SK life science a subsidiary of SK biopharmaceuticals	Policy Title:	Healthcare Professional Interactions
	Policy Number:	COMP-POL-1001

HEALTHCARE PROFESSIONAL INTERACTIONS POLICY

I. PURPOSE

This Policy describes the rules governing interactions between SK Life Science, Inc. (SKLSI or the Company) Associates and Healthcare Professionals (HCPs).

This Policy reflects SKLSI's commitment to ensure that all business interactions with HCPs are consistent with applicable laws and codes including, but not limited to, the Anti-Kickback Statute (AKS), the Federal Food, Drug, and Cosmetic Act (FDCA), and the False Claims Act (FCA). SKLSI also seeks to comply with the ethical standards outlined in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with HCPs.

II. SCOPE

This Policy applies to all SKLSI Associates and their interactions with HCPs in the United States (U.S.), as well as any interactions with HCPs that are licensed to practice in the U.S., regardless of where the interaction occurs.

This Policy does not govern:

- Clinical trials activity;
- Fee-for-Service Arrangements or the engagement of HCPs as consultants; refer to the *Fee-for-Service Arrangements Policy* for more information on this topic.

III. ABBREVIATIONS AND DEFINITIONS

ABBREVIATIONS	
Abbreviation	**Term**
AKS	Anti-Kickback Statute
BNA	Business Needs Assessment
CRC	Copy Review Committee
CRM	Customer Relationship Management
FCA	False Claims Act
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FMV	Fair Market Value
HCO	Healthcare Organizations
HCP	Healthcare Professional
HEI	Healthcare Economic Information
HEOR	Healthcare Economics and Outcomes Research
MCOs	Medical Care Organizations
MIRF	Medical Information Request Form
MRC	Medical Review Committee
PhRMA	Pharmaceutical Research and Manufacturers of America
PI	Package Insert
PMRC	Promotional Materials Review Committee
SKLSI	SK Life Science, Inc

DEFINITIONS	
Term	**Definition**
Adverse Event	Any unfavorable, or unintended sign, symptom or disease, or change of an existing condition, which occurs during or after treatment with a drug or biologic product in humans, whether or not considered drug related.
Conference/Convention	A meeting during which those involved in the healthcare sector gather to discuss medical advances, share research in therapeutic specialties, and promote healthcare products and services through Exhibit marketing. May be centered on members affiliated with a particular society, profession, or specialty in the field of healthcare.
Copy Review Committee	The committee responsible for reviewing and approving certain external and internal communications about SKLSI products and

DEFINITIONS	
Term	**Definition**
	services, or relevant disease areas of interest, including Promotional Materials Review Committee and Medical Review Committee.
Educational Item	An item designed to advance disease or treatment education of an HCP or patient.
Exhibit	A booth, panel, table-top poster, or any other display at a program or event sponsored by a third-party organization.
Fair Balance	According to the FDA, the standard by which the content and presentation of a drug's most important risks are made reasonably similar to the content and presentation of its benefits.
Fair Market Value (FMV)	The price agreed upon between a reasonable willing buyer and a reasonable willing seller (or service provider) and which is comparable to prices ordinarily paid for the service in that particular location by parties in arm's-length transactions (i.e., transactions between independent and unrelated parties).
Field-Based Commercial Associates	Commercial personnel that are responsible for in-person or virtual promotional activities with customers (such as HCPs, payers, etc.) and include Field Sales (e.g., NAAs, NAMs, etc.) and Market Access (i.e., KAMs) professionals.
Healthcare Professional (HCP)	Any individual or entity that can, in their professional capacity, influence the use, purchase, prescription, or recommendation of SKLSI products, or affect the formulary or other preferential or qualifying status of SKLSI products, including but not limited to, doctors, nurses, pharmacists, physician assistants, teaching institutions, formulary committee members, and clinical trial investigators.
Healthcare Organization	Any organization or institution that provides healthcare services to patients. Examples include academic medical centers, hospitals, and clinics.
Meal	Any portion of food or drink, including breakfast, lunch, snacks, or dinner.

