



Primer on Products Liability Insurance for the Dietary Supplement Industry

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Prepared by
The American Herbal Products Association

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Introduction

Products & Completed Operations Liability insurance (referred to in this document as “products liability insurance”) is provided by insurance companies (hereinafter an “insurance company” or “insurer”) to a company (the “insured”) that manufactures and/or sells products to consumers. The insurer guarantees to defend and pay claims filed against the insured and arising out of the manufacture and/or sale of the insured’s products, as covered by the insuring contract (the “policy”).

Like all other consumer-goods industries, manufacturers and distributors of dietary supplements purchase products liability insurance in order to protect their businesses and assets against claims associated with their products. The purpose of this document is to provide some basic understanding of products liability insurance and the processes involved in purchasing this insurance by dietary supplement companies. This primer is organized in a question and answer format and addresses numerous issues that are commonly encountered in obtaining products liability insurance.

This document does not, however, serve as a substitute for a complete understanding of products liability insurance. It is limited in scope, and does not address in any detail other types of insurance that may be needed or desired by a business and its operations, even as it identifies a limited number of the many business coverage options available from insurance companies. In addition, this document is focused primarily on the purchase of products liability insurance, and so provides no guidance whatsoever on topics such as risk management and reduction or dealing with liability claims. This document and the information herein is used at the sole discretion of the company or individual who chooses to do so, and AHPA encourages all such users to seek advice from qualified experts to assist in liability insurance decisions.

Acknowledgements

This document was created through the joint efforts of AHPA staff, member company representatives, and key insurance advisors. Particular appreciation is due to Richard Griffin, Grifcon Enterprises, Inc. and manager of AHPA’s longstanding products liability insurance program, who contributed numerous hours and ideas to the structure and content of this work. A working group of AHPA members was organized at the request of Daniel Gagnon (Herbs, Etc., Inc.) under AHPA’s Finance & Governance Committee, chaired by Matt Redd (AM Todd Botanicals).

Products Liability Insurance for the Dietary Supplement Industry

What is products liability insurance?

Products liability insurance – or in the more complete term: products and completed operations insurance – is a form of insurance that is purchased to cover potential losses from allegations of harm from a company’s goods or operations. This type of insurance covers an insured company for defects in the products they manufacture or sell for others. Products liability insurance in the dietary supplements industry is usually maintained by manufacturers and marketers of supplement ingredients and finished products¹ to protect against claims.

What insurance “markets” provide products liability insurance?

Products liability insurance is written in both the “standard lines” insurance market and the “excess & special risk lines” (also known as “E&S lines” or “surplus lines”) insurance market.

The standard lines insurance market consists of insurance companies that insure businesses that do not present an actual or perceived amount of risk, such as conventional foods (both as raw commodities and finished goods) retail stores; public buildings; etc. Standard lines insurance companies customarily are “admitted insurers,” which means that they are licensed as an admitted insurance company in each state where they sell insurance.

The E&S lines insurance market specializes in business entities that present an actual or perceived higher than ordinary exposure to loss. E&S insurance companies are “non-admitted” insurers, as they are not licensed by the states in which they work, but are required to receive approval for all insurance products sold in each state. They must charge special fees in addition to direct premiums to cover state taxes and other statutory fees in each state where they write business.

It is generally the E&S market that insures the dietary supplement industry and its products, as well as other “life science” products, such as pharmaceutical drugs and medical devices, and virtually all products liability insurance policies insuring the dietary supplement and herbal industry in the United States are written through E&S insurance companies.

¹ Manufacturers of finished products maintain products liability insurance whether manufacturing their own products or engaged as contract manufacturers. Similarly, finished product marketers maintain insurance for the product they sell, whether or not they also manufacture these.

What “forms” of products liability insurance are offered to insured companies?

Products liability insurance is generally available for the dietary supplements industry only in a “claims made” form. Industries with lower perceived risks of liability may have the option of obtaining coverage on an “occurrence” form.

