity between tradition and science. Pharmacognosy has helped illuminate the molecular basis of time-honored remedies, while regulatory frameworks such as the FDA's Botanical Drug Pathway have begun to legitimize their place in evidence-based medicine. Although significant challenges remain – ranging from extract standardization to the economic disincentives of pursuing complex natural products – botanical dermatology is uniquely positioned to deliver treatments that are not only effective, but also culturally meaningful, environmentally conscious, and rooted in the healing potential of the natural world.

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