DEFINITIONS	
Term	**Definition**
Off-Label Information	Information about a SKLSI product inconsistent with the use(s) described in the FDA-approved product labeling.
Package Insert	A pamphlet that accompanies drugs containing details and directions HCPs need to properly prescribe the drug. It is also the basis for how the drug company can advertise its drug.
Product Quality Complaint	Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug after it is released for distribution (e.g., broken tables, missing label).
Sample	A unit of drug not intended for sale, but rather intended to promote the sale of the drug by providing patients access without charge.
Scientific Exchange	The communication of non-promotional information that is truthful, accurate, non-misleading, and intended to advance medical or scientific knowledge and improve public health.
SKLSI Associates	All Employees and officers of SKLSI, as well as any Third Party who is or may be authorized by SKLSI to represent or act on the behalf of SKLSI.
Speaker Program	Live or virtual programs designed to provide scientific and educational information to a group of invited HCPs regarding the use of SKLSI products, disease areas of interest to SKLSI, or other relevant healthcare topics.
Third-Party Personnel	All individuals who provide services to or on behalf of SKLSI. Third-Party Personnel include agency temporary workers, independent contractors, consultants, vendors, and contract workers.
Vouchers	Certificates SKLSI provides to HCPs for Patients that are redeemed at a pharmacy for a free trial or reduced out-of-pocket cost for the prescription of an SKLSI product.

IV. POLICY

A. General Principles

As outlined in the SKLSI Code of Conduct and in compliance with applicable laws and regulations, SKLSI expects Associates to conduct business operations in an ethical and compliant manner. Such conduct must align with the following principles:

- Discussions about SKLSI products and services must be truthful, accurate and not misleading, and must not disparage competitor products and services.
- SKLSI Associates must never provide medical advice.
- SKLSI Associates may provide accurate coverage and reimbursement information only for approved uses of SKLSI products.
- SKLSI Associates must respect patient privacy and the need for confidentiality in health records as required by applicable law.

Interactions with government employees and government officials who meet the definition of HCP may be subject to additional restrictions; SKLSI Associates who interact with government officials should refer to the *Government Official Interactions Policy*.

B. Promotional Interactions with HCPs

Promotional interactions with HCPs provide valuable, approved information to HCPs about SKLSI's products, based on bona fide business needs, with the intent of influencing an HCP's decision to prescribe, purchase, recommend, or encourage the use of SKLSI products. Promotional statements may communicate approved disease state, indication, patient population, dosing, duration of use, stage of the disease, and intended outcome.

SKLSI Associates must ensure that all promotional activities are conducted in an ethical manner with HCPs and external parties. Communications about SKLSI products must:

- Use only PMRC-approved materials
- Be truthful, accurate, and not misleading;
- Be balanced as to discussions of benefits and risks;
- Be adequately substantiated (e.g., by clinical data); and
- Be consistent with approved product labeling and the scope of relevant U.S. Food and Drug Administration (FDA) approvals (in the case of FDA-regulated medical products).

SKLSI Associates are not permitted to:

- Make claims, statements, representations, or omissions that are unsupported, are inaccurate, false, or misleading, are lacking in Fair Balance;
- Promote unapproved products or unapproved uses of approved products;
- Engage in unapproved discussions of the comparative effectiveness or safety of a competitor's product;
- Use or distribute promotional or other materials that have not been approved by the appropriate SKLSI CRC (e.g., no "homemade sales aids");
- Use or distribute promotional or other materials that have been altered after CRC approval, or are expired/retired; or
- Use training materials or any other background materials not authorized for use in interaction with HCPs, HCOs, and other relevant audiences.

1. Sales Professional Interactions with HCPs

Sales professionals engage with HCPs to provide information about SKLSI approved products, relevant disease areas, and related services. During these interactions, SKLSI Associates must provide the following information as appropriate for the interaction:

- Approved indications and dosing
- Relevant safety information, including appropriate warnings, contraindications, precautions, and adverse reactions
- A copy of the current Package Insert (PI)
- As required by state or local law, pricing disclosures

2. Other Commercial Staff

Other Commercial Staff, including Market Access personnel, may engage with HCPs, Healthcare Organizations (HCOs), Managed Care Organizations (MCOs), formulary committees, payers, and other relevant decision makers to provide economic and product information or disease state information that is not drug-specific.

