	Policy Title:	Patient & Patient Organization Interactions
	Policy Number:	COMP-POL-1008

PATIENT & PATIENT ORGANIZATION INTERACTIONS POLICY

I. PURPOSE

This Policy describes the principles and standards that govern the interactions with Patients, Caregivers and Patient Organizations at SK Life Science, Inc. (SKLSI or the Company), and reflects SKLSI's commitment to engage in these interactions in a lawful, ethical, and professional manner.

This Policy is intended to be consistent with the applicable principles set forth in relevant industry codes of conduct.


II. SCOPE

This Policy applies to all SKLSI Associates who engage with members of the Patient community, including individual Patients, Caregivers, and representatives of Patient Organizations.

III. ABBREVIATIONS AND DEFINITIONS

ABBREVIATIONS	
Abbreviation	Term
HCP	Healthcare Professional
PHI	Protected Health Information
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.
Advisory Board	A non-promotional meeting comprised of external healthcare professionals who are engaged as consultants to provide input on scientific, clinical, or other important business objectives.
Company	SK Life Science, Inc.
Conference	A meeting during which members of the healthcare community gather to discuss medical advances, share research in therapeutic specialties, and promote healthcare products and services through Exhibit marketing.


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Conflict of Interest	An actual or perceived conflict between an SKLSI Associate's private interests and their responsibilities to the Company.
Exhibit	A booth, panel, table-top poster, or any other display at a program or event sponsored by a third-party organization.
Healthcare Professional	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.
Off-Label Information	Information about a SKLSI product inconsistent with the use(s) described in the FDA-approved product labeling.
Patient	Any person with a diagnosed health condition who may purchase, consume, or receive medical treatment for the condition.
Caregiver	A person who provides care or support for a Patient. Patient Caregivers are often family members who may have specific insights into the challenges that Patients may face in dealing with the applicable health condition.
Patient Organization	Also referred to as a Patient Advocacy Group, a Patient Organization is a non-profit organization mainly composed of Patients and/or caregivers, that represents the needs and interests of, and provide support to Patients and their caregivers, relatives, and friends.
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 tablets, missing label).
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.
Transfer of Value	A payment or other item of value, whether in cash, in kind, or otherwise, provided by SKLSI to an HCP or HCO or a Patient Organization.

IV. POLICY

A. GENERAL REQUIREMENTS

SKLSI may support activities and otherwise engage with Patients, Caregivers, and Patient Organizations with the goals of improving outcomes for Patients and better understanding the perspectives of Patients and Caregivers to further the Company's legitimate business interests. Such interactions must be transparent,

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ethical, and consistent with all applicable laws and regulations, the Patient Organization’s mission, and the best interests of Patients.

SKLSI Associates must disclose their association with the Company when interacting with Patients, Caregivers, and Patient Organizations.

B. PATIENT ORGANIZATION INTERACTIONS

All interactions with Patient Organizations must be conducted in a transparent manner in support of a legitimate business need consistent with the mission of the organization. SKLSI encourages Patient Organizations to be transparent with their members, and with all relevant third parties, about funding received from and any arrangements with SKLSI.

SKLSI must maintain overall independence from the Patient Organization and must never pressure or require any Patient Organization, or member thereof, to act in a manner that is not aligned with the goals and mission of the organization.

SKLSI Associates must not use interactions with Patient Organizations to:


- Promote, or ask a Patient Organization to promote, or endorse SKLSI products
- Obtain competitor information, or
- Direct Patients to use Company products.

1. Communications with Patient Organizations

SKLSI Associates may provide education to or respond to questions from Patient Organizations about SKLSI’s products, relevant disease states, and SKLSI programs for patient support and product access. Such interactions must be consistent with label and rely only on materials approved by the Promotional Materials Review Committee (PMRC) for use with Patients. Materials intended for use with HCPs should not generally be used with Patient Organizations.

