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#### Goal and Scope of Policy

Blockade Medical, Inc. is committed to being a leader in the field of neurovascular intervention. As part of our vision, we are committed to adhere to ethical and legal standards in our relationships with "Health Care Professionals" (HCPs, as defined below). Interactions between medical device companies and HCPs are highly regulated by the federal and state anti-kickback laws, the Foreign Corrupt Practices Act, and other laws and regulations. This Policy is intended to govern, on a world-wide basis, our interactions with Health Care Professionals. For purposes of this Policy, "Blockade" or the "Company" means Blockade Medical, Inc. and its wholly-owned subsidiaries.

Note that in this Policy, "Health Care Professionals" or "HCPs" include all individuals and entities we interact with who are involved in the decision to use or purchase products, including physicians and other persons licensed by law to prescribe drugs or medical devices for human patients, medical students, members of a procurement committee, physician's office, clinics and hospitals, medical schools, hospital staff, governmental agencies and group purchasing organizations.

All interactions of Blockade's directors, employees and third-parties acting on behalf of the Company (together referred to as "Blockade representative(s)") with customers and HCPs shall conform to the applicable laws, regulations, and medical device industry codes of the state, region or country that applies, which, depending on the law or code at issue, may be where the HCP is based or where the HCP is licensed to practice.

All Blockade representatives are covered by this Policy, regardless of whether located in or outside of the United States, provided that non-employee representatives are covered by this Policy only if (a) they are self-employed individuals whose services to Blockade involve interactions with HCPs; (b) they provide contract sales representative or non-stocking distributor services to Blockade; or (c) they are employed by stocking distributors of Blockade who have agreed to abide by this Policy.

Certain states or countries may impose requirements that are more restrictive than the guidelines presented in this Policy. Blockade representatives must be aware of and comply with these more restrictive rules as applicable, and should contact the Company's Compliance Officer with any requests for additional information on such rules.

The Compliance Officer is responsible for the implementation and oversight of this Policy, with the support of the Compliance Committee. The Compliance Committee is made up of the President and Compliance Officer and other individuals designated pursuant to the Company's Compliance Committee Charter.

Our interactions with HCPs cover a broad range of activities, including:



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- *Promotional Activities.* We promote the sale and use of our products directly and indirectly through employees, agents and distributors to HCPs.
- Training and Product Related Education. We offer education and training on safe and effective use of our products to HCPs.
- Research and Education. We support bona fide medical research and continuing medical education for HCPs to increase access to new technology and enhance the delivery of safe, efficacious and cost-effective health care.
- Advancement of Medical Technology. We collaborate with HCPs to demonstrate the
  effectiveness of our products, to improve the utility and applications of our products and to
  create new products.

Our reputation for honesty, integrity and fair dealing with our customers, others we do business with, our employees and the communities we serve is our most important asset. Accordingly, we require that you act in a manner consistent with the letter and intent of this Policy and the underlying policies. While this Policy addresses many of the interactions we have with HCPs, it is impossible to provide specific guidance for every situation. Matters not specifically addressed in this Policy, should be addressed in light of the following principle:

Blockade insists on ethical business practices and socially responsible conduct and shall not use any unlawful inducement in order to sell, recommend, or arrange for the sale or use of its products.

Our failure to adhere to this Policy could subject us to severe penalties, civil fines and injunctions, and criminal prosecution, fines and imprisonment.

Each Blockade Medical employee who interacts with HCPs are expected to become familiar with these policies and to affirm your agreement to comply with these policies by signing the Compliance Certificate that appears at the end of this Policy. Any questions regarding this Policy or matters not covered by this Policy should be referred to your immediate supervisor or the Company's Compliance Officer.

#### Promotional Activities

We interact with HCPs to discuss product features, contract negotiations, and sales terms, both in the HCPs offices and clinics and at meetings and conferences.