Proactive interactions with payers, formulary committees, or similar entities must only relate to the approved uses of SKLSI products.

In interactions between the Healthcare Economics and Outcomes Research (HEOR) team and payers, formulary committees, or similar entities, SKLSI Associates may provide healthcare economic information (HEI) not contained in the labeling of an FDA-approved SKLSI product if the HEI:

- Is based on competent and reliable scientific evidence;

- Is accurate, truthful, and not misleading;
- Is directly related to the FDA-approved indication;
- Includes a conspicuous and prominent statement describing the material differences from the FDA-approved product labeling; and
- Is inclusive of appropriate context.

3. Unsolicited Requests for Off-Label Information

At times, SKLSI Associates may receive unsolicited questions about unapproved uses of SKLSI products. Such requests may relate to information concerning an approved product or a product in development that is (i) not consistent with that product's labeling, (ii) describes an unapproved use, or (iii) is not contained in materials approved by the CRC.

Medical Affairs is responsible for receiving, documenting, and responding to all unsolicited questions or requests related to unapproved uses of SKLSI products. All other SKLSI Associates who receive such questions must refer the request to Medical Affairs in writing (e.g., via a Medical Information Request Form [MIRF]).

For requests submitted via MIRF, the completed form must be submitted electronically via the Customer Relationship Management (CRM) system. In the event that CRM submission is unavailable, a hard copy of the MIRF must be sent to medicalinfo@sklsi.com.

The restrictions and process in this Section 3 do not apply to interactions between Medical Affairs, HEOR or Market Access teams and payers, formulary committees, or similar entities using CRC-approved materials as described above in Section 2.

4. Promotional Materials

As outlined in the SKLSI *Copy Review Committee SOP*, only materials approved by the PMRC may be used in promotional discussions.

Claims about competitor products may only be discussed if they are included in PMRC-approved materials intended for use with HCPs.

HEI materials may only be used by approved personnel, such as the HEOR and Market Access groups.

If the HEI deals with an unapproved product, or an unapproved use of an approved product, the material must include:

- A clear, conspicuous and prominent statement that the product is under investigation and that its safety or effectiveness has not been established (or differences from the approved product label), and
- Information related to the stage of product development.

5. Samples and Vouchers

SKLSI Associates who have been appropriately trained may provide Samples and/or Vouchers to licensed HCPs eligible to receive such items only as described in SKLSI *Prescription Drug Samples* and *Prescription Drug Vouchers Policies*. Distribution of Samples and Vouchers must be accurately documented in the appropriate system of record.

6. Exhibits

During interactions with HCPs at Conventions, Conferences, or local Exhibits, SKLSI Associates must abide by the requirements outlined in this Policy regarding approved materials, responding to unsolicited requests for information, and reporting Adverse Events. SKLSI Associates must also abide by the requirements of the Convention/Conference or Exhibit space.

At some Conventions, SKLSI may have the opportunity to engage in both promotional and non-promotional interactions with HCPs and Customers. These interactions must occur at separate display areas. SKLSI requires a clear differentiation between promotional and medical Exhibits, such as placing the displays at separate locations within the exhibit hall or clearly delineating the medical section from the promotional section by placing a physical barrier between the two.

Promotional Exhibits must display only approved product information consistent with the approved product label. Medical Exhibits may display information about SKLSI's investigational pipeline as appropriate for the Exhibit.

All Exhibit displays and materials must be reviewed and approved by the SKLSI CRC.

SKLSI Associates may staff an Exhibit booth only for their assigned function (e.g., only Commercial employees may staff promotional Exhibits and may not staff non-promotional Exhibits; Medical personnel are prohibited from staffing promotional Exhibits but may staff non-promotional exhibit spaces). Prior to staffing an Exhibit booth, Associates must complete the appropriate training.

7. Interactions with HCPs from Outside the U.S.

While SKLSI Associates may interact with HCPs from countries or jurisdictions outside of the U.S., either during congresses held domestically or while attending meetings outside their respective region, they should generally avoid promoting SKLSI products to such HCPs.