As described in the *Handling of Unsolicited Requests for Medical Information SOP*, only Medical Affairs may respond to unsolicited Off-Label information requests from Patient Organizations regarding unapproved uses of a marketed SKLSI product or one in clinical development. The Medical Affairs and Clinical groups may provide Patient Organizations with information about actively recruiting Company trials, when the information is already publicly available (e.g., via clinicaltrials.gov). The Patient Organizations may decide to share this information with their members.

While SKLSI Sales personnel may participate in fundraising events (e.g., charity walks, dinner galas, etc.), they are not permitted to engage in discussions about SKLSI products or patient-specific information.

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2. Financial Support

SKLSI may provide financial support for Patient Organizations for organization meetings or other activities, provided the primary purpose of the activity is professional, educational, or scientific in nature, or otherwise furthers the mission of the Patient Organization. SKLSI does not currently support independent foundations that provide co-pay and premium assistance to Patients; requests for this type of funding must be referred to SKLSI Legal.


Requests for financial support will be reviewed by the appropriate SKLSI leadership, which may include Legal, Compliance, and other personnel as appropriate, in alignment with the SKLSI *Educational Grants, Charitable Donations, and Sponsorships Policy*. All funding requests will be approved based on reviewer consensus.

All engagements which provide funding or any other Transfers of Value to a Patient Organization or engage any Patient Organization to perform services for SKLSI, must be documented in a written agreement. Such written agreement may include sponsorship letters, purchase orders, or service agreements. Engagement of individuals who are representatives of or in leadership positions with a Patient Organization should generally be entered into with the Patient Organization rather than the individual. Questions about this should be referred to the Legal Department.

In order to be eligible for support, the Patient Organization must be registered as a 501(c)(3) in the U.S., and the scope of its activities should focus on areas of health, patient education, and patient services.

All requests for financial support must be unsolicited, and must adhere to the following principles:

- SKLSI Sales Associates must not participate in submitting, evaluating, selecting, or approving funding for Patient Organizations.
- SKLSI does not support, financially or otherwise, Patient Organizations or organization events that are purely social in nature or constitute entertainment.
- SKLSI may not request to be the sole supporter of a Patient Organization or any of its major programs and activities. SKLSI may not fund the startup or expansion costs for a Patient Organization.
- Any meals or refreshments provided by SKLSI in connection with Patient Organization meetings or other event sponsorship should be modest as

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judged by local standards as outlined in the *Items of Value Procedural Guide*.

- Any gifts provided by SKLSI to members of the Patient Community must be of nominal value and approved through the appropriate materials review process (e.g., PMRC, Non-Promotional Review Committee, etc.).

SKLSI must not request or require as a condition of funding that any Patient Organization:

- Promote SKLSI or SKLSI products to its membership, Patients, Caregivers, regulators, Healthcare Professionals (HCPs), formulary committees, payers, or any third party, or
- Advocate for the coverage, coding, or pricing of any Company investigational or approved product.
- Endorsement of any SKLSI products.

3. SKLSI Associates Serving on Board or Leadership Positions of a Patient Organization


SKLSI Associates must follow SKLSI's *Conflicts of Interest Policy* and disclose the potential role with a Patient Organization before agreeing to serve in leadership positions of a Patient Organization in the same therapeutic areas where SKLSI sells products to determine if there is a Conflict of Interest. Refer the SKLSI *Conflicts of Interest Policy* for more information.

C. PATIENT AND CAREGIVER INTERACTIONS

Authorized SKLSI Associates may educate Patients and Caregivers about Company products and disease areas or health conditions of interest to SKLSI. Patient- and Caregiver-directed communications must use only PMRC-approved topics and materials intended for use with Patients and Caregivers.

SKLSI complies with Adverse Event and Product Quality Complaint reporting requirements and may interact with Patients and Caregivers directly to ensure accurate data collection for reporting purposes. Only Medical Affairs is permitted to communicate directly with Patients and Caregivers to address Adverse Events, Product Quality Complaints, or safety issues.

