

BEWARE, BEWARE FDA “APPROVED” ROBOTIC PROSTATECTOMY CARE

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FDA and Biased Urology Panelists

Recently, the Food and Drug Administration (FDA) and its urology panel of prostate cancer experts did not approve the application for the non-invasive, high-intensity-focused-ultrasound (HIFU) technology as a treatment option for localized prostate cancer, despite the fact that this innovative treatment modality has been used successfully outside of the US for several years.

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM420537.pdf>

Disturbingly, but buried within this self-serving decision is **the unending charade by urologists for criticizing alternative prostate cancer treatments as if their traditional radical prostatectomy is a scientifically proven benchmark against which all other prostate cancer treatments are to be measured**. Not only is this contention for surgery absolutely false and unsupported by any scientific evidence-based-medicine (EBM) data for safety and/or effectiveness but, shamelessly, urology panelists are not above requiring such EBM data from any other prostate cancer treating technology seeking FDA approval.

FDA Panelists and Conflicts of Interest

The FDA scrutinizes new medical devices for their safety and effectiveness and in doing so engages various clinical experts to assist in these evaluations. Certainly, the public has every right to expect that these consultants assisting the FDA would be fully vested in the merits of sound scientific methodology as well as be free and clear of any financial ties, influence-peddlers and any biases regarding the device under review. Disappointingly, **many of these consultant panelists are affected by blatant conflicts of interest and financial ties which neither the FDA nor the panelists themselves felt important enough to disclose**. Fortunately though, the Wall Street Journal (WSJ) does recognize the potential impact of such conflicts and identified FDA panelists in the fields of cardiology, orthopedics and gynecology who had financial ties and biases with the power to influence FDA decision-making for personal rather than public benefit.

<http://www.wsj.com/articles/fda-advisers-financial-ties-not-disclosed-1418095981>

Maybe it was an oversight, but the field of urology was left off this WSJ list of affected medical specialists engaged by the FDA. Regrettably however, the same concerns for bias, lack of objectivity and conflicts taint also some of these urologist panelists and

they are well detailed in **Ablin and Piana's book, "The Great Prostate Hoax"**. Here, it is quite clear that the healthcare oversight responsibilities of most, if not all, Government agencies such as the FDA (just like the IRS) have been significantly tainted by the blatant prejudices of their consultant panelists. Panelists arrogantly camouflaging their many conflicts-of-interests with the umbrella of academic legitimacy and hollow disclosures but, absolutely corrupted by lucrative consultancy fees and, or, the promise of future biotech employment upon leaving their miserable university practices.

Prostate Cancer Clinical Studies and Design Flaws

Unfortunately, not only is the integrity of urologists tarnished by their blatant influencing of FDA decision-making in order to protect their prostate cancer industry but, they are severely burdened by a trove of highly suspect, non-objective studies and results concerning their traditional "standard" (in reality, studies based upon opinion, herd mentality, consensus or, "eminence-based") surgical treatment of prostate cancer. The root problem with most, if not all, of these many clinical studies is their elementary design flaw. **Urologists assume that their prostate cancer surgical treatment philosophy is inherently valid and then design their studies around this extraordinary but unfounded bias.** Naturally, such a fundamental study design flaw simply endorses and confirms preconceived notions rather than generating reliable and defensible data. In fact, urologists' endless appetite for reliance on non-EBM studies to "prove" the perceived merits of their radical surgery/robotic prostatectomy treatment have long reached the point where urologists cannot separate what is true from what they wish to be true.

<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124> - Ioannidis

Prostate Cancer Diagnoses Troubled by Estimations and Judgements

Compounding these many concerns regarding the integrity, objectiveness and truthfulness of some urologists and their radical prostatectomy information are a litany of additional reliability and subjectivity issues impacting accuracy, reproducibility and therefore credibility of any evaluation for a possible prostate cancer. Leading the charge for credibility and reliability concerns is the prostatic specific antigen (PSA) blood test, which was given a pass by the FDA and its urology panelists for a role as a marker of prostate cancer activity, knowing full well it would be quickly hijacked by the prostate cancer industry for a much more lucrative but highly unreliable and potentially harmful role in prostate cancer detection. From the highly unreliable PSA being used now as a screening marker to detect a possible prostate cancer, every subsequent step in the prostate cancer detection process is loaded with concerns for accuracy because of subjectivity issues. These subjectivity concerns relate to the reliability of individual

