



Creating enterprise excellence consistent with the highest standards of ethics and civic responsibility through best practices.

A Word from the Founder. . .

A Guide For Moral Perfection

A generation before our Founding Fathers declared America a new nation, a young printer worked diligently to make his community a better place to live and in so doing became the model for the concerned citizen and activist that is the backbone of our republic. This young printer is responsible for the modern public library system and volunteer fire departments that are now common throughout the United States. Intellectually curious, he also thought that freed of the restraint of the Old World, mankind could perfect itself and thereby achieve self respect and happiness through living to be good. For himself and as a guide for others, he codified his rules for living into a “a guide for moral perfection” that has been largely forgotten by history.



While much has changed in the last 275 years, humanity remains subject to the same constraints. The printer’s “Project for Moral Perfection” offers some useful guidance still for all of us who seek some time tested advice on how to live a life free of the defects in character that can lead to sleepless nights brought on by a burdened conscience.

The project he outlined in his intentionally modest colonial home came about after he became disgruntled with organized religion. Self-reliance and love of his fellow man were at its core. Though the young man was never an atheist, like Thomas Jefferson, he became a Deist at a young age. This now largely forgotten form of Christianity was based on a view of God as the Great Watchmaker in the sky, who was not directly involved in the day-to-day activities of the world. This young philosopher wholeheartedly adopted the religion which inspired him to rely on himself rather than divine intervention. These beliefs, in turn, led him to construct a method not for mere moral improvement, but for perfection. As is characteristic of his inventive mind, he aimed high, forgoing lowered expectations in favor of pushing the limits of his own humanness and discovering the absolute limits of which he was capable.

He dreamed of an America characterized by unity, purpose, and morality that would thrive and be known the world over for its industry and right dealings. The premise of the project was based on thirteen core values to act as guides in the improvement of one’s character. In his own life he concentrated on one value at a time, and having mastered that one, moved on to the next until he had them all licked. “I wished to live without committing any fault at any time,” he wrote. “As I knew, or thought I knew, what was right and wrong, I did not see why I might not always do the one and avoid the other”. And so, the great inventor Benjamin Franklin used himself as a test subject in his great moral endeavor. He listed the following virtues as those for which all Americans should strive:

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Meet Our Management: Dr. Kenneth J. Roozen, Treasurer

by Devin Eakes

Dr. Ken Roozen came to Charleston, SC in September of 1997 to become the founding Executive Director of the MUSC Foundation for Research Development. Soon after the founding of The Free Enterprise Foundation, The President of MUSC designated him as The Medical College's Board member, and he was elected Treasurer of The Foundation last June. Through his role with our foundation and his other civic activities, he continues to strive to benefit and promote the medical university and our community.

The Research Foundation is a 501 (c)(3) nonprofit organization supporting MUSC with technology transfer and business development expertise which contributes to MUSC's more than \$175 million a year in research grants. It was created by MUSC to help facilitate relationships between MUSC, the public sector, and industry. The Foundation's primary role is to identify and protect the intellectual property of the university, its students and faculty investigators, while also encouraging research leading to the development of patentable procedures and products. Once new technology is identified and protected, the Foundation markets and licenses its potential devices, diagnostics, drugs and other medical products to private industry where they can be further developed for human health benefit and derive a financial benefit to MUSC. The foundation also works closely with the Charleston Angel Partners, Think Tec, SCBio, government at all levels, and businesses to spark further growth of knowledge based business in the Low Country and State.

Founded in 1996, the Foundation has identified and reviewed more than 350 inventions and filed more than 150 patent applications. Options and licenses to industry have already resulted in revenues of more than \$4M to the Foundation and the creation of more than a dozen new companies in which the Foundation generally holds equity. One such company, Micrus Endovascular Corporation recently became the first South Carolina university "spin-off company" to become a publicly traded company.

In coming to Charleston, Dr. Roozen retired from a distinguished career at the University of Alabama

at Birmingham. Dr. Roozen received his PhD in Molecular Biology in 1971 and completed postdoctoral studies before joining the faculty at UAB. Through his 25 years of employment and service there, Dr. Roozen played a key role in UAB's rise to prominence with annual research awards exceeding \$250M and an annual budget of \$1 billion in 1997. Some of the roles he played included Provost and Executive Vice President, Vice President for Research and External Affairs, Dean and Co-Director of the Graduate School, Department Chair, and Executive Director of the UAB Research Foundation. As the MUSC Foundation for Research Development has become for MUSC and Charleston, The UAB Research Foundation became the focal point for high tech industry creation and technology transfer at UAB and in Birmingham. He was attracted to Charleston

because MUSC's leadership had a desire to build its research and technology transfer programs and he looked forward to helping them derive some of the same economic growth he had witnessed in Birmingham.