Under an occurrence form policy the insurer’s liability is for any event that occurs during the term of the insurance policy, even if a claim is made after the policy expires, while claims made insurance provides coverage only for claims made while an insurance policy is in effect. But the normal practice in the insurance industry is for each renewal of an uninterrupted claims made policy (i.e., with the same insurer) to provide retroactive coverage back to the inception date of the original policy. This practice provides some benefit to maintaining coverage with the same insurer for the long term and should be evaluated against any benefits associated with moving to another insurer. Also, an insured that maintains claims made coverage with one insurer and changes to a claims made policy with a different insurer may request a retroactive date to establish coverage for any claims that are made back to that retroactive date. However, if there is no retroactive date established in the new policy, coverage will only apply to claims made in the new policy year.

What insurance coverage is included in a basic products liability insurance policy, and what are the limits of coverage?

Products liability insurance coverage includes bodily injury and property damage to individuals as well as entities that are customers of the insured. Each policy sets limits to the insurer’s liability on behalf of the insured and each insured can ask for whatever limits are appropriate for its business. Products liability insurance limits are established on each of the following:

- Each occurrence for any one loss (e.g., \$1,000,000)
- General aggregate for all losses in a policy year (e.g., \$2,000,000)
- Deductible per claim (e.g., \$2,500)

Options to these limits can be requested on a products liability policy, for example for higher limits of liability or higher or lower deductibles, and requests for higher liability limits can be made any time during the policy year or upon renewal (note that no change in the deductible level can be made during the policy year). As should be obvious, increasing the limits on each occurrence or for the annual general aggregate will result in a higher premium cost. A premium cost can sometimes be reduced by increasing the deductible amount, for example, from \$2,500 to \$5,000 per claim, and this

option is currently offered by many insurers. Deductibles above \$5,000 are also sometimes available for companies with annual sales over \$50 million.

What options are commonly considered as add-ons to products liability insurance?

There are many options that a company may consider as add-ons to basic products liability insurance, and these should be determined based on each insured company's actual business operations. Some add-ons that are often considered include:

- Blanket additional insured vendors liability. This option extends the insured's products liability coverage to the companies that sell their products (e.g., retailers). This option is currently almost always already included in basic products liability insurance.
- Blanket additional insured for landlords, and sponsors of trade shows and exhibits. Similarly, extends coverage as stated: to landlords and to producers of trade events.
- Defense costs outside limits. Liability limits are generally described as having "defense costs inside limits," which means that any legal fees paid on behalf of the insured erode the policy's general aggregate, so that less remains to pay any actual judgment or settlement. The insured has an option to modify this, so that any defense costs are outside of a policy's limits and would be paid in addition to these limits.
- Worldwide products coverage. Ensures that products liability extends to covered products wherever they are sold in the world. Products liability insurance sold to U.S.-based companies covers only their products sold domestically unless worldwide coverage is specified.

Each of these options can be discussed with an insurance agent or broker to determine applicability to any specific insured company.

What other insurance coverage might be considered in addition to products liability coverage?

Products liability insurance may be purchased separately but is often obtained as part of a company's commercial general liability insurance (CGL) policy. A CGL policy itself covers bodily injury, property damage, personal and advertising injury, medical payments, and certain supplemental payments specified in the policy. Companies may also consider insurance for numerous other business risks, including:

- Commercial Automobile Coverage. All owned & hired autos and fleets of autos.

- Commercial Property Coverage. Property owned or leased by the insured for business pursuits.
- Commercial Inland Marine Coverage. Towed vehicles and machinery, off road equipment vehicles, signs on and off premises.
- Commercial Crime. Burglary, safe burglary, robbery, employee theft, forgery.
- Farm. Dwellings, appurtenant structures (i.e., barns, sheds, and other farm buildings), household personal property, and loss of use.
- Pollution Liability. Bodily injury and property damage arising out of pollution losses from insured work.
- Employment-Related Practices Liability Coverage. Business losses arising from wrongful termination, discrimination, sexual harassment and other employment related practices.
- Liquor Liability Coverage. Business liability for manufacturers, distributors, sales, serving, or furnishing alcoholic beverages.
- Professional Liability Coverage. Business liability arising out of rendering or failing to render services of a professional nature (applicable, for example, for a health professional who formulates products for a brand)
- Boiler & Machinery /Equipment Breakdown. Covers insured's losses out of the use of steam boilers or other machinery or equipment scheduled on the policy.
- Products Recall. Covers the insured expenses related to recall of covered products, subject to certain specified limitations.

