STATEMENT OF PRINCIPLES AND INTRODUCTION

Metagenics\(^1\) is committed to maintaining the highest standards of excellence, honesty, integrity, and transparency in its interactions with health care professionals,\(^2\) patients, customers, and government officials.

Metagenics issues its *Policies and Procedures for Health Care Compliance*, which supplement the *Global Code of Conduct*, to provide practical standards and guidelines to assist you in meeting Metagenics’ ethical principles and expectation of legal compliance. The *Policies and Procedures for Health Care Compliance* are not intended to exhaustively cover every type of interaction you may encounter, but provide you with a set of guidelines and procedures to help you understand how to apply Metagenics’ standards in a health care environment, and comply with the letter and spirit of the laws pertaining to health care fraud and abuse.

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Summary of Health Care Fraud and Abuse Laws

All Metagenics employees, contractors, speakers, agents, and distributors are required to conduct Company business in compliance with applicable laws and regulations in whatever jurisdiction or country the Company is doing business. No employee should take any action on behalf of the Company which the employee knows or reasonably should know would violate any law or regulation. The use of Company personnel or assets for any unlawful purpose is strictly prohibited.

All employees are expected to have an understanding of the core health care fraud and abuse laws, which in the United States include, but are not limited to, anti-kickback laws, self-referral laws, patient inducement laws, state disclosure laws, and other state prohibitions. In summary, these laws are so broad as to effectively prohibit many common business practices that may be acceptable or lawful in other non-health care settings.

Please keep in mind that there are additional health care fraud and abuse laws beyond what is summarized below. It is your responsibility to obtain clarification and ensure that your actions are consistent with both federal and state law. Consult the Compliance Officer or the Legal Department with any questions you may have.

Our commitment is to the highest ethical and legal standards. Metagenics understands that not all activities may come within the scope of these laws. Although our products are not typically covered by Federal Health Care Programs (e.g., Medicare, Medicaid, and TRICARE), the federal laws pertaining to these programs still inform our business because we need to ensure that best practices are consistently and responsibly implemented in all our interactions involving health

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1 Metagenics is also referred to throughout this document as the “Company” and includes its subsidiary, Bariatric Advantage.

2 Health care professionals include, but are not limited to, physicians, pharmacists, nurses, chiropractors, naturopaths, osteopaths, nurse practitioners, clinicians, technicians, staff, members of formulary committees, providers, hospital administrators, and anyone in a position to refer, purchase, or arrange for the referral or purchase of Metagenics products.
care professionals. Additionally, many states have laws that substantially mirror the federal laws. Here is a summary of several laws that the principles in this compliance plan are intended to address:

- **State Anti-Kickback Laws:** Anti-kickback laws generally prohibit the offer or payment of anything of value to an entity or individual to induce or reward the individual or entity for the referral or purchase of Metagenics products. State anti-kickback laws sometimes apply to items or services covered by private payors and/or to self-pay patients.

- **Insurance Fraud:** Fraud against public and private health care plans may also be prosecuted under federal and state laws. Most states make it a violation of state civil or criminal law to defraud an insurance company, including a medical insurer. In addition, the HIPAA All-Payor Law criminalizes a wide range of conduct (e.g., theft, embezzlement, false statements) in connection with public and private health plans.

- **State Unfair and Deceptive Trade Practice Laws:** Most states have broad consumer protection laws that prohibit unfair and deceptive trade practices. State Attorneys General and others may deem arrangements that implicate state laws governing the professional practice of health care providers as unfair or deceptive trade practices. As a result, these consumer protection laws could be applied to arrangements that implicate state anti-kickback laws, fee-splitting prohibitions, or other activities deemed “unprofessional conduct” under state law.

- **State Health Care Provider Disclosure Laws:** Some states have adopted strict disclosure and/or reporting laws requiring manufacturers to report and/or disclose certain transactions with health care professionals. Many of these laws apply only to prescription drugs or devices, but some might apply more broadly. In addition, various state laws may prohibit or require the disclosure of financial relationships involving state employees, including individuals employed by a state health care institution.

- **Food Drug and Cosmetic Act:** The federal Food Drug and Cosmetic Act (“FDCA”) requires that all promotional activities present information consistent with the Food and Drug Administration (“FDA”) approved product labeling. The FDCA requires that promotional materials be truthful and not misleading, present a relevant product’s effectiveness and risks in a balanced manner, and contain certain information. Off-label promotional activities may violate the FDCA and other laws, including the False Claims Act. (Please refer to the policy on “Promotional Materials” for a discussion of the appropriate use of such materials.)