<u>Gifts.</u> We may occasionally provide modest gifts to HCPs, but only as set forth in these guidelines and only following advance written approval of the Compliance Officer.



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- For HCPs practicing in the United States: only items that benefit patients or serve a genuine educational function may be provided to HCPs. Other than gifts of medical textbooks or anatomical models used for educational purposes, no gift should have a fair market value of more than \$100. Non-educational, promotional items (pens, notepads, mugs, 'reminder' items) are prohibited for U.S. HCP's.
- For HCPs practicing in Europe, in addition to educational items and items that benefit
  patients, we may provide modest gifts that relate to the HCP's practice (for example, pens
  or clipboards). Other than gifts of medical textbooks or anatomical models used for
  educational purposes, no gift should have a fair market value of more than \$100.
- For HCPs practicing outside of the U.S. and Europe, in addition to the foregoing, modest (US \$25 equivalent or less) gifts may be appropriate at important holidays.

The following prohibitions apply in all cases:

- Under no circumstances may gifts be given in the form of cash or cash equivalents.
- Entertainment and recreation Theater tickets, sporting events, golf, skiing, hunting, sporting equipment, vacations and similar items are prohibited.
- Gifts such as wine, flowers, chocolate, gift baskets, weddings gifts, holiday gifts, except as expressly provided above with regard to HCPs outside of the United States or Europe. Meals with HCPs that comply with the provisions regarding Meals below shall not be deemed to be gifts.
- Meals. We may pay for modest meals and receptions for HCPs that are conducive to the exchange of scientific, educational (training and or in-service) or business information. It is not appropriate to pay for meals of guests or staff of HCPs or any other person who does not have a bona fide professional interest in the information being shared at the meeting. Meals may not be organized for the purpose of providing or facilitating the provision of off-label information.
- The following table represents the per person meal allowances, based on regulatory requirements in these various countries.

#### Meal Allowances\*

Country	Breakfast	Lunch	Dinner
France/Belgium (€)	35	45	60
Germany (€)	35	45	60
US/Canada (\$)	40	75	150



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UK (£)	30	40	80

<sup>\*</sup>Note: Above amounts include all taxes and gratuities.

- Understanding geographic differences in meal costs, employees who must entertain in more expensive locations should obtain pre-approval from their department head for higher reimbursement allowances when justified by unavoidable circumstances (such as dinner meetings in connection with third-party congresses held in high-cost venues).
- For countries not listed above, Blockade representatives must avoid extravagant meals, and cost must not exceed the US limit per person above (based on the currency exchange rate in effect on the date of the meal).
- In order to ensure a valid business purpose for the meal, a ratio of at least one Blockade representative for every 4 or fewer HCP's should be maintained, unless a Senior Director or Vice President (or other corporate officer) is attending, except for Permitted Group Meals (as defined below).
- "Permitted Group Meals" are meals organized by Blockade representatives for training or education purposes, such as in-service training programs and educational dinner symposia.
  - Permitted Group Meals must include a scientific, educational or training presentation approved internally by Blockade's senior management
  - The person organizing a Permitted Group Meal is responsible for requiring all attendees (including both Blockade representatives and HCPs) to sign a sign-in sheet indicating, the name, title, employer/institution and professional e-mail address of the attendee. If the attendees include HCPs licensed in the United States or France, the sign-in sheet should also include the information required for Sunshine Act reporting (see "Aggregate Spend Reporting and Transparency" below.)

Blockade representatives may not avoid responsibility for compliance with the provisions of this Policy by paying for HCP-related expenses "from their own pocket," since their interactions with the HCP will reflect on the Company in all events. All expenses incurred in connection with HCP interactions must be properly reported to the Company. Notwithstanding the foregoing, the Company reserves the right to deny reimbursement of expenses that deviate from the provisions of this Policy.