physician's interpretive skills and them making judgements and opinions rather than recording accurate, reproducible determinations. Clearly, opinions influenced by subjectivity concerns are not always accurate or reproducible and result in an evaluation based upon judgements and approximations. From the highly unreliable PSA, the concerns for accuracy of the rectal prostate examination, the randomness of risky needle biopsy sampling of the prostate, the questionable ability of pathologists to interpret correctly and consistently the presence and real grade of your prostate cancer extend to the concerns for radiologists making correct and reproducible diagnoses from various imaging studies such as CAT scans, bone scans, PET scans and mp-MRI scans. Weighted by the many reliability and subjectivity issues, these various evaluation judgements are then added together for an estimation of the prostate cancer stage.

Not surprisingly, these many estimates and judgements undertaken by physicians during the journey along the PSA-based prostate cancer screening path create significant concerns for accuracy and therefore, patient safety.

However, as if these many issues concerning patient safety during the misguided PSA-based prostate cancer screening process are not enough, an even greater danger to your health is to receive a Gleason 3+3=6 prostate "cancer" diagnosis. In fact, this very common prostate "cancer" behaves as noncancerous and, on both clinical and molecular biology grounds, the Gleason 3+3=6 LACKS the hallmarks of a cancer.

<http://www.cancernetwork.com/prostate-cancer/active-surveillance-not-only-reduces-morbidity-it-saves-lives> (L. Klotz MD)

Prostate "Cancer" Mostly Mislabeled

Basically, there are two types of prostate cancer. A less-common, high-grade prostate cancer which is a health-risk and potentially lethal, and a very common Gleason 3+3=6 disease which, although called a cancer, lacks the very hallmarks of a cancer. This fact that **the Gleason 3+3=6 disease lacks the hallmarks of a cancer but continues to be labeled a cancer represents not only a great public health disservice but a great public health disaster** and, explains much of the confusion and the many misrepresentations surrounding the prostate cancer diagnosis. Naturally, when the Gleason 3+3=6 disease is called a cancer but behaves as non-cancerous, the mere presence of that "cancer" label is enough to shock the life out of most folks leading them to seek an urgent but needless treatment. Furthermore, by categorizing the Gleason 3+3=6 as a cancer when it fails to behave as a cancer and, including this disease in any and all prostate cancer issues grossly overstates the importance of prostate cancer. Indeed, whereas prostate cancer is commonly marketed as the second most common cancer in men, only 3% diagnosed with prostate cancer will die of their disease (the high-grade form) while the other 97% will die from some other cause or old age. This huge discrepancy between prostate cancer incidence and death from prostate cancer is

again easily explained by the fact that most prostate cancers detected are the non-health-risk Gleason 3+3=6 pseudo-cancers. In fact, the skewing of prostate cancer statistics by the common Gleason 3+3=6 disease mislabelled as a cancer also results in the squandering of huge amounts of precious healthcare funds. Not only is the Gleason 3+3=6 disease treated unnecessarily at great cost, but it is commonly treated with a robotic device endorsed in the AUA Guidelines as “standard” but lacking scientific support for safety and effectiveness in treating any prostate cancer. This monumental travesty has enabled the appalling grandstanding of a few predatory urologists exploiting the misrepresentations and hysteria surrounding prostate cancer and robotics for self-gain. Little wonder that most men who took this PSA-based prostate cancer screening journey came away feeling surgically battered, robbed of quality of life and wondering what it was they actually survived. For most, it was surviving only a renegade prostate cancer industry, its bogus “treatment”, the failed guidance of “advocacy” groups and support foundations, indifferent health insurance companies and for a few, being double-crossed by the outrageous false-promises from pharmaceutical companies.