- **Federal and State False Claims Acts:** The federal False Claims Act generally prohibits submitting, or causing to be submitted, a false or fraudulent claim to the federal government for payment or approval. Most states have similar laws, and some states

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3 Even though Metagenics’ products are generally not currently reimbursable by Federal Health Care Programs, Metagenics does business with the Department of Veterans Affairs. Further, given that customers may bill First Line Therapy (“FLT”) services to federal payors, the Company complies with federal anti-fraud statutes, including the federal Anti-Kickback Statute, wherever they may apply.
apply their law broadly to any claim submitted to a third-party payor, including commercial payors. Notably, the federal government takes the position that the federal False Claims Act applies to private insurance obtained through exchanges established under the Affordable Care Act in some circumstances. In addition, any claim that results from a violation of the federal Anti-Kickback Statute is considered false for purposes of the federal False Claims Act. Penalties for violating federal or state False Claims Acts are significant; the laws generally provide for treble damages and per claim penalties.

- Federal Anti-Kickback Statute: The federal Anti-Kickback Statute is a broad criminal statute affecting relationships between manufacturers and health care professionals, customers, and patients. The law generally prohibits the offer or payment of anything of value to any entity or individual to induce or reward the individual or entity for the referral or purchase of Metagenics products, or other items or services which might be reimbursable by Federal Health Care Programs. The law applies to entities (e.g., Metagenics) as well as individuals (e.g., sales representatives).

The **Policies and Procedures for Health Care Compliance** are intended to provide guidelines that will allow Metagenics personnel to operate within this regulatory framework. Importantly, Metagenics will continue to be able to compete, and compete effectively, under these guidelines. For example, Metagenics will continue to be able to offer its customers a wide-array of discounts and rebates, educate providers with regard to the reimbursement environment for its products and services, and provide appropriate business meals under the **Policies and Procedures for Health Care Compliance**. (Please refer to policies regarding “Discounts and Rebates,” “Reimbursement Information” and “Business Meals”.) By undertaking these legitimate business activities, among others, in compliance with the **Policies and Procedures for Health Care Compliance**, Metagenics employees should be confident that their interactions are legitimate and meet the Company’s high ethical standards. Given the complexity of issues that may arise in the health care arena, you are encouraged to ask questions and seek clarification from the Compliance Officer and/or the Legal Department with regard to any activity.

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**Compliance**

The **Policies and Procedures for Health Care Compliance** will be made available on our website, [www.metagenics.com](http://www.metagenics.com), under “Legal/Compliance Program”. All U.S.-based sales, marketing, R&D, and management employees are expected to understand and comply with the law and the **Policies and Procedures for Health Care Compliance**. It is the employee’s responsibility to seek clarification when in doubt about the appropriateness of any contemplated action before that action is taken. As applicable, compliance will be considered in connection with an employee’s performance evaluation.

In addition, all U.S. sales and marketing personnel will be required to certify, on an annual basis, that they have read, understood, complied with, and agree to continue to comply with the **Policies and Procedures for Health Care Compliance**.

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Training

All new employees must complete basic compliance training that covers these *Policies and Procedures for Health Care Compliance* within 30 days of employment. Prior to a new employee’s receipt of training, an employee who has received training will review all of the new employee’s work in the areas of selling, marketing, contracting, and government communications. All employees are required to complete a refresher training on an annual basis.

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Compliance Officer/Compliance Committee

The Compliance Officer is James Fishback. Jim will receive his instructions from Paul Konney, our General Counsel. The Compliance Officer will help the Compliance Committee to implement the *Policies and Procedures for Health Care Compliance*. The Compliance Committee is responsible for the Company’s compliance activities. The Compliance Officer will make periodic reports to the Compliance Committee. The Compliance Committee will consist of Paul Konney, Adam Muchnick, Tonya Ray, James Fishback and Lori Malland.

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Reporting Procedure

If an employee becomes aware or believes that there has been an actual or potential violation of law or the *Policies and Procedures for Health Care Compliance* by a Metagenics employee, the employee must immediately report it to his or her supervisor, the Compliance Officer or the Legal Department. Employees may also report their concerns anonymously through the Compliance Hotline at: (844) 668-7263.

All information will remain confidential, except to the extent necessary to investigate and address issues appropriately. No employee will be subjected to retaliation, intimidation, or disciplinary action as a result of reporting a concern in good faith.

Failure to report a known violation of the *Policies and Procedures for Health Care Compliance* by a Metagenics employee or contractor is in itself a violation of the standards, as is the submission of information about a violation which is known to be false.

If the Company determines, after an appropriate good faith investigation, that there is a violation of law or the *Policies and Procedures for Health Care Compliance*, the Company will take prompt and appropriate corrective action.

If you become aware of a competitor’s practice that violates these standards, you may report this information to the Compliance Officer.

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Disciplinary Action
It is Metagenics’ policy to respond swiftly to potential violations of law and the *Policies and Procedures for Health Care Compliance*, undertake corrective action as applicable, and take appropriate disciplinary action. Employees who violate, or encourage others to violate, the law or the *Policies and Procedures for Health Care Compliance* are subject to disciplinary action. Metagenics reserves the right to impose whatever penalty for a violation as it deems appropriate under the circumstances, up to and including termination of employment. Metagenics is committed to taking appropriate disciplinary action to address inappropriate conduct.