### **Special State Law Considerations:**



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**MA and VT:** Prior to providing meals, permitted gifts or any other transfer of value to a health care provider licensed to practice in Massachusetts or Vermont you must notify the Company's Compliance Officer in writing (an e-mail is sufficient) and may proceed only if authorized in writing by the Company's Compliance Officer. Approvals should be attached to the expense report.

**CA:** The aggregate value of all meals, educational and promotional items and gifts given to any HCP licensed to practice in California may not exceed \$2,000 per HCP per calendar year.

#### "Sunshine Act" Transparency

In some jurisdictions (including the United States and France) gifts and meals provided to HCPs must be disclosed periodically to government or other agencies or published on website. Blockade representatives who incur HCP-related expenses, or provide gifts or meals to HCP's, are responsible for following Company spend-tracking procedures in effect from time to time. If in doubt, contact the Compliance Officer, the Chief Financial Officer or General Manager, or your supervisor.

#### 3. Demonstration and Evaluation Product

We may provide products to HCPs for demonstration and evaluation purposes at no charge. The number of single use products provided should not exceed the amount reasonably necessary for the adequate demonstration and evaluation of the products. Demonstration products should be marked as "Sample", "Not for Human Use", or other suitable designation on the product, packaging or documentation accompanying the product.

#### 4. Product Training and Education

We conduct and sponsor programs focused on education and training in the safe and effective use of our products. Programs can include hands on sessions, lectures, presentations and grand rounds.

- Location. Programs should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective transmission of knowledge. Programs requiring "hands on" training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. Training programs in resort locations are not permitted.
- *Training Staff.* The training staff should have the proper qualifications and expertise to conduct such training. Training staff can include qualified Blockade representatives who have the technical expertise necessary to perform the training.
- Meals. We may provide HCPs attendees with modest meals and refreshments in connection
  with these programs. Any such meals and refreshments should be modest in value and
  subordinate in time and focus to the educational or training purpose of the meeting, and must



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comply with the restrictions regarding venue, cost and guests described above under "Promotional Activities - Meals."

- Travel and Lodging. We may pay for reasonable travel and modest lodging costs incurred by attending HCPs, subject to the advance approval and documentation requirements set forth below.
- Guests. It is not appropriate for us to pay for the meals, travel, or other expenses for guests of
  HCPs or for any other person who does not have a bona fide professional interest in the
  information being shared at the meeting.

Prior to inviting an HCP to attend a training program for which Blockade will reimburse travel or lodging expenses, each Blockade representative must ensure that the program and the travel, lodging and meal arrangements have been approved in writing by the Company's Compliance Officer. Arrangements must be appropriately documented using letter agreements or other forms approved by the Company's Compliance Officer.

For non-US physicians, Blockade representatives must also ensure compliance with the notification requirements of the Eucomed Code and any local law or industry code.

Training and education programs may not be organized for the purpose of disseminating "off-label" information. The Blockade representative organizing the program must ensure that all written materials (including invitations, presentations, and handouts) have been approved under SOP0005, Document Control.

### 5. Third-Party Educational Conferences

We support independent, educational or scientific conferences to promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations; and conferences sponsored by accredited continuing medical education providers.

• Educational Grants. We may provide educational grants when the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse. Such grants should be paid only to organizations with a genuine educational purpose or function, on written request, and may be used only to reimburse the legitimate expenses for bona fide educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organizations and documented in a written agreement. While we may recommend faculty for a conference, the conference sponsor should be independently responsible for and control the selection of program content, faculty, educational methods, and materials. We may provide grants either directly to the conference sponsor to reduce conference costs, or to a training institution or the conference sponsor to allow attendance by



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medical students, residents, fellows, and others who are HCPs in training. Except as otherwise restricted by state-specific or other local laws, the Company may provide grants to conference sponsors or training institutions to cover or defray the costs for HCPs in training (medical students, residents and fellows) to attend CME and other professional meetings, provided that the conference sponsor or training institution selects the attending HCPs who are in training. For non-US HCP's, where local law permits, we may provide grants to cover the reasonable cost of attending valuable educational programs.

