Unknown safety profile of ingredients in hair supplements: A call to action for improved patient safety

To the Editor: Hair loss is common and distressing to patients. A range of effective medical therapies exists for hair disorders, but predicting which patients will respond to treatment is difficult and medical therapy may fail altogether in some patients. Despite advances in the development of new therapies for hair loss, patients look to commercial dietary supplements as adjuvant therapy. The product labels for hair loss supplements often contain limited information. The composition of dietary supplements does not undergo United States Food and Drug Administration (FDA) testing before marketing. Instead, the FDA only investigates products in the postmarket period consequent to consumer complaints or adverse event reports.

Quality data, including randomized control trials examining dietary supplementation for hair growth in well-nourished adults, are limited, and significant concerns exist regarding supplement safety. A recent FDA safety communication reported that excess supplementation of biotin (vitamin B_7), a common ingredient in hair supplements, can interfere with biotinylated laboratory tests, such as cardiac troponin and thyroid panel assays, and has been implicated in at least 1 patient death, underscoring the potential severity of excess supplementation.[1] Apart from the potential safety risks and limited clinical data, use of some hair supplements may cause hair loss, and certain formulations may be unsafe for use during pregnancy.

Hair supplements with high doses of selenium and vitamin A derivatives are of specific concern, because chronic high-dose consumption is reported to cause hair loss (Table I).[1-5] Some commercial hair supplements contain unknown concentrations of saw palmetto extract, which inhibits 5α-reductase.[3] Drugs that inhibit 5α-reductase, including finasteride, have the potential to cause genitourinary defects in male fetuses and are contraindicated in pregnancy. There are no dietary guidelines about safe saw palmetto consumption in pregnancy. Unlike prescription 5α-reductase inhibitors, hair supplements with saw palmetto do not carry a pregnancy risk category X status. Failure of manufacturers to disclose product concentrations or include warnings about the use of a product with potentially teratogenic ingredients during pregnancy is a current barrier to safe consumption of hair supplements.

Sale of counterfeit supplements and supplements with unlisted ingredients poses risk. From 2007 to 2016, the FDA identified 776 dietary supplements with active drug ingredients wrongfully labeled and sold as supplements.[6] Manufacturers that withhold the concentration of ingredients or fail to disclose all ingredients in hair loss supplements for proprietary reasons are ultimately jeopardizing patient safety and potentially causing unintended harms, including hair loss. The FDA recommends patients review supplements with their physician for safety as part of their routine medical care; however, without full disclosure of supplement content and concentrations, physician evaluation of safe supplementation is ultimately impaired.

We call on manufacturers to readily disclose ingredients and concentrations in hair supplements. Furthermore, manufactures seeking to include ingredients with unknown safety profiles in supplements should first demonstrate safety and safe dosing. With adequate information, patients' questions can be appropriately addressed, and serious

Table I. Examples of select common ingredients in hair supplements and potential adverse effects of which clinicians should be aware

Ingredient	RDA*	UL†	Potential concerns
Biotin (B_7)	ND‡	ND‡	Interference with biotinylated laboratory testing including cardiac troponin and thyroid tests[1]
Vitamin E	15 mg	1000 mg	Bleeding disorders may worsen with vitamin E consumption[2]
Saw palmetto	ND‡	ND‡	Inhibition of 5α-reductase, concern for abnormal development of male genitalia[3]
Selenium	55 μg	400 μg	Hair and nail loss or brittleness at high doses.[4] Risk of gastrointestinal and neurologic disease at high doses[4]
Vitamin A	900 μg	3000 μg	Hair loss at high doses[5]

*Recommended daily allowance (*RDA*): Average daily intake that meets requirements for most people.
†Tolerable upper intake level (*UL*): Maximum daily amount unlikely to cause harm.
‡Not determinable (*ND*): Intake should be from diet only to prevent excess.

medication interactions can be identified in the clinical setting. Given the potential for significant risks, physicians should consider advising patients to avoid the use of hair supplements with unknown ingredients or concentrations.

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