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**Monitoring and Auditing**

Metagenics regularly monitors and conducts audits to ensure compliance with the *Policies and Procedures for Health Care Compliance*. The scope and frequency of these reviews depends on a number of factors, such as the introduction of new business practices. Every employee must cooperate with any compliance-related review.

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HEALTH CARE POLICIES AND PROCEDURES

Set forth below are specific Metagenics Health Care Policies and Procedures. Updates, clarifications, and supplements to these policies will be made on an as-needed basis and disseminated to Company employees.

Reimbursement Information

Metagenics may support accurate and responsible billing for its products and services related to its products. For example, Metagenics may provide, under appropriate circumstances, reimbursement information to health care professionals to support the accurate billing for Metagenics products and health care items and services related to the provision of its products. However, any reimbursement information that is provided, in any form, to health care professionals must satisfy all the following criteria:

- Only specified personnel approved by the Legal Department can address reimbursement information. Under no circumstances are sales and marketing personnel allowed to address this topic and/or furnish any reimbursement information to health care professionals or other customers, except sales personnel may transmit approved materials as permitted under the terms of that approval.

- All reimbursement information must be reviewed and approved by the Legal Department before sharing or distribution.

- All content must be truthful and accurate.

- The content must not be used to encourage the purchase of any product based on reimbursement. For example, promotion based on the “spread” – the difference between the price the customer paid for the product and the amount the customer is reimbursed by a third-party payor – is prohibited.

- The provision of such information should not substitute for, or subsidize, activities that are a part of a customer’s normal operational costs.

- Such information should be provided without regard to the volume or value of any purchases and not presented as a price concession or a benefit to a preferred customer. This information has no independent value and is equally available to all customers.

- Although Metagenics can provide generalized information on coverage, coding, and reimbursement, as provided here and in accordance with other guidance from the Legal Department, for the independent consideration of our customers, Metagenics cannot review coverage, reimbursement, or coding decisions made by health care professionals or provide any coverage, reimbursement, or coding advice, suggestions, analyses, related to particular patients or patient services.

All appropriately-provided reimbursement information should be accompanied by compliance language stating that: (1) it is always a provider’s responsibility to determine and submit the
appropriate codes, charges, and modifiers for services rendered; (2) providers should contact third-party payers for specific information on their coding, coverage, and payment policies; (3) all coding must be supported by adequate documentation in the patient’s medical record; (4) the information provided should not be considered legal or coding advice; (5) providers should consider consulting with an attorney, coding expert, or other qualified professional.

In summary, the Company may provide accurate reimbursement information for its products and services related to its products so long as such information is accurate, includes appropriate disclaimers, and is approved by the Legal Department.

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Business Meals, Entertainment, and Travel

Business Meals: Metagenics employees may provide health care professionals modest meals, occasionally, so long as the meal is: (1) for the purpose of a substantive educational or business discussion relating to Metagenics products or health conditions relevant to Metagenics products, and (2) occurs in venues conducive to educational or scientific communication. Providing any meal to induce or reward an individual for prescribing or purchasing Metagenics products is prohibited. The purpose of a business meal must be to provide scientific and educational information to the health care professional and such exchange must occur. Business meals must be modest as judged by local standards. Metagenics’ policy is that a modest meal with a health care professional should not exceed $65 per person, except for dinners in the fifty largest metropolitan areas (a list of which cities is attached to this Plan), where the cost shall not exceed $100 per person. Please keep in mind that some states regulate the type and value of gifts and/or meals that can be offered, and/or require you to report the details regarding a gift or meal provided to a health care professional.

Meals provided to health care professionals must occur in a setting that is conducive to an educational or business discussion. Often, such a setting is the practitioner’s officer or hospital facility, but may include an appropriate restaurant, or area of a restaurant (such as a separate room), that is conducive to educational or scientific communication. In order to facilitate proper discussion and information exchange, a Metagenics employee must be present during the meal; Metagenics employees may not, for example, deliver food to a medical office that is available to physicians or office staff that are not participating in the presentation. Health care professional’s spouses or other guests may not attend the meal unless the spouse or guest independently has a bona fide professional interest in the information being shared at the event. For example, if the spouse of the health care professional fulfills the role of office manager, then the spouse could have an independent bona fide professional interest in the information being shared.

In addition, there are separate and rigorous rules that apply to the provision of business meals and gifts to federal government employees (e.g., the Department of Veterans Affairs, Department of Defense, FDA, and CMS). Before providing a business meal or gift to a federal government employee, please refer to the “Interactions with Policy Makers and Agencies” policy herein to ensure compliance.
**Entertainment and Recreation:** Metagenics employees may not provide entertainment or recreational activities in connection with any interactions with health care professionals. For example, Metagenics employees may not give away tickets to, or entertain healthcare professionals at, a sporting event or concert.