SKLSI Associates should be aware that SKLSI products will have different regulatory statuses and labels in different countries. The pertinent status or label is based on the country where the HCP is licensed, not the location of SKLSI Associates. When speaking with HCPs from a country in which SKLSI products are not approved, SKLSI Associates must state that the product is not approved in that country, specify the country where the product and label are approved, and make clear that the information provided is based on the approved label from the applicable country.

C. Non-Promotional Communications to HCPs

Medical Affairs is primarily responsible for all external non-promotional communications, activities, and engagements with medical and scientific individuals and entities, and for communicating accurate, fair-balanced, and timely scientific information about SKLSI products in all interactions.

Any proactive communications by Medical Affairs personnel related to SKLSI products and disease states must be truthful, accurate, and non-misleading, intended to advance medical or scientific knowledge and improve public health, and non-promotional in purpose and tone.

At times, Medical Affairs may provide scientific information that is outside the scope of an approved product label or scientific information about a product not yet approved by FDA. In such circumstances, Medical Affairs interactions and exchanges with HCPs must be non-promotional in nature and design, as well as limited to what is considered Scientific Exchange. Within the context of Scientific Exchange, communications must be truthful, accurate, and non-misleading. Any activity or communication that involves or is in any way related to promotion of a SKLSI product is outside of the scope of Scientific Exchange.

Certain Medical Affairs materials may require review and approval by the Medical Review Committee prior to use in interactions with HCPs.

For additional information about Medical Affairs activities, refer to the *Medical Affairs Activities Policy*.

D. Meals Provided to HCPs

SKLSI Associates may provide occasional modest Meals for HCPs provided the Meals are:

- Incidental to the bona fide presentation of scientific, educational, or business information;
- Provided in a manner and location conducive to a business discussion;
- Documented appropriately and supported by the required documentation (e.g., sign-in sheets, itemized receipts) in accordance with the requirements outlined in the SKLSI *Transparency Policy*; and
- Modest in value as judged by local standards.

The following activities are strictly prohibited:

- "Dine and Dash" (e.g., delivering or dropping off food)
- Cash or cash equivalents (e.g., gift or credit cards)
- A spouse or guest attendee (unless otherwise independently qualified)

Additional guidelines for providing Meals to HCPs can be found in the Providing Items of Value to Healthcare Professionals Procedural Guide.

1. In-Office Informational Presentations

Authorized SKLSI Associates may provide occasional Meals to HCPs as long as all of the following conditions are met:

- The Meal is provided in conjunction with a bona fide, CRC-approved informational presentation to the HCPs who partake in the Meal.
- The informational presentation provides scientific or educational value, such as discussion of products, disease states relevant to SKLSI products, or other legitimate business discussions.
- An SKLSI Associate is present during the Meal.
- The Meal is provided to each HCP only on an occasional basis and does not distract from or overshadow the focus of the presentation.
- The Meal is provided onsite at an HCP office, clinic, or hospital.
- The Meal is modest and complies with SKLSI's meal spend guidelines as outlined in the *Meals & Items of Value Procedural Guide*.

2. Sign-in Sheets

When Meals are provided to HCPs, field-based personnel must:

- Use the approved SKLSI sign-in sheet to capture all attendees participating in the Meal;

- Document attendees in SKLSI systems (e.g., Concur) in accordance with that activity's requirements; and
- Attach the completed sign-in sheet to the appropriate expense report.

3. Out-of-Office Meetings

Headquarters-based personnel, such as Marketing, Medical Affairs, and Clinical Development, may occasionally provide Meals to HCPs outside of an HCP office, clinic, or hospital setting. The purpose of these meetings must be to share relevant non-promotional scientific information or to achieve specific business-related objectives not related to the promotion of SKLSI products to HCPs. The Meal must be incidental to the primary purpose of the meeting.

Occasionally, SKLSI Sales leadership may interact with HCPs in a business setting, such as a Conference. In those instances, an out-of-office Meal is permitted under the following conditions:

- The meeting is not conducted in order to specifically promote SKLSI products or to reward or incentivize the HCP for past or future prescriptions of SKLSI products.
- The Meal is modest and complies with SKLSI's meal spend guidelines as outlined in the *Meals & Items of Value Procedural Guide.*

Out-of-office Meals may occur only in venues that are modest and conducive and incidental to a business presentation. Luxury venues or venues that include entertainment or recreational activities (e.g., casino, sports, theatre, bars) are strictly prohibited.