- Meals and Hospitality. We may provide funding to the conference sponsor to support conference meals and refreshments. We may provide meals and refreshments for all HCP attendees, but only if they are provided in a manner that is also consistent with the sponsor's guidelines and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all HCPs only if they comply with the requirements for meals to HCPs set forth in Sections 2 and 4 above. Any meals, receptions, and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.
- Faculty Expenses. The Company may make grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for HCPs who are bona fide conference faculty members.
- Advertisements and Demonstration. We may purchase advertisements and lease booth space for our displays at conferences.
- Disclosure and Approval Requirements. We will comply with all national and local laws governing disclosure and approval of our financial support of conferences, faculty and attendees.
- 6. Arrangements with Consultants, Speakers and Clinical Investigators
  We may engage HCPs to serve as consultants (including as speakers or clinical investigators) to provide valuable bona fide consulting services, including research, participation on advisory boards, presentations at our training or other professional meetings, and product collaboration. It is appropriate to pay HCPs reasonable compensation for performing these services.

Each department requiring HCP Services must submit to the Compliance Committee on an annual basis HCP Services Needs Assessment forms covering all anticipated HCP services for the fiscal year. If needs change or additional needs arise during the year, additional or revised forms may be submitted for Compliance Committee review and approval.

HCP services must be requested using the Company's Request for HCP Services Form (which may be obtained from the Compliance Officer). Engagement of HCPs to provide services is also subject to all of the following requirements.



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- Need and Qualification. Consulting agreements may be entered into only where a legitimate need and purpose for the services is identified in advance. Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose, and may not be on the basis of the past or potential volume or value of business generated by the consultant. HCP Services Request will be approved only where an HCP Needs Assessment form covering the requested services has been reviewed and approved by the Compliance Committee.
- Written Agreement and Protocol. All HCP Services arrangements, no matter how short the duration of service, must be in writing, signed by the parties and specify all services and compensation to be provided. Where research services are provided, the agreement must contain a statement of work or research protocol. All agreements must be approved by the Compliance Officer and must be signed by an executive officer of the Company, and by the consultant, prior to the commencement of services. Services agreements with physicians or other individual HCPs practicing outside the U.S. should be signed by the individual and if applicable by an authorized representative of his or her institution to ensure transparency, unless local regulations provide for a different mechanism to ensure transparency (such as CNOM notification in France) in which case the regulations must be complied with.
- Compensation. Compensation paid to consultants must be consistent with the fair market value for the services provided. Fair market value shall be evaluated by the Compliance Officer at the time of contracting.
- Meetings. The venue and circumstances for meetings with consultants should be appropriate to
  the subject matter of the consultation. These meetings should be conducted in clinical,
  educational, conference, or other setting, including hotel or other commercially available
  meeting facilities, conducive to the effective exchange of information. Resort locations and 5star hotels are not permitted unless approved in advance in writing by the Compliance Officer.
- Meals. Meals and refreshments that occur in conjunction with a consultant meeting or consultant's services should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting or services. Recreation and entertainment should not be provided.
- Travel and Lodging. We may pay for reasonable and actual expenses incurred by consultants in
  carrying out the subject of the consulting arrangement, including reasonable and actual travel,
  modest meals and lodging costs incurred by consultants attending meetings with, or on our
  behalf. Resort accommodations are not permitted unless approved in writing in advance by the
  Compliance Officer. The duration of Company-paid lodging may not exceed that amount of time



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reasonably required for performance of services, and we may not pay for or reimburse additional lodging expenses of a spouse or other guest.

- Disclosure and Approval Requirements. We will comply will all national and local laws, and governmental and institutional regulations governing disclosure and approval of our arrangements with consultants, which may include requiring the consultant to notify and seek approval from his or her institution.
- FDA and other Regulatory Restrictions for Clinical Investigators. Our relationships with clinical
  investigators in trials to be submitted to the FDA or other regulatory agencies are governed by
  conflict of interest, disclosure and other rules. Nothing in this Policy is intended to supersede or
  modify our strict compliance with such regulations.