**Travel:** Metagenics may only reimburse reasonable travel and lodging expenses incurred by health care professionals, *bona fide* consultants, and speakers in connection with and incident to consultant meetings, speaker training meetings, and other meetings that are consistent with the policies herein and are part of a *bona fide* consulting service. Metagenics may not reimburse the travel or lodging expenses of spouses or guests who do not have a *bona fide* professional interest in the information being shared at these meetings.

In summary, Metagenics employees may provide health care professionals modest meals, occasionally, so long as the meal is for the purpose of a substantive educational or business discussion relating to Metagenics products or health conditions relevant to Metagenics products. The provision of entertainment is prohibited. Metagenics may only reimburse reasonable travel and lodging expenses incurred by health care professionals that serve as *bona fide* consultants and are incurred as part of a *bona fide* consulting service.

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**Gifts**

A “gift” is any item that would likely result in a feeling or expectation of personal obligation. The offering or provision of any gift to a health care professional is prohibited.

Metagenics may only provide modest educational items to health care professionals on a limited basis. An “educational item” means an item that is designed primarily for the education of patients or health care professionals, and which does not have any value to the health care professional outside of his or her professional responsibilities. For example, a medical textbook may be an appropriate educational item, whereas a DVD player is not because it can be used outside the medical setting. “Modest” in this context means that the retail value of the item must not exceed $100.

The following types of items are considered gifts and therefore should not be offered or provided to a health care professional: (1) Pens, note pads, mugs, and similar items, with or without Metagenics logos; (2) Items for the personal benefit of a health care professional; (3) Cash or the equivalent of cash (*e.g.*, American Express or other gift cards); (4) Any item that would likely result in a feeling or expectation of personal obligation.

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**Payments for and Use of Speakers, Consultants, Key Opinion Leaders, Advisory Boards, and other Fee-For-Service Arrangements with Health Care Professionals**

Metagenics retains health care professionals to provide a wide-range of *bona fide* services to Metagenics, such as providing information regarding Metagenics products, sales practices, marketing programs, clinical research programs, or to train other health care professionals only
based on their experience, qualifications, and expertise. It is not permissible to use such arrangements as a means to reward or encourage the purchase or use of Metagenics products or to promote off-label use of such products.

All fee-for-service arrangements with health care professionals shall comply with the following requirements:

- Metagenics enters into fee-for-service arrangements with health care professionals only where a legitimate need for the services is clearly identified in advance and documented. The health care professional hired must fulfill that specific and legitimate business need, provide necessary and substantive services, and his or her work product must be documented and used.

- Metagenics hires health care professionals based on their experience, qualifications, and expertise.

- All fee-for-service arrangements with health care professionals must be memorialized in a written agreement. This agreement for services must: (1) Be signed by both parties to the agreement; (2) Set forth the specific services the health care professional will provide and the need for these services; (3) Set forth the specific compensation to be paid; and (4) Be reviewed and approved by Metagenics’ Legal Department before the agreement is signed and/or any services commence or payments for such services are rendered.

- Compensation paid to health care professionals must be consistent with fair market value and not be tied to the volume or value of business generated. Ideally, an independent third party appraiser should determine fair market value. Questions about fair market value issues should be directed to the Compliance Officer and/or the Legal Department.

- The venue of any consultant meeting must be conducive to the services being performed.

- Metagenics may pay for documented, reasonable, and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging (provided that these expenses are in compliance with the applicable policies).

In summary, Metagenics may contract with health care professionals to perform any number of services so long as there is a legitimate business need for the service and compensation under the arrangement is consistent with fair market value. Such services may include, but are not limited to, speaking engagements, consultancies, or participation on advisory boards.

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Interactions with Policy Makers and Agencies

Government employees are subject to strict conflict-of-interest and other ethics laws that severely limit the nature of their interactions with the private sector. Government employees include anyone employed full-time or part-time by a federal government entity (military
civilians). For example, a physician who practices privately and who also works part-time at a Department of Veterans Affairs hospital facility is considered a government employee. The physician is considered a government employee regardless of whether he is physically located at his private practice or on the grounds of the Department of Veterans Affairs hospital facility.

To ensure compliance with the federal laws and regulations governing gifts and business meals provided to government employees, you are required to adhere to the following requirements:

- It is prohibited to provide gifts or business meals to government employees, regardless of the dollar value.
- It is prohibited to provide or offer anything of value to a government employee in exchange for or to induce the order or purchase of a Metagenics product.
- It is prohibited to provide or to offer anything of value to a government employee to influence the government employee in his or her official capacity.

Many government entities, as well as other customers, may have more stringent internal policies than those discussed here. You should be sensitive to and respect those more stringent rules.