<http://www.theprovenetrials.org/>

Prostate Cancer Progression and Upgrading Overstated

The very common Gleason 6 is unlikely to need treatment ever as it is not a health-risk and, the chance of harboring one of these “cancers” is roughly the same as one’s age. However, not only are most prostate cancers mislabelled a cancer to allow easy fear-mongering and patient manipulation by unscrupulous doctors but, despite the possibilities of cancer progression and upgrading NOT being inevitable, they are conveniently exaggerated to facilitate self-serving overtreatment. In order to prevent runaway, unnecessary and debilitating treatments of the Gleason 6 disease, the active surveillance program was developed to manage most low-risk and some mid-grade prostate “cancers”. Fortunately, this strategy is suitable for all ethnic and age groups and, although some physicians follow the Epstein criteria, this yardstick has been found much too restrictive in that many more men can be followed safely without “treatment” and, without fear of disease progression. However, a small number of men with Gleason 6 disease may harbor higher risk disease (especially men with high-volume Gleason 6) and, some may demonstrate biological progression to a higher grade (upgrading or, grade progression). Sometimes this progression can be real but, often these events can be explained by the multifocal nature of the disease and differences in prostate biopsy sampling techniques (occult cancers are commonly in the apex or anterior prostate and missed) or, due to subjective interpretation differences between pathologists. Furthermore, upgrading from the common 3+3 occurs only in a minority and, even if confirmed, will be invariably to a 3+4 which behaves like the 3+3 pseudo-cancer, especially if the component of pattern 4 is less than 10%. Should there

be any remaining concerns regarding the biological potential of a prostate cancer, biomarkers studies can be undertaken trying to predict risk but, these tests also like the mp-MRI when used for cancer detection, remain imperfect. However, surveillance monitoring can be continued safely once the confirmatory prostate biopsy some 6-12 months after the initial biopsy reaffirms essentially stable low-risk disease. This program can be continued indefinitely and, if 6 monthly PSAs remain within the patient's normal fluctuating limits no further evaluation or treatment is necessary. However, should there be a persistent upward trending of a PSA during surveillance, another biopsy may be necessary to determine if pattern 4 disease in significant amounts is present as, only validated pattern 4 appears to have lethal potential. Also, since prostate cancer grows slowly, a 12 month or so delay in detecting occult pattern 4 disease during active surveillance is unlikely to compromise curability and, treatment can be undertaken through mp-MRI targeting and focal therapy with either HIFU, laser or cryoablation. On the other hand, those unfortunate men mistreated for their Gleason 6 "cancer", are survivors of their "treatment" not the disease mislabelled a cancer.

Prostate Cancer and the "Cutting to Cure" Myth

The simplistic "cutting to cure" mentality for treating localized prostate cancer was spawned well over 100 years ago by the same surgeons who designed the debilitating radical mastectomy. Like the radical breast surgery, the radical prostatectomy has never been validated scientifically for safety and effectiveness. Although some imperfect clinical studies were undertaken since 1904 as well as other studies profiting from the troubled Veterans Administration (VA) hospitals ready supply of men, it was the description of a "nerve-sparing" prostatectomy approach attempting to deflect one of the many significant complications associated with the radical prostatectomy, that of erectile dysfunction or, impotence which rekindled the interest in prostate cancer surgery. Eventually, **it was the arrival of the "minimally invasive", high-tech era which presented the golden opportunity for urologists to continue their indefensible, unending human experimentation with prostate cancer surgery.** Enabled by a revenue-addicted prostate cancer industry, conventional surgery morphed quickly into a laparoscopic approach and then on to the robotic-assisted radical prostatectomy (robotic scalpel). A "high-tech" surgery which allowed its physician advocates to continue their many false promises and, to abuse the good faith of the defenseless while the inevitable complications stemming from their radical prostate "treatment" were arrogantly dismissed with a feigned surprise along with the customary lie that "it never happened to me before".