While the growth of research programs at MUSC in the last decade has been dramatic, Dr. Roozen acknowledges some disappointment that the infrastructure and environment to support high tech industry creation, recruitment, and growth has not matured more quickly. Only in the very recent past have strategic initiatives and

investments enhancing access to capital, research university faculty and facilities, technology transfer and new business development assistance been implemented by the State of South Carolina. The Charleston area still lacks a new technology business incubator with laboratory facilities critical to housing biomedical companies and this area remains one of the largest metropolitan areas in the southeast without a comprehensive university where traditional students and life-long learners can acquire training in engineering, the physical and chemical sciences, and the compute sciences. He believes all of these elements must be addressed for Charleston to become a more diverse economy with a growing emphasis on research and development driven industry and to "catch up" with other cities that are now capturing the majority of high technology business growth, job quality enhancement, and wealth creation.

Dr. Roozen will be retiring (again) in July as Executive Director of the MUSC Foundation for Research Development but is looking forward to remaining in the beautiful Charleston area. He anticipates continued involvement in several roles which concern the economic development of the region and state.



Bob Pitts
Dean, School of Business and Economics, College of Charleston
by Devin Eakes

When a change in leadership occurs in one of our significant partner institutions, it is worthy of attention. Such a change occurred last summer at the School of Business and Economics (SBE) at the College of Charleston. In the past four years, President Lee Higdon has made sweeping changes throughout campus; many of these are a direct correlation to his Fourth Century Initiative Plan. One of the main focuses of this plan is to become a nationally recognized “preeminent public liberal arts institution.” For such a bold proposal to take shape all areas of the college must join, particularly its School of Business and Economics, one of the largest and most influential schools at the college. This transition was arguably one of the more important instances to date for the SBE since its founding under the leadership of Dean Emeritus Howard F. Rudd, Jr. Following the national search, Robert E. Pitts was selected as the new Dean of the College of Charleston School of Business and Economics.

While Pitts has spent much of his recent time far away from the Southeast, and comes to the School from a similar position at Creighton University in Omaha, Nebraska he sees taking on his new post as a “homecoming” of sorts. He is happy to be back in the area from which he received his highest level of education, a PhD in Business Administration with dual concentrations in Marketing and Behavioral Management from the University of South Carolina. He is excited about the possibilities that are available and the strong base of leadership which he hopes to cultivate and use to further strengthen the SBE. In expressing his optimism, Pitts points out the many opportunities that Charleston has to offer. When comparing it to his most recent stop in Omaha, Charleston is certainly a more internationally focused city; a unique advantage Pitts thinks should be stressed not only in the community but in the classroom as well.



In addition to raising its standards alongside the new objectives of the college, the SBE is also undergoing its own changes as well. Pitts believes that the school must first be able to identify its strengths and weaknesses if it hopes to continue to excel. One of these strengths as well as one of the most prominent and noticeable changes in the SBE is the completion of the Beatty Center. The Beatty Center is the second structure built to house the ever growing SBE. In addition to increased classroom and office space, the building also houses a trading floor for the students to use. Along with these strengths come some weaknesses which the Dean sees as opportunities. Two such opportunities that Pitt points out are the need to offer additional degrees in specialized areas of business graduate school at the College of Charleston and the increased involvement of local leaders and local businesses in the long-term development of the college.

In conjunction with Pitts’ coming, the development and cooperation between the SBE at the College of Charleston, The Citadel School of Business Administration, and the Free Enterprise Foundation will aid in the successful forging of an even stronger program at the SBE as part of a coordinated effort for a world class business education. Setting our community apart as well is the strong reputation our institutions have for ethical leadership and emphasis on the responsibility business has to lead in community service not just in business. The SBE along with The Citadel and The Free Enterprise Foundation emphasize the establishment and perpetuation of a free market economy, in which those who follow ethical practices are free to achieve success without hindrance. Particularly in a society and time where corporate abuses seem to be commonplace, a re-emphasis on “ethics and social responsibility” is essential for the business education.