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Discounts and Rebates

All discounts, rebates, or other price concessions must be pre-approved as a program or individual offering by the Compliance Committee and/or the Legal Department. All discounts, rebates, or other price concessions offered to a customer or a potential customer must adhere to the following standards:

- All discounts, rebates, or other price concessions must be fully and accurately provided in written contracts, or in the case of discounts offered at the time of sale, in an appropriate invoice. For example, if a customer is entitled to a 5% discount on products, this must be documented in the contract or invoice. If the discount is given with any contingencies, such terms and conditions must be fully stipulated in the contract or invoice.
  - If the exact value of the discount, rebate, or other price concession is not known at the time the contract or sale is executed, its existence and any terms and conditions must nevertheless be documented in writing. For example, if a customer is entitled to volume discounts, the various potential discounts associated with different levels of volume purchased must be documented.
  - All contracts or invoices should provide notification to the customer that they may be required to report discounts, rebates, and other price concessions to government payors. If it is not feasible to include this information in a contract or invoice, this information should be provided to the customer in a letter sent on no less than an annual basis.
• Standard volume-based or market share arrangements may be offered so long as the standard terms are approved by the Compliance Committee and/or Legal Department, and the discount is disclosed in a contract or invoice, as set forth above.

• Any transaction where a price concession on one product or service is contingent on the purchase of another product or service (e.g., buy one get one free) is “bundled.” Contracts that contain “bundled” discounts, rebates, or other price concessions must be approved by the Legal Department before being offered to customers since they pose additional compliance issues. A free good that is provided without a purchase contingency may be provided, as appropriate, to allow a customer to gain familiarity with the product and determine whether the product would be appropriate for use in the customer’s practice (e.g., a sample). Free product is without a purchase contingency if the offer of the free product comes without any obligation whatsoever to buy a product at any time, or in exchange for any promise of any kind.

• Contracts that contain discounts, rebates, or other price concessions that are available for a limited duration also must be approved by the Compliance Committee and/or Legal Department before being offered to customers since they may pose compliance issues.

• The provision of free product in place of a price concession is strictly prohibited.

• Under no circumstances should discounts, rebates, or other price concessions be structured in a manner to “hide” another transaction, and vice versa. For example, educational grants should not be provided to a customer to take the place of rebates owed.

In summary, Metagenics may offer discounts, rebates, and other price concessions on its products and services related to its products so long as the program or individual offering is approved by the Compliance Committee and/or the Legal Department and the price concession is appropriately documented and disclosed to the customer.

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Promotional and Support Materials

Metagenics is committed to complying with legal and regulatory requirements and professional standards for advertising and promotion. All Metagenics promotional materials must be truthful and not misleading. All Metagenics marketing and promotional materials must be reviewed and approved by Metagenics’ Regulatory Affairs Department.

Promotional and support materials can include, but are not limited to:

- Visual Aids
- Product Brochures
- PR Materials
- Displays
- Audio-Visual Materials
- Internet Programs
- Product Websites
- Slide/Computer Presentations
Journal Ads  Patient Brochures
Letters to Physicians  Speaker Materials
Printed Advertisements

- Materials must be consistent with the product’s FDA approved product labeling.
- Metagenics employees may never use self-created or “homemade” promotional materials. Metagenics employees must never alter, revise, add to, delete from, or in any way modify any approved promotional materials, such as by highlighting, stickering, underlining, or adding comments to materials approved for promotion.
- Materials must be consistent with the product labeling which has been confirmed by Regulatory Affairs as compliant with FDA laws.
- Metagenics employees should not make comparative or superiority claims if such claims are not provided in the approved promotional materials.

In summary, only Company approved promotional materials may be provided to customers.

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Incentives to Patients

It is prohibited to offer or provide any type of remuneration to patients that would likely influence the patient to order or receive items from a particular health care provider or from Metagenics. Activities that steer patients to particular health care providers or to Metagenics are problematic because they may raise quality of care and cost of care issues as well as kickback concerns.

In light of these concerns, Metagenics may only offer or provide inexpensive health related items or services to patients when the Compliance Committee or Legal Department approves the provision of the item or service. In this context, “inexpensive” means that the retail value must not exceed $10 per item or service, and may not exceed $50 in aggregate for each calendar year. Cash or the equivalent of cash (e.g., American Express or other gift cards) gifts are prohibited in all circumstances.

Metagenics may offer a program in which a patient may accumulate points to purchase Metagenics products so long as the program meets the standards for discounts and rebates discussed above and is approved by the Compliance Committee. In addition, Metagenics may offer or provide items or services to patients under appropriate financial need based patient assistance programs approved by the Legal Department.

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Company Controlled Promotional Programs
“Controlled promotional programs” are Metagenics-hosted educational and/or promotional meetings. This can include a wide range of activities, including an event where the presenter is speaking at the invitation of Metagenics, conventions, health care displays, and research and development tours; e.g., FLT Certification programs, seminar series, Lifestyle Medicine Summit, etc.

While such promotional programs are educational and provide for scientific discussion, Metagenics is responsible for all aspects of the program. This is regardless of whether the program is organized by a third-party vendor on behalf of Metagenics.