Dietary supplement manufacturers may need insurance coverage for any of the above, depending on their particular business operations, and each insured can discuss with its agent or broker the applicability of these coverages to their specific business. Also, the list above is not exhaustive and some insureds may need additional insurance coverage or special coverages not included in any of the above (referred to in the insurance industry as "manuscript endorsements"). It is a good practice to review an insured's exposures at least annually with an insurance professional to make certain every exposure is covered.

What insurance professionals are involved in selling products liability insurance?

The term "insurance professional" covers a variety of individuals who are licensed in the state in which they reside and maintain non-resident licenses in each other state in which they conduct business. Licensees include, among others, life and disability analysts, public adjusters, administrators, and insurance consultants.

In the course of purchasing products liability insurance a company will come into contact with an individual who will provide one or more bids for policies designed to meet the specific company's insurance needs. The insurance industry refers to this person as an "insurance producer," and an insured company in the market for products liability insurance will usually encounter either an insurance "agent" or a "broker,"² or an individual working as both as an agent and a broker, and referred to as an "agent/broker."

An insurance agent is a person authorized by and on behalf of an individual insurer to represent them to the public and to sell insurance.³ An insurance agent may be either an exclusive agent, representing only one insurer, or an independent agent, representing one or more insurers. Admitted (standard market) insurance companies appoint insurance agents who sell their products, whereas insurers in the E&S market work only with insurance brokers. Agents are usually compensated by insurance companies with commissions, calculated from the amounts of premiums on any sales they transact.

An insurance broker is a person who transacts insurance business with, but not on behalf of, an insurance company. Brokers are not appointed by insurance companies; instead, they represent the insurance buyer. Brokers receive commissioned compensation from insurers, again related to premium amounts, and may also charge fees to the insured for additional services provided. Such fees cannot be charged, however, except through a written agreement with the insured for a special service, such as risk management, for extra time involved, or in lieu of a commission received from the insurance company.

As already observed, nearly all products liability insurance policies insuring the dietary supplements industry are currently written through the E&S insurance market. Since these do not use agents, dietary supplement companies generally deal with a broker with regard to products liability insurance, and their broker submits products liability insurance applications to available E&S insurance companies to get quotes for the insured.

² Licensure also exists for "life agents," who are authorized by and on behalf of a life or disability insurer to transact life and/or disability insurance; since this document is concerned only with products liability insurance, no further discussion of life agents is included here. Also, many states formerly licensed insurance "solicitors," employed to aid an agent or broker, and whose actions are the responsibility of the agent or broker. Few states still offer licensure for insurance solicitors so they are now only rarely encountered.

³ Insurance agents are also authorized to provide disability insurance and a combination of Workers Compensation and health insurance called 24-Hour Coverage. These additional authorities, however, are not relevant to the subject matter of this document.

As also already noted, some insurance professionals are licensed as both an agent and a broker simultaneously, and operate as agent/brokers. If the insurance company the agent is appointed by cannot provide the coverage necessary to meet the needs of the insured they may use their broker's license to secure coverage through other standard insurance companies or through E&S lines carriers.

There are also wholesale brokers that only transact business with E&S lines insurance companies. These "wholesale E&S brokers" do not deal directly with the prospective insured, but instead serve as an intermediary between insurance brokers, acting on behalf of these prospective insured, and E&S insurance companies.

What is a "broker of record" and what is a "broker of record letter"?

A broker of record is the insurance agent or broker chosen by the insured to market, quote and service their insurance. The insured always has the right to choose the specific licensed insurance professional with whom they prefer to work at any time. Any insured company that enters into a written and exclusive agreement with a specific agent or broker may wish to ensure that such agreement can be cancelled at any time and with immediate effect at its sole discretion.

Should the insured decide to change their agent or broker, the standard practice is to submit a broker of record letter to their insurer to provide notice of this change. Insurers are required to wait for 10 days before actually making the notified change and it often happens that the incumbent broker convinces the insured to rescind the broker of record letter. If the letter is not rescinded, however, servicing of insurance policies is transferred from the incumbent broker to the new broker. Also, once a broker of record letter is signed it effectively blocks all other agents or brokers from getting a quote from an insurance company that has been queried by the broker of record. Each insured should determine whether submission of a broker of record letter serves its interest, as use of this process is not in and of itself either "good" or "bad," but does have the consequences described here.