<http://www.urologyweb.com/10-shocking-fallacies-and-the-prostate-cancer-surgery-scam/>

FDA “Approval” of Robotics for General Surgery

The “approval” of the robotic system for prostate cancer surgery represents another very shady development in the unending quest by urologists to prove a surgical “truth” which only urologists can see. Disgracefully, the FDA approval of robotics for prostate cancer treatment was based ultimately, upon a small clinical study involving only gallbladder and anti-reflux surgery. Aside from the gross conflict of interest with the robotic company undertaking a trial concerning its own technology and, undertaken in a foreign country using local informed consents, this study looked at comparing standard laparoscopic with robotic approaches for gallbladder removal and Nissen funduplications. The result of this low-level clinical study was that the robotic approach for gallbladder removal was found to be no more effective than the standard, faster and less costly laparoscopic approach. **Despite these study results showing no significant benefits for safety or effectiveness of the robotic device in gallbladder surgery, the FDA panelists voted to approve its use for general surgical procedures simply on the basis of a possible future role in medicine, Wednesday, June 16, 1999.**

<http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3523t1.pdf>

FDA “Approval” of Robotics for Radical Prostatectomy

Soon after this misguided FDA approval of robotics for general surgery, it became very clear, very quickly, that there was no market for the robotic device in gallbladder surgery as the established laparoscopic approach was less complicated. Just as quickly however, the device company locked on to the very lucrative prostate cancer industry and craftily engineered an FDA backdoor approval for this robotic device in “treating” prostate cancer. **Without any supporting scientific data from evidence-based-medical studies comparing conventional radical prostatectomy to robotic prostatectomy and, unchallenged by authorities, the device makers, were able to garner an FDA 510(k) clearance to use the robot for prostate cancer surgery [a 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval] on May 30, 2001 by claiming that the device instruments to be used for robotic prostatectomy were “substantially equivalent” to those already in use for the robotic gallbladder surgery and, already FDA approved.** This monumental regulatory misstep has since facilitated the fraudulent misrepresentation of the FDA “approval” for robotic prostatectomy by urologists as if the approval had been awarded on the basis of principled scientific evaluation when the robotic device was never scientifically evidence-based tested for safety or effectiveness on a single patient with prostate cancer. Not only is the approval intentionally misrepresented by urologists

aiming to preserve their misguided, “standard” surgical treatment philosophy but, this misrepresentation was enabled by academic urology panelists on Government oversight agencies who, at the expense of public health, prostituted themselves to the healthcare marketplace.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K011002>

More FDA Urology Panelists Biases and Conflicts

In contrast to the FDA urology panelists baseless approval of robotics for treating prostate cancer without a single case of prostate cancer ever having been trialed using this technology, these same panelists designed a study for the HIFU application in 2007 with uncommonly restrictive parameters and, whose form can only be interpreted as a sham quest with malevolent intent. Whereas new devices seeking FDA approval for treating prostate cancer can be expected reasonably to be evaluated on virgin cases of prostate cancer, the HIFU study was directed eventually, to be undertaken on men whose prostate cancer had recurred after having failed radiation treatment. Not only are suitable candidates for such a HIFU study hard to come by, but these particular patients are very difficult to treat and the chances of a complication-free cure remote. Indeed, when the HIFU trial data was examined, there were some cures and, not surprisingly, there were some complications. As expected, the FDA urology panelists tabled the HIFU application and presented even more demands designed maliciously, to fail the HIFU evaluation. In effect, **this quasi-scientific study conjured up by unprincipled FDA urology panelists waving AUA membership blatantly abused the privilege of their position on a medical oversight agency simply to torpedo the HIFU application and protect their misguided robotic surgical franchise.** To boot, this robotic franchise benefitting only the prostate cancer industry, lacks any scientific EBM evidence for effectiveness, comes at great patient expense and screams for legal recourse. (Subsequently, in October of 2015, the HIFU device also was able to circumvent more FDA trials and biased scrutiny by employing the FDA 510(k) maneuver and become FDA “approved”).

http://www.accessdata.fda.gov/cdrh_docs/pdf15/den150011.pdf

The Many Dangers of the Robotic Prostatectomy

Warnings to the public about the lack of safety and effectiveness of the radical surgery/robotic prostatectomy have been voiced for many years (see bibliography). Spearheading these many warnings about prostate cancer treatments have been Anthony Horan MD (How to Avoid the OverDiagnosis and OverTreatment of Prostate Cancer) and Otis Brawley MD, Chief Medical Officer of the American Cancer Society.