### 7. Provision on Payment of Royalties

Royalty payments must meet the general compliance standards for consulting arrangements with HCPs, including approval by the Compliance Officer. We should enter into royalty arrangements only when the HCP is expected to make, or has made, a novel, significant, or innovative solution. This may include a contribution to the development of a product, technology, process or method. We should appropriately document a significant contribution of an individual or group if that contribution is the basis for compensation. Any commitment to pay royalties to an HCP is subject to approval by Blockade's Board of Directors.

Royalties should be calculated based on factors that preserve the objectivity of medical decision-making and avoid improper influence. Royalties should not be conditional on HCP purchases, orders, marketing or recommendations of the product or related technology. Royalties shall not be paid on the purchases of product from the practice group, institution or clinic of the individual receiving royalties.



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#### 8. Grants and Charitable Donations

We may make grants and donations for bona fide scientific, educational or charitable purposes, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. We may not make grants or donations for the purpose of unlawfully inducing HCPs to purchase, recommend, use, or arrange for the purchase or use of our products. Grants and donations should not be provided based on the volume or value of purchases made by, or anticipated from, the recipient. To avoid any appearance of impropriety, Blockade representatives are prohibited from soliciting grant requests from HCPs, or from assisting in the completion of grant requests. HCPs inquiring about grants should be directed to, or provided with copies of, our Grant Guidelines in effect at the time of the inquiry, a copy of which can be obtained from the Compliance Officer or any member of the Compliance Committee.

- Recipients. Educational grants may be made to training institutions or conference sponsors.
  Research grants may be made to research organizations or institutions; research grants to forprofit organizations may be made only if permitted by the Company's Grant Guidelines.
  Charitable donations should be made only to charitable organizations or, in rare instances, to
  individuals engaged in genuine charitable missions for the support of that mission, and only
  upon written request.
- Advancement of Medical Education. We may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. Grants to support third-party educational conferences are subject to the provisions of Section 5 above as well as this Section 8.
- Support of Research with Scientific Merit. We may make research grants to support genuine medical research. The purpose of the grant must be clearly documented.
- Public Education. We may make grants for the purpose of supporting education of patients or the public about important health care topics.
- Review and Authorization. The Compliance Committee is responsible for developing Grant Guidelines and updating the Grant Guidelines from time to time to address evolving priorities, resources, and compliance considerations. Any request for grants or charitable donations should be directed from the requesting organization to the person designated in the applicable Grant Guidelines, and must be approved as set forth below.
  - Educational Grant Requests under US \$5,000 (or foreign currency equivalent)
    - US and OUS Requestor:



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- Compliance Committee
- Educational Grant Requests over US \$5,000 (or foreign currency equivalent)
  - Compliance Committee
- Research Grant Requests:

#### **Compliance Committee**

Documentation. All grant arrangements and charitable donations must be documented in a
written grant agreement signed by the Compliance Committee. The Agreement will include
additional documentation requirements set forth in the Grant Guidelines in effect at the time of
contracting.

#### 10. Additional Considerations.

Domestic and International Interactions with Health Care Professionals

We recognize that customs, practices, laws and regulations vary throughout the world. However, it is our intent that the underlying purposes of this Policy, to ensure ethical and legal relationships with HCPs, are equally applicable inside and outside the United States. Interactions that may be customary and not illegal in a particular country may still be unlawful under U.S. law and subject Blockade and the persons involved to criminal liability.