What is an "insurance binder" and who is authorized to provide one?

An insurance binder is an oral or written statement that provides immediate, temporary insurance protection for a specified period until a policy is issued or denied by the insurer.

An insurance agent, as a direct representative of the insurer, has the authority to bind coverage for the insured. On the other hand, neither insurance brokers nor E&S lines brokers can bind coverage until the insuring company itself delivers a binder. Dietary

supplement companies purchasing products liability insurance through the E&S lines market do not receive their binders directly from the insurer, but instead from their individual insurance broker, who in turn receives the binder from an E&S insurance wholesale broker.

How is the cost of products liability insurance determined?

The cost for a products liability insurance premium is computed through the use of established rating processes:

- Judgment rating. The products liability insurance premium is determined solely by considering an individual insured's risk. No book or tables are used, and premiums are established through careful judgment by the underwriters of each individual insurer of the perceived risk presented by each individual insured company.
- Manual rating or class rating. A company's rates are obtained by consulting a manual in which rates are arranged by various categories or classes of products in each of the specific states in which the insured's products are sold. If the insured sells in multiple states a composite rate is determined which is charged for all sales within the United States and its Territories. (As noted above, coverage for sales outside of the United States can be obtained with optional worldwide products coverage, and such international sales should not affect the calculation of the premium cost for domestic sales.) The agent or underwriter classifies the risk according to defined criteria and then looks up the appropriate rate. The printed rate, which is a rate per unit of insurance, is then multiplied by the number of units of insurance being purchased.
- Merit rating. This rating starts with manual or class rates, which are then modified to reflect any unique characteristics of the risk that are not reflected in the manual rate. There are three forms of merit rating:
 - Experience rating is a form of merit rating based on the insured's loss experience (the dollars paid out in claims versus the premium received) over some period of time, generally the three years prior to the current policy year. When past loss experience is poorer than the average loss experience expected for this class of insured, the insured will pay more than the manual premium. When the insured's past loss experience is better than average, the insured may pay less than the manual premium.
 - Retrospective rating, which bases the insured's premium on losses incurred during the policy period.

- Schedule rating, which applies a system of debits or credits to reflect characteristics of a particular insured.

The norm today in the U.S. dietary supplements industry is for an insured to be rated by judgment rating, and the premium cost is calculated as the product of the judgment rate per \$1,000 multiplied by the estimated annual gross sales.

What is the minimum premium cost for products liability insurance for a small company?

The lowest premium cost for basic products liability insurance with standard limits is determined by each individual insurance company. The lowest cost currently available for dietary supplement companies is approximately \$3,500, though it is not known whether this cost will be maintained in the short- or long-term future. Also, not all insurers offer this same minimum price and there are insurers that will not do business with any company with a premium below \$25,000, or even \$50,000.

Are product labels required to be submitted to obtain products liability insurance?

Each of the several insurance companies that provide products liability insurance to the supplement industry has its own requirements with regard to submission of labels or other information that may be used to identify which products and operations are covered under any given insurance policy.

Some insurers specifically require that actual or facsimile product labels, or product lists that include identification of all contained ingredients, be submitted by each potential insured. These insurance companies review and/or maintain records of the submitted labels or lists under the belief that they are providing better protection to the insured by clarifying, at the time that coverage comes into effect, exactly what products are covered. In this way they are preventing any later decision, for example after a claim is made, that any of the insured's products are not included in a policy's coverage. Some insured companies also believe that this extra step provides greater clarity as to the scope of insured coverage and thereby reduces their liability and risk. This same caution may also suggest that labels be submitted for any products newly introduced during the coverage period, though no insurers are currently known to require submission of such new product labels.

Other insurance companies do not require all covered products and their ingredients to be identified with either labels or specific product lists. These companies appear to be more willing to accept that the insurer will pay any eventual claims even if there are some questions as to the specifically identified covered goods.

Any dietary supplement manufacturer or marketer seeking products liability insurance for which this particular issue may be a deciding factor should ask its insurance broker to clarify this point well in advance of a policy purchase or renewal.

How far prior to the expiration of a current policy should the insured company expect to receive quotes for renewal?