<http://annals.org/article.aspx?articleid=1166177>

Even the FDA's own product safety site, MAUDE (Manufacturer and User Facility Device Experience) has pages of self-reported harms (representing only about 8% of actual adverse events) associated with the robotic device for radical prostatectomy. Shockingly, this site has been made difficult intentionally, for accessing and posting data and, it seems the data may be open to editing by both the manufacturer and FDA. <http://www.killingmycareer.com/the-sociopathic-business-model/are-fda-maude-reports-a-fraud/>

Furthermore, a Google-search for complications associated with this procedure reveals scores of product-liability lawsuits against the robot manufacturer and its surgeons and, a class-action lawsuit is likely to follow. As an added insult to the robotic "treatment", more personal but revealing calls from men left crippled by prostate cancer surgery can be heard at times on the SIRIUS Doctor radio channel where they describe in great detail their postoperative complications, misery and extreme dissatisfaction from having been subjected to the robotic prostatectomy. Even the robotic device makers themselves clearly recognise the many dangers of their gadget since their disclaimers are getting longer with each revision. **Complementing these many negative concerns about prostate cancer surgery is the recent "D" grading by the US Preventive Services Task Force (USPSTF) for PSA-based prostate cancer screening.** This unbiased and independent USPSTF (authorized by Congress and supported by the Agency for Healthcare Research and Quality (AHRQ) and, up to now, less easily influenced by physicians than the FDA), serves a very important oversight role in preventive services for the healthcare public and, recently identified critical evidence gaps related to the supposed preventive benefits of PSA-based screening for prostate cancer. In contrast to the urologists self-serving endorsement of PSA-based screening, something which seems intuitively reasonable, a scientific review of the available information by the USPSTF determined that the treatment benefits of screen-detected prostate cancer are outweighed by the harms, plus the process fails to save significant numbers of lives. These results lead to the USPSTF "D" grade, recommending against PSA-based prostate cancer screening.

<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prostate-cancer-screening>

Robotic Prostatectomy Spreads Cancer

Shockingly, during a robotic radical prostatectomy treatment, showers of cancer cells are released from the affected prostate gland into the bloodstream. Studies using PSA reverse transcriptase-polymerase chain reaction assays and other staining techniques **have documented clearly the increased dispersal of cancer cells throughout the body from surgical manipulation.** In fact, other studies have shown that tumor handling during a radical prostatectomy has resulted in a 30-80% rise in the numbers of

circulating prostate cancer cells. Surprisingly, the spread of these cells because of surgery can be delayed. In addition, once dispersed, these cells can be in circulation for several years undetectable by conventional means such as bone scans, PET scans and MRIs. In fact, not only are these scattered cancer cells circulating but, they can exist in the body dormant before reactivating for a possible cancer recurrence years later. This very troubling concern, that the robotic prostatectomy may actually be promoting prostate cancer spread, along with its many other appalling complications and quality of life issues, makes this invasive procedure an indefensible treatment option.

<http://www.urologyweb.com/robotic-prostatectomy-spreads-prostate-cancer-cells/>

Senate Staff and the Misguided Transparency Act

Figuring that the best defense was a good offense for continuing a meritless PSA-based screening process, urologists embarked upon a public relations exercise trying to discredit the USPSTF and foster enough doubt amongst the public so as to preserve patient traffic to their offices. Even more disturbing, urologists used their experience gained from manipulating and influencing FDA decisions concerning HIFU to target the medical illiteracy and gullibility of certain Senate Staff. By using Senate clout, urologists hope to enact a political pushback on the USPSTF and its “D” grading of PSA-based prostate cancer screening through the self-serving USPSTF Transparency and Accountability Act (H.R. 1151, S. 1151). **As if this reprehensible capitalizing on the medical ignorance of Senate Staff and using them to undermine the independence of the USPSTF were not enough, urologists had the gall to demand the inclusion of one of their own (an obvious conflict) to the panel of physicians in order to make the USPSTF more “transparent”.** The utmost embarrassment however, was for a urology representative to assert that “urologists should be involved in the development of prostate cancer screening recommendations to ensure that the guidance is evidence-based and also targets the preferences of individual patients”. Not only is the concern for “preferences of individual patients” totally insincere as it was argued simply to continue the flow of vulnerable and confused men to seek treatment for their Gleason 3+3=6 when none is required but, the brazen demand that “guidance is evidence-based” underscores the depth of subterfuge urologists will resort to regarding their disinformation about prostate cancer since there is nothing evidence-based proving that their radical prostatectomy is safe or effective.