Predicting a tsunami of drug adverse events by finding a few signal needles in a giant noisy haystack

by: Dr. Leigh Thompson

Shortly before Dr. Thompson's death this past January, I received on my computer a few articles from him to be considered for future issues. We are pleased to be able to include one such offering in this issue proposing a special class of FDA approval with heightened scrutiny for critical drugs. We will include additional offerings from Dr. Thompson in future issues. Truly the Doctor has devised a way to keep on giving even when he can't be with us fully. Ed.

The Asian tsunami killed 150,000 folks who were not told it was coming. A FDA "reassessment" of Vioxx noted that 150,000 folks might have died of heart attacks or strokes attributed to Vioxx, before these dangers were fully recognized and addressed. Both were failures of signaling the hazard. How can we recognize those signals and effect the timely warnings?

Preapproval controlled clinical trials may span several thousand patients with excellent data capture and analysis so safety signals are easily recognized and evaluated. However, such trials often include only classical cases of the target disease, resilient patients who lack other diseases and take few concomitant medicines, and treatment of only 300 to 600 patients for six months at appropriate dosages. If no serious adverse events are reported in 300 patients, you can be 95% sure that the incidence in a larger group is less than 1%. But if one or two patients on drug had heart attacks, would they be attributed to the therapy or to the background incidence unrelated to the study?

After approval for marketing, all serious adverse events worldwide are reported to FDA that now has a database of 3,000,000 such reports, adding 400 each day. But only 1% to 10% of events are reported at all and most reports are fragmentary and lack key data. There are no control groups so you can count the number of reports of heart attacks in patients taking Vioxx but are these more or less than would be seen in those patients taking an alternative anti-inflammatory? There are no incentives to report adverse events and powerful disincentives. Physicians must take valuable time to capture, assemble, and report key data and fear that reporting will get them harassed for more data and expose them to the possibility of criticism or lawsuits. Patients may be concerned to maintain confidentiality. Sponsors of new drugs are eager to define safety concerns and modify the label and promotion to protect their valuable product, but the physicians and scientists with the concerns are not the salespeople who are best able to learn of such events but are paid for sales not negative reports.

A new approach would be to create a special tier of approval that carefully monitors patients prescribed a new drug deemed "priority" by FDA. Priority drugs would be those having real potential for significant improvement in the treatment of a serious illness. If the patients are followed carefully, this expanded and relaxed trial mode, simulating more closely the unrestricted market experience to follow, could begin after initial classical clinical trials have established a "proof of principle" of potential safety and efficacy with, for example, careful study of 300 patients for three months.

Usually at that point the sponsor begins two controlled pivotal studies, encompassing several thousand patients treated with drug versus placebo or an active comparator. Because only a few specialized investigators are chosen and they have only a few classical patients to enroll, patient recruitment is slow and, with observations for one year, it may take four years before the data are approved by FDA. Those are four years in which other patients with the serious illness have no access to the therapy even though they may gladly accept the risk of a new and unproven drug.

Instead, suppose fully-informed patients and their physicians could elect to participate in an early marketing trial in which they had access to the therapy at a discounted price and agreed to close monitoring and full reporting of serious adverse events. If the treatment is later marketed without restrictions, they would have had access about four years early, a very significant interval in many serious illnesses. If there are unrecognized safety concerns, they would be detected and lead to modification or cessation of the trial much earlier than would have occurred after unrestricted marketing.

If 25,000 or more patients were in a controlled study for a reasonable period of exposure to the therapy, its safety could be better defined. The sponsor could elect to pay for specific assessment of efficacy, or to rely solely on observations of the patient and physician in parallel with one additional traditional tightly-controlled pivotal study. Physicians would be eligible if they were board-certified and agreed to careful care of the patient with expedited reporting of patient status by the internet, facsimile, or telephone. They also would agree to process frequent communications from the sponsor about the study and any safety signals detected. Patients would have the target illness and be deemed suitable by their physicians, and would agree to frequent reporting of status by internet, facsimile, or telephone. They too would receive frequent bulletins on the study. Drugs would be dispensed by a central pharmacy, perhaps monthly, using expedited delivery to the patient but only after

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A Guide for Moral Perfection: continued from page 1

1. Temperance – Eat not to dullness; drink not to elevation.
2. Silence – Speak not but what may benefit others or yourself; avoid trifling conversation.
3. Order – Let all your things have their places; let each part of your business have its time.
4. Resolution – Resolve to perform what you ought; perform without fail what you resolve.
5. Frugality – Make no expense but to do good to others or yourself; that is, waste nothing.
6. Industry – Lose no time; be always employed in something useful; cut off all unnecessary actions.
7. Sincerity – Use no hurtful deceit; think innocently and justly; and, if you speak, speak accordingly.
8. Justice – Wrong none by doing injuries, or omitting the benefits that are your duty.
9. Moderation – Avoid extremes; forbear resenting injuries so much as you think they deserve.
10. Cleanliness – Tolerate no un-cleanliness in body, clothes, or habitation.
11. Tranquility – Be not disturbed at trifles, or at accidents common or unavoidable.
12. Chastity ... and
13. Humility – Imitate Jesus and Socrates.