There is no set time required to renew an insurance policy to prevent having coverage expire. It is generally a good practice to have a quote for renewal at least two weeks before a current policy expires, though a longer time may be appropriate if the insured intends any significant changes to their insurance coverage. A renewing insured should instruct its agent or broker to provide all information related to renewal at a time that serves the needs of the insured and that provides sufficient time to make thoughtful decisions.

Why are some dietary ingredients excluded in policies offered by some insurance companies, and how do insurers determine which ingredients should be excluded?

As is obvious, insurance companies must limit their own liability by evaluating the risks involved when providing products liability insurance. Some insurers therefore exclude insurance coverage on ingredients that they identify as presenting an unreasonable risk of liability.

Just how an insurer decides which dietary ingredients (including herbal ingredients) should be excluded from their policies is not generally disclosed. In addition, there is not consistency among the various insurers, so that one insurance company may exclude an ingredient that others do not. What has become evident, however, is that many herb exclusions are based on misinformation and a lack of expertise on herbal safety. Over the past several years AHPA has communicated to one or another of the insurance companies to seek removal of exclusions and has provided accurate safety information to support these requests. While there have been occasional agreements by individual insurers to remove an exclusion in its policies, there has been little overall success to date in reducing the number or prevalence of unsubstantiated exclusions. AHPA has established a working group to address this matter.

Can insurance be obtained for products that contain excluded ingredients?

Many of the insurance companies that provide products liability insurance in the supplement industry are willing to remove herbal (and other) exclusions with an “endorsement.” What this means is that the insured can request that any exclusions be removed from its policy, so that products containing excluded ingredients will be

provided insurance coverage. It is not uncommon for insurers to agree to such requests, either with or without an additional fee. The insured will then receive a written amendment to their policy to record that identified products that contain the excluded ingredients are, in fact, covered. This process may need to be repeated each year upon renewal of an insurance policy.

What is the role of State regulators in the insurance industry?

Regulation of the insurance industry for the most part is overseen by individual states. Each state enacts laws, codifies rules and regulations for the various types of insurance companies (usually the “insurance code”), and maintains some sort of insurance agency (a “Department of Insurance”) under the direction of an “Insurance Commissioner.” In some states the governor appoints the commissioner and in other states the Insurance Commissioner is elected by the voters. States’ insurance codes give the Commissioner numerous powers and duties including:

- Protecting the consumer in the insurance industry.
- Examination and approval of insurers.
- Conducting hearings for violation and setting fines and penalties.
- Screening of applicants for licensing.
- Investigating non-licensees performing activities for which a license is required.
- Conducting financial examinations as a review of the insurer’s transactions, records and assets.
- Market Conduct Examinations which monitor compliance audits to affirm the accuracy and conduct overall.

A major function of each state’s Department of Insurance is to establish licensing requirements and procedures for insurers and their representatives. Most states require a certain amount of pre-licensing education and the passing of an examination before issuing licenses to prospective agents and brokers. Once licensed, the agent or broker must complete state-approved continuing education courses, usually on an annual or bi-annual basis. A minimum level of education in the field is needed and most professional insurance agents and brokers strive to improve beyond minimum requirements. In addition many colleges and universities offer undergraduate majors in insurance and graduate degrees at the masters and doctorate level.

What is the AHPA Insurance Program?

The American Herbal Products Association has maintained an active role for over a decade in directing its members to qualified experts in the insurance industry. AHPA has, in cooperation with Grifcon Enterprises, Inc. and RT Specialty of Illinois, LLC (RTS), established the AHPA Founders Dietary Supplements Liability Insurance Program (the AHPA Program). RTS, an E&S insurance wholesale broker, is the exclusive managing general agent for this program and has all normal responsibilities of the managing general agent for an insurance program. Dick Griffin of Grifcon is the program manager, and is responsible for maintaining communications and for providing direct service to companies that participate in the program, as requested and as appropriate. The AHPA Program is specifically designed to allow participants to maintain their current insurance agent or broker relationship while gaining access to the expertise and experience represented by these program partners.