Field-Based Commercial Associates and their managers are not permitted to engage in out-of-office Meals with HCPs.

E. Speaker Programs

SKLSI may sponsor and participate in Speaker Programs to educate and inform HCPs about the benefits, risks, and appropriate uses of SKLSI products and relevant disease states.

SKLSI engages speakers based on their medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills. Speaker compensation is based on SKLSI's established Fair Market Value rates, as outlined in the *Fee-for-Service Arrangements Policy*.

All speakers must complete speaker training prior to participation in speaker bureau programs. Speaker Programs must present information consistent with the FDA-approved product labeling. Presentations must provide Fair Balance and include relevant safety information, warnings or precautions, side effects, or other disclosures.

Speaker Programs must not promote any unapproved uses of SKLSI products, and speakers must not solicit questions regarding unapproved uses of SKLSI products.

All Speaker Program materials must be CRC-approved and clearly identify SKLSI as the presentation sponsor.

For additional details about requirements related to Speaker Programs, refer to the following SKLSI documents:

- *Fee-for-Service Arrangements Policy*
- *Speaker Program Management Best Practices (Speaker Bureau Business Rules)*
- *Field Sales Guide and/or Field Medical Guide*
- *Speaker Selection Training and Compensation Procedural Guide*

1. Legitimate Business Need

All arrangements with HCPs to serve as speakers must fulfill a legitimate business need and otherwise comply with all requirements listed in this policy.

SKLSI Marketing is responsible for creating an annual Speaker Program plan that includes the proposed number of Speaker Programs and the size and composition of the Speaker Bureau, which should be directly proportional to the annual number of planned Speaker Programs.

2. Speaker Selection

SKLSI's Commercial division (including Sales and Marketing) is responsible for creating an annual Speaker Program plan, which includes the number of speakers needed and the number of programs planned. The SKLSI Speaker Selection Committee retains primary responsibility for approving HCPs as speakers.

Sales and Marketing may provide relevant feedback on speaker performance, express a business need for speakers within a given territory,

and refer unsolicited inquiries from HCPs who want to become speakers to the SKLSI Speaker Selection Committee.

Sales and Marketing personnel may not proactively nominate an HCP for use as a speaker or encourage an HCP to request to become a speaker. However, they may escalate an unsolicited HCP request to become a speaker via the appropriate Speaker selection process as outlined in the *Speaker Programs: Speaker Selection, Training, and Compensation Procedural Guide*.

Identified HCPs must be evaluated by the SKLSI Speaker Selection Committee in alignment with the principles outlined in the *Fee-for-Service Arrangements Policy*. Speaker Selection Committee membership may include representation from Legal, Compliance, and Medical Affairs. Commercial personnel may not participate in the evaluation process or otherwise influence speaker selection.

Identification and selection of an HCP must not be intended to influence or reward for the purchase, prescription, or recommendation of products. HCPs must not be engaged as speakers in an effort to build relationships with or gain access to them.

3. Speaker Training Requirements

Prior to allowing speakers to conduct a Speaker Program, SKLSI must train speakers regarding:

- Approved scientific or medical aspects of SKLSI products needed for the speaking engagement;
- Approved information regarding reimbursement (if applicable);
- The appropriate response to unsolicited requests for medical information, as outlined in the SKLSI *Field Sales Guide*;
- FDA regulations and compliance this policy;
- The content of all materials used or made available at a speaker training meeting must be CRC-approved. Speakers must be instructed not to edit, add to, or remove slides from approved speaker presentation slide decks.

Speaker training sessions must be held in venues that are appropriate and conducive to informational communication and training about medical information. Luxury venues or venues that include entertainment or recreational activities (e.g., casino, sports, theatre, bars, theme parks) are strictly prohibited.

The speaker must disclose the following information at the start of each program:

- The program is brought to the audience and controlled by SKLSI;
- The speaker is being compensated by SKLSI in connection with the program and if they have other relationships with SKLSI or its affiliates, disclose those relationships or support;
- The speaker is presenting on behalf of SKLSI and must present information in compliance with FDA requirements applicable to SKLSI; and
- The program is not certified for continuing medical education.