<http://urologytimes.modernmedicine.com/urology-times/news/prostate-cancer-council-bill-earns-aa-support?page=full>

“Truth” in Medicine

The public’s trust in physicians is earned only through sincere patient advocacy and truth in medicine. A truth realized by delivering irrefutable and reproducible data from

scientifically conducted evidence-based-medicine (EBM) studies. Additional checks and balances are undertaken by independent oversight agencies such as the FDA and USPSTF in order to be sure that healthcare delivery is safe and effective. However, when urologists are able to penetrate the independence of an agency like the FDA and exert influence; when the FDA authority can be openly abused by corrupt urology panelists to flaunt biases and demand HIFU trial criteria maliciously designed to fail; when urologists subvert the independence of the USPSTF by engaging misguided Senate Staff to influence the “D” grade determination of the PSA-based screening program for prostate cancer; when urologists support a robotic procedure fraudulently “approved” by the FDA on the basis ultimately, of a small irrelevant gallbladder study; when urologists and the AUA promote this robotic technology as “standard” to “treat” the common **Gleason 3+3=6 “cancer” which lacks the hallmarks of a cancer, we are witness to an indelible trail of medical immorality**, and like the lobotomy and morcellation debacles, anything but patient advocacy and truth in medicine.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708232/>

Prostate Cancer Propaganda

In fact, history has recorded this type of troubling medical herd mentality many times over and this easy acceptance of radical prostatectomy propaganda by urologists, fomented by academic dogma and cronyism, is simply another shameful example of unethical and amoral physician mob mentality failing to honor the interests of patients. Only a determined turn by urologists away from their insolent and deceptive use of fear-mongering and misrepresentations towards the sort of objective scientific studies they require from HIFU can the safety and effectiveness of their “standard” radical and robotic prostatectomy be really evaluated. Sadly, urologists are well aware that if these much needed EBM studies were ever to be undertaken on their most favored radical prostatectomy, these studies would prove that the radical prostatectomy was toxic, ineffective and in fact, a public health nightmare. Until urologists are held accountable to EBM data for their radical prostatectomy and stop discrediting the many challenges to their surgical fairy tale, patients will continue to be harmed. Disappointingly, the actions of urologists represent a level of hypocrisy and feeble moral commitment all too common in medicine today, a violation of patient trust and of the Hippocratic oath and, secures simply, an unenviable legacy which embarrasses the scientific community worldwide.

<http://www.urologyweb.com/robotic-prostate-cancer-surgery-a-public-health-nightmare/>

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About Bert Vorstman MD, MS, FAAP, FRACS, FACS

Dr. Bert Vorstman is a Board Certified urological surgeon. Born to Dutch parents in Indonesia, he grew up in New Zealand. After training at the Otago Medical School in Dunedin, New Zealand he completed a urology residency at Auckland Hospital, Auckland, New Zealand. He

Fellowship trained in Pediatric and Adult Reconstructive Urology at the Eastern Virginia Medical School in Norfolk, Virginia and after NIH sponsored, pioneering research on “Urinary Bladder Reinnervation” he earned the honor of a Masters of Surgery Diploma from the University of Otago in 1988. Dr. Vorstman was a faculty member at the University of Miami, Jackson Memorial Hospital, Miami, Florida and then went on to found Florida Urological Associates, a busy urology practice in Coral Springs, Florida, USA.

Dr Vorstman’s passion and dedication is to help men and their spouses/partners understand fully the implications of their particular prostate cancer as well as the minimally invasive treatment options available in selected men with localized significant prostate cancer.

Dr Vorstman owns healthcare stock. He is the grandson of acclaimed Dutch author, Amy Vorstman/Amy Groskamp-ten Have.

https://nl.wikipedia.org/wiki/Amy_Groskamp-ten_Have