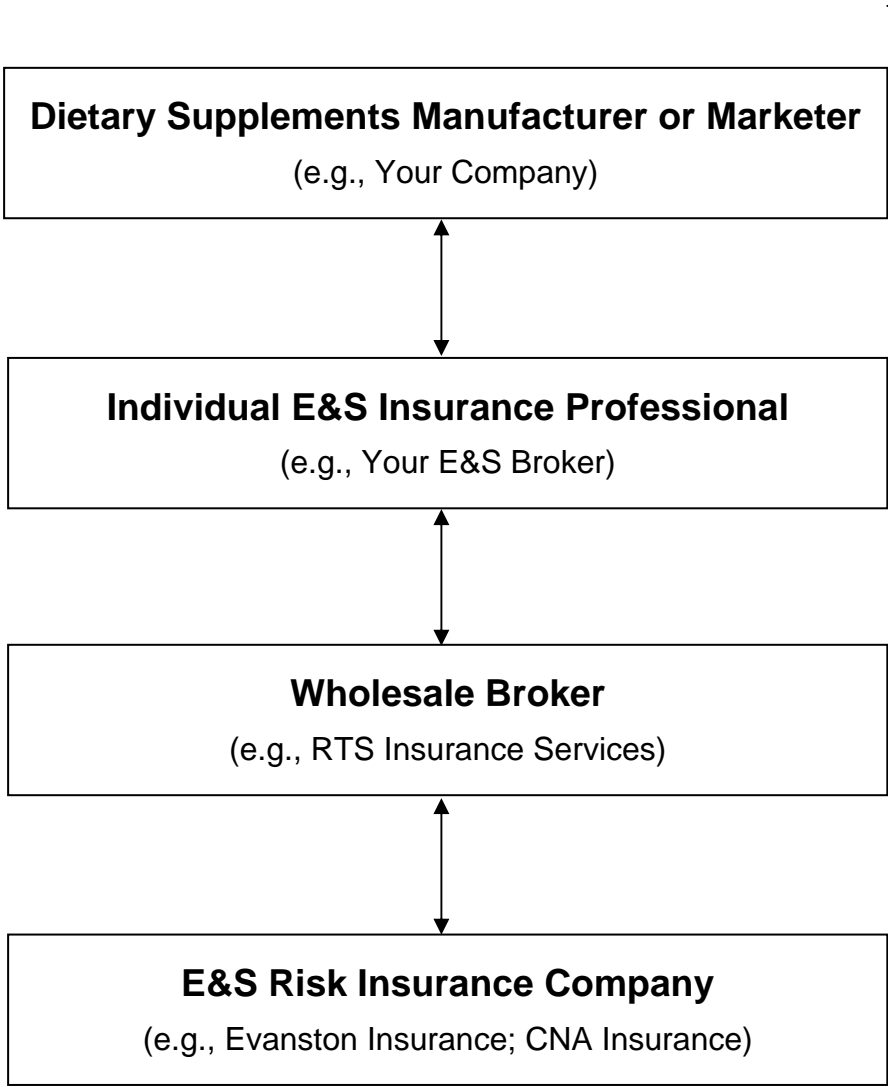
AHPA is paid a royalty calculated from the premiums of any insurance sold under the AHPA Program. By purchasing products liability insurance through the AHPA Program, member companies provide direct financial support to AHPA. AHPA's royalty is paid from the normal commissions received by Grifcon and RTS, so there is no increased cost to offset this royalty.

To participate in this program, request that your policy - regardless of the broker or agent you use and the specific insurer that provides the policy - be placed through RT Specialty of Illinois Insurance Services. An application to provide to your broker or agent can be found [HERE](#).

RTS and Grifcon have compiled a record of insurance loss history for the supplements industry. Losses during the last five years have been very low in both frequency and size, providing convincing evidence that the dietary supplement industry is an excellent opportunity for insurers. Based on this information, RTS and Grifcon have secured an exclusive insurance arrangement with an A.M. Best Rated, A+ XV insurance carrier specific to the needs of the dietary supplement industry and is now introducing this new program.

For information about the AHPA Program or for any products liability insurance questions, contact Dick Griffin (916-434-8874; dick@dickgriffin.com) or AHPA's Chief Operations Officer, Devon Powell (301-588-1171 x102; dpowell@ahpa.org).

Structure of the E&S Products Liability Insurance Market for the Dietary Supplement Industry



CONTACT

RICHARD GRIFFIN
Grifcon Enterprises, Inc.
916-434-8874;
dick@dickgriffin.com

PROGRAM MANAGER
for the AHPA Dietary
Supplements Liability
Insurance Program

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