4. General Requirements for Programs

SKLSI field-based personnel may host or attend promotional Speaker Programs to assist with logistics and ensure compliance in accordance with the following requirements:

- Program hosts will schedule promotional Speaker Programs through the SKLSI Speaker Program vendor.
- Only approved speakers who have completed the required SKLSI training may be scheduled through the Speaker Program vendor.
- Program hosts are responsible for compliance at each Speaker Program.

5. Attendance Requirements

- The purpose of Speaker Programs is the provision of applicable scientific and educational product information by the Speaker to HCP attendees.
- Programs must be planned for the maximum number of HCPs that could reasonably be expected to attend.
- Out-of-office Speaker Programs that do not have a minimum of four (4) confirmed HCP RSVPs one week prior to the program may be subject to cancellation.
- In-office and virtual Speaker Programs that do not have a minimum of two (2) confirmed HCP RSVPs one week prior to the program may be subject to cancellation.
- SKLSI speakers are not permitted to attend Speaker Programs on topics similar to the one on which they are trained to present. Exceptions must be approved by Compliance.
- Speaker Program attendees must independently qualify as appropriate HCPs or supporting staff with a role in patient care (e.g., MA). Guests,

spouses, or other individuals not qualified as appropriate HCPs are prohibited from attending.

- While HCPs may elect to attend multiple programs in a calendar year, they are not permitted to receive a Meal and will not be counted toward the attendee requirement after the first program on the same topic.

6. Meals and Venues

Meals may be provided in conjunction with Speaker Programs as long as the Meals:

- Are coordinated and managed through the Speaker Portal (including virtual Meals);
- Comply with SKLSI's modest Meal guidelines;
- Include documentation of attendance (e.g., sign-in sheet for live programs or list of attendees for virtual programs); and
- Are not provided to HCPs who attend more than one (1) program in a calendar year.

SKLSI Associates are not permitted to provide the speaker or attendees with additional drinks or meals prior to or after the Speaker Program.

SKLSI Associates may not pay for or provide alcohol in connection with a Speaker Program.

Live/in-person Speaker Programs must be held at venues that are conducive to an educational program, private room, or area, modest as judged by local standards, and free from entertainment or recreational activities. It is not appropriate to conduct Speaker Programs at the following:

- Luxury hotels or restaurants
- Spas, resort facilities, amusement parks, museums, or country clubs (i.e., no facilities that require an entrance fee)
- Casinos, cocktail bars, or smoking lounges
- A customer's home

Virtual Speaker Programs must be coordinated through the Speaker Portal and conducted using SKLSI-approved virtual meeting platforms.

7. Speaker Responses to Unsolicited Off-Label Questions

Speakers may respond to unsolicited Off-Label questions from audience members, if they are comfortable with responding. When responding to such a question, speakers must:

- Disclose to the audience that the question relates to an unapproved use or to information not included in the approved product labeling;
- State the approved indications for the product, as appropriate;
- Provide an answer to the question based on their personal experience that is factual, objective, and non-promotional; and
- Not engage in further Off-Label discussion and immediately return to the presentation.

If further information is desired, the program owner should submit a MIRF as described in Section B.3.

8. Speaker Program Monitoring

SKLSI must periodically monitor Speaker Programs for compliance with FDA regulatory requirements using a function which does not involve the Sales or Marketing departments (e.g., Compliance or independently retained monitor).

F. Advisory Boards

Advisory Boards are used solely to engage HCPs to provide consulting services when there is an identified business, medical, or scientific need. SKLSI utilizes Advisory Boards only to answer specific questions related to SKLSI's business which are not available through other mechanisms. Examples of Advisory Board topics include developing product marketing strategies, third-party payer tactics, clinical trial strategy, or other topics where external expertise or experience is required.

1. Purpose of Advisory Boards

Advisory Boards must be designed to obtain, capture, and use expert feedback and advice on predetermined topics as documented in a Business Needs Assessment (BNA) Form approved by Compliance. Advisory Boards are not promotional events and the information presented must be limited to that needed to solicit feedback from the attendees. Advisory Boards must not be used as a method to communicate product updates unless the approved objective is to obtain feedback on specific questions.