All Metagenics-controlled promotional programs must adhere to the following standards:

- Metagenics is responsible for the conduct, content, and message of all controlled promotional programs.
- The purpose of the controlled promotional program is to educate health care professionals about the proper use and effectiveness of Metagenics’ products.
- All controlled promotional programs must be consistent with labeling which has been confirmed by Regulatory Affairs as compliant with FDA laws.
- All materials shared, provided, or used at controlled promotional programs must be pre-approved by Regulatory Affairs.
- The venue for a controlled promotional program must be conducive to information communication and not lavish.
- Attendees may not receive anything of value (cash, cash equivalents, gifts, etc.) in return for their attendance to the controlled promotional program, with the following exceptions:
  - Metagenics may provide a modest meal and refreshments to attendees in connection with the controlled promotional program, but the meal and refreshments should be subordinate in time and focus to the program.
  - Metagenics may not pay for the attendance or travel costs of anyone for these programs, except that health care professionals serving as consultants for Metagenics (consistent with the relevant policies) and providing bona fide services on behalf of Metagenics can receive appropriate reimbursement for their travel costs incurred in connection with providing such services.
- Speakers at such programs must be selected based on medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Speaker arrangements cannot be used as inducements or rewards for recommending a product or course of treatment. In addition:
  - Speakers must be approved by the Legal Department.
 Speakers may receive a reasonable fee for their services that is consistent with fair market value, and be reimbursed for legitimate expenses incurred in connection with those services.

 Compensation paid to health care professionals who participate on appropriate advisory boards and/or focus groups must not be excessive and must not prevent the participant from making an appropriate decision to participate.

 Speakers must be engaged pursuant to a written contract specifying the services and fees. The written contract must be pre-approved by the Legal Department. The Metagenics employee who engages the speaker is responsible for ensuring that an appropriate written contract is in place prior to any services rendered by the speaker.

 Speakers must be properly trained about their speaking obligations. For example, all speakers must inform the audience that they are speaking on behalf of Metagenics, and that they are presenting information that is consistent with FDA guidelines.

 - All controlled promotional programs must inform attendees that Metagenics is the sponsor. Speakers and all materials must disclose that Metagenics is the sponsor.

 - Controlled promotional programs may not provide attendees with Continuing Medical Education (“CME”) credits.

In summary, the purpose of company controlled promotional program is to educate health care professionals about the proper use and effectiveness of the Company’s products. Metagenics is responsible for all of the content at controlled programs; therefore, all messaging must be consistent with product labeling and approved by Regulatory Affairs. The venue for promotional programs may not be lavish and must be conducive to information communication. Attendees may not receive anything of value in return for their attendance. Speakers must be selected based on medical expertise and reputation and must enter into contracts with the Company.

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Support for Independent Third Party Conferences (Not Controlled by Metagenics)

Metagenics may support bona fide independent, educational, and scientific conferences that promote scientific knowledge, medical advancement, and the delivery of effective health care. These conferences are typically sponsored by national, regional, or specialty medical associations or accredited continuing medical education providers. This section does not apply to conferences or events that are sponsored or controlled by Metagenics (such conferences are addressed in the preceding policy). For all types of support, Metagenics must receive the request for support in writing; the request must specify the various sponsorship levels available; Metagenics must clearly outline in writing the nature of the support being provided; and Metagenics must be satisfied with the educational value of the conference.

Metagenics may support these independent conferences in the following ways:
Faculty Expenses. Metagenics may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for health care professionals who are *bona fide* conference faculty members.

Conference Grants. Metagenics may provide a grant to reduce conference costs or to allow attendance by medical students, residents, fellows, and others who are health care professionals in training only if the grant or subsidy is provided directly to the conference sponsor.

- Metagenics may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending health care professionals who are in training.
- Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities.
- Such grants also should be consistent with applicable standards established by the conference sponsor and any entity that is accrediting the educational activity.
- The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Conference Meals and Refreshments. Metagenics may provide funding directly to the conference sponsor to support the provision of meals and refreshments to conference attendees.

- Metagenics itself may provide meals and refreshments for health care professional attendees if such meals and refreshments are provided: (1) to all health care professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity.
- Meals and refreshments may be provided to fewer than all health care professional attendees if all other principles related to meals set forth in the section on business meals are satisfied.
  - For example, any meals and refreshments should be modest in value, subordinate in time, and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

Advertisements and Demonstration. Metagenics may purchase advertisements and lease booth space for Metagenics’ displays at conferences under appropriate fair market value arrangements.

In summary, Metagenics may support *bona fide* independent, educational, and scientific conferences that promote scientific knowledge, medical advancement, and the delivery of effective health care. Specifically, the Company may provide grants to support: (1) faculty expenses, (2) scholarships for health care professionals in training, and (3) meals and refreshments. In addition, Metagenics may purchase advertisements and lease booth space at conferences under appropriate fair market value arrangements.

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Research
**Research Grants:** At Metagenics, the grant-making function is separate from the sales and marketing functions. The sales and marketing functions shall have no role in the identification or selection of potential research partners or in the grant making process. All requests for external research grants should be directed to John Troup, Ph.D. Funding decisions will be made by Dr. Troup. In making the funding decision, Dr. Troup will review the research protocol that is the subject of the request for a research grant for the following: (1) clinical and scientific merit; (2) investigator competence; (3) patient safety, (4) confidentiality and protection of rights; (5) probability of publication in a journal; (6) appropriate regulatory status; (7) ethical concerns; and (8) alignment with a defined product development or other clinical need. The scientific rational for providing the research grant must be documented.

Dr. Troup shall coordinate with the Compliance Committee and/or Legal Department to ensure that concerns with respect to the FDA, other regulatory, or intellectual property are addressed.

If funding is approved by Dr. Troup, checks will be mailed directly to the recipient. Metagenics sales and marketing personnel may not personally deliver checks.

**Metagenics-Sponsored Research:** “Metagenics-sponsored research” is research that is designed, conducted, or supervised by Metagenics. Research intended to support a change in the labeling of a product or proposed advertising claim should generally be conducted as Metagenics-sponsored research. Metagenics is dedicated to ensuring that sponsored research is conducted ethically and in the best interest of the participants. The sales and marketing functions shall have no role in the selection of potential investigators.

All Metagenics-sponsored research must adhere to the following standards.

- The sponsored research must be scientifically valid, and likely to generate data that will be relevant to a defined clinical, product development, or business need.

- The clinical investigators must establish the purpose of the sponsored research and how the data generated is likely to be used, as well as a timeline for the sponsored research’s completion.

- The clinical investigators must be fully informed of the potential benefits and risks of the product before anyone may enroll and participate in the sponsored research.

- A qualified Institutional Review Board (“IRB”) must review all sponsored research to be conducted in the United States or to support FDA approval of a new product, indication, or dosage form.

- At all times, sponsored research must ensure that the safety of the participants is respected and protected, be conducted in accordance with the principals of good clinical practice, and ensure the integrity of the research data. Any misconduct must be immediately reported to the Legal Department.

- All participants must provide voluntary informed consent.
• All patients must be free to withdraw from the sponsored research at any time without penalty or loss of benefits to which they are otherwise entitled.

• Compensation to participants should be fair and IRB approved.

• The sponsored research protocol should address the cost of medical care for physical injury or illness that occurs during or after an individual’s participation in sponsored research, as well as post-research care issues.

• Metagenics generally assumes the appropriate costs of all products and services offered in the context of sponsored research.

• Compensation for investigators of sponsored research must be documented in the written agreement with the investigator, consistent with the fair market value of the activities and expenses undertaken to perform the research or clinical study. The compensation must not be tied to the outcome of the sponsored research.
  
  o Compensation for sponsored research services must not include any Company stock or stock options.

  o Only health care professional who participate in the sponsored research may be compensated for their services. For example, physicians who refer individuals for participation in a sponsored trial cannot be compensated for any referral.

  o The compensation must be disclosed in the informed consent documents provided to the IRB where applicable.

• The investigator must not have a significant investment in Metagenics, and must provide financial disclosures to Metagenics regarding any related compensation, proprietary interests, equity interests, and payment of other sorts.

• Neither the investigator nor her immediate families may hold any direct ownership interests in the specific compound being studied, though ownership of Metagenics stock is not prohibited.

• The venue and any amenities associated with the meetings for the sponsored research must not be lavish, and must be appropriate for the business purpose of the meeting.

• Data must be presented in a truthful, complete, accurate, and balanced manner. Any report must discuss the sponsored research’s strengths and limitations, and must disclose the fact of Metagenics’ support.

In summary, Metagenics-sponsored research must be scientifically valid and designed to protect study subjects. Arrangements with clinical investigators should be written and any compensation arrangement should consistent with fair market value and disclosed to the IRB and study subjects. Investigators should not have a financial conflict of interest and should disclose any financial interest with Metagenics.
Publication Activities

Metagenics is committed to the responsible and ethical publication of the results of clinical trials and other research involving Metagenics products. The publication of the results of clinical trials and other research is an important part of the scientific process and Metagenics is committed to supporting medical progress through the dissemination of new research findings.

The policies set forth in this section apply to publications in biomedical journals, presentations at scientific meetings, peer-reviewed publications, and non-peer reviewed scientific communications, such as posters, lectures, and book chapters. They do not cover the publication of promotional materials.

Metagenics requires its employees involved in publication activities to follow the guidelines set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals issued by the International Committee of Medical Journal Editors. In addition, Metagenics requires publication activities to be in compliance with the following standards below.

Publication: Metagenics is committed to timely and appropriate disclosure of meaningful results from controlled clinical trials of investigational and marketed products. Study results must be reported in an objective, accurate, balanced, and complete manner. The report must also discuss study strengths and limitations and the study authors must have final sign-off authority on all publications.

Disclosure of Financial Support: All publications which relate to or result from research supported in whole or in part by a grant or other financial support from Metagenics shall disclose Metagenics’ financial support.

External Investigators: Any arrangements between Metagenics and external investigators must be documented in a written agreement. Metagenics does not enter into publication agreements in order to influence or reward prescribing practices of an external investigator.

- The agreement should specifically address publication policies (including disclosure of financial support) and ownership of data.
- The agreement shall disclose any financial support provided by Metagenics and acknowledge that the researcher, and not Metagenics, is responsible for the content of any publications.

Authorship: To be named an author of a Metagenics-sponsored study, an individual must contribute meaningfully to the publication. The authors determine the order of the names on the byline based on the degree of contribution to the work. The authors control the publication decision, which includes choosing the target journal and deciding what type of publication to prepare, such as an abstract, letter to the editor, or full paper. The authors are collectively responsible for the decisions that are taken regarding these matters.
**Contributors:** Contributors should be listed in the “Acknowledgements” section or in an Appendix, generally as a “contributor,” “clinical investigator,” or “scientific advisor.” A “contributor” is anyone who makes a significant contribution to the study but does not meet the authorship standards. Metagenics employees who help analyze and interpret data and who produce manuscripts and presentations must work with a qualified author and must be recognized appropriately in resulting publications.

**Professional Writers:** A professional medical writer may be used to provide publication expertise and assist in the editing and preparation of manuscripts or collating comments from contributors. Use of a professional medical writer, however, must never substitute for the professional responsibility of each of the named authors to be independently responsible for both the content and the conclusions of any publication. When a professional medical writer is involved with the publication, the following guidelines should be followed:

- The medical writer should begin drafting the manuscript only after consultation and discussion with the named author(s)/contributors.
- The named author(s)/contributors should be given adequate time to comment on the early draft of the manuscript.
- The named author(s)/contributors should approve the final version of the manuscript before it is submitted; the primary author should submit the manuscript to the journal/association.
- The contribution of the medical writer should be acknowledged.

In summary, Metagenics requires its employees involved in publication activities to follow the guidelines set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals issued by the International Committee of Medical Journal Editors.

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19
## Fifty Largest Metropolitan Areas

<table>
<thead>
<tr>
<th>Rank</th>
<th>City, State</th>
<th>Population*</th>
<th>Rank</th>
<th>City, State</th>
<th>Population*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New York, NY</td>
<td>8,491,079</td>
<td>26</td>
<td>Baltimore, MD</td>
<td>622,793</td>
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<tr>
<td>2</td>
<td>Los Angeles, CA</td>
<td>3,928,864</td>
<td>27</td>
<td>Oklahoma City, OK</td>
<td>620,602</td>
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<tr>
<td>3</td>
<td>Chicago, IL</td>
<td>2,722,389</td>
<td>28</td>
<td>Portland, OR</td>
<td>619,360</td>
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<tr>
<td>4</td>
<td>Houston, TX</td>
<td>2,239,558</td>
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<td>Las Vegas, NV</td>
<td>613,599</td>
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<tr>
<td>5</td>
<td>Philadelphia, PA</td>
<td>1,560,297</td>
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<td>Louisville, KY</td>
<td>612,780</td>
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<td>6</td>
<td>Phoenix, AZ</td>
<td>1,537,058</td>
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<td>Milwaukee, WI</td>
<td>599,642</td>
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<tr>
<td>7</td>
<td>San Antonio, TX</td>
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<td>32</td>
<td>Albuquerque, NM</td>
<td>557,169</td>
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<tr>
<td>8</td>
<td>San Diego, CA</td>
<td>1,381,069</td>
<td>33</td>
<td>Tucson, AZ</td>
<td>527,972</td>
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<tr>
<td>9</td>
<td>Dallas, TX</td>
<td>1,381,069</td>
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<td>Fresno, CA</td>
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<tr>
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<td>Mesa, AZ</td>
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<td>Indianapolis, IN</td>
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<td>Atlanta, GA</td>
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<td>Charlotte, NC</td>
<td>809,958</td>
<td>42</td>
<td>Colorado Springs, CO</td>
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<td>18</td>
<td>Detroit, MI</td>
<td>680,250</td>
<td>43</td>
<td>Raleigh, NC</td>
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<td>Miami, FL</td>
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<td>Denver, CO</td>
<td>663,862</td>
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<td>Minneapolis, MN</td>
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<td>22</td>
<td>Washington, DC</td>
<td>658,893</td>
<td>47</td>
<td>Tulsa, OK</td>
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<td>23</td>
<td>Memphis, TN</td>
<td>656,860</td>
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<td>Cleveland, OH</td>
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<td>Boston, MA</td>
<td>655,884</td>
<td>49</td>
<td>Wichita, KS</td>
<td>388,413</td>
</tr>
<tr>
<td>25</td>
<td>Nashville, TN**</td>
<td>644,014</td>
<td>50</td>
<td>New Orleans, LA</td>
<td>384,320</td>
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</tbody>
</table>

*July 1, 2014 (est.)

**Nashville-Davidson City is consolidated with Davidson County