Responses to Patients and Caregivers about Company products must be limited to information contained within the Company product's prescribing information and a recommendation to speak with their treating HCP or healthcare team. SKLSI Associates may not provide Patients and Caregivers with Off-Label Information or pipeline-related clinical information, though information may be provided on where to find company-sponsored clinical study information.

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In the course of interactions with Patients and Caregivers, SKLSI Associates must NOT:

- Interfere in the HCP-Patient relationship or any Patient’s treatment plan,
- Be present for or participate in an HCP’s consultation with a Patient or Caregivers,
- Attempt to obtain or document a Patient’s Protected Health Information (PHI), or
- Provide medical advice to any Patient or Caregiver

D. ENGAGING WITH PATIENTS, PATIENT CAREGIVERS AND PATIENT ORGANIZATIONS ON SOCIAL MEDIA

Only authorized SKLSI Associates may interact via social media with Patients, Patient Caregivers, or Patient Organizations. All such interactions must comply with the guidelines for social media outlined in SKLSI’s *Code of Conduct*.

E. ENGAGING PATIENTS OR PATIENT ORGANIZATIONS FOR SERVICES


SKLSI may directly, or indirectly through a third party, engage Patients, Caregivers, or Patient Organizations for legitimate and necessary services such as consulting, speaking, Advisory Boards, market research, and services related to clinical development activities, including input on clinical trial design. Refer to SKLSI’s *Fee-for-Service Arrangements Policy* for more information. All such engagements must be conducted pursuant to a written agreement executed prior to the start of any work.

F. PROTECTED HEALTH INFORMATION

Federal and state laws regulate the manner in which SKLSI may gain access to certain patient health information. SKLSI Associates are expected to comply with all relevant laws, regulations, and government guidance, and applicable state and local rules, concerning privacy and consumer protection. Refer to SKLSI’s *Data Privacy Policy* for more information.

G. TRANSPARENCY AND REPORTING

SKLSI is committed to tracking and reporting any Transfers of Value to HCPs that occur during interactions with Patients or Patient Organizations in compliance with federal and state transparency laws. Refer to SKLSI’s *Healthcare Professional Interactions Policy* for more information. SKLSI is also committed to tracking Transfers of Value to Patients and Patient Organizations and reporting such Transfers of Value where required in accordance with local laws, regulations and industry codes.

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V. DOCUMENTATION REQUIREMENTS

Records related to the consulting 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, Human Resources, or the Compliance Hotline at (833) 490-0007 or the Compliance Hotline website www.lighthouse-services.com/sklsi. The Company 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


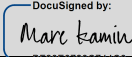
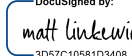
- Conflicts of Interest Policy
- Data Privacy Policy
- Educational Grants, Charitable Donations, and Sponsorships Policy
- Fee-for-Service Arrangements Policy
- Healthcare Professional Interactions Policy
- Information Handling and Record Retention Policy
- Handling of Unsolicited Requests for Medical Information SOP

VIII. REVISION HISTORY

Version Number	Effective Date	Description of Change	Name of Individual Responsible for Change
1.0	1/1/2022	New Policy	

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IX. APPROVALS

APPROVED BY:		Effective:
1	Jooyup Chae	 Signature 11/14/2021 Date (DD MMM YYYY)
	Print Name	
	General Counsel	
2	Marc Kamin	 Signature 11/11/2021 Date (DD MMM YYYY)
	Print Name	
	Chief Medical Officer	
3	Matt Linkewich	 Signature 11/10/2021 Date (DD MMM YYYY)
	Print Name	
	Chief Commercial Officer	
Policy Author: Compliance Department		
Policy Reviewers:		Joshua McLaughlin, Associate General Counsel Daniel Dorfman, Senior Counsel Monica Schroeter, Head of Compliance & Privacy Gary Ball, VP, Sales & Marketing Lou Ferrari, VP, Medical Affairs