The Advisory Board agenda must reflect the specific objectives of the meeting and focus on obtaining input rather than presenting information. A significant portion of the Advisory Board must be dedicated to obtaining feedback from attendees. This information should be captured and utilized in an appropriate manner consistent with program objectives.

2. Materials

Materials used at Advisory Boards should not make use of product-specific branding, unless the stated objective of the Advisory Board is to gather feedback on product-specific marketing materials. All Advisory Board materials must be reviewed and approved by the CRC. The Advisory Board venue markings should not use product branding nor disclose the purpose of the Advisory Board in areas accessible to public.

3. Attendees

Attendees must not be selected based on prescribing or purchasing habits. Individuals involved in advisory board attendee selection are responsible for ensuring compliance with appropriate policies and procedures.

Attendee selection must be limited to the minimum number of participants reasonably required to obtain the required feedback and who have specific expertise related to the topics to be discussed at the Advisory Board. As a general rule, there should be no more than ten (10) advisors per meeting; Advisory Boards requiring more than ten (10) advisors require prior approval from Compliance. All attendees are expected to provide feedback during the Advisory Board and the event agenda must be structured to allow sufficient time to collect feedback from each attendee.

Where appropriate and approved by Legal and/or Compliance, SKLSI may engage special focus groups (e.g., the SKLSI Epilepsy Council) to meet strategic business objectives distinct from Advisory Boards. In such instances, SKLSI may choose to engage a higher number of participants to meet the defined objectives.

For additional details related to attendee selection and compensation, refer to the *Fee-for-Service Arrangements Policy*.

4. Venue

The venue for the Advisory Board must be modest as judged by local standards and conducive to the gathering of necessary feedback. Venues that include entertainment or recreational activities (e.g., casino, sports, theatre, bars, theme parks) are strictly prohibited.

G. Educational Items

SKLSI may provide items to HCPs that serve a genuine educational function, so long as those items comply with the following standards:

- Items must be CRC-approved.
- Items must not be capable of use by the HCP (or their family members, office staff, or friends) for non-educational or non-patient-related purposes.
- Items may only be provided to the HCP on an occasional basis.
- Any SKLSI logo or product name on the item must be CRC-approved and should not be the primary feature or purpose of the item.
- The Fair Market Value (FMV) of any such item must be modest, and in any event less than $100. Potential exceptions to the cost limit, such as medical textbooks or anatomical models, must be raised to the Compliance Department prior to providing the items.

Permissible items include:

- Medical textbooks, including hardback, paperback, and electronic delivery
- Anatomical models
- Clinical reprints
- Informational sheets and brochures
- Patient self-assessment and tracking tools, or written materials that inform patients about adherence to medicine regimens
- Written materials that inform patients about healthy lifestyle choices or the availability of patient assistance programs

Prohibited items may include, but are not limited to:

- Non-Educational Items (e.g., pens, note pads, mugs, reminder items)
- Medical equipment and supplies (e.g., stethoscopes, tongue depressors, ice packs)
- Personal items (e.g., birthday gifts, flowers, wine, tickets, books not included in the permissible items noted above, items personalized for an individual HCP)
- Items with an independent value (e.g., tablets, step trackers, smart watches)
- Cash or cash equivalents (e.g., gift cards)

H. Restrictions

1. Prohibition on Entertainment and Recreation

SKLSI Associates are not permitted to engage non-employee HCPs at luxury venues or provide entertainment, recreational activities or items (regardless of value) to any non-employee HCP even if:

- SKLSI engages the HCP as a speaker or Consultant.
- The item or activity is secondary to an educational purpose.
- The funding for the item or activity comes through a third party.

2. State, Local, and Institutional Restrictions

SKLSI Associates interacting with HCPs that are licensed in states or geographies with specific restrictions must be trained on the relevant regulations prior to planning an activity involving Meals or other non-monetary compensation and lobbying.