#### **Anti-Kickback Laws**

The purpose of the "anti-kickback" laws is to prevent improper inducements to HCPs that could result in the referral of business reimbursable under Federal or State health care programs. The "anti-kickback" laws generally make it illegal to offer remuneration or payment of any kind, direct or indirect, if any one purpose of the remuneration or payment is to encourage or reward the prescribing or purchase of any reimbursable product. Remuneration can be almost anything of value, including grants, referral fees, cash, frequent flier miles, lottery tickets, entertainment or gifts. There are a limited number of exceptions (or "safe harbors") to the anti-kickback laws that allow us to offer certain price concessions to customers without violating the law. Please contact the Compliance Officer for a more comprehensive explanation of the "anti-kickback" laws or if you have any questions regarding their application.

#### **Activities Outside the United States**

The Foreign Corrupt Practices Act makes it a criminal offense under U.S. federal law to pay, offer, or give anything of value to a foreign official, a foreign political party (or any official thereof) or candidate for foreign office, for the purpose of obtaining or keeping business with, or influencing the decisions of,



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those officials, parties or candidates. It is also unlawful to make a payment to any person, while knowing that all or a portion of the payment will be offered, given, or promised, directly or indirectly, to any foreign official (or foreign political party, candidate, or official) for the purposes of assisting a U.S. company in obtaining or retaining business. The term "foreign official" has a broad meaning. For example, it is likely that physicians who are reviewers for, or advisors to, foreign regulatory or reimbursement agencies would be considered a "foreign official" under the FCPA. Although there is no definitive authority on the issue, it is likely that a foreign (private) health care professional employed by a public, state-owned hospital is deemed to be a "foreign official" under the FCPA. Thus, any payments, including improper hospitality, to such persons could implicate the FCPA.

In addition, many other countries have similar "anti-kickback" and "anti-bribery" laws.

### Spend Transparency ("Sunshine Laws").

Some countries, including the United States and France, require medical device manufacturers and their representatives to track and disclose transfers of value to HCP's. The company has implemented internal procedures to ensure compliance with these laws. All Blockade representatives who provide or pay for transfers of value to HCP's are responsible for knowing and complying with these procedures. Please be aware that all of the interactions governed by this policy – including gifts, meals, free products, consulting arrangements, and grants – are likely to trigger disclosures under these laws. If you are in doubt about what procedures apply to transfers of value you are responsible for, contact the Compliance Officer or the Company's controller for more information.

#### **Legal Product Promotion**

FDA laws and regulations, and the laws and regulations of other countries, regulate our ability to sell and promote our products. Blockade representatives must not promote our products for uses for which they have not been approved, or in countries where they are not approved or registered for sale. To avoid off-label promotion, Blockade personnel must ensure that their discussions with HCPs are consistent with the labeling, including the instructions for use, approved in the country where the HCPs are licensed to practice, and may not distribute or use written materials regarding our products unless they have been approved for such distribution or use in accordance with Company SOPs. Limited exceptions to these restrictions may apply to Blockade personnel whose responsibilities include non-promotional activities (such as R&D and regulatory or medical affairs). When in doubt as to whether a discussion or activity is appropriate, you should consult with our regulatory affairs department, the compliance officer, or Company legal counsel.

Blockade personnel should avoid online or social media discussion of Blockade or its products, unless expressly authorized in accordance with Company SOPs.

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### **Standard Operating Procedure**

Policy and Procedure for Interactions With Health Care Professionals (HCPs)

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**Blockade Medical, Inc.** 

# COMPLIANCE PROGRAM AND POLICY ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS COMPLIANCE CERTIFICATE

I have read and understand the Blockade Medical, Inc. Policy and Procedure on Interactions with Health Care Professionals (the "Policy"). I will adhere in all respects to the ethics and standards of conduct described in the Policy. I further confirm my understanding that any violation of the Policy will subject me to appropriate disciplinary action, which may include termination of my employment or other service relationship with Blockade Medical, Inc. or its affiliates.

I certify to the Company that I am not in violation of the Policy, and I am not aware of any violation by others.

Date:	
· · · · · · · · · · · · · · · · · · ·	Name:
	Title/Position: