

STATEMENT OF KRISTOPHER KING, CHIEF EXECUTIVE OFFICER,
SURACELL, INC. BEFORE THE SPECIAL COMMITTEE ON AGING, UNITED
STATES SENATE

“Direct To Consumer Genetic (DNA) Testing”

July 27, 2006

Introduction

Mr. Chairman and Members of the Committee, my name is Kristopher King, and I am the Chief Executive Officer of Suracell Inc.(biography attached). Suracell is looking forward to helping provide clarity and substance to questions related to direct to consumer genetic testing. We welcome the opportunity to provide the committee with Suracell's business approach, and the steps we have taken on behalf of our clients in the area of consumer protection.

Our original response to the Committee, that we respectfully decline to appear, was based purely on the fact that we are a small company and we felt that the unavailability of our Chief Science Officer, Dr. Vincent Giampapa, on such short notice would make our response inadequate.

I have been asked to provide the Committee with a response that is as comprehensive as possible under these circumstances, that addresses the concerns and interest of the Committee, as they have been conveyed to me by the Chairman's staff.

Introduction to Suracell, Inc.

There are seven key points that should be noted with regard to Suracell:

1. Suracell does not perform genetic (DNA) testing.
2. Suracell offers nutritional advice and supplements to our clients.
3. Suracell does not make any recommendations or diagnoses in relation to disease, medical conditions or prescription drugs.
4. Suracell has a privacy policy carefully designed and implemented to protect the privacy of client information.
5. Suracell's program has a comprehensive informed consent process.
6. Suracell's program is based on sound and accepted scientific research.
7. Suracell is committed to the ongoing education of an informed client base.

Suracell was incorporated in 2004 with the mission of providing consumers with state of the art **personalized nutritional information and products** that can help optimize wellness. Suracell's Chief Science Officer is Vincent C. Giampapa, MD, FACS, whose biography can be found on Suracell's website at

http://www.suracell.com/about_us/giampapa.asp .

Based on his ten years of practicing age management medicine, Dr. Giampapa observed that with specific types of DNA and biomarker testing, and focused nutritional advice, including specific nutritional supplements, his patients' overall health status in several areas greatly improved in a relatively short period of time, and this improvement could be

measured by follow-up testing.

This research was published, and further advances in the field of nutrigenomics confirmed this research, which led to the company's inception.

Suracell is further guided by a **scientific advisory board** comprised of specialists in genetics, microbiology, gerontology, and several MDs.

Suracell's Program

Suracell does not perform DNA testing.

Suracell's program is not designed or intended to diagnose any disease, medical or genetic condition, or recommend any treatment for any disease, medical or genetic condition.

Suracell's program has no involvement, coverage or reimbursement of any kind from either health insurance carriers, Medicare, Medicaid or any other program.

Aging is a complex and multifactorial process that includes reduced cell replication, impaired cell maintenance and impaired cellular repair.

Current medical practice places great emphasis on the use of prescription drugs for

disease prevention or control because they are an easy alternative to implementing changes in diet and lifestyle. Studies have clearly shown that lifestyle and diet changes have not only psychological and economic benefits but are also important in disease prevention and longevity.

Suracell's program is designed and intended to provide clients with information enabling them to optimize their general wellness, via supplements, diet and lifestyle changes.

Suracell provides a service to consumers enabling them to receive nutritional advice and a supplement regimen that is personalized to their needs. For example, millions of consumers visit retail locations that sell vitamins and supplements and purchase various products without any real knowledge of which of those products are appropriate for them. Suracell's program brings efficiency to the process by recommending any needed supplementation at a personal level, which then means that a consumer may not take unnecessary supplements.

One of the three components of Suracell's personalized nutritional program is an analysis based on information obtained from the results of a **buccal cell based gene variant test** that identifies **twenty-six** gene variants that are associated with the efficiency of five metabolic processes: glycation, inflammation, methylation, oxidative stress and DNA repair.

The results of the analysis can help educate a client about the type of nutritional support that may benefit them. For example, a consumer whose profile reveals a deficient value for gene SNP (variant) LEPR K109R, which relates to the regulation of insulin and blood sugar, may benefit from including supplements containing polyphenolic polymers in their diet.

Another example would be for a consumer whose profile reveals a deficient value for gene SNP (variant) MTHFR C677T, which relates to homocysteine levels. This consumer would benefit from increasing their intake of folic acid.

The correlations between particular genetic variations and optimum nutritional support are based on **peer reviewed scientific literature**. Suracell maintains thousands of pages of study and reference data for review and analysis. Suracell is prepared to supply supporting studies and literature for the genetic science that supports the Suracell program, on further request from the committee.

Financial Issues Related To Suracell's Program

Because providing genetic testing is **not the purpose** of Suracell's business, Suracell **does not** make a financial profit from any DNA testing performed to provide information for analysis as part of its nutritional program.

Laboratories Performing DNA Testing for Suracell's Nutritional Program

The DNA test used by the laboratory to provide information for Suracell's nutritional program is performed by **SeraCare BioServices**, based in **Maryland**. SeraCare uses a "**home brew**" method for processing DNA samples submitted as part of Suracell's nutritional program.

Suracell has previously received confirmation from SeraCare that **CLIA** certification is in place for their facilities in Maryland.

Suracell Program Results

Suracell provides **clients and their health care professionals** with the results of the analysis provided by our program, and recommends nutritional supplements based on those results. To date, the percentage of Suracell clients receiving their results from a **physician or health care practitioner is 72%** -- which means that **28%** of Suracell clients have begun the program at home, and received their results in the manner of a direct to consumer approach. Clients who participate in this way are requested to select a Suracell affiliated physician or health care practitioner in their locality. If there are none available in their area, clients can choose to be assigned to the oversight of Dr. Giampapa, and may request that Dr. Giampapa provide any follow-up consultation needed to explain the analysis they receive, and to answer any questions that may arise as a result of their participation in the program.

Suracell's Clients

The Suracell program is designed for informed clients between the ages of **40 to 60**, because the processes affecting glycation, inflammation, methylation, oxidative stress and DNA repair are typically less efficient at this age, due to genetic inheritance, environmental exposures and lifestyle, but research indicates that improvements can still be made within this age range to enhance overall wellness. For example, simple dietary changes can significantly reduce oxidative stress levels which in turn can lead to improved overall wellness. The vast majority (approximately **85%**) of Suracell's customers are in the **40 to 55** age range.

Consumer Access to the Suracell Program

The Suracell program is recommended for consumers with the oversight of a licensed physician, genetic counselor or health care practitioner. Suracell's website lists the following organizations as additional resources for consumers:

National Society of Genetic Counselors

<http://www.nsgc.org>

National Human Genome Research Institute, NIH:

<http://www.genome.gov>

National Institute on Aging, NIH:

<http://www.nia.nih.gov>

The American College of Medical Genetics:

<http://www.acmg.net>

The American Medical Association:

<http://www.ama-assn.org>

GeneClinics:

<http://www.geneclinics.org>

The American Aging Association:

<http://www.americanaging.org>

American Association on Aging:

<http://www.asaging.org>

Suracell Disallows Online Purchase of DNA Test Kits In Accordance With State

Laws

Suracell's website is designed to **disallow online purchase** of DNA test kits in states which may not allow such tests to be purchased directly by consumers. There are approximately twelve states that may restrict testing in this way. Suracell **closely monitors** all existing laws that apply at the **state and federal level** related to Suracell's business, and can immediately make adjustments to comply with any new regulations.

Suracell's Consent Process

Suracell does not sell to anyone under the age of 18 and requires each customer to provide informed consent. The consent forms for the Suracell program are available online both to affiliated physicians and consumers. Suracell has established a comprehensive **FAQ** section on our website (link at <http://www.suracell.com/faqs/>) to ensure that consumer questions are answered and that the answers are clearly understood.

The consent process requires that customers actively consent to the testing of the samples they provide, in advance of any testing procedures, and, separately, that they consent to having their physician / health care practitioner receive the results of the analysis of such tests. While it is possible to provide the required consent online, most affiliated physicians print consent forms to discuss with their patients and keep completed printed versions in the patient files.

Notably, the laboratories performing the tests for Suracell destroy specimens upon testing completion, so the samples cannot be used for any other purpose.

Suracell's Privacy Protections

Suracell has a detailed, published privacy policy, available on our website at <http://www.suracell.com/privacy.asp> . Suracell adheres to the FTC standards for privacy and protection of consumer information. In addition, Suracell maintains compliance with the privacy and information provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as the Gramm-Leach-Bliley Act (GLBA) and other applicable state and federal privacy laws. Suracell's internet system is housed in a HIPAA compliant data center, and uses technology methods such as SSL and PKE to secure and encrypt client data. Suracell's privacy policies and procedures are reviewed annually by TRUSTe, an outside privacy auditing agency.

Direct to Consumer Genetic Testing: Current State of the Business

By using an internet search engine, it appears that there are at least **fifty** or so companies

currently offering **direct to consumer** genetic (DNA) testing, particularly via the internet. There are roughly **five** categories of genetic tests being offered (in order of greatest number): paternity; genealogy; pre-natal; disease screening; nutrigenomics.

Suracell does not appear in the search results for “DNA testing” because this is not our business, and we do not promote Suracell in that way.

There are **several things** that become apparent as we search through the lists of companies offering these services: there is **no definitive way** for the consumer to determine the true **accuracy** of these test; there does not appear to be any “seal of approval” or oversight offered by any organization that would provide an **independent verification** of the usefulness and accuracy of the testing (although some companies appear to have accreditation by the American Association of Blood Banks); there does **not appear** to be a single, comprehensive standard for **follow-up, advice or support** offered to consumers with regard of the outcome of these tests.

Suracell’s Concerns Related To Direct To Consumer Genetic Testing

The overriding concern about direct to consumer testing must be the protection of the public from misleading and inaccurate information. The most important aspect of this is the **accuracy** of the testing and results provided. Consumers may be making life-altering decisions based on the results of these tests, particularly in the area of paternity, disease screening and pre-natal screening. Therefore, the public needs to be **protected** by oversight and validation of the laboratories providing test results. **An expansion of**

the CLIA standard to include the sub-specialty of genetic testing would be a useful step in this process.

Suracell's Views On Article: Federal Neglect: Regulation of Genetic Testing:

Gail H. Javitt, Kathy Hudson (“**Issues in Science and Technology**”, Spring 2006).

This article, specifically referenced by the Senate Committee on Aging, on which we were asked to provide comment, appears to raise several salient points related to direct to consumer DNA testing:

Suracell is in agreement with the following points raised by the article:

- the FDA should expand its oversight of ASRs
- there should be a specific CLIA standard for the sub-specialty of genetic testing
- there needs to be governmental oversight of the accuracy and predictive value of tests, particularly with regard to pharmacogenomic tests that involve disease prediction
- the FTC should closely examine advertising claims made by companies offering direct to consumer DNA testing, to make sure the advertising is not misleading, or making false or exaggerated claims about the accuracy and meaning of test results

Suracell's Recommendations

Suracell knows of **no way** in which the providing of genetic and nutritional information

to clients as part of Suracell's nutritional program can result in any harm to those clients, as long as the accuracy and confidentiality of that information is maintained.

Suracell **strongly believes** that informed consumers can benefit from knowing their genetic variance as it relates to the aforementioned metabolic processes because such knowledge enables them to make **dietary and behavioral changes** to improve their overall wellness.

In addition, Suracell believes that in order for the benefits of new genetic knowledge and technologies to be realized, the public **must be assured** that genetic testing is accurate. Suracell believes that **increased governmental oversight is necessary to protect the public** from companies selling inaccurate tests or services.

Suracell recognizes and **recommends** that establishing a genetic testing specialty certification within CLIA may be an **effective strategy** to achieving oversight of genetic testing, and is supportive of this action. Furthermore, Suracell welcomes and supports actions at the federal level to provide consumer protection and assurance in the area of genetic testing, believing that such actions would be beneficial to companies, such as Suracell, that seek to provide accurate and ethical services to the public.

It is Suracell's belief that the federal government should **lead the way**, even if congressional action and **further legislation** is needed. Suracell **voluntarily** offers its services in support of any such effort, and is committed to making whatever adjustments

or changes might be necessary to comply with any new regulations or provisions of law.

Concluding Statement

Suracell thanks the committee for the opportunity to submit testimony to the Senate Committee on Aging, and is happy to answer any further questions it may have of Suracell, and supply any further assistance that may be requested.

Suracell's team looks forward to reviewing the report of the GAO on the issue of direct to consumer genetic testing, and the recommendations made therein. If requested so by the Committee, we would be happy to provide written comments in response to the Report's findings and recommendations, once we have had the opportunity to review the documents.

I would be happy to respond to any questions the Committee Members might want me to address.

Kristopher King - Biography

Kristopher King has been prominent in the business world for many years, during which time he has been a consultant to some of the world's largest companies, as well as founding several high-growth companies himself.

Kristopher has utilized his experience and skills to create successful technology focused companies in both the technology service and product areas. He has served as CEO of several of these companies.

Kristopher currently sits on several boards, including the Boy Scouts of America, and Norwalk Community College Foundation Board.

He attended Fairfield University in Fairfield, Connecticut.