The experiment is all about forming right habits and forgoing those harmful to oneself or others. With corporate scandal rearing its ugly head and political division to disturb our tranquility, the inventor's little project offers hope of a better America. Benjamin Franklin relied on his values to carry him through numerous crises involving the Revolution, the founding of a new nation, and the guarding of all Americans' rights and values that are still sacred today. They are worth a try!

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When not engrossed with the dealings of the SBE, Pitts likes to focus on one of his most beloved hobbies, Aikido. This is something he brings to Charleston, having already earned the rank of second degree black belt before his move. Pitts looks forward to continued success in this ancient art. In addition to his extracurricular activities his wife Cheryl is also a very avid and accomplished artist.

Pitts continues to see great potential in an already very noteworthy institution and school. Through the use of the many local businesses, the mindset of the city, and the college as a player in the global market, students already have access to an assortment of opportunities and potentials. Pitts attributes much of this to the college's strong base of stakeholders, its rich history, and its drive for excellence. While the achievement of national preeminence is yet to be seen, the pieces necessary to complete this puzzle abound; they simply require continued dedication and strong leadership to see the whole picture as a complete work.

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receipt of the protocol–required reports from patients, physicians, and central laboratories.

Patients who are informed and engaged in the care of their illness make careful observers of their status and when enabled by modern technologies to give and receive information directly would speed its access by sponsors who otherwise often wait months for validated data to be retrieved from busy investigators. Sponsors could subsidize some of the costs of the trial, such as the higher cost of an experimental drug.

The study would need to be controlled, with placebo or with an active comparator. It might also be conducted with two doses of the test drug. To reassure the patient, after an appropriate interval to assess efficacy, for example two months, if the patient and physician deemed the efficacy insufficient, the patient could be reallocated, blindly, to one of the alternative treatments. If the treatment were successful, the sponsor would agree that all participants could continue until unrestricted marketing. To minimize the patients who need start on ineffective therapy, an adaptive allocation design would permit reports of the response of prior patients to condition the probability of allocation of new patients. If prior patients had reported little efficacy with placebo, fewer new patients would be allocated to initial placebo therapy but sufficient numbers would remain for safety evaluation.

Patients would have to pay for an “experimental” therapy, including the possibility of being initially allocated to controlled therapy, but in return could have access to a valuable treatment four years earlier than usual. They would learn more from the sponsor about their illness and its treatments and assume a more active role in their care. Excellent physicians could gain early access for their patients, be actively engaged in an exciting trial, and be asked to do little more than they would already be doing for their patients. They certainly would “own” their own data and have the ability to publish their own results alone or combined with those of their colleagues. Sponsors would have a better definition of efficacy and safety from patients more closely resembling those in the unrestricted marketplace and be able to tailor their label and promotional materials to best present their new product. If the drug is not approved, its withdrawal after such a study would be far less painful than withdrawal after marketing, a fate of about 2% of new drugs. Insurers could evaluate the risk–benefit and decide to reimburse patients for their participation as many new treatments will reduce overall health care costs while enhancing quality of life.

Pipelines of new promising drugs are shrinking, concerns about safety are growing, and a new approach to “preapproval” trials could be tested for public health benefits.

The Free Enterprise Foundation has been created as an independent nonpartisan institute dedicated to preserving and promoting those enterprises and practices that are consistently the best in our free market economy.

The Foundation, a tax exempt 501 (c) (3) organization, relies on donors to provide both critical financial support but also intellectual leadership to the Foundation in its discourse on policy and extending the institutions outreach into the education of the public on the vital role of free enterprise and setting the highest standards of ethics and civic responsibility through study, research, the funding of scholarship, publications, and awards. Please help us not only with your tax-deductible donation, but by forwarding names and addresses of those who would enjoy being added to our mailing list.



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