In addition to state and federal laws, some teaching hospitals, academic medical centers, and other healthcare institutions impose restrictions, limits, or additional requirements on manufacturer interactions and relationships with HCPs who are employed or affiliated with such entities. For example, some teaching hospitals, academic medical centers, or other HCOs may:

- Prohibit faculty or employees from serving as a speaker or Consultant for, or receiving any compensation from, SKLSI;
- Prohibit SKLSI from providing any Meals or entering hospital/clinic property; or
- Require SKLSI Associates to complete vendor credentialing requirements before being permitted access to the facility.

SKLSI Associates must ensure that any proposed interactions, activities, or arrangements do not violate applicable institutional restrictions.

For a complete list of state and local restrictions including lobbying laws, or for any questions related to such laws and restrictions, contact the Compliance department.

For questions related to vendor credentialing requirements, contact credentialing@sklsi.com.

I. Adverse Event and Product Quality Complaint Reporting

SKLSI is required to report Adverse Events and other safety-related information (e.g., unexpected or untoward medical occurrences, including lack of effect and medication errors) or Product Quality Complaints (e.g., packaging, quality, manufacture) associated with SKLSI products, including investigational products, to the FDA in compliance with US laws and FDA regulations (and potentially to other health authorities outside the US) and the SKLSI *Adverse Events Reporting for SKLSI Employees SOP*.

SKLSI Associates must complete training on and adhere to the processes outlined in the *Adverse Events Reporting for SKLSI Employees SOP*, including reporting identified Adverse Events and Product Quality Complaints within twenty-four (24) hours of becoming aware of the information to 866-OKSKLSI (866-657-5574).

J. Transparency Reporting

SKLSI is committed to tracking and reporting payments and other transfers of value provided to HCPs in accordance with the Federal Sunshine Act and any state transparency laws.

SKLSI Associates are expected to document all transfers of value provided to HCPs in accordance with SKLSI's *Transparency Policy*.

V. DOCUMENTATION REQUIREMENTS

Records related to the activities addressed in this policy must be recorded and archived in compliance with *SKLSI's Information Handling and Record Retention Policy*.

VI. COMPLIANCE

Failure to follow this Policy may subject an Employee to disciplinary action, up to and including termination. Any SKLSI Associate who becomes aware of an actual or potential violation of this or any Policy must promptly report it to their manager, and/or one of the following SK Life Science, Inc. departments: Compliance, Legal Affairs, Human Resources, or the Compliance Hotline at (833) 490-0007 or the Compliance Hotline website www.lighthouse-services.com/sklsi. SKLSI follows a policy of non-retaliation and no SKLSI Associate will be subject to retaliatory action for reporting in good faith a suspected violation of this Policy.

VII. REFERENCES, FORMS, AND TEMPLATES

- SKLSI Code of Conduct
- Fee-for-Service Arrangements Policy
- Government Official Interactions Policy
- Medical Affairs Activities Policy
- Transparency Policy
- Prescription Drug Samples Policy
- Prescription Drug Vouchers Policy
- Field Sales Compliance Manual
- Field Medical Compliance Manual
- Speaker Selection, Training, and Compensation Procedural Guide
- Meals & Items of Value Procedural Guide
- Speaker Program Management Best Practices

VIII. REVISION HISTORY

Version Number	Effective Date	Description of Change	Name of Individual Responsible for Change
1.0	3/01/2022	New Policy	

IX. APPROVALS

APPROVED BY:			Effective:
1	Jooyup Chae		DocuSigned by: Jooyup Chae 43F66C003BA74E3...
	Print Name		**Signature**
	General Counsel		10/17/2021
	Title		**Date (DD MMM YYYY)**
2	Matt Linkewich		DocuSigned by: matt linkewich 3D57C10581D3408...
	Print Name		**Signature**
	Chief Commercial Officer		10/15/2021
	Title		**Date (DD MMM YYYY)**
3	Marc Kamin		DocuSigned by: Marc Kamin BF28E8728C744C6...
	Print Name		**Signature**
	Chief Medical Officer		10/19/2021
	Title		**Date (DD MMM YYYY)**

Policy Author:	Compliance Department
Policy Reviewers:	Joshua McLaughlin, Associate General Counsel Monica Schroeter, Head of Compliance & Privacy Gary Ball, VP, Sales & Marketing Rich Ciorra, VP, Commercial Operations Robert Polans, VP, Market Access Lou Ferrari, VP, Medical Affairs